

## EXECUTION VERSION

### BUILD-OUT AND COMMERCIAL SUPPLY AGREEMENT

This Build-Out and Commercial Supply Agreement (“**Agreement**”) is made as of this 1<sup>st</sup> day of May, 2013 (“**Effective Date**”), by and between Pharmacyclics, Inc., a Delaware corporation, with a place of business at 995 East Arques Avenue, Sunnyvale, CA 94085 (“**Client**”), and Catalent CTS, LLC, a Delaware limited liability company, with a place of business at 10245 Hickman Mills Drive, Kansas City, MO 64137, USA (“**Catalent**”).

#### RECITALS

A. Client is a pharmaceutical company that develops, markets and sells pharmaceutical products, including the API;

B. Catalent is a leading provider of advanced technologies, and development, manufacturing and packaging services for pharmaceutical, biotechnology and consumer healthcare companies.

C. Client desires to engage Catalent to provide commercial manufacturing services to Client in connection with Client’s Product, and Catalent desires to provide such services, all pursuant to the terms and conditions set out in this Agreement.

D. In connection with the performance of such services, the Parties have agreed that Building Contractor (as defined below) will renovate certain Catalent space (“**Client Space**”) within Catalent’s manufacturing facility [\*\*] which Client Space shall be dedicated solely to the performance of services for Client with financial support from Client as set forth in this Agreement.

**THEREFORE**, in consideration of the mutual covenants, terms and conditions set forth below, the Parties agree as follows:

#### ARTICLE 1 DEFINITIONS

The following terms have the following meanings in this Agreement:

1.1 “**Affiliate(s)**” means, with respect to Client or any Third Party, any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with such entity; and with respect to Catalent, Catalent Pharma Solutions, Inc. and any corporation, firm, partnership or other entity controlled by Catalent Pharma Solutions, Inc. For purposes of this definition, “**control**” shall mean the ownership of at least 50% of the voting share capital of entity or any other comparable equity or ownership interest.

1.2 “**Annual Meeting**” has the meaning set out in Section 3.3.

1.3 “**API**” means the compound Ibrutinib, as further described in the Specifications set forth in Attachment A that has been released by Client and provided to Catalent, along with a certificate of analysis, as provided in this Agreement.

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- 1.4 “**API Inventions**” has the meaning set forth in Article 14.
- 1.5 “**API Procurement Tracking Report**” has the meaning set forth in Section 6.1.
- 1.6 “**Applicable Laws**” means all laws, ordinances, rules and regulations of the United States applicable to the Processing or any aspect thereof and the obligations of Catalent or Client, as the context requires, under this Agreement, as amended or promulgated from time to time, including (A) all applicable federal, state and local laws and regulations of the United States, (B) the U.S. Federal Food, Drug and Cosmetic Act and (C) cGMP.
- 1.7 “**Batch**” means a [\*\*] blend containing API and excipients that has been or is being processed into Product in accordance with the Specifications.
- 1.8 “**Additional Country**” has the meaning set forth in Section 5.6.
- 1.9 “**Additional Product Proposal**” has the meaning set forth in Section 5.6.
- 1.10 “**Batch Pricing**” has the meaning set forth in Section 10.1.
- 1.11 “**Breakage Costs**” has the meaning set forth in Section 19.2.
- 1.12 “**Building Contract**” means that certain building contract of October 18, 2012 between Pharmacyclics, Inc. and [\*\*] identified as “AIA Document A133 - 2009” or “Standard Form of Agreement Between Owner and Construction Manager as Constructor *where the basis of payment is the Cost of Work Plus a Fee with a Guaranteed Maximum Price*”, along with any exhibits, and appendices thereto and any related appointments or contracts (together with any variations thereto) for the Construction Work or performance of consulting services relating to the same, as it may be amended from time to time. A copy of the main text of the Building Contract is attached as Attachment E hereto.
- 1.13 “**Building Contractor**” means [\*\*], which entity the Parties hereby designate as the building contractor or manager of the Construction Work under the Building Contract, such entity to act in the capacity of the building contractor for the purposes of undertaking the Construction Work or performing consulting services relating to the same.
- 1.14 “**Building Plans**” means the detailed plans, specifications, drawings, sections, elevations, specifications, priced bills of quantities, engineer’s drawings and calculations and other design and building details for the Improvements. The Building Plans shall be listed in Schedule 1 and attached to this Agreement upon approval by the SG. Building Plans shall include all amendments thereto.
- 1.15 “**Catalent Defective Processing**” has the meaning set forth in Section 8.1.
- 1.16 “**Cash Deposit**” has the meaning set forth in Section 4.1.
- 1.17 “**Catalent**” has the meaning set forth in the introductory paragraph, or any successor or permitted assign. Provided that Catalent obtains the prior written consent of Client for any such

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delegation of Catalent's obligations, Catalent shall have the right to cause any of its Affiliates to perform any of its obligations hereunder, and Client shall accept such performance as if it were performance by Catalent.

1.18 **"Catalent Equipment"** means **[\*\*]** listed in or added to Schedule 3. Schedule 3 shall be amended from time to time to reflect any additional equipment **[\*\*]**. The initial Catalent Equipment shall be listed on Schedule 3 (which shall be initialed and dated by the Parties) and attached hereto upon designation by the SG.

1.19 **"Catalent Indemnitees"** has the meaning set forth in Section 16.2.

1.20 **"Catalent IP"** has the meaning set forth in Article 14.

1.21 **"cGMP"** means current Good Manufacturing Practices promulgated by the Regulatory Authorities, including within the meaning of 21 C.F.R. Parts 210 and 211, as amended, and equivalent non-U.S. regulations (including 2003/94/EEC Directive as implemented in any country of the Territory, as supplemented by Volume 4 of EudraLex published by the European Commission, **[\*\*]**, as amended, solely to the extent such non-U.S. regulations are otherwise included in Applicable Laws.

1.22 **"Client"** has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.23 **"Client Equipment"** means all the equipment for use exclusively in the Client Space invoiced to or paid for by Client and for which Client shall hold title, as agreed upon by the Parties in accordance with Section 2.1 and listed in or added to Schedule 3. Schedule 3 shall be amended from time to time to reflect any additional equipment purchased by Client. The initial Client Equipment shall be listed on Schedule 3 (which shall be initialed and dated by the Parties) and attached hereto upon designation by the SG.

1.24 **"Client Indemnitees"** has the meaning set forth in Section 16.1.

1.25 **"Client IP"** has the meaning set forth in Article 14.

1.26 **"Client Space"** means the unshaded part of the Facility as shown on the plan attached hereto as Schedule 1, **[\*\*]**.

1.27 **"Client-supplied Materials"** means any materials to be supplied by or on behalf of Client to Catalent for Processing, as provided in Attachment A, including API.

1.28 **"Commencement Date"** means the first date upon which a Regulatory Authority approves Catalent as a manufacturer of the Product.

1.29 **"Completion Date"** means the date on which all of the following have occurred: (i) the Improvements have been substantially completed in accordance with the terms of the Building Contract; (ii) a certificate/statement of completion, as applicable, is issued to enable occupancy of the Client Space; (iii) the Client Equipment and Catalent Equipment have been fully installed,

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satisfactorily tested, qualified and validated; (iv) the Client Equipment and Catalent Equipment are fully operational; and (v) no Liens related to the Construction Work exist on the Site and Catalent has received all final lien waivers required by Section 4.5(A) from Client.

1.30 “**Conditions**” means (i) all approvals required by the applicable authorities to construct the Improvements have been obtained; and (ii) if the Site has any outstanding Liens, all approvals required from Lien holders have been obtained.

1.31 “**Confidential Information**” has the meaning set forth in Section 13.2.

1.32 “**Construction Costs**” means the amounts invoiced to Client by the Building Contractor, the hard and soft costs incurred by Catalent and reasonable internal costs for the Construction Work incurred in accordance with the terms of this Agreement in the course of the design and construction of the Improvements, costs incurred by Catalent for support services to monitor the Construction Work and provide input as to the Construction Work and other matters as detailed in Schedule 2. The Construction Costs shall be calculated in accordance with Schedule 2.

1.33 “**Construction Work**” means all demolition or construction works required to be carried out at the Site to construct the Improvements in accordance with the Building Plans including:

- (a) the demolition of current improvements within the Client Space;
- (b) the removal and cGMP storage of any equipment or other materials that previously were kept in the Client Space including any ancillary construction works necessary to relocate such equipment and materials elsewhere in the Facility, all in accordance with the Quote;
- (c) the construction of the Improvements in the Client Space as will be set out in the Building Plans [\*\*], and any associated Site clearance and Site preparation, including the cost of equipment and materials outside the Client Space which are necessary to support the Client Space;
- (d) all works carried out pursuant to any planning and other approvals required by the applicable governmental authorities;
- (e) all ancillary works and facilities required for the Improvements to the Client Space including the provision of and connection to all services which are relevant to the operation of the Equipment; and
- (f) consulting services relating to any of the same.

1.34 “**Contract Year**” means each consecutive 12 month period beginning on the earlier of the Completion Date or July 1, 2014, and each anniversary thereof, as applicable.

1.35 “**Costs**” has the meaning set forth in Section 4.1.

1.36 “**Defective Product**” has the meaning set forth in Section 8.1.

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1.37 “**Design Documents**” means all or any documents (including the Building Plans) that relate to the Improvements, Client Equipment, Catalent Equipment or installation of such equipment, including any designs, drawings, models, plans, specifications, design details, photographs, brochures, reports, notes of meetings, CAD materials and other materials produced in relation to the Client Space and any additions or alterations made to them or other areas of the Site required in support of the operation of the Client Space.

1.38 “**Effective Date**” has the meaning set forth in the introductory paragraph.

1.39 “**Client Equipment Costs**” means the actual cost of the Client Equipment (which is anticipated to be as set out in Schedule 3) and is payable by Client in accordance with Section 4.5.

1.40 “**Equipment Notice**” has the meaning set out in Section 19.5 (E).

1.41 “**Estimate**” has the meaning set out in Section 2.6.

1.42 “**Exception Notice**” has the meaning set forth in Section 8.1.

1.43 “**Facility**” means the building located on the Site identified by an address in the definition thereof and shown on Schedule 1. The Client Space is located within the Facility [\*\*].

1.44 “**Facility Construction Support Fee**” means the fee due upon the Effective Date as is set out in Attachment C.

1.45 “**Facility Fee**” means the annual fee due upon the earlier of the Completion Date or July 1, 2014 and each anniversary thereafter as is set out in Attachment C as adjusted pursuant to Section 10.2.

1.46 “**Firm Commitment**” has the meaning set forth in Section 7.1.

1.47 “**Improvements**” means all improvements to the Client Space generally described on Schedule 1 and specifically as reflected in the Building Plans and other Design Documents.

1.48 “**Initial Batches**” has the meaning set forth in Section 7.2 (B).

1.49 “**Intellectual Property**” means all intellectual property (whether or not patented or registered), including patents, patent applications, know-how, trade secrets, copyrights, trademarks, designs, concepts, technical information, manuals, standard operating procedures, instructions, specifications, processes, inventions, improvements, developments, technology, and all intellectual, industrial or proprietary rights of any kind.

1.50 “**Invention**” has the meaning set forth in Article 14.

1.51 “**Latent Defect**” means a defect in the Product attributable solely to Catalent’s manufacturing process that occurred while the Product was under the sole control and possession of Catalent, which could not have been discovered by Client through its testing of the Batch in

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accordance with Article 8 and could not have occurred after delivery of Product pursuant to Section 9.1.

1.52 **“Lien”** means any legal charge, debenture, mortgage, deed of trust, security interest, pledge, lien, assignment or other form of security or trust arrangement granting any legal or equitable charge over the Site or the Facility (as it may be enlarged or reconfigured), or the Equipment, whether fixed or floating, or conferring priority of payment.

1.53 **“Losses”** has the meaning set forth in Section 16.1.

1.54 **“Party”** means Catalent or Client, as applicable. **“Parties”** means Catalent and Client.

1.55 **“Process”** or **“Processing”** means the formulating, filling or pressing, producing and bulk packaging (but not secondary or retail packaging) of the API and Raw Materials into Product, in accordance with the Specifications and under the terms of this Agreement.

1.56 **“Processing Date”** means the day on which Product is scheduled to be formulated by Catalent, as identified in an Acknowledgement in accordance with Section 7.2.

1.57 **“Process Inventions”** has the meaning set forth in Article 14.

1.58 **“Product”** means the fully formulated bulk pharmaceutical product containing the API that has been Processed in accordance with the Specifications.

1.59 **“Product Maintenance Services”** has the meaning set forth in Section 5.4.

1.60 **“Project Plan”** means the work schedule as described in the [\*\*] set out in Schedule 5 together with the underlying work packages. Schedule 5 shall be added to this Agreement upon agreement of the Project Plan with the Building Contractor.

1.61 **“Purchase Order”** has the meaning set forth in Section 7.2.

1.62 **“Quality Agreement”** has the meaning set forth in Section 12.6.

1.63 **“Quarter”** means a period of three consecutive calendar months commencing on 1 January, 1 April, 1 July or 1 October in any year.

1.64 **“Quarterly Meetings”** has the meaning set out in Section 3.3.

1.65 **“Quote”** means that certain quote number [\*\*] entitled [\*\*] signed by Client.

1.66 **“Raw Materials”** means all raw materials, supplies, components and packaging necessary to manufacture and ship Product in accordance with the Specifications, as provided in Attachment A, but not including Client-supplied Materials.

1.67 **“Recall”** has the meaning set forth in Section 12.5.

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1.68 **“Regulatory Approval”** means any approvals, permits, product and/or establishment licenses, registrations or authorizations, including approvals pursuant to U.S. Investigational New Drug applications, New Drug Applications and Abbreviated New Drug Applications (or equivalent non-U.S. filings, such as European marketing authorization applications), as applicable, of any Regulatory Authorities that are necessary or advisable in connection with the manufacture of Product for commercial sale or transport in the U.S. or in any other country in the Territory.

1.69 **“Regulatory Authority”** means the international, federal, state or local governmental or regulatory bodies, agencies, departments, bureaus, courts or other entities in the United States (including the United States Food and Drug Administration) or any other country in the Territory responsible for (A) the regulation of any aspect of pharmaceutical or medicinal products intended for human use or (B) health, safety or environmental matters generally.

1.70 **“Residual Value”** means, [\*\*].

1.71 **“SC Initial Phase”** has the meaning set out in Section 2.1.

1.72 **“Site”** means 10245 Hickman Mills Drive, Kansas City, MO 64137.

1.73 **“Specifications”** means the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth in Attachment A, along with any valid amendments or modifications thereto, in accordance with Article 11.

1.74 **“Statutory Consents”** means any statutory approvals, consents, licenses or permissions desirable or required from any local or other applicable authority to enable the Parties lawfully to carry out and complete the Construction Work and install, connect and operate the Equipment in the Client Space. Statutory Consents includes the approval of any reserved matters under the building permit for the Improvements, any approval from Regulatory Authorities, and any relevant utility supplier.

1.75 **“Steering Group”** or **“SG”** means a group consisting of [\*\*].

1.76 **“Subsequent Phase”** has the meaning set out in Section 2.1.

1.77 **“Supplier”** has the meaning set out in Section 6.2.

1.78 **“Target Completion Date”** means the date set out in the Project Plan.

1.79 **“Term”** has the meaning set forth in Section 19.1.

1.80 **“Termination Date”** means the date that this Agreement terminates expires or terminates in accordance with Section 4.4 or Article 19.

1.81 **“Territory”** means [\*\*].

1.82 **“Third Party”** means a party other than either of the Parties.

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1.83 “**Validation Services**” has the meaning set forth in Section 5.2.

### ARTICLE 2 CONSTRUCTION WORK

2.1 Steering Group. Immediately following the Effective Date the Parties shall establish a Steering Group. Each Party shall appoint [\*\*] members to the Steering Group (each a “**Member**”). The initial members of the SG shall be the individuals named in Schedule 7, attached hereto and incorporated herein by reference. Each Party may change either of its Members by written notice to the other. The role of the SG is one of review, approval, information dissemination and reporting with respect to the Construction Work and Client Equipment. The Catalent-appointed Members shall be responsible for keeping Catalent informed of all matters relating to the Construction Work, Client Equipment and Catalent Equipment, and the Client-appointed Members shall be responsible for keeping Client informed of all matters relating the Construction Work, Client Equipment and Catalent Equipment. The initial role of the SG shall be to approve the Building Plans and designate and approve the Client Equipment and Catalent Equipment. The process for such approval is further described on Schedule 4 (the “**SG Initial Phase**”). Thereafter the role of the Steering Group is to resolve matters that arise with respect to the Construction Work (the “**Subsequent Phase**”). For the avoidance of doubt, matters relating to the Construction Work shall initially include any issues that may need to be resolved, any likely delays in the completion of the Construction Work and any proposed design changes required to any element of the Improvements. In fulfilling the roles the SG shall:

- A. consider the Building Plans and other Design Documents;
- B. review any change in Construction Work and refer any concerns or deviations of more than [\*\*]% in excess of the Guaranteed Maximum Price (as that term is used and defined in the Building Contract) to the senior management of the Parties prior to incurring such expense;
- C. approve any and all subcontractors performing Construction Work;
- D. review the operating procedures for commissioning, validation and quality/GMP approval;
- E. oversee transfer of manufacturing from outside the Client Space into the Client Space, any future construction projects or the purchase of additional equipment;
- F. oversee forecasting and utilization of Client Equipment; and
- G. have such other responsibilities as may be assigned to the SG pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

2.2 Steering Group Meetings. During the Subsequent Phase, the Steering Group will meet as often as is required provided that there will be at least [\*\*] per month and [\*\*] at the Site (unless agreed otherwise) in each [\*\*] month period. Either Party may invite a suitably qualified [\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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technical consultant to attend Steering Group meetings subject to that consultant entering into terms of confidentiality with the Parties. A Client-appointed Member shall be responsible for the circulation of papers and an agenda, within a reasonable period of time prior to the meeting and for the circulation of minutes of the meeting within a reasonable time after the meeting. The role of the Steering Group shall be review and coordination of all matters relating to the items set forth in Section 2.1 (A) - (G). The Steering Group shall not be entitled to make any decision which affects either Party's rights under this Agreement except as provided in this Agreement. Any Member may call a meeting with the other Members upon [\*\*] prior written notice.

2.3 Steering Group Decision Making. The SG may make joint decisions with respect to any subject matter described in Section 2.2. The SG shall use its good faith efforts to resolve by consensus any issue before it. The SG shall give consideration to the views, position and recommendations of each Party on any issue that has been brought before it. All decisions of the SG shall be made by [\*\*], as indicated by [\*\*]. If the SG cannot reach consensus on a matter brought to its attention within [\*\*] days, then Section 21.10 shall apply. For the avoidance of doubt, the decision-making authority of the SG shall be limited to matters relating to the items set forth in Section 2.1 (A) - (E) and (G). Except to the extent expressly provided herein, the SG shall have no decision-making authority following the completion of the Subsequent Phase, after which the SG shall serve as a forum for discussion of issues.

2.4 Building Contractor and Design Documents. The Parties hereby acknowledge and confirm that [\*\*] is the Building Contractor responsible for the performance of the Construction Work. Catalent will receive a copy of all of the Design Documents completed and approved as of the Effective Date. From and after the Effective Date, Client shall promptly provide copies of new Design Documents and amended Design Documents to Catalent by and through the Steering Group.

2.5 General Obligations of the Parties With Respect to Construction Work. Each Party undertakes to carry out its obligations and will procure that the obligations in relation to the Construction Work are at all times and at all stages carried out in a good and proper manner in accordance with any Applicable Laws and with all reasonable care and skill including, as appropriate:

- A. the appointment of the members of the Steering Group; and
- B. subject to this Article 2, the carrying out of the Construction Work.

2.6 Building Contract. Catalent and Client shall discuss any variations to the Building Contract by and through the SG, and any variation or proposed change shall be subject to the consent of both Parties, as evidenced by [\*\*], such consent not to be unreasonably withheld or delayed. If it becomes necessary or desirable to appoint any further contractor or consultant relating to the Improvements whose cost exceeds [\*\*] percent ([\*\*]%) of the Guaranteed Maximum Price (as that term is defined and used in the Building Contract) the process set forth in Section 2.6.1 below shall be followed and references in this Agreement to Building Contract and Building Contractor shall be taken to include the relevant contract and contractor respectively.

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2.6.1. Client shall request that the proposed contractor or consultant provide an estimate of the Construction Costs and ongoing change orders involved for such Improvements (“**Estimate**”).

- A. If the SG is unable to approve the Estimate the Client shall first approach the Building Contractor and try to negotiate a reduction in the Construction Costs. If the SG is still unable to approve the Estimate, the Client shall approach an alternative Building Contractor for such Improvements.
- B. If the SG approves the Estimate, Client shall negotiate the terms and conditions of the Building Contract with the Building Contractor. At regular intervals, Client shall discuss all of the key terms with Catalent by and through the Steering Group. In addition, the Building Contract shall contain a provision stating that Client, at Client’s sole risk, shall be entitled to access the Site to review the Construction Work at all times on reasonable notice (subject to compliance with the Building Contractor’s and Catalent’s reasonable requirements) and to make any comments, generally and as to whether or not the Construction Work has been properly completed (such comments to be implemented if the Parties agree). For the avoidance of doubt, Catalent shall make all comments in writing to Client-appointed Members of the SG and not to the Building Contractor.

2.7 Statutory Consents. Before commencement of the Construction Work, Client shall ensure that Building Contractor files all Design Documents, plans and specifications, pay all fees and obtain all Statutory Consents required under Applicable Law to begin the Construction Work. Client shall ensure that Building Contractor prosecutes the Statutory Consents diligently and Catalent shall cooperate with the prosecution of and join in or execute the applications for Statutory Consents as required by Applicable Law. Client shall ensure that Building Contractor pays all expenses incurred in connection with the application for Statutory Consents including all expenses incurred by Catalent. Client shall ensure that Building Contractor promptly furnishes to Catalent copies of all Statutory Consents required by Applicable Law,

2.8 Delay. Building Contractor shall keep the Parties informed of the progress of the Construction Work and shall promptly inform the Parties of any actual delay. Client shall promptly report any delays to the Steering Group. Except with respect to delays directly and solely due to a breach of this Agreement by Catalent, Catalent will be deemed not to be in breach of this Agreement with respect to the Processing to the extent that the delay caused to the Target Completion Date renders Catalent unable to comply with such obligations.

2.9 No Liability. Client acknowledges that Catalent shall have no liability including for any direct, indirect or consequential loss (all three of which terms include, without limitation, pure economic loss, loss of profits, loss of business, depletion of goodwill and like loss) however caused (including as a result of negligence by the Building Contractor) for any delay or failure of or a breach of the Building Contract by the Building Contractor or Client or breach of any other contractor.

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2.10 Intellectual Property and Title. Notwithstanding the terms of Article 14, as between the Parties any and all Intellectual Property with respect to the Design Documents, Improvements and Construction Work shall (to the extent permitted under the terms of the Building Contract) vest in Catalent and Client shall have no title or, except as set out in this Agreement, rights whatsoever in respect of the Client Space and/or the Facility (including any parts of the Facility which are created as a result of the Client Space) following the performance of the Construction Work nor shall Client obtain or be entitled to exercise any form of Lien through the payment of the Construction Costs. Catalent or its Affiliate shall own all right, title and interest in and to the Improvements and the Client Space, subject to the rights, licenses and interests in and to the Improvements and Client Space provided to Client under this Agreement, including, without limitation, the dedication of the Improvements and Client Space as a facility used exclusively for the Processing of Products for Client in accordance with and subject to the provisions of Section 3.3 below. Catalent hereby grants to Client a [\*\*].

2.11 Performance of Construction Work. Client shall cause Building Contractor not to permit the accumulation of building supplies, equipment, waste, material or rubbish within the Client Space, the Site or the Facility, and during the construction and upon completion shall cause all rubbish, implements, material and equipment to be timely removed from the Facility and Site. If any damage is done to any part of the Facility or the Site outside the Client Space, Client shall ensure that Building Contractor, at Building Contractor's cost and expense, repairs and/or replaces same, in a manner satisfactory to Catalent, to the condition existing prior to commencement of the Construction Work. Client shall ensure that the Building Contractor and all subcontractors and material men employ the services of labor that will work in harmony with each other, and any others working in the area. If labor disputes arise, from any cause whatever, Client shall ensure that Building Contractor makes every effort to end same. Catalent may place its supervisory personnel and representatives on the job during the course of the Construction Work, at Catalent's expense (except as set forth in Section 3.4), for the purpose of making any inspections and insuring that Client, Building Contractor, and Building Contractor's subcontractors and material men comply with the terms of this Agreement. Client shall ensure that Building Contractor complies with all Catalent policies and procedures relating to safety, security, work processes and the procedures as outlined in [\*\*] as directed by Catalent. Notwithstanding the foregoing enumeration of restrictions and conditions, Catalent may at any time during the course of the Construction Work impose such other reasonable restrictions, rules and conditions as may be reasonably necessary to ensure the proper completion of the Construction Work. Notwithstanding anything to the contrary in this Agreement, Client shall obtain Catalent's prior written consent to shutting off any utilities to the Facility or the Site. Construction Specifications "Division 1" shall be completed by Client and approved by Catalent prior to construction activities. To the extent Catalent communicates the directive to Client, Client shall ensure that Building Contractor implements any directive of [\*\*] pertaining to the performance of the Construction Work. To the extent Catalent ensures that such approval is sought from [\*\*] and is not unreasonably denied, Client shall ensure that Building Contractor's performance of the Construction Work achieves the approval of [\*\*]. The SG shall oversee the implementation of [\*\*]'s directives and the achievement of [\*\*]'s approval for Building Contractor's performance of the Construction Work. Unless otherwise agreed in writing by the Parties, each week between the Effective Date and the Completion Date, Client or its designee

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shall meet with a designated Catalent representative to review the upcoming weekly schedule of construction activities, which shall be subject to Catalent's approval not to be unreasonably withheld.

2.12 Termination of Building Contract. Catalent shall have the right to request that Client terminate the Building Contract by providing written reasons or evidence, which request shall not be unreasonably denied by Client. In the event that the Building Contract is terminated or treated as terminated, for whatever reason, Parties shall promptly use commercially reasonable efforts to replace the Building Contract and Building Contractor as soon as practically possible.

2.13 No Liens. Client has no right, title or interest in the Facility, the Site or the Client Space against which any Lien may be granted. Client shall amend the Building Contract to obligate Building Contractor to: (a) not create or permit to be created or remain, and promptly discharge, at Building Contractor's sole cost and expense, any Lien on the Facility, the Site or the Client Space or any part thereof or upon fixtures to the Facility, the Site or the Client Space and (b) keep the Facility, the Site and the Client Space and fixtures thereon free and clear of any Lien as the result of any of Building Contractor's subcontractors, suppliers, employees or material men. In the event that any such Lien shall be filed against the Facility, the Site or the Client Space or fixtures thereto or part thereof, upon Client's receipt of notice of filing of such Lien, Client shall withhold payment of any amount then due or that becomes due and payable by Client to Building Contractor until such time as Building Contractor causes such Lien to be released or discharged by payment or bonding. The foregoing notwithstanding, in the event that Catalent notifies Client that any such Lien must be removed as required by Catalent's loan obligations or lender, then Client shall promptly post such bond or provide other security as is reasonably necessary to release or discharge such lien or to assure that the priority of the mortgagee's mortgage over such Lien will not be lost. If Client fails to post such bond(s) or otherwise obtain discharge and release of such Lien or provide such security and save Catalent and Catalent's lender harmless from all threat of loss or damage that could arise therefrom, Catalent, after notice to Client, may pay and/or otherwise obtain discharge of such Lien (including by use of funds obtained from the Cash Deposit pursuant to Section 4.1), and all expenditures and costs incurred thereby shall be payable as additional fees hereunder and shall accrue interest at the rate set forth in Section 10.4 until paid. Failure by Client to comply with this Section shall be a material breach of this Agreement. Nothing contained herein shall imply any consent or agreement on the part of Catalent to subject Catalent's estate to liability under any mechanics' or other lien law.

## ARTICLE 3 EQUIPMENT

3.1 Orders. With the exception of the initial Client Equipment ordered on or before the Effective Date, Catalent and Client shall agree on Client Equipment to be ordered, by and through the Steering Group, pursuant to the process set forth in Section 2.1 and Schedule 4. Client shall purchase, pay for, own title to and bear risk of loss for all Client Equipment identified in or added to Schedule 3 within [\*\*] months after the date that Schedule 3 is added or amended to reflect such Client Equipment. Client shall be responsible for all costs associated with delivery, installation, qualification and validation of the Client Equipment. Client Equipment will be used by Catalent in accordance with Section 3.3, and Client Equipment costs

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shall be paid in full by Client. To the extent Catalent agrees to purchase equipment for use in connection with this Agreement, Catalent shall purchase, pay for, own title to and bear risk of loss for all such Catalent Equipment. Notwithstanding the foregoing, without the advance written consent of Client, which consent shall not be unreasonably denied, there shall be no material modification of any part or item of Client Space, Improvements or Client Equipment, or any portion, part, or component thereof.

3.2 Title to Equipment and Security Interest. Subject to Section 3.8 and Section 19.5(F), Client shall own title to all Client Equipment notwithstanding the installation of Client Equipment at the Facility. Catalent shall not do or permit or cause anything to be done whereby Client's rights in and title to the Client Equipment are prejudiced.

3.3 Use of Equipment. Except as provided in Section 3.8 or Article 19, no item of Client Equipment shall be moved from the Facility without the prior written agreement of the Parties, not to be unreasonably withheld or delayed. Except as provided in this Article 3, Catalent shall not use the Client Space or Client Equipment for any purpose other than Processing Products in accordance with this Agreement (or any other relevant supply agreement which may be entered into between the Parties) without Client's prior written consent (such consent not to be unreasonably withheld or delayed).

- A. The Parties shall meet to consider, forecast, plan and agree the utilization of the Client Equipment, by and through the Steering Group, as follows:
  - (i) The Parties shall meet to discuss the forecast utilization of the Client Equipment approximately [\*\*] months in advance of the anticipated Completion Date and thereafter in December of each calendar year (the "**Annual Meeting**"). At the Annual Meeting the Parties shall discuss the forecast for the forthcoming calendar year.
  - (ii) In addition to the Annual Meeting, the Parties shall meet in March, June and September (together with the Annual Meeting the "**Quarterly Meetings**") to discuss the use of the Client Equipment in the Quarter after the full Quarter that follows the meeting and agree on a production schedule for Products for Client.
- B. At Client's cost, Catalent shall mark each individual unit of Client Equipment in a conspicuous manner to indicate that such Client Equipment is owned by Client.
- C. Catalent has no right, title or interest in the Client Equipment and as such, Catalent has no right, title or interest in the Client Equipment against which any Lien may be granted by Catalent.
- D. Except pursuant to Section 3.2, Client shall not grant a Lien on the Client Equipment, shall ensure that the Building Contractor and its subcontractors do not take a Lien on Client Equipment and shall keep the Client Equipment free and clear of any Lien as a result of Client.

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## EXECUTION VERSION

3.4 Facility Construction Support Fee [\*\*] Commencing upon the Effective Date and ending on the earlier of the Completion Date or July 1, 2014, Client will pay to Catalent the Facility Construction Support Fee as provided in Attachment C, which shall cover the following the Costs associated with the Client Space through the earlier of the Completion Date or July 1, 2014 [\*\*]

3.5 Facility Fee. Subject to the payment of the Facility Construction Support Fee, on the earlier of the Completion Date or July 1, 2014, Catalent shall, for a fee provided in Attachment C and referenced in Article 10, maintain the Client Space, Improvements, Client Equipment and the Catalent Equipment in accordance with the below:

- A. such maintenance shall be performed to at least the standards adopted in respect of its other equipment in the Facility required to be maintained in compliance with cGMP;
- B. Catalent shall use trained and competent maintenance personnel for such maintenance;
- C. Catalent shall keep and update as appropriate all documents relating to the Client Equipment (whether they exist in paper or electronic form) including a copy of all maintenance records for a minimum period of [\*\*] years. All such documents shall be available for Client to inspect at the Facility on reasonable notice by Client to Catalent. Catalent shall provide to Client a complete copy of such documents on the termination of this Agreement except termination by Catalent pursuant to Section 19.3(A) or (B); and
- D. Client shall be responsible for the cost of maintenance of the Client Equipment. Catalent shall inform Client of the need for any upgrades, replacements and repairs which are identified as Significant Repairs. Significant Repairs shall include any upgrade, replacement or repair which exceeds a total cost of \$[\*\*]. Catalent shall perform all such Significant Repairs and Client shall be responsible for the cost of any Significant Repairs to Client Equipment including Catalent's reasonable costs for performing the same. Catalent will seek Client's approval before proceeding with any Significant Repairs, such approval not to be unreasonably withheld, conditioned or delayed.
- E. If at any time any further modification to the Facility, Client Space, Improvements, Client Equipment or Catalent Equipment is required by a Regulatory Authority, such modification shall be undertaken upon the Parties' mutual agreement by and through the Steering Group and at Client's expense.
- F. Subject to Section 3.5(D) above, Client shall have no responsibility to maintain the Facility, Client Space, Improvements, Client Equipment, and Catalent Equipment to cGMP and production readiness.

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3.6 Risk of Loss of Client Equipment. For such period as Client has title in the Client Equipment and Catalent has possession of the Client Equipment in the Facility, as between Client and Catalent, Client shall bear all risk of:

- A. loss of or damage to the Client Equipment including normal wear and tear; and
- B. loss or damage caused by the Client Equipment to Products Processed for Client.

In addition, the Parties agree that:

- (i) Client shall have no liability for Batches not released by Catalent if the failure to release the Batch is due to Catalent Defective Processing; and
- (ii) In the event of any such loss or damage of any item of Client Equipment due to the gross negligence or willful misconduct (including gross negligence or intentional misconduct in relation to the operation (including to properly prepare SOPs), inspection or maintenance the Client Equipment) of Catalent, its Affiliates, employees, contractors or representatives, Catalent shall at Client's option either:
  - (a) repair or replace such item of Client Equipment as soon as reasonably practical at Catalent's sole cost and expense; or
  - (b) pay to Client the Residual Value of such Client Equipment at the date the loss occurred.

Catalent's obligations under this Section 3.6 shall be Client's exclusive remedy and Catalent's sole liability with respect to loss of or damage to the Client Equipment and any Products as contemplated in this Section 3.6.

3.7 Liability for Stoppage. Catalent shall not be liable for any loss or damage (other than where caused by Catalent's gross negligence or willful misconduct) suffered by Client through the breakdown or stoppage of the Client Equipment or the Catalent Equipment. Catalent will use commercially reasonable efforts to repair and cause Client Equipment, Catalent Equipment, Improvements, Client Space and Facility to be in manufacturing ready state as soon as reasonably practical.

3.8 Disposal of Equipment. If the Client Equipment has remained idle for a period of in excess of twelve (12) calendar months or, in the reasonable judgment of the Parties, has reached the end of its useful life then Client and Catalent will discuss means of best protecting their respective positions in respect of the Client Equipment, with a view to either Client removing the Client Equipment or Catalent having the right to use, purchase or destroy the Client Equipment in accordance with Section 19.5.

3.9 Taxes. Client shall be responsible for all personal property and all other taxes and governmental charges imposed or levied on the Client Equipment by any and all applicable

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government authorities. Catalent shall provide adequate documentation to substantiate such taxes.

### ARTICLE 4 TERMS APPLICABLE TO CONSTRUCTION WORK AND CLIENT EQUIPMENT

#### 4.1 Security Deposit.

- A. Promptly after the Effective Date, but no later than [\*\*] business days following Client's receipt of Catalent's written wiring instructions therefor, Client shall deposit to the account of Catalent by wire transfer an additional payment of [\*\*] dollars (\$[\*\*]) in cash ("**Cash Deposit**") (together with the [\*\*] dollars wired previously to Catalent pursuant to the Letter Agreement), to be held by Catalent (a) as security for the faithful performance by Client of the payment obligations under Section 4.5 (the "**Costs**"); and (b) the discharge of Liens pursuant to Section 2.13. If Client defaults with respect to the payment of Costs or any portion thereof, time being of the essence, Catalent may (but shall not be required to) withdraw from the Cash Deposit, up to the entirety of the Cash Deposit the amount required to pay the costs then due and to use, apply or retain the proceeds thereof for the payment of any other Costs or to compensate Catalent for any other loss or damages which Catalent may suffer as a result of Client's failure to pay the Costs.
- B. In the event of the use of any portion of the Cash Deposit, Client shall, within [\*\*] days after Client's receipt of another written request from Catalent therefor, replenish the Cash Deposit to the full amount set forth above, time being of the essence.
- C. Any Cash Deposit shall be transferable by Catalent to its successor in accordance with Section 21.7 or to Catalent's lender if requested.
- D. In the event of bankruptcy or other debtor/creditor proceedings against Client, the proceeds of the Cash Deposit shall be deemed to be applied first to the payment of Costs due to Catalent or the Building Contractor for all periods prior to the filing of such proceedings.
- E. Catalent shall deliver the Cash Deposit, and any proceeds thereof, to any successor-in-interest of Catalent and thereupon Catalent shall be discharged from any further liability with respect thereto provided that such successor has agreed to assume the obligations of Catalent hereunder. This provision shall also apply to any subsequent transfers.
- F. The balance remaining of the Cash Deposit, if any, and any proceeds thereof shall be delivered to Client within [\*\*] days after the invoices for all Costs have been paid by Client and all lien waivers required under this Agreement have been delivered to Catalent.

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- G. The amount owed by Client to Catalent and the Building Contractor shall not be limited by the Cash Deposit. Catalent's right to draw under the Cash Deposit shall be in addition to, and not in lieu of, all other rights and remedies of Catalent for the failure of Client to pay the Costs or breach of Section 2.13.

4.2 Insurance Coverage for Construction Work and Equipment. Client shall, at its cost, maintain throughout the term of this Agreement, with a reputable insurer rated a minimum of A- by Best's Rating Service, insurance for the Facility, Construction Work and all Client Equipment. Client may, but will not be obliged to, obtain a waiver of any exclusion in respect of terrorism but will seek to ensure that any policy exclusions and excesses fall within normal commercial practice in the United States insurance market. Client will, upon request by Catalent, provide Catalent with a certificate of insurance evidencing reasonable levels of liability insurance in respect to the Facility and Construction Work customary with this type of project. Catalent, at Catalent's cost and expense, may procure additional insurance to ensure that the Facility, Improvements and the Client Equipment are insured as it deems appropriate. The Parties agree that insurance maintained by Client or Building Contractor shall be primary and non-contributing with insurance or self-insurance maintained by Catalent. In addition, prior to the commencement of Construction Work and continuing through the completion of the Work, Client shall secure or require the Building Contractor to secure from an insurer reasonably acceptable to Catalent, rated a minimum of A- by Best's Rating Service: (a) Builders Risk Insurance on an All Risk basis with Catalent, Catalent's mortgage lenders, and Client as named additional insureds, in an amount not less than [\*\*]; and (b) insurance against claims under Workers' Compensation Acts in compliance with all legal requirements; (c) Automobile liability insurance covering all owned, non-owned or hired vehicles used in the project in a minimum amount of \$[\*\*] combined single limit (d) Comprehensive General Liability Insurance covering the Construction Work (including Broad Form Contractual Liability Insurance and Products and Completed Operations Insurance) with a combined single limit of not less than \$[\*\*] bodily injury and/or property damage liability and not less than \$[\*\*] aggregate liability; and (e) umbrella liability insurance in a minimum amount of \$[\*\*] providing excess or broader coverage over the liability limits contained in subparagraph (e) and (d). Catalent shall be a named additional insured in all such insurance policies of Client and Building Contractor and a loss payee under the Builders Risk insurance. Prior to the commencement of Construction Work, Client shall deliver or require Building Contractor to deliver to Catalent certificates evidencing the foregoing insurance and evidencing the foregoing endorsements, and Client shall provide or require Building Contractor to provide [\*\*] days prior written notice to Catalent of cancellation or changes in such insurance.

4.3 Casualty. In the event of any loss or damage occurring to the Facility, Improvements, Catalent [\*\*], Client Equipment or Client Space, the Steering Group shall meet and determine whether to rebuild or repair the Facility, Client Space, Improvements, Catalent Equipment and Client Equipment, in which case Section 4.3(A) shall apply or whether to forego rebuilding or repair, in which case, Section 4.3(B) shall apply. The Steering Group shall use commercially reasonable efforts to make a determination regarding repairing or rebuilding within [\*\*] days of the occurrence of the loss, provided that any reconstruction undertaken by Client shall be subject to any restriction imposed by any local authority on the right to access or reconstruct the Facility

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and performed at the risk of any decision not to rebuild taken by Catalent within [\*\*] days of the occurrence of the loss.

- A. If by unanimous decision the Steering Group agrees to rebuild or repair the Facility, Client Space, improvements, Client Equipment and/or Catalent Equipment, Client may claim on its insurance and/or fund the obligation from its own resources. In either case, the principle that Client owns any new Client Equipment and Catalent owns the Improvements and Catalent Equipment shall be preserved and immediately following the reconstruction or replacement, the Residual Value of the Client Equipment and Improvements shall be equal to the Residual Value immediately prior to the loss of or damage to the Client Equipment or Improvements. To the extent that (i) Catalent has additional insurance or (ii) it has insured for a risk that is not included in Client's insurance obligation in Section 4.2, and if Catalent is able to make a claim in its insurance, then Catalent shall contribute to the cost of reconstruction of the Client Space, provided Catalent's obligation to contribute shall be limited to the lesser of (i) the difference between the reconstruction cost less the Residual Value of the Improvements and the Client Equipment and (ii) the amount that Catalent receives from its insurer. Until such time as the rebuilding or repair specified in this Section 4.3(A) is complete, Catalent shall [\*\*] prioritize the use of any suitable shared space of the Site, and [\*\*] prioritize the use of any suitable shared space of any other Catalent facility, for Product Processing for Client, except that the foregoing obligations shall not apply to any portion of a Catalent facility, including any portion of the Site, which is dedicated exclusively to use by or for another customer, nor shall Catalent be required to breach any of its contractual commitments to other customers.
- B. If by unanimous decision the Steering Group agrees not to rebuild or repair the Facility, Client Space, Improvements, Client Equipment or Catalent Equipment, or if Catalent does not agree to any such rebuilding or repair, or if Client does not agree to any such rebuilding or repair, the provisions of this Section 4.3(B) shall apply.
  - i. Subject to paragraph (ii) below, if the loss falls within Client's insurance obligation under Section 4.2, Client shall retain the Residual Value of the Client Equipment and pay the remainder of the insurance proceeds for the Client Equipment to Catalent; to the extent a loss falls outside Client's insurance obligation under Section 4.2, Client shall not be obliged to pay any amount to Catalent;
  - ii. Catalent shall allow Client to remove any of the Client Equipment that is in Client's reasonable view salvageable;
  - iii. If the loss is a loss of the Facility's functionality on which the Client Space depends and if the loss is a loss for which rebuilding or repair is not commercially reasonable, then Catalent may elect to terminate the

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Agreement and remove the Client Equipment at Client's expense. If the immediately preceding sentence does not apply or if the sentence applies but Catalent elects not to terminate the Agreement, Client may elect to (a) terminate the Agreement and remove the Client Equipment at Client's expense or (b) reestablish the Process at a dedicated space in another manufacturing facility of Catalent, such facility to be selected by mutual agreement of the Parties, and in such event this Agreement shall apply to the rights and obligations of the Parties mutatis mutandis, provided that (1) until such time as the reestablishment of the Process at a dedicated space in another facility is completed, Catalent shall [\*\*] prioritize the use of any suitable shared space at the Site, and [\*\*] prioritize the use of any suitable shared space of any other Catalent facility, for Product Processing for Client, except that the foregoing obligations shall not apply to the any portion of a Catalent facility, including any portion of the Site, which is dedicated exclusively to use by or for another customer, nor shall Catalent be required to breach any of its contractual commitments to other customers, (2) the Parties shall agree upon a reasonable adjustment to pricing for Processing of Product at the shared space and the new facility, (3) subject to the prior exhaustion of any remainder of insurance proceeds that otherwise would be paid to Catalent as provided in Section 4.3(B)(i) above, Client shall bear the cost of moving and installing Client Equipment at the new facility along with the cost of any renovations that may be necessary to establish the Process at such facility, (4) Client shall bear the cost of obtaining any Regulatory Approval for the Process at such facility, and (5) the Parties shall agree upon changes to the applicable quality agreement as appropriate for the new facility; and

iv. Catalent shall be entitled to retain any monies it receives from its insurer.

4.4 Condemnation. If the Client Space or a part of the Facility shall be taken by the exercise of the power of eminent domain (or sold to the holder of such power pursuant to a threatened taking):

- A. Catalent shall be entitled to receive all condemnation awards or purchase price; and
- B. Either Party may elect to terminate the Agreement and remove the Client Equipment at Client's expense or the Parties may agree to reestablish the Process at another manufacturing facility of Catalent, such facility to be selected by mutual agreement of the Parties, and in such event this Agreement shall apply to the rights and obligations of the Parties mutatis mutandis, provided that (i) until such time as the reestablishment of the Process at a dedicated space in another facility is completed, Catalent shall [\*\*] prioritize the use of any shared space at the Site and [\*\*] prioritize the use of any shared space of any other Catalent facility for Product Processing for Client, except that the foregoing obligations do not apply to the any portion of a Catalent facility, including any portion of the

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Site, which is dedicated exclusively to use by or for another customer, nor shall Catalent be required to breach any of its contractual commitments to other customers; (ii) the Parties shall agree upon a reasonable adjustment to pricing for Processing of Product at the shared space and the new facility; (iii) Client shall bear the cost of moving and installing Client Equipment at the new facility along with the cost of any renovations that may be necessary to establish the Process at such facility; (iv) Client shall bear the cost of obtaining any Regulatory Approval for the Process at such facility; and (v) the Parties shall agree upon changes to the applicable quality agreement as appropriate for the new facility.

### 4.5 Costs. Construction Costs shall be calculated and paid as follows:

- A. Building Contractor shall receive invoices directly from contractors employed by Building Contractor to perform the Construction Work. Building Contractor shall forward all invoices received from contractors for the invoiced period to the party designated as authorized by Client to issue authorizations for payment of invoices (the “Client’s Designee”). For each invoice, Client’s Designee shall determine the percentage of progress towards completion of the segment of Construction Work reflected by the invoice and issue either (a) an authorization for payment of a sum equal to the percentage of progress toward completion of the segment of Construction Work (the “Percentage Completion”) multiplied by that portion of the Guaranteed Maximum Price (as that term is defined and used in the Building Contract) applicable to the segment of Construction Work, minus any amounts previously invoiced and paid for the segment of Construction Work (any such sum, the “Authorized Payment Amount”) or (b) a denial of authorization for payment if the Percentage of Completion multiplied by that portion of the Guaranteed Maximum Price (as that term is defined and used in the Building Contract) applicable to the segment of Construction Work is less than or equal to the amount(s) previously invoiced and paid for the segment of Construction Work. Upon Building Contractor’s receipt of an authorization to pay the Authorized Payment Amount(s), Building Contractor shall issue a monthly consolidated invoice to Client for the Authorized Payment Amount(s) plus the Building Contractor’s fee, along with the supporting contractors’ invoices. Client shall pay to Building Contractor the amount(s) reflected in the monthly consolidated invoice, subject to receipt of applicable lien waivers. Building Contractor shall pay and have sole responsibility for payment of the contractors’ invoices that gave rise to Authorized Payment Amount(s) in the monthly consolidated invoice. Client shall amend the Building Contract to obligate Building Contractor, at the time of payment of any subcontractor’s invoice, to (1) secure a conditional partial lien waiver for the amount of such payment and an unconditional release of each prior payment from such subcontractor substantially in the form attached as Schedule 8 and (2) provide such conditional partial lien waiver and unconditional release to Catalent promptly after the payment of such invoice. For purposes of this Section 4.5, a “conditional partial lien waiver” shall mean a partial lien waiver that effects the subject waiver only upon the satisfaction of the condition precedent of payment to the grantor of the amount

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specified in the conditional partial lien waiver. Client shall ensure that Building Contractor promptly provides copies of all invoices and payments to Catalent. Promptly after Client pays to Building Contractor any Authorized Payment Amount pursuant to a final Certificate of Payment (as that term is defined in the Building Contract) issued by Client's Designee, Client shall ensure that Building Contractor secures and provides to Catalent conditional final lien waivers for the amounts reflected in such payment, and, promptly after the subcontractors' receipt of corresponding disbursements from Building Contractor, accompanying unconditional releases for the amounts reflected in such payment, which conditional final lien waivers and unconditional releases are substantially in the form attached as Schedule 8 and signed by the Building Contractor and all contractors, subcontractors, material men and suppliers for labor, services and materials furnished in connection with the Construction Work and Improvements. For purposes of this Section 4.5, a "conditional final lien waiver" shall mean a final lien waiver that effects the subject waiver only upon the satisfaction of the condition precedent of payment to the grantor of the amount specified in the conditional final lien waiver.

- B. Except as otherwise agreed by the Parties, all sums payable by Client to Catalent under this Agreement will be made within [\*\*] days of the date of receipt of the invoice in US dollars to the credit of a bank account to be designated in writing from time to time by Catalent.
- C. All Costs payable to Catalent under this Agreement are exclusive of VAT or other applicable duties, sales tax or other taxes. Any of the foregoing shall be payable by Client to Catalent in addition to the Costs.
- D. Within [\*\*] days of the date of execution of this Agreement by both Parties, Catalent shall credit Client the amount Client paid to Catalent under the Quote denoted as [\*\*] to be applied toward clinical or commercial services at Client's discretion.

4.6 Completion Date Certificate. Within thirty (30) days following the Completion Date, the Parties shall execute a Completion Date Certificate in the form attached as Schedule 6.

## ARTICLE 5 PROCESS VALIDATION, PROCESSING & RELATED SERVICES

5.1 Location of Services. Prior to the Completion Date, any Validation Services, Processing or other services required to be performed by Catalent under this Article 5 shall be performed in parts of the Facility other than the Client Space. Beginning no earlier than the Completion Date and subject to payment in full for all Costs and other outstanding amounts as of the Completion Date, Catalent shall perform the services described in this Article 5 in the Client Space. For the avoidance of doubt, Catalent shall have no obligation to perform any services in the Client Space in the event that (i) the Construction Work is not satisfactorily completed; (ii) Client Equipment

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or Catalent Equipment is not successfully installed, qualified, validated and operational; or (iii) such Costs and any other amounts owed by Client under this Agreement are not fully paid.

5.2 Validation Services. The Parties will negotiate in good faith the provision of qualification, validation and stability services described in Attachment B (the “**Validation Services**”) and whether the Validation Services will be performed in the Client Space or outside the Client Space.

5.3 Supply and Purchase of Product. Catalent shall Process Product in accordance with the Specifications, the Applicable Laws and the terms and conditions of this Agreement. Client and its Affiliates shall purchase from Catalent, and Catalent will be the supplier to Client and its Affiliates for Client’s and its Affiliates’ requirements of Product in countries in the Territory in which Client and/or its Affiliates have the right to sell, have sold, or grant a license to sell the Product, as follows. Following the Commencement Date and throughout the remainder of the Term, Client and its Affiliates shall purchase from Catalent no less than [\*\*] percent ([\*\*]%) of their requirements of Product in countries in the Territory in which Client and/or its Affiliates have the right to sell, have sold, or grant a license to sell the Product. However, to the extent Catalent [\*\*] Client and its Affiliates shall have the right to [\*\*].

5.4 Product Maintenance Services. Client will receive the following product maintenance services (the “**Product Maintenance Services**”): [\*\*] audit (as further described in Section 12.5); [\*\*] regulatory audits (as further described in Section 12.4); one annual Product review (within the meaning of 21 CFR § 221.180); drug master file updates for the Territory, if applicable; access to document library over and above the Quality Agreement, including additional copies of Batch paperwork or other Batch documentation; assistance in preparing Regulatory Approvals; Product document and sample storage relating to cGMP requirements; vendor re-qualification; maintenance, updates and storage of master batch records and audit reports; bulk stability (6 months, warehouse conditions); and tooling and filter bag maintenance, as applicable. For avoidance of doubt, the following services and items are not included in Product Maintenance Services: technology transfer; analytical work; stability, other than the bulk stability described above; process rework (except to the extent process rework is due to Catalent’s gross negligence or willful misconduct); Validation Services and replacement HPLC columns, as applicable.

5.5 Other Related Services. Catalent shall provide such Product-related services, other than Validation Services, Processing or Product Maintenance Services, as agreed to in writing by the Parties from time to time. Such writing shall include the scope and fees for any such services and be appended to this Agreement. The terms and conditions of this Agreement shall govern and apply to such services.

5.6 Expansion of Territory. In the event Client desires to expand the Territory under this Agreement to include one or more additional countries (each, an “**Additional Country**”), Client will, on each such occasion, provide written notice to Catalent. If meeting the regulatory requirements applicable to the Processing of Product intended for distribution in such Additional Country is technically feasible using commercially reasonable efforts, and Catalent is not otherwise restricted under applicable law or other obligations, including without limitation those

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imposed by the U.S. Office of Foreign Asset Control, Catalent will provide Client with a proposal that describes the additional costs to be paid by Client as a result of the additional regulatory requirements in such country applicable to the Processing of Product, and a time-line for being able to Process Product that conforms to such additional requirements (the “**Additional Product Proposal**”), and the Parties will negotiate the Additional Product Proposal in good faith. The Additional Product Proposal will serve as the basis for an amendment to this Agreement to expand the Territory. No expansion of the Territory will be effective unless a written amendment to this Agreement defining the expanded Territory and the additional work and costs, if any, associated with such expansion has been signed by both Parties. Catalent will not unreasonably withhold its consent to an amendment to this Agreement to expand the Territory.

### ARTICLE 6 MATERIALS

#### 6.1 API.

A. Client shall supply to Catalent for Processing, at Client’s sole cost and risk, API, applicable reference standards and any other Client-supplied Materials, DDP (Incoterms 2010) the Facility in quantities sufficient to meet Client’s requirements for Product, as set forth in Article 7. Client shall deliver such items, together with associated certificates of analysis, to the Facility no later than [\*\*] days before the Processing Date upon which such items will be used by Catalent. Client shall be responsible at its expense for securing any necessary export or import clearances or permits required in respect of supply to Catalent of such items. Catalent shall use such items solely and exclusively for Processing. Prior to delivery of any such items, Client shall provide to Catalent a copy of all associated material safety data sheets, safe handling instructions and health and environmental information, and shall promptly provide any updates or revisions thereto. In addition, beginning no earlier than [\*\*] months prior to the Commencement Date, Client shall deliver to Catalent a monthly report, together with the Rolling Forecast submitted pursuant to Section 7.1, which tracks the following supply chain information with respect to raw materials for each API batch ordered by Client for use in Product: order date, manufacture lot number, quantity, ship date, customs clearance date and arrival date at Catalent (the “**API Procurement Tracking Report**”). The API Procurement Tracking Report shall be provided in substantially the form set forth in Attachment F.

B. Within [\*\*] days of receipt of API or any other Client-supplied Materials by Catalent, Catalent shall inspect and test such items to verify their identity. Unless otherwise expressly required by the Specifications, Catalent shall have no obligation to test such items to confirm that they meet the associated specifications or certificate of analysis or otherwise; but in the event that Catalent detects a nonconformity with Specifications, Catalent shall give Client prompt oral and written notice of such nonconformity. Catalent shall not be liable for any defects in API or any other Client-supplied Materials, or in Product as a result of defective API or any other Client-supplied Materials, unless Catalent failed to properly perform the foregoing obligations. Catalent shall follow Client’s reasonable written instructions in respect of return or disposal of defective API or any other Client-supplied Materials, at Client’s sole cost and risk.

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C. Client shall retain title to API and any other Client-supplied Materials at all times and shall bear the risk of loss thereof, except and to the extent any such loss arises from the gross negligence or willful misconduct of Catalent. Notwithstanding the foregoing, Catalent retains liability of up to [\*\*] dollars (\$[\*\*]) for any loss or damage to API per Batch in Process per event to the extent such loss or damage arises from the negligence of Catalent,

### 6.2 Raw Materials.

A. Catalent shall be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed to by the Parties in writing. Catalent shall not be liable for any delay in delivery of Product if Catalent placed orders for such Raw Materials promptly following receipt of Client's Firm Commitment. In the event that any Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the Parties will negotiate in good faith an appropriate amendment to this Agreement, including Sections 6.4 and 7.1.

B. In certain instances, Client may require a specific supplier, manufacturer or vendor ("**Supplier**") to be used for Raw Material and such Supplier shall be used by Catalent. In such an event, (i) such Supplier will be identified in the Specifications, (ii) Client shall be responsible for the timeliness, quantity and quality of supply of Raw Materials from such Supplier, (iii) Catalent shall not be liable for any defects in Raw Materials from such Supplier, or in Product as a result of such defective Raw Materials unless Catalent failed to properly perform any testing required by the Specifications, and (iv) the Raw Materials from such Supplier shall be deemed, for purposes of liability hereunder, Client-supplied Materials. If the cost of the Raw Material from any such Supplier is greater than Catalent's costs for the same raw material of equal quality from other suppliers, Catalent shall add the difference between Catalent's cost of the Raw Material and the Supplier's cost of the Raw Material to the Batch Pricing. Client will be responsible for all costs associated with qualification of any such Supplier who has not been previously qualified by Catalent.

6.3 Artwork and Packaging. Client shall provide or approve, prior to the procurement of applicable components, all artwork, advertising and packaging information necessary for Processing, if any. Such artwork, advertising and packaging information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising and packaging information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder.

6.4 Reimbursement for Materials. In the event of (A) a Specification change for any reason, (B) obsolescence of any Raw Material or (C) further to Section 19.4 (C), termination or expiration of this Agreement, Client shall bear the cost of any unused Raw Materials (including packaging), so long as Catalent purchased such Raw Materials in quantities consistent with Client's most recent Firm Commitment and the supplier's minimum purchase obligations.

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### ARTICLE 7 PURCHASE ORDERS & FORECASTS

7.1 Forecast and Maximum Requirement. On or before the [\*\*] of each calendar month, beginning at least [\*\*] months prior to the anticipated Commencement Date, Client shall furnish to Catalent a written [\*\*] rolling forecast of the quantities of Product that Client intends to order from Catalent during such period (“**Rolling Forecast**”), provided that Catalent has the right to reject any portion of the amount by which the quantity of Product forecasted in any Rolling Forecast exceeds [\*\*] percent ([\*\*]%) of the quantity of Product purchased in the preceding [\*\*] months not to exceed the capacity of the dedicated equipment. The capacity of the dedicated equipment is currently estimated to be approximately [\*\*] Batches of Product per Contract Year. The capacity of the dedicated equipment will be reviewed and updated after the Completion Date. The first [\*\*] of such Rolling Forecast shall constitute a binding order for the quantities of Product specified therein (“**Firm Commitment**”) and the following [\*\*] of the Rolling Forecast shall be non-binding, good faith estimates.

7.2 Purchase Orders.

A. From time to time as provided in this Section 7.2 (A), Client shall submit to Catalent a binding, non-cancelable purchase order for Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit batches of different sizes and the Parties have agreed on the terms applicable to manufacture of such different batch sizes) and the requested delivery date for each Batch (“**Purchase Order**”). Concurrently, with the submission of each Rolling Forecast, Client shall submit a Purchase Order for the Firm Commitment.

B. Without limiting the generality of Sections 7.1 and 7.2 (A), Client will submit one or more Purchase Orders for a minimum of [\*\*] Batches of Product to be manufactured between the Effective Date and the earlier of the Completion Date or July 1, 2014 (the “Initial Batches”). The Initial Batches may be for clinical or commercial use and shall be considered Batches manufactured under this Agreement.

C. Within [\*\*] days following receipt of a Purchase Order, Catalent shall issue a written acknowledgement (“**Acknowledgement**”) that it accepts such Purchase Order. Each acceptance Acknowledgement shall either confirm the delivery date set forth in the Purchase Order or set forth a reasonable alternative delivery date, and shall include the Processing Date.

D. Notwithstanding Section 7.2 (C), in the event Client orders any quantity of Product for a period that is greater than the quantity of Product forecasted in the then-current Rolling Forecast for such period (any portion of the ordered quantity that is in excess of the forecasted quantity for such period, the “Excess Quantity”), in addition to filling the forecasted quantity of Product for such period, Catalent shall use commercially reasonable efforts to fill the Excess Quantity of Product ordered for such period subject to Catalent’s other supply commitments and manufacturing, packaging (to the extent applicable) and equipment capacity provided: (i) Catalent did not reject any portion of the Excess Quantity and thereby prevent its inclusion in the then-current Rolling Forecast in accordance with Section 7.1, and (ii) the

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quantity of Product ordered for the period including the Excess Quantity does not exceed [\*\*] percent of the quantity of Product purchased in the preceding [\*\*] months not to exceed the capacity of the dedicated equipment. Catalent's failure to supply Client with quantities in excess of the quantities specified in the Firm Commitment shall not constitute a breach of this Agreement by Catalent.

E. In the event of a conflict between the terms of any Purchase Order or Acknowledgement and this Agreement, the terms of this Agreement shall control.

7.3 Catalent's Cancellation of Purchase Orders. Notwithstanding Section 7.4, Catalent reserves the right to cancel all, or any part of, a Purchase Order upon written notice to Client, and Catalent shall have no further obligations or liability with respect to such Purchase Order, if Client refuses or fails to timely supply conforming API or any other Client-supplied Materials in accordance with Section 6.1. Any such cancellation of Purchase Orders shall not constitute a breach of this Agreement by Catalent.

7.4 Client's Modification or Cancellation of Purchase Orders.

A. Client may modify the delivery date or quantity of Product in a Purchase Order only by submitting a written change order to Catalent at least [\*\*] days in advance of the earliest Processing Date covered by such change order. Such change order shall be effective and binding against Catalent only upon the written approval of Catalent, and notwithstanding the foregoing, Client shall remain responsible for the Firm Commitment unless otherwise agreed by the Parties in writing signed by authorized signatories of both Parties.

B. Notwithstanding any amounts due to Catalent under Section 7.3, if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment, Catalent shall inform Client of such shortfall. Client shall, have the options to a) [\*\*] days of receipt of such notification from Catalent, and at least [\*\*] days prior to the delivery date, [\*\*].

7.5 Unplanned Delay. Catalent shall use commercially reasonable efforts, [\*\*], to meet the Purchase Orders, subject to the terms and conditions of this Agreement. Catalent shall provide Client with as much advance notice as possible (and will use commercially reasonable efforts to provide at least [\*\*] days advance notice where possible) if Catalent determines that any Processing will be delayed.

7.6 Observation of Processing. In addition to Client's audit right pursuant to Section 12.4, Client may send up to [\*\*] to the Facility to observe Processing for the [\*\*] after the Commencement Date, and thereafter, for a maximum of [\*\*] per calendar year (unless otherwise agreed by Catalent in writing), so long as Client provides Catalent at least [\*\*] advance written notice of the attendance of such Client representatives. Such representatives shall abide by all Catalent safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance. Client shall indemnify and hold harmless Catalent for any action, omission or other activity of such representatives while on Catalent's premises. Catalent reserves the right to require such representatives to enter into separate confidentiality agreements

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directly with Catalent in such persons' individual capacities on terms substantially similar to those set forth in Article 13.

### ARTICLE 8 TESTING; SAMPLES; RELEASE

8.1 Testing; Releasing; Rejection. Unless otherwise agreed to by the Parties during their ordinary course of dealings, after Catalent completes Processing of a Batch, Catalent shall provide Client or its designee with a certificate of analysis for such Batch and copies of Batch records prepared in accordance with the Specifications; *provided*, that if testing reveals an out-of-Specification result, Catalent shall provide such Batch records promptly following resolution of the out-of-Specification result. Issuance of a certificate of analysis constitutes release of the Batch by Catalent to Client. Client shall be responsible for final release of Product (including any additional testing Client may require beyond standard release testing performed by Catalent in connection with release of a Batch by Catalent to Client in accordance with the Specifications), at its cost to the market. Following Client's receipt of a shipment of a Batch, Client or Client's designee may test samples of such Batch to confirm that the Specifications have been met. Within [\*\*] days after Client's receipt of a Batch ("**Review Period**"), Client or its designee shall notify Catalent in writing of Client's acceptance or rejection of such Batch. In the event of any Latent Defect in a Batch, Client shall notify Catalent in writing of such Latent Defect within [\*\*] of Client's discovery of such Latent Defect, but in no event later than [\*\*] following delivery of the Product pursuant to Section 9.1. In case of Client's rejection of a Batch or notification of a Latent Defect, the written notice (an "**Exception Notice**") shall indicate that such Batch does not meet the warranty set forth in Section 15.1 ("**Defective Product**") and Client shall provide a sample of the alleged Defective Product. Upon timely receipt of an Exception Notice from Client, Catalent shall conduct an appropriate investigation in its discretion to determine whether or not it agrees with Client that Product is Defective Product and to determine the cause of any nonconformity. If Catalent agrees that Product is Defective Product and determines that the cause of nonconformity is [\*\*] ("**Catalent Defective Processing**"), then Section 8.3 shall apply. For avoidance of doubt, where the cause of nonconformity cannot be determined or assigned, it shall be deemed not Catalent Defective Processing and Client shall be responsible to pay Catalent for such Batch or Batches in accordance with the provisions of this Agreement.

8.2 Discrepant Results. In the event of a disagreement between the Parties regarding whether Product is Defective Product and/or whether the cause of the nonconformity is Catalent Defective Processing, which disagreement cannot be resolved by the Parties within [\*\*] days of the date of the Exception Notice, the Parties shall cause a mutually agreeable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Product and its components, including API and other Client-supplied Materials. The independent party's results as to whether or not Product is Defective Product and the cause of any nonconformity shall be final and binding. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by Catalent if Product is Defective Product attributable to Catalent Defective Processing, and by Client in all other circumstances.

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8.3 Defective Processing. Catalent will, at its option, either reprocess at its cost any Batch of Defective Product attributable to Catalent Defective Processing (and Client shall be liable to pay for either the rejected Batch(es) or the reprocessed Batch(es), but not both), or credit any payments made by Client for such Batch. THE OBLIGATION OF CATALENT TO [\*\*] REPLACE CATALENT DEFECTIVE PROCESSING IN ACCORDANCE WITH THE SPECIFICATIONS OR CREDIT PAYMENTS MADE BY CLIENT FOR DEFECTIVE PRODUCT ATTRIBUTABLE TO CATALENT DEFECTIVE PROCESSING [\*\*].

8.4 Supply of Material for Defective Product. In the event Catalent reprocesses Defective Product pursuant to Section 8.3, Client shall supply, at its cost, Catalent with sufficient quantities of API and other Client-supplied Materials, if required, in order for Catalent to complete such reprocessing.

### **ARTICLE 9 DELIVERY**

9.1 Delivery. Catalent shall tender Product for delivery [\*\*] (Incoterms 2010) the [\*\*] promptly following Catalent's release of Product. Catalent shall segregate and store all Product until tender of delivery. Client shall be responsible for all costs and risk of loss associated with shipment of the Product.

9.2 Failure to Take Delivery. If Client fails to take delivery of any Product on any scheduled delivery date, Catalent shall store such Product as Client's agent. If the Product is stored outside the Client Space, Client shall be invoiced, at Catalent's then current standard storage rate per pallet per month, [\*\*]

### **ARTICLE 10 PAYMENTS FOR PROCESSING**

10.1 Fees. In consideration for Catalent performing services hereunder:

A. Client shall pay to Catalent the fees for any Validation Services agreed by the Parties to be set forth on Attachment B. Such fees shall be paid within [\*\*] days following receipt of invoice.

B. During each Contract Year, Client shall pay to Catalent a non-refundable Facility Fee as set forth on Attachment C. Catalent shall invoice Client for the Facility Fee in quarterly installments beginning on the earlier of the Completion Date or July 1, 2014 and every three (3) months thereafter. In consideration of the Facility Fee, Catalent shall Process up to [\*\*] Batches of Product according to Purchase Orders submitted by Client in accordance with Section 7.2 above, and Catalent shall maintain the Client Space, Improvements, Client Equipment and Catalent Equipment in accordance with above, provided that the cost of Client Equipment maintenance incurred shall be invoiced separately and payable by Client. The Facility Fee and any above-referenced Client Equipment maintenance costs shall be paid within [\*\*] days following receipt of applicable invoice.

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C. The first [\*\*] Client shall pay Catalent the Batch pricing for Product set forth on Attachment C (“**Batch Pricing**”). Such fees shall be paid within [\*\*] days following the [\*\*] For the avoidance of doubt, the foregoing provisions of this Section 10.1 (C) and the Batch Pricing set forth in Attachment C shall not apply to [\*\*]. Such quotations shall be subject to the terms of this Agreement (other than pricing).

D. Client shall pay Catalent the annual fees for Product Maintenance Services set forth on Attachment C. Such fees shall be paid within [\*\*] days following the date of invoice, which invoice shall be submitted to Client by Catalent upon the Commencement Date and upon each anniversary of the Commencement Date during the Term.

E. Other Fees. Client shall pay Catalent for all other fees and expenses of Catalent owing in accordance with the terms of this Agreement, including but not limited to pursuant to Sections 5.4, 9.2, 10.5 and 19.4. Such fees and expenses shall be paid within [\*\*] days following the date of invoice, which invoice shall be submitted to Client by Catalent as and when appropriate.

10.2 Price Increases. Beginning on the [\*\*] anniversary of the Commencement Date, the Facility Fee and Batch Pricing shall be adjusted on an annual basis, such price adjustment to be effective on the [\*\*] anniversary date of the Commencement Date and each subsequent anniversary date of the Commencement Date, upon [\*\*] days written notice from Catalent to Client. Notwithstanding the foregoing, to the extent Catalent’s costs for Processing increase due to increases in Raw Materials prices of more than [\*\*] percent, Catalent shall have the right to adjust the Facility Fee and Batch Pricing immediately upon written notice to Client to reflect increases in the prices of the Raw Materials. [\*\*].

10.3 Product Approval. Notwithstanding anything to the contrary set forth in this Agreement, Client shall use its best efforts to expedite and obtain all Regulatory Approvals necessary for Catalent to commence Processing at the Facility for the manufacture of Product for commercial sale or transport in the U.S.

10.4 Payment Terms. Client shall make payment in U.S. dollars In the event payment is not received by Catalent on or before the [\*\*] day after the date of the invoice, then Catalent may, in addition to any other remedies available at equity or in law, at its option, elect to do any one or more of the following: (A) charge interest on the outstanding sum from the due date (both before and after any judgment) at [\*\*]% per month until paid in full (or, if less, the maximum amount permitted by Applicable Laws); (B) suspend any further performance hereunder until such invoice is paid in full.

10.5 Taxes. All taxes, duties and other amounts assessed (excluding tax based on net income and franchise taxes) on services, components, API or Product prior to or upon provision or sale to Catalent or Client, as the case may be, and on any other Client-supplied Materials, are the responsibility of Client, and Client shall reimburse Catalent for all such taxes, duties or other expenses paid by Catalent or such sums will be added to invoices directed at Client, where applicable. If any deduction or withholding in respect of tax or otherwise is required by law to be made from any of the sums payable hereunder, Client shall be obliged to pay to Catalent such

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greater sum as will leave Catalent, after deduction or withholding as is required to be made, with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding.

10.6 Client and Third Party Expenses. Except as may be expressly covered by Product Maintenance Service fees, Client shall be responsible for 100% of its own and all Third Party expenses associated with the development, Regulatory Approvals and commercialization of Product, including regulatory filings and post-approval marketing studies.

10.7 Development Batches. Each Batch produced under this Agreement, including those necessary to support the validation portion of Client's submissions for Regulatory Approvals, will be considered to be a "development batch" unless and until Processing has been validated. Client shall be responsible for the cost of each such Batch, even if such Batch fails to meet the Specifications, unless Catalent was grossly negligent in the manufacture of the out-of-Specification Batch. Catalent and Client shall cooperate in good faith to resolve any problems causing the out-of-Specification Batch.

## **ARTICLE 11 CHANGES TO SPECIFICATIONS**

All Specifications and any changes thereto agreed to by the Parties from time to time shall be in writing, dated and signed by the Parties. Impact to the Specifications from any Process change shall be agreed in writing by the Parties, dated and signed by an authorized signatory for each of the Parties. No change in the Specifications shall be implemented by Catalent, whether requested by Client or requested or required by any Regulatory Authority, until the Parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Batch Pricing). Catalent shall respond promptly to any request made by Client for a change in the Specifications, and both Parties shall use commercially reasonable, good faith efforts to agree to the terms of such change in a timely manner. As soon as possible after a request is made for any change in Specifications, Catalent shall notify Client of the costs associated with such change and shall provide such supporting documentation as Client may reasonably require. Client shall pay all costs associated with such agreed upon changes. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control. Catalent reserves the right to postpone effecting changes to the Specifications until such time as the Parties agree to and execute the required written amendment.

## **ARTICLE 12 RECORDS; REGULATORY MATTERS RELATED TO PROCESSING**

12.1 Recordkeeping. Catalent shall maintain materially complete and accurate books, records, test and laboratory data, reports and all other information relating to Processing, including all information required to be maintained by Applicable Laws, in accordance with Catalent standard operating procedures. Such information shall be maintained in forms, notebooks and records for

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a period of at least [\*\*] years from the relevant finished Product expiration date or longer if required under Applicable Laws.

12.2 Regulatory Compliance. Client shall be solely responsible for and will obtain all Regulatory Approvals, including any applications and amendments in connection therewith. Catalent will be responsible to maintain all permits and licenses required by any Regulatory Authority with respect to the Facility generally. Client shall reimburse Catalent for any payments Catalent is required to make to any Regulatory Authority pursuant to Applicable Laws resulting from Catalent's Processing or testing of Client's Product at the Facility. During the Term, Catalent will assist Client with all regulatory matters relating to Processing, at Client's request and at Client's expense. Each Party intends and commits to cooperate to satisfy all Applicable Laws relating to Processing.

12.3 Governmental Inspections and Requests. Catalent shall promptly advise Client if an authorized agent of any Regulatory Authority visits the Facility concerning the Processing. Catalent shall furnish to Client a copy of the report by such Regulatory Authority, if any, within [\*\*] days of Catalent's receipt of such report. Further, upon receipt of a Regulatory Authority request to inspect the Facility or audit Catalent's books and records with respect to Processing, Catalent shall promptly notify Client, and shall provide Client with a copy of any written document received from such Regulatory Authority.

### 12.4 Client Inspections and Audits.

A. During the Term, duly authorized employees, agents and representatives of Client shall be granted access upon at least [\*\*] prior notice and at reasonable times during regular business hours to (i) the Client Space, (ii) relevant personnel involved in Processing and (iii) Processing records described in Section 12.1, in each case solely for the purpose of inspecting and verifying that Catalent is Processing in accordance with cGMPs, the Specifications and the Product master Batch records. For purposes of this Section 12.4, Client's duly authorized agents and representatives shall be required to sign Catalent's standard Confidential Disclosure Agreement prior to being allowed access to the Facility.

B. Client's Quality Assurance Manager will arrange audit visits with Catalent Quality Management. Inspections shall be designed to minimize disruption of operations at the Facility. Client may not conduct an inspection under this Section 12.4 more than [\*\*] during any 12 month period; *provided*, that additional inspections may be conducted in the event there is a material quality, for cause or compliance issue concerning Product or its Processing.

12.5 Recall. Subject to this Section 12.5, the Client has the sole right to initiate a Recall. In the event Catalent believes a recall, field alert, Product withdrawal or field correction ("**Recall**") may be necessary with respect to any Product provided under this Agreement, Catalent shall immediately notify Client in writing. Catalent will not act to initiate a Recall without the express prior written approval of Client. Notwithstanding the foregoing, provided that Catalent notifies Client in advance of Catalent's intention to comply with any such notice requirement, Catalent may notify any Regulatory Authority of facts or circumstances that could require the initiation of a Recall to the extent such notification is required by Applicable Laws. In the event Client

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believes a Recall may be necessary with respect to any Product provided under this Agreement, Client shall immediately notify Catalent in writing and Catalent shall provide all necessary cooperation and assistance to Client. Client shall initiate a Recall if Client's counsel advises Client that Client is required to do so by Applicable Laws. The cost of any Recall shall be borne by Client and Client shall reimburse Catalent for expenses incurred with any Recall, in each case unless such Recall is caused solely by Catalent's breach of its obligations under this Agreement or Applicable Laws or its negligence or willful misconduct, then such cost shall be borne by Catalent. For purposes hereof, such cost shall be limited to reasonable, actual and documented administrative costs incurred by Client for such Recall and replacement of the Product subject to Recall, in accordance with Article 8; provided, that NEITHER PARTY SHALL BE LIABLE IN ANY EVENT FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST REVENUES OR PROFITS OR DAMAGES TO BUSINESS REPUTATION RESULTING FROM ANY RECALL.

12.6 Quality Agreement. Within [\*\*] after the Effective Date, and in any event prior to the first Processing of Product hereunder, the Parties shall negotiate in good faith and enter into a Quality Agreement substantially in the form attached hereto as Attachment D (the "**Quality Agreement**"). The Quality Agreement shall in no way determine liability or financial responsibility of the Parties for the responsibilities set forth therein. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

## ARTICLE 13 CONFIDENTIALITY AND NON-USE

13.1 Mutual Obligation. Catalent and Client each agrees that it will not use the other Party's Confidential Information except in connection with the performance of its obligations hereunder and will not disclose the other Party's Confidential Information to any Third Party without the prior written consent of the other Party, except as required by law, regulation or court or administrative order; provided, that prior to making any such legally required disclosure, the Party making such disclosure shall give the other Party as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Notwithstanding the foregoing, each Party may disclose the other Party's Confidential Information to any of its Affiliates, partners, collaborators or consultants that (A) need to know such Confidential Information for the purpose of performing obligations or exercising rights granted or retained under this Agreement, (B) are advised of the contents of this Article and (C) agree to be bound by the terms of this Article, provided that the disclosing Party shall be responsible for any breach of confidentiality by its Affiliates, partners, collaborators or consultants.

13.2 Definition. As used in this Agreement, the term "**Confidential Information**" includes all such information furnished by Catalent or Client, or any of their respective representatives or Affiliates, to the other Party or its representatives or Affiliates, whether furnished before, on or

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after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other intellectual property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either Party, or any of their respective representatives or Affiliates, containing or based in whole or in part on any such information furnished by the other Party or its representatives or Affiliates. Confidential Information also includes the existence of this Agreement and its terms.

13.3 Exclusions. Notwithstanding Section 13.2, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known by the receiving Party at the time of disclosure as evidenced by the receiving Party's written records, (C) becomes available to the receiving Party on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis or (D) was or is independently developed by or for the receiving Party without reference to the Confidential Information of the other Party as evidenced by the receiving Party's written records.

13.4 No Implied License. Except as expressly set forth in Section 13.1, the receiving Party will obtain no right of any kind or license under any Confidential Information of the disclosing Party, including any patent application or patent, by reason of this Agreement. All Confidential information will remain the sole property of the Party disclosing such information or data, subject to Article 14.

13.5 Return of Confidential Information. Upon expiration or termination of this Agreement, the Party receiving Confidential Information will cease its use and, upon request, within 30 days either return or destroy (and certify as to such destruction) all Confidential Information of the other Party, including any copies thereof, except for a single copy thereof which may be retained for the sole purpose of determining the scope of the obligations incurred under this Agreement.

13.6 Survival. The obligations of this Article will terminate [\*\*] years from the expiration or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Article will continue for so long as such information remains a trade secret under applicable law.

## ARTICLE 14 INTELLECTUAL PROPERTY

For purposes hereof, "**Client IP**" means all Intellectual Property and embodiments thereof owned by or licensed to Client as of the date hereof or developed by Client other than in connection with this Agreement; "**Catalent IP**" means all Intellectual Property and embodiments thereof owned by or licensed to Catalent as of the date hereof or developed by Catalent other than in connection with this Agreement; "**Invention**" means any Intellectual Property developed by either Party in connection with this Agreement; "**API Inventions**" means any Invention that relates exclusively to the Client IP or Client's patented API; and "**Process Inventions**" means any Invention, other than an API Invention, that relates exclusively to the Catalent IP or relates

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to [\*\*]. All Client IP and API Inventions shall be owned solely by Client and no right therein is granted to Catalent under this Agreement, except that Catalent shall have a [\*\*] license to such items solely to the extent necessary to perform its obligations under this Agreement, All Catalent IP and Process inventions shall be owned solely by Catalent and no right therein is granted to Client under this Agreement. The Parties shall cooperate to achieve the allocation of rights to Inventions anticipated herein and each Party shall be solely responsible for costs associated with the protection of its intellectual property.

### ARTICLE 15 REPRESENTATIONS AND WARRANTIES

15.1 Catalent. Catalent represents, warrants and undertakes to Client that at the time of delivery by Catalent as provided in Section 9.1, Product shall have been Processed in accordance with Applicable Laws and in conformance with the Specifications and shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws; *provided*, that Catalent shall not be liable for defects attributable to API or other Client-supplied Materials (including artwork, packaging and labeling).

15.2 Client. Client represents, warrants and undertakes to Catalent that:

A. the API and all other Client-supplied Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable specifications, including the Specifications, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement;

B. no specific safe handling instructions, health and environmental information or material safety data sheets are applicable to Product, API or any other Client-supplied Materials, except as provided to Catalent in writing by Client in sufficient time for review and training by Catalent;

C. all Product delivered to Client by Catalent will be held, used and disposed of by or on behalf of the Client in accordance with all applicable laws, including Applicable Laws, and Client will otherwise comply with all laws, rules, regulations and guidelines applicable to Client's performance under this Agreement and its use of Product provided by Catalent under this Agreement;

D. Client will not release any Batch of Product if the required certificates of analysis indicate that Product does not comply with the Specifications;

E. Client shall not market or sell, or license any other party to market or sell, the Product without first making every reasonable effort to ensure that Product is safe and effective for its intended purpose or any other purpose for which such Product might reasonably be utilized;

F. Client has all necessary authority to use and to permit Catalent to use pursuant to this Agreement all intellectual property related to Product, API, all other Client-supplied [\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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Materials (including artwork), and the Processing of the foregoing, including any copyrights, trademarks, trade secrets, patents, inventions and developments;

G. the content of all artwork provided to Catalent shall comply with all Applicable Laws; and

H. the work to be performed by Catalent under this Agreement will not violate or infringe upon any trademark, trade name, copyright, patent, trade secret, or other intellectual property or other right held by any person or entity.

I. with respect to the Construction Work, all materials shall be new, and both workmanship and materials shall be of first class quality; the Building Contractor and all architects, contractors and subcontractors shall be duly licensed and insured and all workmen shall be skilled in their profession and trades. All Construction Work shall be performed in compliance with the Design Documents, the Construction Contract and all Applicable Law.

15.3 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

## ARTICLE 16 INDEMNIFICATION

16.1 Indemnification by Catalent. Catalent shall indemnify and hold harmless Client, its Affiliates, and their respective directors, officers, employees and agents (“**Client Indemnitees**”) from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys’ fees and reasonable investigative costs) in connection with any suit, demand or action by any Third Party (“**Losses**”) arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement or (B) any negligence or willful misconduct by Catalent; in each case except to the extent that any of the foregoing arises out of or results from any Client Indemnities’ negligence, willful misconduct or breach of this Agreement.

16.2 Indemnification by Client. Client shall indemnify and hold harmless Catalent, its Affiliates, and their respective directors, officers, employees and agents (“**Catalent Indemnitees**”) from and against any and all Losses arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement, (B) any manufacture, packaging, sale, promotion, distribution or use of or exposure to Product, API or any other Client-supplied Materials, including product liability or strict liability, (C) Client’s exercise of control over the Processing, to the extent that Client’s instructions or directions violate Applicable Laws, (D) the conduct of any clinical trials utilizing Product or API, (E) any actual or alleged infringement or violation of any Third Party patent, trade secret, copyright, trademark or other proprietary rights by intellectual property or other information provided by

[\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

## **EXECUTION VERSION**

Client, including Client-supplied Materials, (F) the Construction Work, whether as a result of acts or omissions of Client, its agents, employees, the architect, the Building Contractor or any subcontractors, suppliers or material men; or (G) any negligence or willful misconduct by Client; in each case except to the extent that any of the foregoing arises out of or results from any Catalent Indemnitee's negligence, willful misconduct or breach of this Agreement. In addition, Client shall indemnify and hold harmless the Catalent Indemnites from and against any and all Losses arising out of or resulting from any federal regulatory filings by or on behalf of Client or any of its Affiliates, including Losses incurred by Catalent arising from filings under 21 U.S.C. 355 and/or Section 505 of the Food and Drug Act (or non-U.S. equivalents) and related claims or proceedings (including Losses associated with Catalent's obligation to respond to Third Party subpoenas).

16.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the Party seeking indemnification (A) promptly notifying the indemnifying Party of any claim or liability of which the Party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying Party of any of its obligations hereunder except to the extent the indemnifying Party is prejudiced by such failure, (B) allowing the indemnifying Party, if the indemnifying Party so requests, to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying Party's expense), (C) cooperating with the indemnifying Party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying Party's expense) and (D) not compromising or settling any claim or liability without prior written consent of the indemnifying Party.

## **ARTICLE 17 LIMITATIONS OF LIABILITY**

17.1 CATALENT SHALL HAVE NO LIABILITY UNDER THIS AGREEMENT FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED API OR OTHER CLIENT SUPPLIED MATERIALS, WHETHER OR NOT SUCH API OR CLIENT-SUPPLIED MATERIALS ARE INCORPORATED INTO PRODUCT, EXCEPT TO THE EXTENT ANY SUCH LOSS ARISES FROM THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OF CATALENT. NOTWITHSTANDING ANY PROVISION TO THE CONTRARY IN SECTION 3.6, THE FOREGOING LIMITATION OF LIABILITY SHALL NOT APPLY TO CATALENT'S LIABILITY OF UP TO [\*\*] DOLLARS (\$[\*\*]) FOR LOSS OR DAMAGE TO API PER BATCH IN PROCESS PER EVENT, TO THE EXTENT ANY OF SUCH LOSS OR DAMAGE ARISES FROM THE NEGLIGENCE OF CATALENT, PROVIDED THAT NORMAL API YIELD LOSS DURING PROCESSING SHALL NOT CONSTITUTE NEGLIGENCE OR BREACH OF THE AGREEMENT BY CATALENT.

17.2 CATALENT'S TOTAL LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED THE TOTAL FEES PAID BY CLIENT TO CATALENT UNDER THIS AGREEMENT FOR THE BATCH OR SERVICES GIVING RISE TO THE CLAIM EXCEPT TO THE EXTENT ANY SUCH LOSS ARISES FROM THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OF CATALENT AND EXCEPT FOR THIRD PARTY DAMAGES

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## **EXECUTION VERSION**

FOR BODILY INJURY OR DEATH CAUSED BY THE NEGLIGENCE OF CATALENT. THE FOREGOING LIMITATION OF LIABILITY SHALL NOT APPLY TO CATALENT'S LIABILITY OF UP TO [\*\*] DOLLARS (\$[\*\*]) FOR LOSS OR DAMAGE TO API PER BATCH IN PROCESS PER EVENT, TO THE EXTENT ANY OF SUCH LOSS OR DAMAGE ARISES FROM THE NEGLIGENCE OF CATALENT, PROVIDED THAT NORMAL API YIELD LOSS DURING PROCESSING SHALL NOT CONSTITUTE NEGLIGENCE OR BREACH OF THE AGREEMENT BY CATALENT.

17.3 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR LOSS OF REVENUES, PROFITS OR DATA ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

### **ARTICLE 18 INSURANCE RELATED TO PROCESSING**

In addition to the insurance requirements set forth in Section 4.2, each Party shall, at its own cost and expense, obtain and maintain in full force and effect after the Commencement Date during the Term the following: (A) Commercial General Liability Insurance with a per-occurrence limit of not less than \$[\*\*]; (B) Products and Completed Operations Liability Insurance with a per-occurrence limit of not less than \$[\*\*]; (C) Workers' Compensation Insurance with statutory limits and Employers Liability Insurance with limits of not less than \$[\*\*] per accident; and (D) All Risk Property Insurance, including transit coverage, in an amount equal to the full replacement value of its property while in, or in transit to, a Catalent facility as required under this Agreement. Each Party may self insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than \$[\*\*] or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than \$[\*\*]. Each required insurance policy, other than self-insurance, shall be obtained from an insurance carrier with an A.M. Best rating of at least A- VII. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the Term and for a period of at least [\*\*] years thereafter. Each Party shall obtain a waiver of subrogation clause from its property insurance carriers in favor of the other Party. Each Party shall be named as an additional insured within the other Party's products liability insurance policies; *provided*, that such additional insured status will apply solely to the extent of the insured Party's indemnity obligations under this Agreement. Such waivers of subrogation and additional insured status obligations will operate the same whether insurance is carried through third Parties or self-insured. Upon the other Party's written request from time to time, each Party shall promptly furnish to the other Party a certificate of insurance or other evidence of the required insurance.

### **ARTICLE 19 TERM AND TERMINATION**

19.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of the tenth anniversary of the earlier of the Completion Date or July 1, 2014, unless earlier terminated in accordance with Section 19.2 or 19.3 (as may be extended in accordance with this

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## EXECUTION VERSION

Section, the “**Term**”). The Term shall be automatically extended for successive 5-year periods up to a maximum total extension of 20 years, unless and until Client gives Catalent at least three (3) years prior written notice, or Catalent gives Client at least three (3) years prior written notice, of the noticing Party’s desire to terminate the Agreement as of the end of the then-current Term or extension period, as the case may be. In the event Catalent provides Client with such three (3) years prior written notice of termination, during the final three (3) years of the Term (or then-current extension thereof) Catalent shall exert commercially reasonable efforts to assist and support the transfer of the Process from Catalent to any Third Party contract manufacturing organization or other manufacturer selected by Client, at Client’s expense.

19.2 Termination for Failure to Obtain Marketing Authorization, Failure to Commercialize, Revocation of Marketing Authorization, or Withdrawal from Markets. In the event that Client does not receive Regulatory Approval for the Product in any country in the Territory or fails to launch the Product commercially somewhere in the Territory within [\*\*] months following the Effective Date, then Catalent may terminate the Agreement upon [\*\*] days written notice from Catalent. In the event that Client fails to launch the Product commercially in the U.S., Client may terminate the Agreement upon [\*\*] days written notice to Catalent. In the event that the United States Food and Drug Administration (“FDA”) effects the complete revocation (exclusive of any suspension, temporary withdrawal or partial revocation) of all then-current Regulatory Approval(s) of the Product in the United States, either Party may terminate the Agreement upon [\*\*] days written notice to the other Party. In the event the Product is completely withdrawn from the U.S. market because Client determines in good faith that it is no longer commercially viable, the Parties will meet and negotiate in good faith an appropriate amendment to this Agreement. For the avoidance of doubt, a change in indication, dosage strength or dosage form for the API shall not enable Client to terminate this Agreement pursuant to this Section 19.2. Without limiting each Party’s obligations under Sections 19.4 and 19.5, in the event of any termination under this Section 19.2, Client shall pay Catalent the following “**Breakage Costs**”:

A. All Construction Costs and Equipment Costs (if applicable) actually incurred and all amounts due under outstanding invoices;

B. Amounts due for work performed, any other fees that may be due under this Agreement (including any Milestone Payments, Facility Construction Support Fees and Facility Fees, if applicable) whether invoiced or not yet invoiced, and any non-cancelable commitments made by Catalent prior to date of termination;

C. All amounts owed under the Quote (if applicable);

D. All reasonable costs incurred in connection with the removal of Client Equipment and restoration of the Client Space to cGMP conditions;

E. [\*\*] U.S. dollars (\$[\*\*]) to reimburse Catalent for lost opportunity costs and unreimbursed costs associated with installing and qualifying the Client Equipment, Catalent Equipment, and the operations in preparation for launch (if applicable), including but not limited to labor costs (e.g., reduction in force).

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## EXECUTION VERSION

In addition, at Catalent's option, Catalent may purchase the Client Equipment from Client for an amount not to exceed the amount actually incurred by Client.

19.3 Termination for Cause. This Agreement may be terminated immediately at any time without further action:

A. by either Party if the other Party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within 30 days, or takes any equivalent or similar action in consequence of debt in any jurisdiction; or

B. by either Party if the other Party materially breaches any of the provisions of this Agreement and such breach is not cured within [\*\*] days after the giving of written notice requiring the breach to be remedied; provided, that in the case of a failure of Client to make payments in accordance with the terms of this Agreement, Catalent may terminate this Agreement if such payment breach is not cured within [\*\*] days of receipt of notice of non-payment from Catalent and further provided that Catalent may terminate this Agreement if the Cash Deposit is not replaced or replenished as required by Section 4.1, time being of the essence.

19.4 Effect of Termination after Commencement Date. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either Party prior to such expiration or termination including without limitation the Facility Fees due hereunder. In the event of a termination of this Agreement after the Commencement Date (in addition to the provisions set forth in 19.5):

A. Catalent shall promptly return to Client, at Client's expense and at Client's direction, any remaining inventory of Product, API or other Client-supplied Materials; *provided*, that Catalent shall have no obligation to so return such items until all outstanding invoices sent by Catalent to Client have been paid in full;

B. Client shall pay Catalent all invoiced amounts outstanding hereunder, plus, upon receipt of invoice therefor, for any (i) Product that has been shipped pursuant to Purchase Orders but not yet invoiced, (ii) Product Processed pursuant to Purchase Orders that has been completed but not yet shipped, and (iii) in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 19.3 (A) or (B) all Product in process of being Processed pursuant to Purchase Orders (or, alternatively, Client may instruct Catalent to complete such work in process, and the resulting completed Product shall be governed by clause (ii)); and

C. In the event that this Agreement is terminated for any reason other than by Client pursuant to Section 19.3 (A) or (B), Client shall pay Catalent for (i) all costs and expenses incurred, and all noncancellable commitments made, in connection with Catalent's performance of this Agreement, so long as such costs, expenses or commitments were made by Catalent consistent with Client's most recent Firm Commitment. Nothing in this Section 19.4 shall

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## EXECUTION VERSION

operate as a waiver of any other damages or remedies to which Catalent may be entitled at law or in equity.

### 19.5 Removal of Equipment, Construction Costs and Residual Value.

- A. Client shall be entitled to remove or procure the removal of the physically removable items of Client Equipment from the Facility immediately upon termination of this Agreement by Client pursuant to Section 19.3;
- B. Provided that termination is not as a result of a material breach of the terms of this Agreement by Catalent, Client shall reimburse Catalent for any and all outstanding Construction Costs (or Equipment Costs, if applicable);
- C. Provided that termination is not as a result of a material breach of the terms of this Agreement by Catalent, Client shall pay to Catalent any Construction Costs in respect of which Catalent is committed as at the termination date and Client shall either remove Client Equipment from the Facility or pay to Catalent all reasonable costs incurred in connection with the removal of Client Equipment;
- D. In the event of termination of this Agreement for any reason other than termination by Catalent pursuant to Section 19.3 (A) or (B), the Parties agree that Client shall have the right to remove such of the physically removable items of Client Equipment that has any Residual Value, such right exercisable by Client on written notice to Catalent (the “**Equipment Notice**”) to be received by Catalent within [\*\*] days of Client receiving or giving notice of termination of this Agreement. In the event that Client exercises this right Catalent shall surrender possession of such Client Equipment to Client in the same order, condition and repair as received, (fair wear and tear excepted) at the Facility or such other location as may be reasonably designated by Client subject to the payment of all removal and transportation expenses of the Client Equipment by Client and Client renovating and repairing the Facility in order to repair any damage to the Facility caused during or as a result of such removal. If Client does not collect the Client Equipment within a period of [\*\*] days following the Equipment Notice, Catalent may arrange for the removal of the Client Equipment from the Client Space itself and may either cause the Client Equipment to be stored or destroyed at its option. If Client does not renovate and repair the Facility as specified above, Client shall reimburse Catalent in full for any and all costs incurred by Catalent in carrying out such reconstruction itself.
- E. In the event that Client does not exercise its right to remove such of the physically removable items of Client Equipment that has any Residual Value, pursuant to Section 19.5 (D), Catalent shall have the option to purchase such Client Equipment in whole or in part or such item(s) of Client Equipment. In order to exercise such option to purchase the Client Equipment or any item(s) of the Client Equipment, Catalent shall:

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## EXECUTION VERSION

- (i) provide written notice to Client within [\*\*] days following receipt of the Equipment Notice or, if there is none, within [\*\*] after the last date when Client could have served an Equipment Notice of Catalent's intention to purchase the Client Equipment; and
- (ii) pay to Client within [\*\*] days following the Equipment Notice the Client Residual Value of the Client Equipment or such item(s) of Client Equipment.

If Catalent does not wish to purchase the Client Equipment and Client has not served an Equipment Notice within the prescribed time, Catalent shall on Client's behalf, arrange for the removal of the Client Equipment from the Facility and cause the Client Equipment to be destroyed. Client shall bear all Catalent's costs in undertaking the removal (including any costs of renovation or repair of the Facility as set forth in Section 19.5 (D)) and destruction of the Client Equipment. If Catalent uses the Client Equipment for the manufacture of any product after the termination date or has not had the Client Equipment removed within [\*\*] months of the termination date, it will be deemed to have served a notice in accordance with Section 19.5 (E) of this Agreement.

19.6 Survival. The rights and obligations of the Parties shall continue under Articles 14 (Intellectual Property), 16 (Indemnification), 17 (Limitations of Liability), 20 (Notice), 21 (Miscellaneous); under Articles 13 (Confidentiality and Non-Use) and 18 (Insurance Related to Processing), in each case to the extent expressly stated therein; and under Sections 10.4 (Payment Terms), 10.5 (Taxes), 10.6 (Client and Third Party Expenses), 12.2 (Recordkeeping), 12.6 (Recall), 15.3 (Limitations on Warranties), 19.4 (Effect of Termination), 19.5 (Removal of Equipment) and 19.6 (Survival), and under Articles 20 and 21, in each case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

## ARTICLE 20 NOTICE

All notices and other communications hereunder shall be in writing and shall be deemed given: (A) when delivered personally; (B) when delivered by facsimile transmission (receipt verified); (C) when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered if sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof):

To Client: Pharmacyclics, Inc.  
995 East Arques Avenue  
Sunnyvale, CA 94085  
[\*\*]  
Facsimile: +[\*\*]

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## EXECUTION VERSION

To Catalent: Catalent CTS, LLC  
10245 Hickman Mills Drive  
Kansas City, MO 64137 USA  
Attn: General Manager  
Facsimile: +[\*\*]

With a copy to: Catalent Pharma Solutions, LLC  
14 Schoolhouse Road  
Somerset, NJ 08873 USA  
Attn: General Counsel (Legal Department)  
Facsimile: +[\*\*]

### ARTICLE 21 MISCELLANEOUS

21.1 Entire Agreement; Amendments. This Agreement, together with all Schedules and Attachments hereto, including the Quality Agreement, constitutes the entire understanding between the Parties, and supersedes any contracts, agreements or understandings (oral or written) of the Parties, with respect to the subject matter hereof, except that the letter agreement between the Parties, [\*\*] (the “Letter Agreement”), while terminated, shall not be superseded by this Agreement and any post-termination obligations of the Parties under such letter agreement shall continue according to the terms of the Letter Agreement. No term of this Agreement may be amended except upon written agreement of both Parties, unless otherwise expressly provided in this Agreement.

21.2 Captions; Certain Conventions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular shall include the plural, and vice versa, (D) the words “include(s)” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation” or words of similar import, (E) the word “or” shall be deemed to include the word “and” (e.g., “and/or”) and (F) references to “Article,” “Section,” “subsection,” “clause” or other subdivision, or to an Attachment or other appendix, without reference to a document are to the specified provision or Attachment of this Agreement. This Agreement shall be construed as if it were drafted jointly by the Parties.

21.3 Further Assurances. The Parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement so long as such acts do not increase the obligations of such Party.

21.4 No Waiver. Failure by either Party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

[\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

## EXECUTION VERSION

21.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

21.6 Independent Contractors. The relationship of the Parties is that of independent contractors, and neither Party will incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the Parties the relationship of joint ventures, co-partners, employer/employee or principal and agent. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or contractors or for any employee benefits of any such employee or contractor.

21.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party, except that either Party may, without the other Party's consent, assign this Agreement to an Affiliate or to a successor to substantially all of the business or assets of the assigning Party or the assigning Party's business unit responsible for performance under this Agreement.

21.8 No Third Party Beneficiaries. This Agreement shall not confer any rights or remedies upon any person or entity other than the Parties named herein and their respective successors and permitted assigns.

21.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of Delaware, USA, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement. The Parties hereby consent to the jurisdiction of the Chancery Courts of the State of Delaware for all disputes between the Parties relating or arising under this Agreement, and hereby waive any right to contest venue in such courts on grounds of forum non conveniens.

21.10 Dispute Resolution. Any dispute, controversy or claim arising out of or relating to the Construction Work, the Client Space, the Improvements, the Client Equipment or the Catalent Equipment which the Parties are unable to amicably settle themselves shall first be submitted to the SG for resolution. The SG shall have [\*\*] days to attempt to resolve such dispute, and will set forth any resolution in writing. If the SG is unable to resolve such dispute within the [\*\*] day period, such dispute shall be referred to a nominated senior officer of each Party within [\*\*] following of break-down of negotiations. Such nominated senior officers shall have [\*\*] from the time that the SG referred such dispute to attempt to resolve such dispute, and will set forth any resolution in writing. If such dispute is not resolved by the nominated senior officers within such [\*\*] period, each Party shall have the right to seek resolution through other legal means. Notwithstanding the foregoing, each Party has the right, before or during any dispute resolution, to seek from the appropriate court provisional, equitable or injunctive remedies to avoid irreparable harm, maintain the status quo or preserve the subject matter of the dispute.

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## EXECUTION VERSION

21.11 Prevailing Party. In any dispute resolution proceeding between the Parties in connection with this Agreement, the prevailing Party will be entitled to recover its reasonable attorney's fees and costs in such proceeding from the other Party.

21.12 Publicity. Neither Party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party's express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing Party are listed, in which case the Party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other Party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

21.13 Setoff. Without limiting Catalent's rights under law or in equity, Catalent and its Affiliates, parent or related entities, collectively or individually, may exercise a right of set-off against any and all amounts due to Catalent from Client. For purposes of this Section, Catalent, its Affiliates, parent or related entities shall be deemed to be a single creditor.

21.14 Force Majeure. Except as to payments required under this Agreement, neither Party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such Party's performance hereunder if such default or delay is caused by events beyond such Party's reasonable control, including acts of God, law or regulation or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or weather, labor disturbances, epidemic or failure of suppliers, public utilities or common carriers; *provided*, that the Party seeking relief under this Section shall immediately notify the other Party of such causes) beyond such Party's reasonable control. The Party that may invoke this Section shall use commercially reasonable efforts to reinstate its ongoing obligations to the other Party as soon as practicable. If the cause(s) shall continue unabated for [\*\*] days, then both Parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s).

21.15 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

*[Signature page follows]*

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## EXECUTION VERSION

**IN WITNESS WHEREOF**, the Parties have caused their respective duly authorized representatives to execute this Agreement effective as of the Effective Date.

Catalent CTS, LLC

Pharmacyclics, Inc.

By:  [\*\*]

By:  /s/ Robert W. Duggan

Name:  [\*\*]

Name:  Robert W. Duggan

Title:  President

Title:  CEO

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## **SCHEDULE 1**

[\*]

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### **4. CATALENT      [\*] IBRUTINIB CAPACITY EXPANSION**

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Catalent.

## *Ibrutinib Capacity Expansion*

**PHARMACYCLICS INC.**  
**SUNNYVALE, CA**

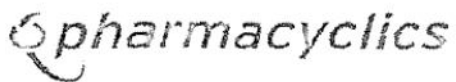
**CATALENT PHARMA SOLUTIONS**  
**KANSAS CITY, MO**

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Catalent

Ibrutinib Capacity Expansion  
Feasibility Evaluation

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Signatures

Signatures below indicate approval of the

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Signatures

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Signature [**]	Signature
Printed Name [**]	Printed Name
Title [**]	Title [**]
Date	Date
Comments: [**]	Comments:

Pharmacyclics Inc. [**]	Pharmacyclics Inc.
Signature [**]	Signature
Printed Name [**]	Printed Name
Title [**]	Title
Date	Date
Comments: [**]	Comments:

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APRIL 23, 2013

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**Ibrutinib Capacity Expansion  
Feasibility Evaluation**

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**Signatures**

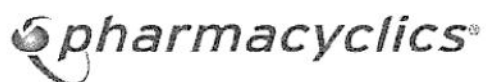
<b>Catalent Pharma Solutions</b> [**]	<b>Catalent Pharma Solutions</b> [**]
Signature [**]	Signature [**]
Printed Name [**]	Printed Name [**]
Title [**]	Title [**]
Date [**]	Date [**]
Comments: [**]	Comments: [**]

<b>Catalent Pharma Solutions</b> [**]	<b>Catalent Pharma Solutions</b> [**]
Signature [**]	Signature [**]
Printed Name [**]	Printed Name [**]
Title [**]	Title [**]
Date [**]	Date [**]
Comments: [**]	Comments: [**]

<b>Catalent Pharma Solutions</b> [**]	<b>Catalent Pharma Solutions</b> [**]
Signature [**]	Signature [**]
Printed Name [**]	Printed Name [**]
Title [**]	Title [**]
Date [**]	Date [**]
Comments: [**]	Comments: [**]

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APRIL 23, 2013



Ibrutinib Capacity Expansion  
Feasibility Evaluation

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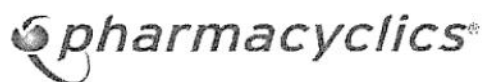
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APRIL 23, 2013

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**Ibrutinib Capacity Expansion  
Feasibility Evaluation**

**[\*\*]  
Executive Summary**

**1 EXECUTIVE SUMMARY**

**1.1 Project Overview**

This [\*\*] describes a [\*\*] of an [\*\*] in the Catalent facility in [\*\*] for the production of Pharmacyclics' new product Ibrutinib. The project includes [\*\*] [\*\*] for operations and a [\*\*] [\*\*]. The project area is an [\*\*] [\*\*]. The [\*\*] facility will produce approximately [\*\*] batches of [\*\*] product per year at a maximum batch size of [\*\*] [\*\*].

**1.2 Project Description**

The project includes [\*\*] [\*\*] [\*\*] meet production requirements. [\*\*] [\*\*]

The primary production unit operations include: [\*\*] [\*\*]

Production equipment items are [\*\*] [\*\*] [\*\*] Product packaging is [\*\*] [\*\*] [\*\*]

Supporting [\*\*] are [\*\*] [\*\*] [\*\*]

**1.3 Project Cost and Schedule**

The target for completion of the [\*\*] project [\*\*] is [\*\*] A project cost estimate [\*\*] [\*\*]

APRIL 23, 2013

[\*\*]



[\*\*]

**EXECUTION VERSION**

**SCHEDULE 2**

**Construction Costs**

[\*\*]

## EXECUTION VERSION

**SCHEDULE 3**

## Equipment

## Catalent and Pharmacyclics Ibrutinib Capacity Expansion Equipment List

[illegible]

[\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2013 2. May 2013

## EXECUTION VERSION

[\*\*]

5/14 2 May 2013

## EXECUTION VERSION

### SCHEDULE 4

#### SG Initial Phase

##### Construction Work:

Client shall submit the Building Plans to Catalent as soon as reasonably practical after the Effective Date. Catalent shall approve or disapprove of the Building Plans within [\*\*] business days. If Catalent disapproves any portion of the Building Plans, then Catalent shall return the Building Plans to Client for correction and revision. Client shall then deliver corrected Building Plans to Catalent no later than [\*\*] business days thereafter, i.e., after Client's receipt of the returned Building Plans. Thereafter this procedure for approval/disapproval as set forth herein shall be followed until agreement is reached. When approved, a list of the Building Plans shall be attached to this Agreement as Schedule 1 and the Parties shall initial and date the same.

##### Client Equipment:

Client shall submit the list of and description of all equipment to Catalent as soon as reasonably practical after the Effective Date. Catalent shall approve or disapprove of the Client Equipment within [\*\*] days; provided, in no event shall Catalent require changes to the Client Equipment that would adversely affect the Processing of the Product. If Catalent disapproves any portion of the Client Equipment, then Catalent shall return the Client Equipment list and description to Client for correction and revision. Client shall then deliver a corrected Client Equipment list and description to Catalent no later than [\*\*] business days thereafter, i.e., after Client's receipt of the returned Client Equipment list and description. Thereafter this procedure for approval/disapproval as set forth herein shall be followed until agreement is reached. When approved, a list and description of Client Equipment and Catalent Equipment shall be attached to this Agreement as Schedule 3 and the Parties shall initial and date the same.

**EXECUTION VERSION**

**SCHEDULE 5**

**Project Plan**

[\*\*]

**EXECUTION VERSION**

**SCHEDULE 6**

**Completion Date Certificate**

This Certificate is attached to and made a part of the Build-Out and Commercial Supply Agreement by and between Catalent CTS, LLC and Pharmacyclics, Inc. with an Effective Date of \_\_\_\_\_, 20\_\_ (the "Agreement"). By executing this Certificate, the Parties agree that the Completion Date for purposes of the Agreement is \_\_\_\_\_, 20\_\_.

This the \_\_\_\_ day of \_\_\_\_\_, 20\_\_.

CATALENT CTS, LLC

PHARMACYCLICS, INC.

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Its: \_\_\_\_\_

Its: \_\_\_\_\_

**SCHEDULE 7**

**Initial SG Members**

**Catalent-appointed Members:**

[\*\*]

**Client-appointed Members:**

[\*\*]

**EXECUTION VERSION**

**SCHEDULE 8**

**CONDITIONAL FINAL LIEN WAIVER**

PROJECT:

Pharmacyclics Ibrutinib Capacity Expansion  
10245 Hickman Mills Drive  
Kansas City, MO 64137

OWNER: Catalent CTS, LLC

WHEREAS THE UNDERSIGNED ☐ Contractor ☐ Subcontractor ☐ Supplier ☐ Architect or Engineer, or ☐  
[\*\*] has provided labor, services, materials or equipment, for the above project. Under an agreement with:

in its capacity as ☐ Owner or Owner's agent ☐ Contractor ☐ Subcontractor ☐ Architect or Engineer

Section A: (check and initial only one of the following)

☐ ( ) PARTIAL WAIVER AND RELEASE IN CONSIDERATION OF PARTIAL PAYMENT for labor services materials or equipment provided in the amount of (\$)  
& \_\_\_\_\_ Cents covering the following Partial Payment Request(s) or invoice(s): (attach additional pages if necessary)

DATE: PAY REQUEST or INVOICE NUMBER Amount

Together with any previous payment(s) already received, but excluding any retainage or any labor services materials or equipment provided after the date of: \_\_\_\_\_

☐ ( ) FINAL WAIVER AND RELEASE IN CONSIDERATION OF FINAL PAYMENT for all labor services materials or equipment provided in the amount of: (\$)

THE UNDERSIGNED DOES HEREBY WAIVE AND RELEASE all bond claims, liens, or claims or right of lien. Statutory or otherwise against the property project. Owner and any sureties for labor services materials or equipment as provides by the Undersigned but only to the extent of payment received as indicated above and as limited below:

Section B: (check and initial only one of the following)

☐ ( ) CONDITIONAL RELEASE: THIS WAIVER AND RELEASE IS CONTINGENT UPON RECEIPT OF PAYMENT and final bank clearance of said remittance in the above amount. The remittance identified as payment and endorsed by the Undersigned marked "paid" or otherwise cancelled by the bank against which said remittance was drawn, shall constitute conclusive proof that said invoice or pay request was paid and that payment thereof was received by the Undersigned and thereupon this waiver and release shall become effective automatically without the requirement of any further act acknowledgment or receipt on the part of the Undersigned.

\* ADDITIONALLY, THE UNDERSIGNED ACKNOWLEDGES RECEIPT of the total amount of \$ \_\_\_\_\_  
On previous and does hereby grant unconditional release of all above described claims for that amount.

☐ ( ) UNCONDITIONAL RELEASE: THE UNDERSIGNED ACKNOWLEDGES RECEIPT OF PAYMENT in the above amount for labor services materials or equipment as described herein, and does hereby grant this release unconditionally.

THE PERSON SIGNING below does hereby certifies that he or she is fully authorized and empowered to execute this instrument and to bind the Undersigned hereto and does in fact so execute this instrument.

State of: \_\_\_\_\_

County of: \_\_\_\_\_

\* COMPANY NAME:

ADDRESS:

Subscribed and sworn to before  
me this \_\_\_\_\_ day \_\_\_\_\_, 20  
NOTARY PUBLIC.

SIGNED: \_\_\_\_\_  
MY COMMISSION EXPIRES

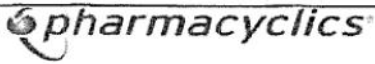
SIGNED: \_\_\_\_\_  
TITLE: \_\_\_\_\_ DATE \_\_\_\_\_

**EXECUTION VERSION**

**ATTACHMENT A**

**SPECIFICATIONS**

**I. Client-Supplied Materials and associated specifications (attached hereto)**

 <b>DRUG PRODUCT SPECIFICATION</b> <b>Ibrutinib Capsule,                      [**]</b>	<b>Part No.</b> [**]
	<b>Specification No.</b> [**]
	<b>Page:</b> 1 of 1

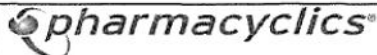
**Approval Date:**    2 7 MAR 2013

**Effective Date:**    2 7 MAR 2013

<b>Approval Signatures:</b>	
Owner:                      [**]	Date:                      [**]
Print and Sign Name                      [**]	
Analytical Chemistry:                      [**]	Date:                      [**]
Print and Sign Name	
Chemical Operations:                      [**]	Date:                      [**]
Print and Sign Name	
QC:                      [**]	Date:                      [**]
Print and Sign Name                      [**]	
Regulatory Affairs:                      [**]	Date:                      [**]
Print and Sign Name	
Other:                      [**]	Date:                      [**]
Print and Sign Name                      [**]	
QA:                      [**]	Date:                      [**]
Print and Sign Name	

<b>Expiration Period:</b> [**]	<b>Subsequent Retest Period:</b> [**]
<b>Sample Size:</b> [**]	<b>CFR Reserve Sample:</b> [**]
<b>Storage Conditions:</b> [**]	

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 <b>DRUG PRODUCT SPECIFICATION</b> <b>Ibrutinib Capsule,                    [**]</b>	<b>Part No.</b> [**]
	<b>Specification No.</b> [**]
	<b>Page:</b> 1 of 2

Primary Packaging Configuration	Per Bottle
[**] PCYC Part No:    [**]  [**] PCYC Part No.:    [**]  [**] PCYC Part No:    [**]	[**]

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**ATTACHMENT A Continued**

**SPECIFICATIONS**

**II. Raw Materials and associated specifications (attached hereto)**

# Catalent-Kansas City

## Raw Material Specification

[\*\*]

Page 0 of 4  
Document No.:  
Issue Date:

[\*\*]

APR 29 2013

### Approvals:

[\*\*]

Signature  
Quality Control

Print Name

Date

[\*\*]

Signature  
Development Solutions

Print Name

Date

[\*\*]

Signature  
Microbiology

Print Name

Date

[\*\*]

Signature  
Materials Management

Print Name

Date

[\*\*]

Signature  
Quality Assurance

Print Name

Date

[\*\*]

Signature  
Pharmacyclics

Print Name

Date

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# Catalent-Kansas City

## Raw Material Specification

[\*\*]

Page 0 of 4

Document No.: [\*\*]

Issue Date: APR 29 2013

### Approvals:

[\*\*]

Signature  
Quality Control

Print Name

Date

[\*\*]

Signature  
Development Solutions

Print Name

Date

[\*\*]

Signature  
Microbiology

Print Name

Date

[\*\*]

Signature  
Materials Management

Print Name

Date

[\*\*]

Signature  
Quality Assurance

Print Name

Date

Signature  
Pharmacylics

Print Name

Date

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# Catalent-Kansas City

## Raw Material Specification

[\*\*]

Page 1 of 4

Document No.:

[\*\*]

Issue Date:

APR 29 2013

### A. Physical Specifications:

Appearance (E.2):

[\*\*]

Size (E.2):

[\*\*]

### B. Chemical Specifications:

Disintegration (E.1):

[\*\*]

Loss on Drying (E.1):

[\*\*]

### C. Biological Specifications:

Microbiological Examination of Non-Sterile Products (E.1):

Microbial Enumeration Tests:

Total Aerobic Microbial Count (TAMC):

[\*\*]

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# Catalent-Kansas City

## Raw Material Specification

[\*\*]

Page 2 of 4

Document No.: [\*\*]

Issue Date: APR 29 2013

---

Total Yeasts and Molds Count (TYMC):

[\*\*]

Test for Specified Microorganisms:

[\*\*]

**D. Storage Conditions:**

[\*\*]

**E. Special Requirements:**

[\*\*]

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# Catalent-Kansas City

## Raw Material Specification

[\*]

Page 3 of 4

Document No.: [\*\*]

Issue Date: APR 29 2013

---

### F. Minimum Sampling Requirements

Microbiology: [\*\*]  
Analytical:  
Identification:  
Retain:

Retest Sample Size:  
Microbiology: [\*\*]  
Analytical:

### G. Sampling Method

[\*\*]

### H. Retest Cycle:

[\*\*]

### I. History:

Issue Date: [\*\*]

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# **Catalent-Kansas City**

## **Raw Material Specification**

[\*]

Page 4 of 4

Document No.: [\*\*]

Issue Date:

**APR 29 2013**

---

**Approved Suppliers:**

**Primary Manufacturer**

[\*]

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# Catalent-Kansas City

## Client Release Specification

Ibrutinib <sup>[""]</sup> Drug Substance Page 0 of 3  
QID <sup>[""]</sup> Document No.: <sup>[""]</sup>  
Issue Date: MAY 22 2013

### Approvals:

<sup>[""]</sup>

\_\_\_\_\_  
Author Signature  
Small Molecule Analytical Chemistry

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

<sup>[""]</sup>

\_\_\_\_\_  
Signature  
Large Molecule Analytical Chemistry

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

<sup>[""]</sup>

\_\_\_\_\_  
Signature  
Materials Management QA

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

<sup>[""]</sup>

\_\_\_\_\_  
Signature  
Quality Assurance

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

<sup>[""]</sup>

\_\_\_\_\_  
Client Signature  
Pharmacyclics QC Lynn Wallace  
Pharmacyclics, Inc.

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

<sup>[""]</sup>

\_\_\_\_\_  
Client Signature  
Pharmacyclics QA Rajeshni Maharaj  
Pharmacyclics, Inc.

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

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# Catalent-Kansas City

## Client Release Specification

Ibrutinib  
QID

[\*\*]

Drug Substance

Page 0 of 3

Document No.: [\*\*]

Issue Date: MAY 22 2013

### Approvals:

[\*\*]

Author Signature  
Small Molecule Analytical Chemistry

Print Name

Date

[\*\*]

Signature  
Large Molecule Analytical Chemistry

Print Name

Date

[\*\*]

Signature  
Materials Management QA

Print Name

Date

[\*\*]

Signature  
Quality Assurance

Print Name

Date

Client Signature  
Pharmacyclics QC Lynn Wallace  
Pharmacyclics, Inc.

Print Name

Date

Client Signature  
Pharmacyclics QA Rajeshni Maharaj  
Pharmacyclics, Inc.

Print Name

Date

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# Catalent-Kansas City

## Client Release Specification

Ibrutinib  
QID    [\*\*]

Drug Substance

Page 1 of 3

Document No.: [\*\*]

Issue Date: **MAY 22 2013**

### A. Specifications (performed on each container):

Appearance: [\*\*]

Identification by FTIR: [\*\*]

### B. Storage Conditions:

[\*\*]

### C. Special Requirements:

[\*\*]

### D. Retest Cycle:

[\*\*]

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# Catalent-Kansas City

## Client Release Specification

Ibrutinib  
QID [\*\*]

[\*\*]

Drug Substance

Page 2 of 3

Document No.: [\*\*]

Issue Date: MAY 22 2013

### E. Minimum Sampling Requirements:

[\*\*]

### F. Sampling Method:

[\*\*]

### G. History

Issue Date:

[\*\*]

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# Catalent-Kansas City

## Client Release Specification

Ibrutinib ["]  
QID ["]

Drug Substance

Page 3 of 3

Document No.: ["]

Issue Date: MAY 22 2013

Client-Approved Supplier:

["]

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<b>pharmacyclics</b> <b>SPECIFICATION</b> <b>Bulk Ibrutinib</b> <b>[**]</b>	<b>Specification No.:</b> <b>[**]</b>
	<b>Legacy No.</b> <b>[**]</b>
	<b>Page:</b> <b>1 of 2</b>

<b>Approval Date:</b> 19 Sep 2013	<b>Effective Date:</b> 28 Oct 2013
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<b>Approval Signatures: (Signatures on File)</b>	
Owner: <b>[**]</b>	Date: <b>[**]</b>
Print and Sign Name	
Analytical Chemistry: <b>[**]</b>	Date: <b>[**]</b>
Print and Sign Name	
Chemical Operations: <b>[**]</b>	Date: <b>[**]</b>
Print and Sign Name	
QC: <b>[**]</b>	Date: <b>[**]</b>
Print and Sign Name	
Regulatory Affairs: <b>[**]</b>	Date: <b>[**]</b>
Print and Sign Name	
Other: <b>[**]</b>	Date: <b>[**]</b>
Print and Sign Name	
QA: <b>[**]</b>	Date: <b>[**]</b>
Print and Sign Name	

<b>Description:</b> Regulatory commercial specification for ibrutinib <b>[**]</b>			
<b>Product ID</b>	Ibrutinib <b>[**]</b>	<b>Part Number:</b>	<b>[**]</b>
<b>Material type:</b>	Drug Product	<b>NDC Number</b>	<b>[**]</b>
<b>Expiration Period:</b>	<b>[**]</b>	<b>Bulk Hold Interval</b>	<b>[**]</b>
<b>Sample Size:</b>	<b>[**]</b>	<b>CFR Reserve Sample:</b>	<b>[**]</b>
<b>Storage Conditions:</b>	<b>[**]</b>		
<b>Shipping Conditions:</b>	<b>[**]</b>		
<b>Configurations:</b>	<b>[**]</b>		

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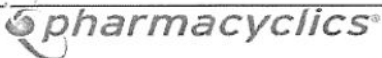
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Spec Temp 1554v13

Printed on: 05 Nov 2013, 01:32:35 pm; Printed by: RKUEHL.

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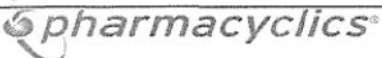
Effective Effective Effective

 <b>SPECIFICATION</b> <b>Bulk Ibrutinib</b> [**]	<b>Specification No.:</b> [**]
	<b>Legacy No.</b> [**]
	<b>Page:</b> 2 of 2

Testing Requirements	Pharmacyclics Method	Catalent Method	Specification
Appearance	[**]	[**]	[**]
I.D. by UV-vis Spectrum	[**]	[**]	[**]
I.D. by LC Retention Time	[**]	[**]	[**]
Assay by LC	[**]	[**]	[**]
Content Uniformity	[**]	[**]	[**]
Total Degradation Products	[**]	[**]	[**]
Specified Degradation Products	[**]	[**]	[**]
Any Unspecified Degradation Product	[**]	[**]	[**]
Water Content by KF	[**]	[**]	[**]
Dissolution	[**]	[**]	[**]

[\*\*]

Effective Effective Effective

 <b>SPECIFICATION</b> <b>Ibrutinib</b> [**]	<b>Specification No.:</b> [**]
	<b>Page:</b> 1 of 1

**Document History**

Effective Date	DCR	Rev.	Description/Changes
[**]			

Effective Effective Effective

### Signature Manifest

**Document Number:** [\*\*]

**Revision:** 1

**Title:** Bulk Ibrutinib [\*\*]

All dates and times are in Pacific Standard Time.

### Quick Approval

### Approve Now

Name/Signature	Title	Date	Meaning/Reason
		[**]	

# Catalent-Kansas City

## Client Specification

Bulk Ibrutinib  
QID: [\*\*]

[\*\*]

Page 0 of 4

Document No.: [\*\*]

Issue Date:

JUN 04 2013

### Approvals:

[\*\*]

Author Signature  
Small Molecule Analytical Chemistry

Print Name

Date

[\*\*]

Signature  
Dissolution

Print Name

Date

[\*\*]

Signature  
Development and Analytical Solutions

Print Name

Date

[\*\*]

Signature  
Materials Management QA

Print Name

Date

[\*\*]

Signature  
Quality Assurance

Print Name

Date

[\*\*]

Client Signature  
Pharmacyclics

Print Name

Date

[\*\*]

Client Signature  
Pharmacyclics

Print Name

Date

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# Catalent-Kansas City

## Client Specification

Bulk Ibrutinib  
QID: [ ]

[\*\*]

Page 0 of 4  
Document No.: [\*\*]  
Issue Date: JUN 04 2013

### Approvals:

[\*\*]

Author Signature  
Small Molecule Analytical Chemistry

Print Name

Date

[\*\*]

Signature  
Dissolution

Print Name

Date

[\*\*]

Signature  
Development and Analytical Solutions

Print Name

Date

[\*\*]

Signature  
Materials Management QA

Print Name

Date

[\*\*]

Signature  
Quality Assurance

Print Name

Date

Client Signature  
Pharmacyclics

Print Name

Date

Client Signature  
Pharmacyclics

Print Name

Date

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# Catalent-Kansas City

## Client Specification

Bulk Ibrutinib  
QID: [\*\*]

[\*\*]

Page 1 of 4  
Document No.: [\*\*]  
Issue Date: JUN 04 2013

### A. Client:

Pharmacyclics

### B. Client Specification Number:

[\*\*]

### C. Client Specification Name:

Bulk Ibrutinib [\*\*]

[\*\*]

### D. Source:

[\*\*]

### E. Comments:

[\*\*]

### F. Client Requirements:

[\*\*]

### G. Storage Conditions:

[\*\*]

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# Catalent-Kansas City

## Client Specification

**Bulk Ibrutinib**  
**QID:** [\*\*]

[\*\*]

**Page 2 of 4**  
**Document No.:** [\*\*]  
**Issue Date:** JUN 04 2013

---

### H. Minimum Sampling Requirements:

[\*\*]

### I. Sampling Method:

[\*\*]

### J. Retest Cycle:

[\*\*]

### K. History:

**Issue Date:**

[\*\*]

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**Catalent-Kansas City  
Client Specification**

**Bulk Ibrutinib**                      [\*\*]  
**QID:**                      [\*\*]

**Page 3 of 4**  
**Document No.:**                      [\*\*]  
**Issue Date:**                      **JUN 04 2013**

<b>pharmacyclics</b> <b>SPECIFICATION</b> <b>Bulk Ibrutinib</b> [**]	<b>Specification No.:</b> [**]
	<b>Page:</b> 1 of 2

<b>Approval Date:</b> 23 MAY 2013	<b>Effective Date:</b> 23 MAY 2013
-----------------------------------	------------------------------------

<b>Approval Signatures:</b>	
<b>Owner:</b> [**]	<b>Date:</b> [**]
<b>Analytical Chemistry:</b>	
<b>Chemical Operations:</b>	
<b>QC:</b>	
<b>Regulatory Affairs:</b>	
<b>Other:</b> [**]	
<b>QA:</b>	

<b>Description:</b> Regulatory commercial specification for ibrutinib                      [**]	
<b>Product ID</b>	<b>Ibrutinib</b> [**]
<b>Material type:</b>	<b>Drug Product</b>
<b>Expiration Period:</b>	<b>Bulk Hold Interval</b>
<b>Sample Size:</b>	<b>CFR Reserve Sample:</b>
<b>Storage Conditions:</b>	
<b>Shipping Conditions:</b>	
<b>Configurations:</b>	

[\*\*]

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**Confidential**

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**Catalent-Kansas City  
Client Specification**

**Bulk Ibrutinib**                      **[\*\*]**  
**QID:**    **[\*\*]**

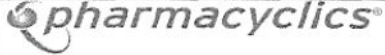
**Page 4 of 4**  
**Document No.:**    **[\*\*]**  
**Issue Date:**    **JUN 04 2013**

<b>pharmacyclics</b> <b>SPECIFICATION</b> <b>Bulk Ibrutinib</b> <b>[**]</b>	<b>Specification No.:</b> <b>[**]</b> <b>Page:</b> <b>2 of 2</b>
---	---

<b>Testing Requirements</b>	<b>Pharmacyclics Method</b>	<b>Catalent Method</b>	<b>Specification</b>
Appearance	<b>[**]</b>		
I.D. by UV-vis Spectrum			
I.D. by LC Retention Time			
Assay by LC			
Content Uniformity			
Total Degradation Products			
Specified Degradation Products			
Any Unspecified Degradation Product			
Water Content by KF			
Dissolution			

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Confidential

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 <b>SPECIFICATION</b> <b>Ibrutinib</b> [**]	<b>Specification No.:</b> [**]
	<b>Legacy No.</b> [**]
	<b>Page:</b> 1 of 3

<b>Approval Date:</b> 16 Sep 2013	<b>Effective Date:</b> 25 Oct 2013
-----------------------------------	------------------------------------

<b>Approval Signatures: (Signatures on File)</b>	
Owner: [**]	Date: [**]
Print and Sign Name	
Analytical Chemistry: [**]	Date: [**]
Print and Sign Name	
Chemical Operations: [**]	Date: [**]
Print and Sign Name	
QC: [**]	Date: [**]
Print and Sign Name	
Regulatory Affairs: [**]	Date: [**]
Print and Sign Name	
Other: [**]	Date: [**]
Print and Sign Name	
QA: [**]	Date: [**]
Print and Sign Name	

<b>Description:</b> Ibrutinib drug substance			
<b>Product ID</b>	Ibrutinib	<b>Part Number:</b>	[**]
<b>Material type:</b>	Drug substance	<b>NDC Number</b>	[**]
<b>Expiration Period:</b>	[**]	<b>Initial Retest Period</b>	[**]
		<b>Subsequent Retest Period:</b>	[**]
<b>Sample Size:</b>	[**]	<b>CFR Reserve Sample:</b>	[**]
<b>Storage Conditions:</b>	[**]		
<b>Shipping Conditions:</b>	[**]		
<b>Configurations:</b>	[**]		

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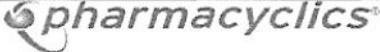
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Effective Effective Effective

 <b>SPECIFICATION</b> <b>Ibrutinib</b> [**]	<b>Specification No.:</b> [**]
	<b>Legacy No.</b> [**]
	<b>Page:</b> 2 of 3

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Effective Effective Effective

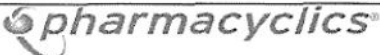
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 <b>SPECIFICATION</b> <b>Ibrutinib</b> <b>[**]</b>	<b>Specification No.:</b> <b>[**]</b>
	<b>Legacy No.</b> <b>[**]</b>
	<b>Page:</b> <b>3 of 3</b>

Testing Requirements	Method	Specification
[**]		

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Effective Effective Effective

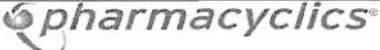
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 <b>SPECIFICATION</b> <b>Ibrutinib</b> [**]	<b>Specification No.:</b> [**]
	<b>Legacy No.</b> [**]
	<b>Page:</b> 1 of 1

**Internal Testing Requirement**

Testing Requirements	Method	Specification
[**]		

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 <b>pharmacyclics</b> <b>SPECIFICATION</b> <b>Ibrutinib</b> [**]	<b>Specification No.:</b> [**]
	<b>Legacy No.</b> [**]
	<b>Page:</b> 1 of 1

#### Document History

Effective Date	DCR	Rev.	Description/Changes
[**]			

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### Signature Manifest

**Document Number:** [\*\*]

**Revision:** 1

**Title:** Ibrutinib [\*\*]

All dates and times are in Pacific Standard Time.

### Quick Approval

### Approve Now

Name/Signature	Title	Date	Meaning/Reason
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Effective

# Catalent-Kansas City

## Compendial Specification

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Page 0 of 4

Document No.: [\*\*]

Issue Date: MAR 07 2013

### Approvals:

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Signature  
Development Solutions

Print Name

Date

[\*\*]

Signature  
Quality Control

Print Name

Date

[\*\*]

Signature  
Microbiology

Print Name

Date

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Signature  
Materials Management

Print Name

Date

[\*\*]

Signature  
Quality Assurance

Print Name

Date

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# Catalent-Kansas City

## Compendial Specification

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Page 1 of 4

Document No.: [\*\*]

Issue Date: MAR 07 2013

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### A. Compendia:

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### B. Material Name:

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### C. Comments:

[\*\*]

### D. Compendial Provisions:

#### 1. Material Identity Assurance Test (per container):

[\*\*]

#### 2. If Ph. Eur. and/or JP qualification is required, perform the following additional tests as per the current, applicable compendia:

[\*\*]

#### 3. Microbial Testing:

##### Microbiological Examination of Non-Sterile Products:

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##### Microbial Enumeration Tests:

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# Catalent-Kansas City

## Compendial Specification

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Page 2 of 4

Document No.:

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Issue Date:

MAR 07 2013

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Test for Specified Microorganisms:

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4. The following are to be performed at retest:

[\*\*]

5. Additional Provisions:

[\*\*]

E. Storage Conditions:

[\*\*]

F. Minimum Sampling Requirements:

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# Catalent-Kansas City

## Compendial Specification

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Page 3 of 4

Document No.: [\*\*]

Issue Date: MAR 07 2013

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### G. Sampling Method:

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### H. Retest Cycle:

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### I. History:

Issue Date:

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Page 4 of 4

Document No.: [\*\*]

Issue Date: MAR 07 2013

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**Distributor**

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**Prime Manufacturer**

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# Catalent-Kansas City

## Compendial Specification

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Page 0 of 5

Document No.:

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Issue Date:

MAR 03 2013

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### Approvals:

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\_\_\_\_\_  
Signature  
Quality Control

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

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\_\_\_\_\_  
Signature  
Development Solutions

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

[\*\*]

\_\_\_\_\_  
Signature  
Microbiology

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

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\_\_\_\_\_  
Signature  
Materials Management

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

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\_\_\_\_\_  
Signature  
Quality Assurance

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

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Page 1 of 5

Document No.:

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Issue Date:

MAR 03 2013

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### A. Compendia:

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### B. Material Name:

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### C. Comments:

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### D. Compendial Provisions:

#### 1. Material Identity Assurance Test (per container):

[\*\*]

#### 2. If Ph. Eur. and/or JP qualification is required, perform the following additional tests as applicable:

[\*\*]

#### 3. The following tests are to be performed at retest:

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## Compendial Specification

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Page 2 of 5

Document No.:

[\*\*]

Issue Date:

MAR 03 2013

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### 4. Microbiological Examination of Non-Sterile Products:

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#### Microbial Enumeration Tests:

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[\*\*]

#### Test for Specified Microorganisms:

[\*\*]

### 5. Additional Provisions:

[\*\*]

### E. Storage Conditions:

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## Compendial Specification

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Page 3 of 5

Document No.:

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Issue Date:

MAR 03 2013

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### F. Minimum Sampling Requirements:

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### G. Sampling Method:

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### H. Retest Cycle:

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### I. History:

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Page 0 of 4

Document No.: [\*\*]

Issue Date: APR 11 2012

### Approvals:

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Signature  
Quality Control

Print Name

Date

[\*\*]

Signature  
Pharmaceutical Development and  
Manufacturing

Print Name

Date

[\*\*]

Signature  
Quality Control - Microbiology

Print Name

Date

[\*\*]

Signature  
Materials Management QA

Print Name

Date

[\*\*]

Signature  
Quality Assurance

Date

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Page 1 of 4  
Document No.:  
Issue Date:

[\*\*]  
APR 11 2012

### A. Compendia:

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### B. Material Name:

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### C. Comments:

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### D. Compendial Provisions:

#### 1. Material Identity Assurance Test (per container):

[\*\*]

#### 2. If Ph. Eur. qualification is required, perform the following additional tests as per the current Ph. Eur.:

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#### 3. The following tests are to be performed at recontrol:

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#### 4. Microbial Testing:

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#### 5. Additional Provisions:

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**Catalent-Kansas City**  
**Compendial Specification**

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Page 2 of 4  
Document No.: [\*\*]  
Issue Date: APR 11 2012

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**E. Storage Condition:**

[\*\*]

**F. Minimum Sampling Requirements:**

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**G. Sampling Method:**

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**H. Retest Cycle:**

[\*\*]

**I. History:**

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Document No.: [\*\*]  
Issue Date: APR 11 2012

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Page 4 of 4  
Document No.: [\*\*]  
Issue Date: APR 11 2012

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## Compendial Specification

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Page 0 of 5

Document No.:

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Issue Date: JUN 21 2012

### Approvals:

[\*\*]

Signature  
Development and Analytical  
Solutions - Manufacturing

Print Name

Date

[\*\*]

Signature  
Development and Analytical  
Solutions - Quality Control

Print Name

Date

[\*\*]

Signature  
Development and Analytical  
Solutions - Microbiology

Print Name

Date

[\*\*]

Signature  
Materials Management QA

Print Name

Date

[\*\*]

Signature  
Quality Assurance

Print Name

Date

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## Compendial Specification

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Page 1 of 5

Document No.:

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Issue Date:

JUN 21 2012

### A. Compendia:

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### B. Material Name:

[\*\*]

### C. Comments:

[\*\*]

### D. Compendial Provisions:

#### 1. Material Identity Assurance Test (per container):

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#### 2. If Ph. Eur. and/or JP qualification is required, perform the following tests as per the current, applicable compendia:

[\*\*]

#### 3. Microbial Testing:

##### Microbiological Examination of Non-sterile Products:

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##### Microbial Enumeration Tests:

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## Compendial Specification

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Document No.: [\*\*]

Issue Date: JUN 21 2012

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**Test for Specified Microorganisms:**

[\*\*]

**4. The following tests are to be performed at retest:**

[\*\*]

**5. Additional Provisions:**

[\*\*]

**E. Storage Conditions:**

[\*\*]

**F. Minimum Sampling Requirements:**

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Document No.:

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Issue Date:

JUN 21 2012

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### G. Sampling Method:

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### H. Retest Cycle:

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### I. History:

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Issue Date: JUN 21 2012

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**EXECUTION VERSION**

**ATTACHMENT A continued**

**SPECIFICATIONS**

**III. Product Specifications (attached hereto)**

## **EXECUTION VERSION**

### **ATTACHMENT B**

#### **VALIDATION SERVICES**

*To be agreed by the Parties and attached upon execution of the Validation Services Quotation which will be in standard Catalent quotation format and will include pricing.*

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**WORK ORDER FOR IBRUTINIB**

[\*\*]

**VALIDATION STABILITY STUDY**

**WORK ORDER #**

[\*\*]

This work order (the "Work Order") is entered into and effective as of the date of the last signature hereto (the "Work Order Effective Date") pursuant to the Build-Out and Commercial Supply Agreement between Pharmacyclics, Inc. and Catalent CTS, LLC dated May 1, 2013 (the "Agreement"). Capitalized terms used in this Work Order and not otherwise defined herein shall have the same meaning as set forth in the Agreement.

The parties hereby agree as follows:

1. **Work Order.** This document constitutes a Work Order as defined in the Agreement, and the Services to be provided hereunder are subject to the terms and conditions of the Agreement.
2. **Project Scope, Budget and Timelines.** The specific Services contemplated by this Work Order and the related payment terms and obligations are set forth in the following sections of Contractor's proposal dated June 12, 2013 which is incorporated herein by reference and attached hereto as Exhibit A (the "Exhibit A").

SCOPE OF WORK Section 1  
PROJECT BUDGET Section 2 not to exceed [\*\*] without prior written approval  
of both parties in accordance with Section 6 of this Work Order  
PAYMENT SCHEDULE Section 3  
SCHEDULING/DELIVERABLES Section 4  
ADDITIONAL PROJECT TERMS Section 5  
VERSION HISTORY Section 6

Contractor shall provide the following Product deliverables: [\*\*] month validation stability study

3. **Payment and Invoices.** Invoices will be sent electronically to Pharmacyclics' Accounts Payable Department at [\*\*]. An authorized Purchase Order will be issued upon execution of this Work Order containing invoicing instructions.

4. **Key Personnel.**

For Contractor:

For Pharmacyclics:

Name: [\*\*]  
Title: [\*\*]  
Phone: [\*\*]  
Address: [\*\*]

Name: [\*\*]  
Title: [\*\*]  
Phone: [\*\*]  
Address: [\*\*]

5. **Term.** The term of this Work Order will commence on the Work Order Effective Date and will continue until the Services described on Exhibit A are complete or this Work Order or the Agreement is terminated earlier in accordance with the Agreement.

6. **Amendments.** Any change in the details of this Work Order or the assumptions upon which this Work Order is based (including, but not limited to, changes in the starting date for the Project or a delay

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or suspension of the Project by Pharmacyclics, changes in the Project budget and/or timelines) will require an amendment. No amendment of this Work Order will be effective unless in writing and signed by authorized representative of each Party. For the purposes of this Section 6, authorized representatives of Pharmacyclics shall be defined as Pharmacyclics' employees at Vice President level and above, and authorized representatives of Contractor shall be defined as Contractor's employees at Director level and above.

**7. Delivery.** A copy of the fully-executed Work Order should be delivered as follows:  
emailed in PDF format to:

If to Contractor: [\*\*]

If to Pharmacyclics: [\*\*]

Hard copies should be mailed to:  
:

If to Contractor  
Catalent  
Attn: Contracts  
10245 Hickman Mills Drive  
Kansas City, MO 64137, U.S.A

If to Pharmacyclics  
Pharmacyclics, Inc.  
Attn: Contracts Management/Legal  
995 E. Arques Avenue  
Sunnyvale, CA 94085

**IN WITNESS WHEREOF**, this Work Order has been executed by the Parties hereto through their duly authorized representatives and is effective as of the Work Order Effective Date.

**FOR CATALENT CTS, LLC**  
[\*\*]

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**FOR PHARMACYCLICS, INC.**

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

JUL 25 2013

A Purchase Order is required at Pharmacyclics  
to process invoices from Aptuit:

☒ Yes ☐ N/A

Please email a copy of PO to: [\*\*]



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## Exhibit A

### Section 1. Scope of Work

#### 1.1. Analytics

##### Standards and Materials

It is assumed that Pharmacyclics will be providing any required standards to Catalent. Should Pharmacyclics request Catalent to source standards, the prices will be issued through to Pharmacyclics.

It is assumed Catalent will use routine materials for analytical work to be performed. For any materials that are client-specific, additional charges may apply depending on the availability and type of materials.

##### Stability Studies

A stability protocol will be written by Catalent and agreed to by both parties. The protocol will be approved by Catalent QA. [\*\*]

[\*\*] Stability reports will be provided in standard Catalent cumulative format.

##### Validation Stability

Pricing assumes that all lots are set down and tested at the same time. Stability testing of [\*\*] batches of drug product in [\*\*] packaging configurations [\*\*] will be conducted as below:

Storage Condition	Interval (Months)								
	*T <sub>0</sub>	1	3	6	9	12	18	24	36
[**]									

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### 2.1. Fixed Fees

Activity and Description of Work	Price
["*"]	["*"]
Total Fixed Fee Project Price	["*"]
["*"]	["*"]
["*"]	["*"]
Total Estimated Project Price	["*"]

Catalent reserves the right to revise quoted price for any project as a result of initial scope change, planned deviations, revisions in specifications, modifications of test methods, undocumented requirements, retesting, requirements outside of Catalent SOPs, or any unforeseen difficulty in executing the project. In addition, the quoted prices are subject to annual review to account for changes in inflation, increased overhead charges, etc. Any additional work will be performed based on written agreement from Pharmacyclics and will be documented on a Catalent Quotation Amendment Record (OAR).

### Fixed Fees

[illegible]

DESCRIPTION	PRICE
[**]	
TOTAL ESTIMATED ADDITIONAL FEES	[**]

## Section 4. Scheduling

### 4.1. Scheduling

Catalent must receive a signed Quotation, a signed protocol (if applicable), and all final product samples in order for this project to be scheduled. Subsequently, a Purchase Order number (where applicable) must be received within [\*\*] days of receipt of the signed quote. A signed and effective Quality Agreement (if applicable) must be on file in order for this project to be scheduled. Once scheduled, Pharmacyclics will be notified by the Project Manager of the anticipated start and completion date of the project activities.

## Section 5. Additional Project Terms

### 5.1. Rush Services

Rush services may be available if requested, dependent upon customer notification timeframe, site capacity and availability of materials. If rush services are agreed between Pharmacyclics and Catalent at the time of request, additional charges may apply based on the expedited turnaround times and % up charges outlined in the table below. A change order will only be issued if changes to the below schedule are required due to the specific request

Turn Around Time (TAT) Reduction	Rush Charge (% of service/timepoint testing, etc. being expedited)
[**]	

### 5.2. Additional Fees

In addition to the fixed fees, the following charges may apply.

No charges will be issued unless the materials are required or the service is needed.

Activity	Description	Unit Price
[**]		
Administrative Fees	Administrative tasks such as photocopying raw data	[**]
Other Charges	Description	
[**]		

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### 5.3. Project Management

Following execution of this Contract, Catalent will conduct the work detailed herein under the leadership of a Project Manager. As the client advocate, the Project Manager will serve as the primary point of contact for communication between Pharmacyclics and Catalent to ensure effective flow of information and rapid resolution of any issues. To achieve this, Catalent will establish and maintain a cohesive and highly effective project team throughout the project lifecycle.

The Project Manager will:

- Strive to understand Pharmacyclics' goal and will manage the strategy to meet those goals.
- Lead the performance of the project tasks per the agreed upon scope of work.
- Act as the focal point for all internal and external project communications.
- Schedule, monitor and communicate the status of the project tasks to the project team.
- Conduct team meetings.
- Prepare the overall project and communication plan with the assistance of the project team.
- Monitor the compliance to the project plan and update the plan, as needed.
- Monitor the project deliverables to ensure milestones are delivered per agreed-upon timeline.
- Identify project risks and ensure they are recognized and satisfactorily addressed.
- Monitor adherence to the project budget and initiate Quotation Amendment Records (QARs) as needed.

### 5.4. Cancellation/Postponement

If this project is cancelled by Pharmacyclics, Catalent will invoice Pharmacyclics the cost of [\*\*]  
[\*\*]  
purchased by Catalent specifically for this project.

### 5.5. Project Notes/Assumptions

- Pharmacyclics acknowledges that the results of experimental/development work and the outcome of pre-validated manufacturing [\*\*]
- Any individual testing that does not meet specifications will be charged the nominal fee for the particular analysis.
- Prices are based on using [\*\*] If additional services are required that exceed the standard Catalent practices (i.e. per a client specific Quality Agreement) additional costs may be incurred.
- Catalent has commercial agreements with its suppliers and vendors that are not limited to the goods and services to be procured under this work order; Catalent does not pass through benefits (cash discounts, trade discounts, rebates or allowances), if any, received under such agreements.

## Section 6. Version History

Version	Date Issued	Reason(s)
01	07 Jun 13	New Issue

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V1  
Page 4 of 4

WORK ORDER FOR IBRUTINIB [\*\*] MANUFACTURE PROCESS VALIDATION

WORK ORDER # [\*\*]

This work order (the "Work Order") is entered into and effective as of the date of the last signature hereto (the "Work Order Effective Date") pursuant to the Build-Out and Commercial Supply Agreement between Pharmacyclics, Inc. and Catalent CTS, LLC dated May 1, 2013 (the "Agreement"). Capitalized terms used in this Work Order and not otherwise defined herein shall have the same meaning as set forth in the Agreement.

The parties hereby agree as follows:

1. **Work Order.** This document constitutes a Work Order as defined in the Agreement, and the Services to be provided hereunder are subject to the terms and conditions of the Agreement
2. **Project Scope, Budget and Timelines.** The specific Services contemplated by this Work Order and the related payment terms and obligations are set forth in the following sections of Contractor's proposal dated May 31, 2013, which is incorporated herein by reference and attached hereto as Exhibit A (the "Exhibit A").

SCOPE OF WORK Section 1  
PROJECT BUDGET Section 2 not to exceed [\*\*] without prior written approval  
of both parties in accordance with Section 6 of this Work Order  
PAYMENT SCHEDULE Section 3  
SCHEDULING/DELIVERABLES Section 4  
ADDITIONAL PROJECT TERMS Section 5  
VERSION HISTORY Section 6

Contractor shall provide the following Product deliverables: manufacture and release testing of 3 process validation batches, validation summary report.

3. **Payment and Invoices.** Invoices will be sent electronically to Pharmacyclics' Accounts Payable Department at [\*\*] An authorized Purchase Order will be issued upon execution of this Work Order containing invoicing instructions.

4. **Key Personnel.**

For Contractor:

Name: [\*\*]  
Title: [\*\*]  
Phone: [\*\*]  
Address: Catalent  
10245 Hickman Mills Dr  
Kansas City, MO 64137

For Pharmacyclics:

Name: [\*\*]  
Title: [\*\*]  
Phone: [\*\*]  
Address: Pharmacyclics, Inc.  
995 E Arques Ave  
Sunnyvale, CA 94085

5. **Term.** The term of this Work Order will commence on the Work Order Effective Date and will continue until the Services described on Exhibit A are complete or this Work Order or the Agreement is terminated earlier in accordance with the Agreement.

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6. **Amendments.** Any change in the details of this Work Order or the assumptions upon which this Work Order is based (including, but not limited to, changes in the starting date for the Project or a delay, or suspension of the Project by Pharmacyclics, changes in the Project budget and/or timelines) will require an amendment. No amendment of this Work Order will be effective unless in writing and signed by authorized representative of each Party. For the purposes of this Section 6, authorized representatives of Pharmacyclics shall be defined as Pharmacyclics' employees at Vice President level and above, and authorized representatives of Contractor shall be defined as Contractor's employees at Director level and above.

7. **Delivery.** A copy of the fully-executed Work Order should be delivered as follows:  
emailed in PDF format to:

If to Contractor: [\*\*]

If to Pharmacyclics: [\*\*]

Hard copies should be mailed to:

If to Contractor

Catalent

Attn: Contracts

10245 Hickman Mills Drive

Kansas City, MO 64137, U.S.A

If to Pharmacyclics

Pharmacyclics, Inc.

Attn: Contracts Management/Legal

995 E. Arques Avenue

Sunnyvale, CA 94085

**IN WITNESS WHEREOF,** this Work Order has been executed by the Parties hereto through their duly authorized representatives and is effective as of the Work Order Effective Date.

FOR CATALENT CTS, LLC

[\*\*]

By:

Name:

Title:

Date:

RECEIVED

JUN 17 2013

FOR PHARMACYCLICS, INC.

By:

Name:

Title:

Date:

Robert W Duggan  
Robert W Duggan  
CEO  
13 June 2013



A Purchase Order is required at Pharmacyclics to process invoices from Aptuit:

☒ Yes

☐ N/A

Please email a copy of PO to:

[\*\*]

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## Exhibit A

### Section 1. Scope of Work

#### 1.1. Project Materials

##### Active Pharmaceutical Ingredient (API)

API shall be supplied to Catalent having been assayed, analyzed and tested and shall be accompanied with copies of all relevant Certificates of Analysis, Certificates of Approval, expiry date or shelf-life information, TSE and Residual Solvents information, and MSDS for the API. Upon delivery, the API shall be free from defect and fit for the purpose of carrying out the Services.

An identification test (ID by FTIR and visual observation) will be performed on each container of API received.

##### Raw Materials

Catalent will seek to source the necessary raw materials to undertake the activities detailed herein, unless otherwise directed by Pharmacyclics.

Raw materials will be client specific and will be released to NF/USP and/or Ph. Eur parameters.

Full release testing to other compendia (e.g., BP, JP) will incur an additional charge.

#### 1.2. Warehouse Storage and Non-Clinical Distribution

Receipt, storage, distribution and destruction of API, bulk drug product, and client specific raw materials will be billed under [\*\*]

#### 1.3. Manufacture

##### Manufacture of Validation Batches

Catalent will manufacture [\*\*]

All activities will take place in the shared manufacturing space.

- Batch size – [\*\*]
- [\*\*]
- [\*\*]
- [\*\*]

Manufacturing activities will be undertaken at Catalent's Kansas City facility. Master Batch Records (MBRs) will be approved by Catalent's Quality Group and Pharmacyclics.

##### Validation Report

Catalent will prepare a validation report that summarizes results and data generated during the validation activities. Report will receive 100% technical review and a QA review.

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Page 1 of 6

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## Cleaning Verification

Cleaning verification of all equipment used during transfer and manufacturing will be carried out post-manufacture. [\*\*]

A cleaning method is already in place at Catalent.

## 1.4. Analytics

### Standards and Materials

It is assumed that Pharmacyclics will be providing any required standards to Catalent. Should Pharmacyclics request Catalent to source standards, the prices will be issued through to Pharmacyclics.

It is assumed Catalent will use routine materials for analytical work to be performed. For any materials that are client-specific, additional charges may apply depending on the availability and type of materials.

### Microbiological Examination of Non-sterile Products

Routine Microbiological Examination testing will be performed according to the verified product specific method. [\*\*]

[\*\*] An assessment of the possible presence of the microorganism(s) in the product will be made based on the nature of the recovered microorganism(s), and any information on the product that is made available to Catalent.

### Finished Product Testing

Release testing of finished bulk drug product will be according to the tests below. A release specification will be agreed between both parties.

TEST	ACTIVE
[**]	

Packaged material will be tested as below

TEST	ACTIVE
[**]	

Upon completion of release testing, a Certificate of Analysis or an Analytical Report Form (ARF), as appropriate, will be issued by Catalent.

On release of bulk drug product, a Product Release Certificate, including a statement of Catalent GMP Compliance, will be issued. This Certificate will be signed off by Catalent according to Catalent internal procedures. Copies of the Certificate and the executed batch manufacturing record (MBR) will be sent to Pharmacyclics.

Pricing assumes standard turn around time for release testing issuance of CoA). If Pharmacyclics requests expedited testing additional fees per Section 5.1 will be captured in a Change Order. [\*\*]

Standard turnaround time does not include: delays due to investigations and/or deviations that are not attributed to Catalent error, dissolution requiring S2/S3 testing and microbiology testing requiring identification.

## Section 2. Project Pricing Detail

### 2.1. Fixed Fees

Activity and Description of Work	Price
[**]	

### 2.2. Revisions to Pricing

Catalent reserves the right to revise quoted price for any project as a result of initial scope change, planned deviations, revisions in specifications, modifications of test methods, undocumented requirements, retesting, requirements outside of Catalent SOPs, or any unforeseen difficulty in executing the project. In addition, the quoted prices are subject to annual review to account for changes in inflation, increased overhead charges, etc. Any additional work will be performed based on written agreement from Pharmacyclics and will be documented on a Catalent Quotation Amendment Record (QAR).

### Fixed Fees

DESCRIPTION	PRICE
[**]	
TOTAL	[**]

### Fee-For-Service

DESCRIPTION	PRICE (\$)
[**]	
TOTAL	[**]

#### 4.1. Scheduling

Catalent must receive a signed Quotation, a signed protocol (if applicable), and all raw materials/intermediates/final product samples in order for this project to be scheduled. Subsequently, a Purchase Order number (where applicable) must be received within [\*\*] of receipt of the signed quote. A signed and effective Quality Agreement (if applicable) must be on file in order for this project to be scheduled. Once scheduled, Pharmacyclics will be notified by the Project Manager of the anticipated start and completion date of the project activities.

### 5.1. Rush Services

If rush services are agreed between Pharmacyclics and Catalent at the time of request, additional charges may apply based on the expedited turnaround times and % up charges outlined in the table below.

Turn Around Time (TAT) Reduction	Rush Charge (% of service/timepoint testing, etc. being expedited)
	[**]

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## 5.2. Additional Fees

In addition to the fixed fees, the following charges may apply.  
No charges will be issued unless the materials are required or the service is needed.

Activity	Description	Price per Unit
	[**]	
	[**]	
	[**]	

Other Charges	Description
	[**]
	[**]
	[**]

[\*\*]

## 5.3. Project Management

Following execution of this Contract, Catalent will conduct the work detailed herein under the leadership of a Project Manager. As the client advocate, the Project Manager will serve as the primary point of contact for communication between Pharmacyclics and Catalent to ensure effective flow of information and rapid resolution of any issues. To achieve this, Catalent will establish and maintain a cohesive and highly effective project team throughout the project lifecycle.

The Project Manager will:

- Strive to understand Pharmacyclics' goal and will manage the strategy to meet those goals.
- Lead the performance of the project tasks per the agreed upon scope of work.
- Act as the focal point for all internal and external project communications.
- Schedule, monitor and communicate the status of the project tasks to the project team.
- Conduct team meetings.
- Prepare the overall project and communication plan with the assistance of the project team.

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- Monitor the compliance to the project plan and update the plan, as needed.
- Monitor the project deliverables to ensure milestones are delivered per agreed-upon timeline.
- Identify project risks and ensure they are recognized and satisfactorily addressed.
- Monitor adherence to the project budget and initiate Quotation Amendment Records (QARs) as needed.

#### 5.4. Cancellation/Postponement

Pharmacyclics shall have the right to cancel or postpone their reserved manufacturing slot at any time upon written notice to Catalent.

If this project is cancelled by Pharmacyclics, Catalent will invoice Pharmacyclics the cost of any sample/materials, work performed before cancellation, reference materials, equipment, and supplies purchased by Catalent specifically for this project.

For manufacturing, if Pharmacyclics cancels or postpones their reserved manufacturing slot, Catalent reserves the right to invoice fees according to the following calendar day schedule:

Notification Prior to Date of Compounding/Manufacturing	Fee (% of Total Batch Manufacture Cost)
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

#### 5.5. Project Notes/Assumptions

- Any individual testing that does not meet specifications will be charged [\*\*] for the particular analysis.
- Prices are based on utilizing Catalent approved suppliers for raw materials and/or packaging components. If raw materials and/or packaging components are required to be supplied by un-approved vendors the Client may either supply the raw material and/or packaging component from a Pharmacyclics approved vendor or Catalent will audit the vendor at Pharmacyclics cost.
- Prices are based on using Catalent's standard practices. If additional services are required that exceed the standard Catalent practices (i.e. per a client specific Quality Agreement) additional costs may be incurred.
- Catalent has commercial agreements with its suppliers and vendors that are not limited to the goods and services to be procured under this work order; Catalent does not pass through benefits (cash discounts, trade discounts, rebates or allowances), if any, received under such agreements.

#### Section 6. Version History

Version	Date Issued	Reason(s)
01	31 May 13	New Issue

ATTACHMENT C**BATCH PRICING AND FEES\***

<b>BATCH PRICING FOR BATCHES IN EXCESS OF 10 BATCHES PER CONTRACT YEAR**</b>			
<b>Product</b>	<b>Dosage Form / Unit Strength</b>	<b>Batches in Contract Year</b>	<b>Initial Price Per Batch</b>
<b>Ibrutinib</b>	[**]		

\* Pricing for Initial Batches shall be agreed by the Parties in separate quotations signed by both Parties.

\*\* Prices do not include

[\*\*]

<b>ADDITIONAL FEES</b>		
<b>Type of Fee</b>	<b>Amount</b>	<b>Payable</b>
Facility Construction Support Fee	[**]	[**]
Milestone Payments & Manufacturing Incentive Payments	[**]	[**]
Facility Fee	[**]	[**]

## EXECUTION VERSION

	[**]	[**]
Product Maintenance Fee	[**]	[**]

**EXECUTION VERSION**

**ATTACHMENT D**  
**QUALITY AGREEMENT**

## Quality Technical Agreement *Ibrutinib*

*Between*

**CATALENT CTS, LLC (KCM)**  
10245 Hickman Mills Drive  
Kansas City, MO 64137

Hereinafter referred to as "Catalent"

*And*

**Pharmacyclics, Inc.**  
995 E. Arques Avenue  
Sunnyvale, CA 94085

Hereinafter referred to as "Pharmacyclics"

This Quality Technical Agreement is effective upon final approval and will be reviewed annually by both parties; and updated as needed.

### Catalent Approvals:

CATALENT		
Name/Title	Signature	Date
[**]	[**]	[**]
Name/Title	Signature	Date
[**]	[**]	[**]

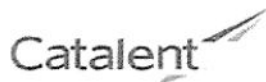
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**Pharmacyclics Approvals:**

Pharmacyclics		
Name/Title [**]	Signature [**]	Date [**]
Name/Title [**]	Signature [**]	Date [**]

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## 1. Purpose

The intent of this Quality Technical Agreement (QTA or Agreement) is to establish, clarify, and communicate the roles and responsibilities as well as quality expectations for clinical and commercial ibrutinib Drug Product or Services performed by Catalent (Contract Acceptor) for Pharmacyclics (Contract Giver). Collective referred to as "Parties".

## 2. Scope

The services contracted by Pharmacyclics may include contract manufacture, packaging and labeling, product release testing, stability program, and product storage and distribution, and other responsibilities as they relate to commercial processing of ibrutinib, [\*\*]. See *Attachment B, Product and Material List*, for a detailed listing of all Products and Services covered under this Agreement.

## 3. Effective Date

This Quality Technical Agreement (QTA) is effective when approval signatures of all parties are complete. The agreement shall be in effect until the expiration date of the last lot produced under the Build-out and Commercial Supply Agreement, effective May 1, 2013 (CSA) between Catalent CTS, LLC and Pharmacyclics, Inc. This QTA can be terminated per the terms of the CSA. This QTA will be reviewed [\*\*] by both parties and updated, as needed.

## 4. Relationship to Other Agreements

The QTA does not replace or override any existing Commercial Supply Agreement or Master Service Agreements (CSA or MSA), business agreement or contract in place between Pharmacyclics and Catalent, but serves to augment and clarify roles and responsibilities relating to quality. In the event that there is a conflict between the QTA and the CSA, the business agreement will take precedence. If the event is a quality related issue between any of the provisions in the business agreement and this QTA; the QTA shall override the business agreement.

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<b>5. Definitions and Abbreviations (Capitalized in Document)</b>	
API	Active Pharmaceutical Ingredients (drug substance)
Annual Product Review	Report prepared annually to summarize product data from Catalent to client in support of client's Annual Report to FDA. Also called Commercial Data Report at Catalent.
Annual Report	Report submitted to FDA annually within 60 days of approval anniversary that contains information defined in 21CFR314.81(b)2.
Bulk drug product	Medicinal product that has not undergone all stages of production.
CAPA	Corrective and Preventive Action
Change	A planned alteration, replacement, origination of a new item (e.g., product, equipment, facility) or alteration or elimination of specifications, methods, facilities, utilities, equipment, computer systems, master records or controls that are used for the manufacture, processing, packaging, or holding of product.
CFR	Code of Federal Regulations of FDA
CofA	Certificate of Analysis
CofM	Certificate of Manufacture
CSA	Commercial supply agreement
Deviation	A departure from an approved process/procedure or applicable regulation or standard.
EP	European Pharmacopoeia
FDA	Food and Drug Administration of United States of America
Finished Product	Medicinal Product that has undergone all stages of production, including packaging and labeling in its final container.
Master Service Agreement (MSA)	A master agreement that applies to several projects or products with a supplemental agreement containing specific terms for each one.
OOS	Out of Specification
OOT	Out of Trend
Process Validation	The collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality products.
Reference Sample (Eudralex, Volume 4, Annex 19)	A sample of a batch of starting material, packaging material or finished product which is stored for the purpose of being analysed should the need arise during the shelf life of the batch concerned. Typically Reference Samples are API, raw materials, primary packaging components or bulk finished product.
Retention Sample (Eudralex, Volume 4,	A sample of a fully packaged unit from a batch of finished product. It is stored for identification purposes.

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Annex 19)	
Reserve Sample (21CFR211.170(a) and (b))	An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained or an appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling.
Reprocessing	Catalent defines reprocessing as the reworking of all or part of a batch of product of unacceptable quality from a defined stage of production, so that its quality may be rendered acceptable by one or more additional operations.
Significant (or critical)	Anything having the potential to affect safety, identity, strength, purity or quality.
SISPQ	Safety, Identity, Strength, Purity, and Quality
USP	United States Pharmacopoeia
Validation Master Plan (VMP)	Provides the overall purpose and direction for the process validation efforts. The VMP lists all the individual validation processes that comprise the overall validation of the complete process.

6. General Requirements	Responsible Party	
	Pharmacyclics	Catalent
<u>Quality Technical Agreement Approval</u> The QTA will be approved, signed and dated by representatives of Quality or Regulatory for both Catalent and Pharmacyclics.	X	X
<u>Review Process of QTA</u> A review of the QTA should be conducted [**] as part of the Product Annual Review process. Either party may initiate a revision to the QTA through written communication to the other party. The Catalent document control process will be used to manage revisions to the QTA and updates will be made to <i>Attachment A, Document History</i> .	X	X
<u>Attachments to the Agreement</u> The QTA includes Attachments that contain or reference documentation that apply to the manufacturing/processing operations of the Product.  These Attachments can be revised and updated as necessary by the approval and sign-off of designated Quality Representatives (minimum of one from each Party) without the full re-approval of the QTA. Revision will be handled through the Catalent document control process, as well as updates documented in <i>Attachment A, Document History</i> .	X	X

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<u>Subcontracting</u> Catalent agrees not to subcontract (including to other Catalent sites) any portion of the manufacturing, processing, testing, labeling, release and/or handling of the Product entrusted to it, unless express prior written authorization is obtained from Pharmacyclics.	X	X
<u>Manufacturing/Processing Facilities</u> Catalent must ensure that all GMP operations are conducted in facilities that are designed and operated to accommodate the operations, and that proper environmental conditions are met in order to reduce the risk of cross-contamination or error, and permit effective cleaning and maintenance.  Catalent must obtain prior written approval from Pharmacyclics before moving any portion of the manufacturing/processing operation of the Product to an alternate facility, or production line/area. Such move or change would be managed under the KCM site change control process.	X	X
<u>Personnel Contact Listing</u> Pharmacyclics and Catalent must establish and maintain a current Contact Listing of individuals from each company who are to be contacted, depending on the requirements or situation. The Contact List should include contact name, title, department/function, phone number(s), and email address. See <i>Attachment C, Contact Listings</i> .	X	X
<u>Person In Plant</u> Pharmacyclics reserves the right to be on-site at Catalent KCM (as mutually agreed upon) for the following activities <ul style="list-style-type: none"> <li>• Manufacture/processing of Product</li> <li>• Process validation</li> <li>• Qualification of Pharmacyclics purchased equipment</li> <li>• Assistance with analytical method qualification</li> <li>• Investigation of process or product failures</li> <li>• Other activities jointly agreed to</li> </ul>	X	X

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7. Regulatory Requirements	Responsible Party	
	Pharmacyclics	Catalent
Prepare and submit all regulatory filings, including supplements, variations and any changes to approved drug registrations.	X	
Prepare and submit the post-marketing Product Annual Report(s) to regulatory agencies, as applicable.	X	
Prepare and provide to Pharmacyclics Product data and documentation (Data Compilation Report) in support of the post-marketing Product Annual Report(s), for all services provided by KCM, as applicable.		X
Communicate with regulatory agencies regarding submissions and changes or variations to the approved Product registrations.	X	
Notify any changes to the approved registrations that are relevant to the manufacture of Product	X	X
Notify either party of any written or verbal communication of inspection by a regulatory agency that directly relates to the manufacturing/processing/testing of Product.	X	X
In the event there are written observations resulting from a regulatory inspection directly relating to Product, both parties will collaborate on responses directly related to the observation(s).	X	X
8. Quality Systems	Responsible Party	
	Pharmacyclics	Catalent
Catalent must have a system in place that describes how site procedures and processes interact to accomplish the objectives of the Catalent's quality systems. Sections 8.1 to 8.14 describe minimum requirements for quality systems. 8.16 LME 30 MAY 13		X
Catalent must maintain a quality plan to identify and track continuous improvement activities and corrective and preventive actions that have an impact on Pharmacyclics Product.		X

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8.1 Batch Release	Responsible Party	
	Pharmacyclics	Catalent
<u>Batch release to market responsibility</u> The Final Release of the Product, which is defined as the release to the marketplace, is the responsibility of Pharmacyclics.	X	
<u>Batch release record definition and notification requirements</u> Catalent has the responsibility to release the Product to Pharmacyclics. Upon release by Catalent the following batch documentation and records are required for review during the batch release to market process that will be sent to Pharmacyclics Quality contacts identified in Attachment C, Contacts List: <ul style="list-style-type: none"> <li>• All executed production records and quality control data</li> <li>• CofA, CofM, and CofC documents</li> <li>• Deviation reports, laboratory investigations, manufacturing investigations associated with the batch, if applicable.</li> </ul>		X
Notification to Pharmacyclics Quality unit is required within [**] [**]		X
Catalent must notify Pharmacyclics within [**] [**]		X
The information required on the Catalent CofA: <ul style="list-style-type: none"> <li>• Catalent Name and Address (letterhead)</li> <li>• Product name and description</li> <li>• Batch Number</li> <li>• Manufacturing Date</li> <li>• Expiration Date</li> <li>• Product Item Code</li> <li>• Test methods</li> <li>• Test results</li> <li>• Test specifications</li> <li>• Storage conditions</li> <li>• Compliance statement</li> <li>• Review and approval signature and date</li> </ul>		X

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<b>Batch Identification Number or Product Lot Number</b> The Product is assigned a unique lot number generated by Catalent from a validated inventory system which has the format of L plus seven-digit sequential number (e.g., L0000001). This unique lot number is pre-assigned prior to the start of manufacturing or packaging of a batch.		X
<b>Date of Manufacture and Expiration Date Conventions</b> <ul style="list-style-type: none"> <li>Catalent will assign the date of manufacture based on the date the active ingredient is added to the product or the date the active ingredient is first manipulated (e.g., screened).</li> <li>Catalent will calculate the expiration date from the date of manufacture using the currently approved expiration-dating period as determined by Pharmacyclics. The expiration date will be calculated from the last day of the month computed above.</li> </ul>	X	X

8.2 Change Management	Responsible Party	
	Pharmacyclics	Catalent
Catalent change management procedure will be utilized to document changes initiated by Catalent, as they relate to the Product. Changes that have potential to impact the Product require prior written approval by Pharmacyclics: <ul style="list-style-type: none"> <li>Manufacturing/packaging facility change</li> <li>Critical manufacturing/packaging equipment</li> <li>Master batch record</li> <li>Master packaging records</li> <li>Product test methods</li> <li>Product specifications</li> <li>Any package label or container changes</li> <li>Raw materials (including suppliers)</li> </ul> Pharmacyclics will utilize its internal change control to document changes by Pharmacyclics and communicate critical and major changes to Catalent for approval.	X	X

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8.3 Deviation Management	Responsible Party	
	Pharmacyclics	Catalent
<p>Catalent will use its internal deviation management process (per site SOPs) to document, investigate and report deviations and investigation reports.</p> <ul style="list-style-type: none"> <li>Catalent must notify Pharmacyclics within [**] of deviations or investigations with potential to impact the Product.</li> <li>Catalent must conduct the investigation and supply Pharmacyclics Quality Unit with a draft report for review prior to Catalent approval for Deviation and Investigation Reports which have the potential for product impact.</li> </ul>		X
In the event a deviation or quality issue is identified by Pharmacyclics during their review of Catalent batch or product documents, Pharmacyclics will notify Catalent of the issue in order for Catalent to initiate an investigation and applicable report (i.e., deviation, investigation, complaint).	X	X
Catalent is responsible for [**], but Pharmacyclics Quality Unit reserves the right to [**]	X	X
8.4 Documentation and Data	Responsible Party	
	Pharmacyclics	Catalent
<p><u>Document management system</u></p> <p>Catalent must maintain a GMP document management system with retention policies that meet applicable regulatory requirements.</p>		X
<p>Catalent is responsible for the maintenance and retention of records/documents that support the manufacturing and processing of the Product as defined in the table below. Catalent agrees to notify Pharmacyclics in writing prior to destruction of any Pharmacyclics records that has reached the end of its retention period.</p>		X
Should Catalent go out of business, Pharmacyclics will have the opportunity to retrieve all stored Pharmacyclics related records.	X	X

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**Records requiring retention, schedule, and responsible party:**

Document Type	Retention Period [**]
Material Specifications	
Analytical Methods	
Batch Records (mfg & pkg)	
Site SOPs	
Label Proof Copy	
Deviation, Investigation or Complaint Reports	
Change Controls	
Laboratory Notebooks	
Protocols	
Stability Data and Reports	
Equipment/Instruments: Qualifications, Periodic Reviews, Logbooks, Preventative Maintenance	
Certificate of Analysis	
Distribution Records	

8.5 Annual Product Review		Responsible Party	
		Pharmacyclics	Catalent
Pharmacyclics is responsible for the preparation and filing of the Annual Report (AR) Catalent will provide an Annual Product Review (APR) to Pharmacyclics in support of their AR. Catalent requires [**] notification on AR due date for APR preparation. Pharmacyclics to provide APR due date to Catalent.		X	X

**Items to be included in Catalent Annual Product Review (as applicable)**

Items
Review of all deviation reports, laboratory and manufacturing Investigations (OOS), and CAPA closure, including trending as applicable.
Review of all batches processed and released, confirming conformance to product specifications.
Review of any batches reworked, reprocessed, salvaged (recovered) or rejected, including applicable root cause.

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Review of any batches recalled, including reason for recall and ultimate disposition.
Review of all product quality complaints and adverse event reports processed by Catalent.
Annual inspections of drug product reference and reserve samples stored at Catalent.
Review of stability data performed as part of the on-going stability program; including stability failures, and any changes to the stability program.
Changes to Product specifications and methods
Review of change controls/document controls related to or that have an impact on the product to ensure that changes have no affect on the qualified equipment/utilities and approved processes
Review of the effectiveness of corrective and preventive actions from previous year's annual assessment.

8.6 Personnel Qualification and Training	Responsible Party	
	Pharmacyclics	Catalent
Catalent must maintain records of employee qualifications, experience and training for those engaged in GMP activities. Catalent must ensure that all personnel involved in manufacturing/packaging/testing or processing activities for the Product are current on all required training.		X
Pharmacyclics reserves the right to review training records of personnel involved in the manufacturing/processing/testing activities of the Product.	X	
8.7 Specifications	Responsible Party	
	Pharmacyclics	Catalent
As applicable, Pharmacyclics will create and maintain API, Product and Packaging Specifications, and provide these to Catalent. Catalent will create internal specifications based on those provided by Pharmacyclics.	X	X
Catalent must assure API, raw materials, in-process materials, finished products and packaged product meet applicable material specifications.		X

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8.8 Stability	Responsible Party	
	Pharmacyclics	Catalent
Catalent is responsible for creating and approving the Stability Protocol for the Product, and Pharmacyclics is responsible for the review and approval of the Stability Protocol	X	X
Catalent must store and maintain stability samples and execute one annual stability study of the finished product in accordance with the provided stability protocol and Catalent internal procedures. Catalent must have validated stability chambers with various storage conditions as defined in the stability protocol for storage of stability samples. Catalent is responsible for data reporting and writing stability reports for the Product. Catalent must provide stability reports to Pharmacyclics at time intervals designated in the stability protocol.		X
Catalent must contact Pharmacyclics Quality Unit representative within [**] of confirmed stability OOS or out of trend (OOT) results.		X
A copy of the draft Laboratory Investigation Report (LIR) will be provided to Pharmacyclics for review and approval prior to final Catalent approval. Pharmacyclics will participate in the investigation of the OOS or OOT stability result for the Product, as applicable.	X	X
8.9 Validation Practices	Responsible Party	
	Pharmacyclics	Catalent
Catalent is responsible for creating and maintaining the Master Validation Plan (MVP) which lists the individual process validation activities and reports scheduled for the Product. Process Validation reports are created by Catalent with input and approval by Pharmacyclics, and contain the required activities and the acceptance criteria for an individual process validation. Process Validation protocols are executed on at least [**] of product produced by Catalent. <ul style="list-style-type: none"> <li>If there are any problems during execution of a Process Validation, they must be communicated to Pharmacyclics, within [**]</li> <li>If the problems cannot be resolved, Pharmacyclics and Catalent will conduct a joint investigation and determine what follow-up or further validation studies are required.</li> </ul>	X	X

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8.10 Auditing Catalent	Responsible Party	
	Pharmacyclics	Catalent
<u>GMP audits</u> Pharmacyclics reserves the right to audit Catalent's facilities and systems as they relate to manufacturing/processing/testing/services of the Product. Audits may be performed [**] at a mutually agreed upon time. If observations result from the audit, Catalent will respond to Pharmacyclics within [**] calendar days upon receipt the audit report and include any applicable CAPA, with completion dates.	X	X
<u>For Cause Audit</u> Pharmacyclics reserves the right to audit Catalent's facilities and systems as a result of circumstances such as product failure, product recall/withdrawal, negative regulatory inspections, or significant quality related issues.	X	
<u>Self inspection</u> Catalent Quality will maintain a GMP self-inspections (internal audit) program of the facility, processes, operational departments and quality systems per site SOPs. Quality will monitor and trend quality systems and key performance indicators, and will report trends and effectiveness checks to Operations and Quality Management who will participate in any necessary remediation.		X
8.11 Regulatory Interactions with Government Agencies	Responsible Party	
	Pharmacyclics	Catalent
Catalent agrees to inform Pharmacyclics Quality Unit within [**] of any inquiry, communication, inspection or notification of inspection by a regulatory agency which directly relates to the manufacture, processing or handling of the Product.  During the course of the inspection that involves the Product, Catalent will provide periodic updates of the inspection. In the event there are written observations or any type of injunction by a Regulatory Agency which involve the Product, Pharmacyclics will be informed within [**] and be provided with copies of all documentation (such as 483 observations). Pharmacyclics will have the opportunity to review the documentation and provide input to responses that directly relate to the Product, if applicable. If Pharmacyclics elects to provide	X	X

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input to the proposed response, Pharmacyclics will do so as promptly as possible, but within no more than three business days. Catalent will give full consideration to Pharmacyclics input for incorporation as appropriate. Catalent will provide a copy of final responses to Pharmacyclics.		
Pharmacyclics may have a representative present at Catalent's facility during a regulatory agency inspection directly relating to the Product. Pharmacyclics interaction with the Regulatory Agency will be at the discretion of the Agency.	X	
<b>8.12 Reference Samples and Reserve Samples</b>		
	<b>Responsible Party</b>	
	Pharmacyclics	Catalent
An appropriately identified sample that is representative of each lot in each shipment of API will be retained in accordance to Catalent internal procedures and US and EU regulatory requirements.		X
When applicable, an appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. Reference and reserve samples will be visually examined [**] a year for evidence of deterioration, unless it would affect the integrity of the sample.		X
Reference and reserve samples will be processed and maintained by Quality in a secure area under controlled conditions consistent with product labeling. Reference and reserve samples will consist of sufficient quantity to permit at least [**] times testing required to determine product meets established specifications (except sterility and pyrogens) retained for a period of time at least equivalent to one year past the expiration date of the Product or [**] after the distribution of the last lot of drug product containing the active ingredient.		X

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8.13 Product Complaints	Responsible Party	
	Pharmacyclics	Catalent
<p><u>Complaint Reporting</u> Pharmacyclics will typically receive customer complaints related to the Product. Pharmacyclics will forward complaints to Catalent for investigation, as applicable to the nature of the complaint and the services provided by Catalent.</p> <p>Complaints from the field received directly by Catalent will be forwarded to Pharmacyclics Quality within [**] of receipt. All Product complaints are carefully assessed upon receipt to determine if immediate action is required to protect patient safety.</p> <p>Catalent has appropriate procedures in place for receipt, assessment, investigation and documentation of product complaints.</p>	X	X
<p><u>Complaint Investigation and Evaluation</u> Catalent will conduct an investigation to determine root cause and perform an impact assessment to other batches or products based on the complaint. A complaint report will be provided to Pharmacyclics in within [**]. If an assessment or investigation is required sooner (for recall, medical emergencies) Pharmacyclics will communicate/notify Catalent and timing for completing investigation will be agreed between both parties.</p>	X	X
<p>For complaints that may qualify for immediate regulatory reporting or suspect counterfeit/tampered product, Catalent will expedite the complaint investigation and provide Pharmacyclics with an initial written complaint investigation report within [**] business days from the date of notification, per regulations.</p>		X
<p><u>Customer and Regulatory Authority Communication</u> Pharmacyclics will be responsible for all applicable regulatory reporting requirements, including adverse reaction reports.</p> <p>Pharmacyclics is responsible for reporting the result of the investigation to the complainant, in accordance with internal procedures.</p>	X	

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8.14 Product Recalls, Corrections and Market Withdrawals	Responsible Party	
	Pharmacyclics	Catalent
Pharmacyclics shall be responsible for making all decisions regarding the recall or withdrawal of the Product. In the event Pharmacyclics will be required or will voluntarily decide to recall, or withdraw Product or API, Pharmacyclics will coordinate such recall or withdrawal and Catalent will work in conjunction with Pharmacyclics, at their directions, per respective site procedures.		
Catalent shall inform Pharmacyclics immediately of any Product related issues which may have a potential to result in a product recall or withdraw. Catalent will conduct a detailed investigation and provide a written report to Pharmacyclics as quickly as possible.	X	X
In the event of a recall or withdrawal, Catalent will not make any public statement relative to the recall/withdrawal without the prior written consent of Pharmacyclics.		
Pharmacyclics reserves the right to initiate a recall or withdrawal of Product at any time should Pharmacyclics reasonably determine that the Product represents a threat to patient health, safety or welfare. Pharmacyclics will communicate such decision to Catalent, once determined.		
Catalent reserves the right to recommend a recall or withdrawal to Pharmacyclics, if deemed necessary for patient safety, Catalent agrees to abide by Pharmacyclics decision as to whether a product recall or withdraw is required, unless it is clearly evident patient safety is at risk and Pharmacyclics fails to make required regulatory notifications. In this case, it may be necessary for Catalent Quality or QP to perform the notification to appropriate regulatory authorities and inform Pharmacyclics of such.	X	X

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8.15 Process and Conditions for Returns Management		Responsible Party	
		Pharmacyclics	Catalent
Pharmacyclics's Quality Unit is responsible for determining the acceptability of all returned products and determining its suitability for resale.		X	
If Catalent were to receive returned commercial goods Catalent will inform Pharmacyclics and obtain authorization to ship these returns to Pharmacyclics's designated third party logistics.			X
8.16 Reprocessing, Rework and Rejections		Responsible Party	
		Pharmacyclics	Catalent
In general, rework or reprocessing of the product is not permitted by Catalent and Pharmacyclics. Reprocessing or otherwise manipulating GMP materials outside of the defined validated processes written in manufacturing or packaging record is done only by exception under the deviation management and change control process and with prior written approval from Pharmacyclics.		X	X
9. Facilities, Equipment and Computer Systems		Responsible Party	
9.1 Facilities, Equipment and Utilities		Pharmacyclics	Catalent
All specific requirements for the facilities, utilities, and equipment controls, are the responsibility of Catalent and must be in conformance to requirements listed in the Regulatory Application for the Product. Catalent agrees to meet and comply with Pharmacyclics specifications, US (21 CFR 210 & 211), EU (EC/91/356 Directive), and local regulatory requirements as set forth in this agreement.			X
For commercial product, the process, manufacturing and control procedures (including cleaning procedures where applicable) must be validated/qualified by Catalent in the facility Catalent intends to utilize for manufacture/packaging the Product.			X
The Qualification of major pieces of processing equipment, instrumentation, storage areas and facility systems (i.e. HVAC, purified water) are performed to ensure that the equipment/instrument/utility or system is functioning according to Catalent's and the manufacturer's expectations and to provide documented evidence that the item is qualified for GMP processing. All qualified items are periodically reviewed on a			X

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criticality based time schedule to ensure the qualified status is maintained.		
Procedures are in place that govern computer system validation through each phase of the system life cycle: pre-implementation, implementation, operation, and retirement. The degree of criticality as well as the level of complexity of each system is evaluated to determine the level of validation required.		X
Catalent must supply and test purified water, compressed air, and nitrogen to be used in the formulation and manufacturing process, which must meet Catalent and all applicable compendial (USP and EP) requirements (as applicable).		X
Catalent must have an approved environmental monitoring program and must perform routine monitoring of manufacturing areas following site procedures.		X
Catalent must have a bioburden control strategy developed and applied to Raw Materials and Product. Catalent must be aware of normal flora within the manufacturing environment.		X
<b>9.2 Calibration and Measurements</b>		<b>Responsible Party</b>
	Pharmacyclics	Catalent
Catalent is responsible for ensuring that all equipment and instrumentation associated with the manufacturing/packaging/testing of the Product is subject to the appropriate calibration checks and maintenance in accordance with an established written program. These activities must be properly scheduled and documented.		X
Catalent must ensure that the manual and electronic measuring and recording devices that are used in GMP areas are calibrated against a traceable reference standard/device and that the records include pre- and post-calibration readings and details of any adjustments/corrections made.		X
Instruments, apparatus, gauges, and recording devices not meeting established specifications must not be used and will be taken out of service at the time.		

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10. Materials	Responsible Party	
10.1 Materials Management	Pharmacyclics	Catalent
<p><u>Procurement of Raw Materials</u> Catalent is responsible for the procurement of raw materials used in manufacturing of ibrutinib, [**], with the exception of API, which is provided by Pharmacyclics. Catalent must ensure that raw materials are procured from approved Suppliers, and are received with supplier's CofA and appropriate BSE/TSE statement. Catalent will receive, inspect, sample (for testing and reserve), perform release testing, issue an internal CofA and release raw materials procured by Catalent according to internal procedures, registered material specifications, and applicable compendial (USP and EP) requirements. See Attachment B: Product and Materials List for materials procured by Catalent, and their respective Catalent approved suppliers.</p>	X	X
<p><u>Materials supplied by Pharmacyclics for Catalent</u> Pharmacyclics is responsible for ensuring that all materials and components supplied by Pharmacyclics for use in the manufacturing of the Product are in compliance with registered specifications. Pharmacyclics will ensure Catalent is provided with a Certificate of Analysis, BSE statement, and a supplier approval/management letter or audit certificate, as applicable. Pharmacyclics is responsible for providing Customs with applicable material values, per regulations (where applicable). See Attachment B <i>Product and Materials List</i> for materials supplied by Pharmacyclics and their respective Pharmacyclics approved suppliers.</p>	X	
<p><u>Inspection of container</u> Upon receipt of raw materials, Catalent will inspect all containers for external conditions, intact tamper evident seals or locks, absence of damage and confirmation of material identification, number of containers, container labeling and delivery documents, per site procedures. Catalent will process all temperature monitoring devices sent with such shipment and report the data to Pharmacyclics, if applicable.</p>		X

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<p><b>Storage of Raw Materials and Drug Product</b> Catalent agrees to store raw materials and the Product under the appropriate storage conditions and in a secure GMP area to ensure that they comply with all quality specifications, marketing authorizations and attributes provided by Pharmacyclics.</p> <p>Catalent does not manufacture, store or otherwise process penicillins, cephalosporins, beta lactam antibiotics, biological products (as defined in 21 CFR 600.3 (h)), toxic pesticides, fungicides, and rodenticides at its facility. Certain hormones, cytotoxic compounds, highly potent drugs and biological preparations shall only be handled if accepted via a risk assessment and based on Catalent site capabilities and license restrictions.</p>		X
<p>Catalent must monitor GMP storage areas for temperature and humidity and have alarm systems as applicable.</p> <p>Catalent must have secure, restricted and segregated areas for the storage of rejected, recalled, and returned materials and products.</p>		X
<p><b>Storage Procedure and Review of Record</b> Catalent must have a written procedure that describes the control and monitoring of storage temperatures and the calibration of measuring devices.</p> <p>Designated responsible persons at Catalent must review monitoring records following Catalent's internal procedure. This review must be documented and any excursion noted during the review must be investigated following Catalent's internal procedure for excursions. Client notification of excursions will be made within one business day, as applicable to the excursion and client product storage.</p>		X
<b>10.2 Distribution of Bulk Product or Finished Products</b>		
	<b>Responsible Party</b>	
	Pharmacyclics	Catalent
<p><b>Release for Shipment</b> Pharmacyclics will provide Catalent with a Certificate of Release for Bulk Product, or Finished Product final release if applicable, and a Shipment Authorization Form for release to ship, according to Pharmacyclics' internal procedures.</p>	X	

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<p><u>Product Shipment Requirement</u>  Catalent will only ship batches that have been released for shipment by Pharmacyclics per their Shipping Authorization Form.</p> <p>Catalent will utilize only qualified shippers as defined by Pharmacyclics.</p> <p>Catalent will be responsible for preparing the product and paperwork for shipment according to Pharmacyclics requirements. Shipment will be arranged by Pharmacyclics, utilizing Pharmacyclics identified carrier(s) to Pharmacyclics identified packaging facility(s).</p> <p>At the time of shipment, Catalent will ensure that all appropriate documentation (including shipment documentation), and temperature control/monitoring devices as defined in the Pharmacyclics Shipping Authorization Form accompany each shipment. The proper placement and number of temperature-monitoring devices for the bulk drug product will be agreed upon by both Parties, as applicable to the Product requirements.</p>	X	X
<p><u>Documentation Requirement for Distribution of Finished Product</u>  Catalent is responsible for retaining all transaction documentation necessary to facilitate the withdrawal or recall of a Pharmacyclics product.</p> <p>Catalent is responsible for maintaining a record of each shipment:</p> <ul style="list-style-type: none"> <li>• Description of the product (e.g., dosage form, strength)</li> <li>• Batch number</li> <li>• Name and address of the consignee</li> <li>• Date and quantity shipped</li> <li>• Transportation company utilized</li> </ul>		X

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10.3 Supplier Quality Management	Responsible Party	
	Pharmacyclics	Catalent
<p><u>Supplier Management Program</u></p> <p>Catalent must have a supplier management program to ensure that appropriate controls are in place to assess the criticality of raw materials/services and provides ongoing evaluation of GMP suppliers. Catalent is responsible for the on-going quality management of raw material suppliers/service providers and must evaluate suppliers' quality system on a periodic basis, including a Supplier Agreement.</p> <p>Catalent must communicate in writing any changes to raw material supplier to following requirements outlined in the section 8.2 <i>Change Management</i> of this agreement.</p> <p>Pharmacyclics is responsible for the on-going quality management of raw material or API suppliers for materials provided by Pharmacyclics to Catalent.</p>	X	X
11. Production	Responsible Party	
11.1 Production Practices	Pharmacyclics	Catalent
<p>All specific requirements for manufacturing equipment, manufacturing environment, equipment cleaning and storage, line clearance, training of the manufacturing personnel, in-process testing equipment are the responsibility of Catalent and in conformance to all requirements listed in the NDA or Regulatory Application for the subject products. Catalent agrees to meet and comply with Pharmacyclics requirements, US 21 CFR 210 &amp; 211, and Part 11, and local regulatory requirements as set forth in this agreement.</p>		X
<p>Catalent must ensure that only authorized personnel are permitted access to production areas where Pharmacyclics product is being manufactured. Catalent must have a process describing access requirements for visitors and untrained personnel.</p>		X
<p>Catalent must have a proper air control that prevents the generation and dissemination of dust (e.g., supply and exhaust of air of suitable quality).</p>		X

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Any waste product or labeling materials must be destroyed in a secure and legal manner, preventing unauthorized use and/or environmental problems.		X
Pharmacyclics retains the right to view and or request copies of any and all relevant manufacturing, labeling and packaging documentation of Pharmacyclics product.	X	
<b>11.2 Master and Batch Production Records</b>		
Catalent is responsible for preparing a master production record for the Product. Master production record must be reviewed and approved by both Pharmacyclics and Catalent Quality units.	X	X
The manufacture of the Product at Catalent will be done according to the master batch record approved by Pharmacyclics and in compliance with cGMPs and any other applicable regulatory requirements.		X
Catalent must have a process to ensure that the correct, approved master production record is used for generating a batch production record.		X
Changes to a master production record must be made in accordance with requirements outlined in the <i>Section 8.2 Change Management</i> of this agreement.		X
Catalent will prepare, for each batch of product manufactured for Pharmacyclics, the complete manufacturing batch documentation as agreed upon between Pharmacyclics and Catalent. Catalent must retain this complete documentation in accordance with appropriate document retention schedules as defined in <i>Section 9.4 Documentation and Data</i> of this agreement. This documentation must be readily accessible for review and inspection by Pharmacyclics and/or Regulatory Authorities, if requested. <i>DATE 30 MAY 13</i>		X
<b>11.3 Production Equipment Cleaning</b>		
Catalent must have a cleaning program that provides a high degree of assurance that equipment is free from materials having the potential impact on quality of Pharmacyclics product.		X
Catalent must have a cleaning program that confirms the effectiveness of cleaning where residues or potential contaminants pose a risk to quality of Pharmacyclics product.		

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12. Packaging and Labeling (as applicable)	Responsible Party	
	Pharmacyclics	Catalent
If Catalent performs finished product packaging and labeling, the following processes and controls will be applied:		
Pharmacyclics is responsible for the final selection/approval of the Product packaging configuration, including packaging components, label design and artwork for printed packaging material.	X	
Catalent will maintain strict controls over Product labeling materials and operations, in accordance with Federal Regulations, and internal procedures in order to prevent mix-ups and cross-contamination.		X
Labels and other printed labeling or packaging materials for the Product must be properly stored separately and securely maintained by Catalent, with proper identification to prevent mix-ups. Obsolete and outdated labels and packaging materials shall be properly destroyed.		X
Catalent must perform reconciliation upon completion of packaging of Finished Product. Reconciliation must meet established limits, or Catalent must perform an investigation according to internal procedures.		X
Catalent must perform packaging line clearance prior to and after packaging of the Product according to Catalent's internal procedure. This must be documented in the packaging record.		X
Catalent will carry out the inspection of the primary packaged product according to Catalent's internal procedure. The procedure must describe defect types, criticality and acceptance limits.		X
Printing devices used to imprint or ink jet labeling must be adequately monitored and qualified to assure imprinted or printed labeling conforms to the specification.		X
Catalent must use appropriate electronic equipment qualified to conduct a 100% examination for correct labeling during or use visual inspection to conduct a 200% examination for correct labeling. Such examination shall be performed by one person and verified by a second person.		X

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Any waste packaging or labeling material must be destroyed in a secure and legal manner, preventing unauthorized use and/or environmental problems.		X
<b>13. Laboratory</b>	<b>Responsible Party</b>	
	<b>Pharmacyclics</b>	<b>Catalent</b>
<u>Analytical Test Methods</u> Catalent must be qualified by Pharmacyclics to perform the release and stability testing of the Product. Pharmacyclics will provide validated and approved test methods for the Product to Catalent. Catalent will work with Pharmacyclics to transfer validated test methods per protocol. Catalent will provide method transfer report to Pharmacyclics  Catalent will issue test methods internally and must conduct testing according to approved test methods, applicable regulations and internal procedures. Any changes to test methods must be managed according to requirements outlined in <i>Section 8.2 Change Management</i> of this agreement.	X	X
<u>Analytical Testing</u> Catalent must maintain laboratory records that include complete data derived from all testing necessary to assure compliance with established specifications. Product must meet the approved specifications provided by Pharmacyclics for Product release.		X
<u>Reference Standard</u> Catalent must ensure that appropriate USP reference standards or reference standard supplied by Pharmacyclics are used for testing of the API and the Product, as applicable. Pharmacyclics will supply Catalent with documentation describing the qualification, storage conditions, and expiration dates for those reference standards supplied by Pharmacyclics.	X	

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<p><b>Suspect Analytical Results</b></p> <p>Catalent must notify Pharmacyclics within one business day of the following confirmed suspect analytical results:</p> <ul style="list-style-type: none"> <li>• OOS or OOT release test results</li> <li>• Anomalous release test results</li> <li>• Failure to meet in-house release limit</li> </ul> <p>Catalent must conduct an investigation following requirements outlined in <i>Section 8.3 Deviation Management</i> of this agreement whenever an OOS/OOT, anomalous, and test results outside of in-house limit result is obtained for the Product or for other supporting system (e.g., water, environmental monitoring) that may have an impact on SISPQ of the Product. This investigation must determine the validity of the result and thus, allow for appropriate disposition of the Product.</p>		<p>X</p>
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## Attachment A – Document History

Revision History			
Version	Section	Summary	Date Revised
01	N/A	New Quality Technical Agreement for Commercial and includes clinical materials	New

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[\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.



Catalent QTA #:

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GMP Quality Technical Agreement  
Effective Upon Final Signature

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## Attachment B – Product, Material, and Sub-contractor List

### B.1 Product List

Product Name	Pharmacyclics Item Code	Catalent Item Code
Bulk Ibrutinib <sup>(**)</sup>	<sup>(**)</sup>	<sup>(**)</sup>

## B.2 Material List

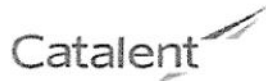
Material Name	Pharmacyclics Item Code	Catalent Item Code	Supplier	Procured by
[**]				

### B.3 Sub-contractor List

Sub-Contractor Name/Address	Contacts	Managed By
[**]		

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[\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.



## Attachment C – Contact List

### C.1 *Pharmacyclics Key Contacts*

NAME	TITLE	CONTACT NUMBERS
[**]		

### C.2 *Catalent Key Contacts*

NAME	TITLE	CONTACT INFORMATION
[**]		

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## Attachment D – Summary of Notification

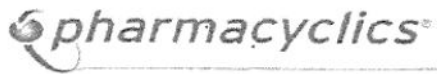
Section No.	Description	Timing for Notification to Pharmacocycles
	[**]	

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## Attachment E – Example of Certificate of Analysis

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995 East Arques Avenue · Sunnyvale, CA · 94085-4521  
P: 408-774-0330 · Fax: 408-774-0340 · www.pcy.com

### Certificate of Analysis

<b>Material Description:</b>	[**]		
<b>Specification:</b>	[**]	<b>Part Number:</b>	[**]
<b>Manufacturer Name:</b>	[**]	<b>Manufacturer Lot Number:</b>	
<b>Date of Manufacture:</b>		<b>Packaging Job Number:</b>	
<b>Storage Conditions:</b>	[**]	<b>Drug Substance Lot Used:</b>	
<input type="checkbox"/> <b>Expiration /</b>			
<input type="checkbox"/> <b>Retest Date:</b>			

Testing Requirements	Method	Specifications	Results
[**]			



Testing Requirements	Method	Specifications [**]	Results

[\*\*]

QC: \_\_\_\_\_  
Print and Sign

Date: \_\_\_\_\_

QA: \_\_\_\_\_  
Print and Sign

Date: \_\_\_\_\_

Lot Number    Rev 0  
11Oct12 CaA R3

Page 2 of 2

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Catalent QTA #: **[\*\*]** GMP Quality Technical Agreement  
Effective Upon Final Signature  
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## Attachment F – Example of Certificate of Manufacture

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[\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.



Catalent Quality Assurance  
Certificate of Manufacture

Product: \_\_\_\_\_  
Catalent Lot #: \_\_\_\_\_ Date of Manufacture: \_\_\_\_\_  
Material ID#: \_\_\_\_\_ Version: \_\_\_\_\_  
Theo. Batch Size: \_\_\_\_\_ Finished Batch Size: \_\_\_\_\_  
Adjusted Theo. Yield: \_\_\_\_\_

Storage Conditions: \_\_\_\_\_

All manufacturing documents for the above batch have been reviewed and approved by the Catalent – Kansas City Quality Assurance Department.

AQL (Criteria set forth by ANSI-ASQC Z-1.4): \_\_\_\_\_

The above batch has been manufactured in accordance with current Good Manufacturing Practices per the Code of Federal Regulations Parts 210 and 211 and the approved Batch Record. This facility complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

All Deviation Reports are included in the batch record as report number(s):  
\_\_\_\_\_

Where materials are derived from animal sources, our suppliers have issued statements concerning compliance with guideline EMA/410/01 Rev. 3 if manufactured on or after July 1, 2011 or with guideline EMEA/410/01 Rev. 2 if manufactured prior to July 1, 2011.

Where materials are not derived from animal sources, our suppliers have issued statements confirming their products are not derived or have not been in contact with specified risk materials.

Based on information received from our raw material suppliers and knowledge of the manufacturing process, Catalent declares that to the best of our knowledge the above mentioned lot is free from Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).

Certified By / Date:

\_\_\_\_\_  
Catalent Quality Assurance

Date: \_\_\_\_\_

**EXECUTION VERSION**

**ATTACHMENT E**

**Main Text of Building Contract**

# AIA® Document A133™ – 2009

## **Standard Form of Agreement Between Owner and Construction Manager as Constructor where the basis of payment is the Cost of the Work Plus a Fee with a Guaranteed Maximum Price**

**AGREEMENT** made as of the 18th day of October in the year 2012  
(In words, indicate day, month and year.)

**BETWEEN** the Owner:  
(Name, legal status and address)

Pharmacyclics, Inc.  
995 E. Arques Avenue  
Sunnyvale, CA 94085

and the Construction Manager:  
(Name, legal status and address)

[\*\*]

for the following Project:  
(Name and address or location)

Ibrutinib Capacity Expansion  
10245 Hickman Mills Drive  
Kansas City, MO 64137Sample

The Architect:  
(Name, legal status and address)

[\*\*]

The Owner's Designated Representative:  
(Name, address and other information)

The Construction Manager's Designated Representative:

### **ADDITIONS AND DELETIONS:**

The author of this document has added information needed for its completion. The author may also have revised the text of the original AIA standard form. An *Additions and Deletions Report* that notes added information as well as revisions to the standard form text is available from the author and should be reviewed. A vertical line in the left margin of this document indicates where the author has added necessary information and where the author has added to or deleted from the original AIA text.

This document has important legal consequences. Consultation with an attorney is encouraged with respect to its completion or modification.

AIA Document A201™–2007, General Conditions of the Contract for Construction, is adopted in this document by reference. Do not use with other general conditions unless this document is modified.

Init.

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User Notes: (2035437857)

1

(Name, address and other information)

[\*\*]

The Architect's Designated Representative:  
(Name, address and other information)

[\*\*]

The Owner and Construction Manager agree as follows.

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### ARTICLE 1 GENERAL PROVISIONS

#### § 1.1 The Contract Documents

The Contract Documents consist of this Agreement, Conditions of the Contract (General, Supplementary and other Conditions), Drawings, Specifications, Addenda issued prior to the execution of this Agreement, other documents listed in this Agreement, and Modifications issued after execution of this Agreement, all of which form the Contract and are as fully a part of the Contract as if attached to this Agreement or repeated herein. Upon the Owner's acceptance of the Construction Manager's Guaranteed Maximum Price proposal, the Contract Documents will also include the documents described in Section 2.2.3 and identified in the Guaranteed Maximum Price Amendment and revisions prepared by the Architect and furnished by the Owner as described in Section 2.2.8. The Contract represents the entire and integrated agreement between the parties hereto and supersedes prior negotiations, representations or agreements, either written or oral. If anything in the other Contract Documents, other than a Modification, is inconsistent with this Agreement, this Agreement shall govern.

#### § 1.2 Relationship of the Parties

The Construction Manager accepts the relationship of trust and confidence established by this Agreement and covenants with the Owner to cooperate with the Architect and exercise the Construction Manager's skill and judgment in furthering the interests of the Owner; to furnish efficient construction administration, management services and supervision; to furnish at all times an adequate supply of workers and materials; and to perform the Work in an expeditious and economical manner consistent with the Owner's interests. The Owner agrees to furnish or approve, in a timely manner, information required by the Construction Manager and to make payments to the Construction Manager in accordance with the requirements of the Contract Documents.

#### § 1.3 General Conditions

For the Preconstruction Phase, AIA Document A201™-2007, General Conditions of the Contract for Construction, shall apply only as specifically provided in this Agreement. For the Construction Phase, the general conditions of the contract shall be as set forth in A201-2007, which document is incorporated herein by reference. The term "Contractor" as used in A201-2007 shall mean the Construction Manager.

### ARTICLE 2 CONSTRUCTION MANAGER'S RESPONSIBILITIES

The Construction Manager's Preconstruction Phase responsibilities are set forth in Sections 2.1 and 2.2. The Construction Manager's Construction Phase responsibilities are set forth in Section 2.3. The Owner and

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Construction Manager may agree, in consultation with the Architect, for the Construction Phase to commence prior to completion of the Preconstruction Phase, in which case, both phases will proceed concurrently. The Construction Manager shall identify a representative authorized to act on behalf of the Construction Manager with respect to the Project.

#### § 2.1 Preconstruction Phase

§ 2.1.1 The Construction Manager shall provide a preliminary evaluation of the Owner's program, schedule and construction budget requirements, each in terms of the other.

#### § 2.1.2 Consultation

The Construction Manager shall schedule and conduct meetings with the Architect and Owner to discuss such matters as procedures, progress, coordination, and scheduling of the Work. The Construction Manager shall advise the Owner and the Architect on proposed site use and improvements, selection of materials, and building systems and equipment. The Construction Manager shall also provide recommendations consistent with the Project requirements to the Owner and Architect on constructability; availability of materials and labor; time requirements for procurement, installation and construction; and factors related to construction cost including, but not limited to, costs of alternative designs or materials, preliminary budgets, life-cycle data, and possible cost reductions.

§ 2.1.3 When Project requirements in Section 3.1.1 have been sufficiently identified, the Construction Manager shall prepare and periodically update a Project schedule for the Architect's review and the Owner's acceptance. The Construction Manager shall obtain the Architect's approval for the portion of the Project schedule relating to the performance of the Architect's services. The Project schedule shall coordinate and integrate the Construction Manager's services, the Architect's services, other Owner consultants' services, and the Owner's responsibilities and identify items that could affect the Project's timely completion. The updated Project schedule shall include the following: submission of the Guaranteed Maximum Price proposal; components of the Work; times of commencement and completion required of each Subcontractor; ordering and delivery of products, including those that must be ordered well in advance of construction; and the occupancy requirements of the Owner.

#### § 2.1.4 Phased Construction

The Construction Manager shall provide recommendations with regard to accelerated or fast-track scheduling, procurement, or phased construction. The Construction Manager shall take into consideration cost reductions, cost information, constructability, provisions for temporary facilities and procurement and construction scheduling issues.

#### § 2.1.5 Preliminary Cost Estimates

§ 2.1.5.1 Based on the preliminary design and other design criteria prepared by the Architect, the Construction Manager shall prepare preliminary estimates of the Cost of the Work or the cost of program requirements using area, volume or similar conceptual estimating techniques for the Architect's review and Owner's approval. If the Architect or Construction Manager suggests alternative materials and systems, the Construction Manager shall provide cost evaluations of those alternative materials and systems.

§ 2.1.5.2 As the Architect progresses with the preparation of the Schematic Design, Design Development and Construction Documents, the Construction Manager shall prepare and update, at appropriate intervals agreed to by the Owner, Construction Manager and Architect, estimates of the Cost of the Work of increasing detail and refinement and allowing for the further development of the design until such time as the Owner and Construction Manager agree on a Guaranteed Maximum Price for the Work. Such estimates shall be provided for the Architect's review and the Owner's approval. The Construction Manager shall inform the Owner and Architect when estimates of the Cost of the Work exceed the latest approved Project budget and make recommendations for corrective action.

#### § 2.1.6 Subcontractors and Suppliers

The Construction Manager shall develop bidders' interest in the Project.

§ 2.1.7 The Construction Manager shall prepare, for the Architect's review and the Owner's acceptance, a procurement schedule for items that must be ordered well in advance of construction. The Construction Manager shall expedite and coordinate the ordering and delivery of materials that must be ordered well in advance of construction. If the Owner agrees to procure any items prior to the establishment of the Guaranteed Maximum Price, the Owner shall procure the items on terms and conditions acceptable to the Construction Manager. Upon the

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establishment of the Guaranteed Maximum Price, the Owner shall assign all contracts for these items to the Construction Manager and the Construction Manager shall thereafter accept responsibility for them.

#### § 2.1.8 Extent of Responsibility

The Construction Manager shall exercise reasonable care in preparing schedules and estimates. The Construction Manager, however, does not warrant or guarantee estimates and schedules except as may be included as part of the Guaranteed Maximum Price. The Construction Manager is not required to ascertain that the Drawings and Specifications are in accordance with applicable laws, statutes, ordinances, codes, rules and regulations, or lawful orders of public authorities, but the Construction Manager shall promptly report to the Architect and Owner any nonconformity discovered by or made known to the Construction Manager as a request for information in such form as the Architect may require.

#### § 2.1.9 Notices and Compliance with Laws

The Construction Manager shall comply with applicable laws, statutes, ordinances, codes, rules and regulations, and lawful orders of public authorities applicable to its performance under this Contract, and with equal employment opportunity programs, and other programs as may be required by governmental and quasi governmental authorities for inclusion in the Contract Documents.

#### § 2.2 Guaranteed Maximum Price Proposal and Contract Time

§ 2.2.1 At a time to be mutually agreed upon by the Owner and the Construction Manager and in consultation with the Architect, the Construction Manager shall prepare a Guaranteed Maximum Price proposal for the Owner's review and acceptance. The Guaranteed Maximum Price in the proposal shall be the sum of the Construction Manager's estimate of the Cost of the Work, including contingencies described in Section 2.2.4, and the Construction Manager's Fee.

§ 2.2.2 To the extent that the Drawings and Specifications are anticipated to require further development by the Architect, the Construction Manager shall provide in the Guaranteed Maximum Price for such further development consistent with the Contract Documents and reasonably inferable therefrom. Such further development does not include such things as changes in scope, systems, kinds and quality of materials, finishes or equipment, all of which, if required, shall be incorporated by Change Order.

§ 2.2.3 The Construction Manager shall include with the Guaranteed Maximum Price proposal a written statement of its basis, which shall include the following:

- .1 A list of the Drawings and Specifications, including all Addenda thereto, and the Conditions of the Contract;
- .2 A list of the clarifications and assumptions made by the Construction Manager in the preparation of the Guaranteed Maximum Price proposal, including assumptions under Section 2.2.2, to supplement the information provided by the Owner and contained in the Drawings and Specifications;
- .3 A statement of the proposed Guaranteed Maximum Price, including a statement of the estimated Cost of the Work organized by trade categories or systems, allowances, contingency, and the Construction Manager's Fee;
- .4 The anticipated date of Substantial Completion upon which the proposed Guaranteed Maximum Price is based; and
- .5 A date by which the Owner must accept the Guaranteed Maximum Price.

§ 2.2.4 In preparing the Construction Manager's Guaranteed Maximum Price proposal, the Construction Manager shall include its contingency for the Construction Manager's exclusive use to cover those costs considered reimbursable as the Cost of the Work but not included in a Change Order.

§ 2.2.5 The Construction Manager shall meet with the Owner and Architect to review the Guaranteed Maximum Price proposal. In the event that the Owner and Architect discover any inconsistencies or inaccuracies in the information presented, they shall promptly notify the Construction Manager, who shall make appropriate adjustments to the Guaranteed Maximum Price proposal, its basis, or both.

§ 2.2.6 If the Owner notifies the Construction Manager that the Owner has accepted the Guaranteed Maximum Price proposal in writing before the date specified in the Guaranteed Maximum Price proposal, the Guaranteed Maximum Price proposal shall be deemed effective without further acceptance from the Construction Manager. Following

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acceptance of a Guaranteed Maximum Price, the Owner and Construction Manager shall execute the Guaranteed Maximum Price Amendment amending this Agreement, a copy of which the Owner shall provide to the Architect. The Guaranteed Maximum Price Amendment shall set forth the agreed upon Guaranteed Maximum Price with the information and assumptions upon which it is based.

§ 2.2.7 The Construction Manager shall not incur any cost to be reimbursed as part of the Cost of the Work prior to the commencement of the Construction Phase, unless the Owner provides prior written authorization for such costs.

§ 2.2.8 The Owner shall authorize the Architect to provide the revisions to the Drawings and Specifications to incorporate the agreed-upon assumptions and clarifications contained in the Guaranteed Maximum Price Amendment. The Owner shall promptly furnish those revised Drawings and Specifications to the Construction Manager as they are revised. The Construction Manager shall notify the Owner and Architect of any inconsistencies between the Guaranteed Maximum Price Amendment and the revised Drawings and Specifications.

§ 2.2.9 The Construction Manager shall include in the Guaranteed Maximum Price all sales, consumer, use and similar taxes for the Work provided by the Construction Manager that are legally enacted, whether or not yet effective, at the time the Guaranteed Maximum Price Amendment is executed.

### § 2.3 Construction Phase

#### § 2.3.1 General

§ 2.3.1.1 For purposes of Section 8.1.2 of A201-2007, the date of commencement of the Work shall mean the date of commencement of the Construction Phase.

§ 2.3.1.2 The Construction Phase shall commence upon the Owner's acceptance of the Construction Manager's Guaranteed Maximum Price proposal or the Owner's issuance of a Notice to Proceed, whichever occurs earlier.

#### § 2.3.2 Administration

§ 2.3.2.1 Those portions of the Work that the Construction Manager does not customarily perform with the Construction Manager's own personnel shall be performed under subcontracts or by other appropriate agreements with the Construction Manager. The Owner may designate specific persons from whom, or entities from which, the Construction Manager shall obtain bids. The Construction Manager shall obtain bids from Subcontractors and from suppliers of materials or equipment fabricated especially for the Work and shall deliver such bids to the Architect. The Owner shall then determine, with the advice of the Construction Manager and the Architect, which bids will be accepted. The Construction Manager shall not be required to contract with anyone to whom the Construction Manager has reasonable objection.

§ 2.3.2.2 If the Guaranteed Maximum Price has been established and when a specific bidder (1) is recommended to the Owner by the Construction Manager, (2) is qualified to perform that portion of the Work, and (3) has submitted a bid that conforms to the requirements of the Contract Documents without reservations or exceptions, but the Owner requires that another bid be accepted, then the Construction Manager may require that a Change Order be issued to adjust the Contract Time and the Guaranteed Maximum Price by the difference between the bid of the person or entity recommended to the Owner by the Construction Manager and the amount and time requirement of the subcontract or other agreement actually signed with the person or entity designated by the Owner.

§ 2.3.2.3 Subcontracts or other agreements shall conform to the applicable payment provisions of this Agreement, and shall not be awarded on the basis of cost plus a fee without the prior consent of the Owner. If the Subcontract is awarded on a cost-plus a fee basis, the Construction Manager shall provide in the Subcontract for the Owner to receive the same audit rights with regard to the Subcontractor as the Owner receives with regard to the Construction Manager in Section 6.11 below.

§ 2.3.2.4 If the Construction Manager recommends a specific bidder that may be considered a "related party" according to Section 6.10, then the Construction Manager shall promptly notify the Owner in writing of such relationship and notify the Owner of the specific nature of the contemplated transaction, according to Section 6.10.2.

§ 2.3.2.5 The Construction Manager shall schedule and conduct meetings to discuss such matters as procedures, progress, coordination, scheduling, and status of the Work. The Construction Manager shall prepare and promptly distribute minutes to the Owner and Architect.

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§ 2.3.2.6 Upon the execution of the Guaranteed Maximum Price Amendment, the Construction Manager shall prepare and submit to the Owner and Architect a construction schedule for the Work and submittal schedule in accordance with Section 3.10 of A201-2007.

§ 2.3.2.7 The Construction Manager shall record the progress of the Project. On a monthly basis, or otherwise as agreed to by the Owner, the Construction Manager shall submit written progress reports to the Owner and Architect, showing percentages of completion and other information required by the Owner. The Construction Manager shall also keep, and make available to the Owner and Architect, a daily log containing a record for each day of weather, portions of the Work in progress, number of workers on site, identification of equipment on site, problems that might affect progress of the work, accidents, injuries, and other information required by the Owner.

§ 2.3.2.8 The Construction Manager shall develop a system of cost control for the Work, including regular monitoring of actual costs for activities in progress and estimates for uncompleted tasks and proposed changes. The Construction Manager shall identify variances between actual and estimated costs and report the variances to the Owner and Architect and shall provide this information in its monthly reports to the Owner and Architect, in accordance with Section 2.3.2.7 above.

#### § 2.4 Professional Services

Section 3.12.10 of A201-2007 shall apply to both the Preconstruction and Construction Phases.

#### § 2.5 Hazardous Materials

Section 10.3 of A201-2007 shall apply to both the Preconstruction and Construction Phases.

### ARTICLE 3 OWNER'S RESPONSIBILITIES

#### § 3.1 Information and Services Required of the Owner

§ 3.1.1 The Owner shall provide information with reasonable promptness, regarding requirements for and limitations on the Project, including a written program which shall set forth the Owner's objectives, constraints, and criteria, including schedule, space requirements and relationships, flexibility and expandability, special equipment, systems sustainability and site requirements.

§ 3.1.2 Prior to the execution of the Guaranteed Maximum Price Amendment, the Construction Manager may request in writing that the Owner provide reasonable evidence that the Owner has made financial arrangements to fulfill the Owner's obligations under the Contract. Thereafter, the Construction Manager may only request such evidence if (1) the Owner fails to make payments to the Construction Manager as the Contract Documents require, (2) a change in the Work materially changes the Contract Sum, or (3) the Construction Manager identifies in writing a reasonable concern regarding the Owner's ability to make payment when due. The Owner shall furnish such evidence as a condition precedent to commencement or continuation of the Work or the portion of the Work affected by a material change. After the Owner furnishes the evidence, the Owner shall not materially vary such financial arrangements without prior notice to the Construction Manager and Architect.

§ 3.1.3 The Owner shall establish and periodically update the Owner's budget for the Project, including (1) the budget for the Cost of the Work as defined in Section 6.1.1, (2) the Owner's other costs, and (3) reasonable contingencies related to all of these costs. If the Owner significantly increases or decreases the Owner's budget for the Cost of the Work, the Owner shall notify the Construction Manager and Architect. The Owner and the Architect, in consultation with the Construction Manager, shall thereafter agree to a corresponding change in the Project's scope and quality.

§ 3.1.4 Structural and Environmental Tests, Surveys and Reports. During the Preconstruction Phase, the Owner shall furnish the following information or services with reasonable promptness. The Owner shall also furnish any other information or services under the Owner's control and relevant to the Construction Manager's performance of the Work with reasonable promptness after receiving the Construction Manager's written request for such information or services. The Construction Manager shall be entitled to rely on the accuracy of information and services furnished by the Owner but shall exercise proper precautions relating to the safe performance of the Work.

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mandatory and customary contributions and benefits related thereto, such as employment taxes and other statutory employee benefits, insurance, sick leave, holidays, vacations, employee retirement plans and similar contributions.

#### § 4.2 Payments

§ 4.2.1 Unless otherwise agreed, payments for services shall be made monthly in proportion to services performed.

§ 4.2.2 Payments are due and payable upon presentation of the Construction Manager's invoice. Amounts unpaid  
[\*\*] days after the invoice date shall bear interest at the rate entered below, or in the absence thereof at the legal rate prevailing from time to time at the principal place of business of the Construction Manager.  
(Insert rate of monthly or annual interest agreed upon.)

%

#### ARTICLE 5 COMPENSATION FOR CONSTRUCTION PHASE SERVICES

§ 5.1 For the Construction Manager's performance of the Work as described in Section 2.3, the Owner shall pay the Construction Manager  
[\*\*]

##### § 5.1.1 The Construction Manager's Fee:

(State a lump sum, percentage of Cost of the Work or other provision for determining the Construction Manager's Fee.)

[\*\*]

§ 5.1.2 The method of adjustment of the Construction Manager's Fee for changes in the Work:

§ 5.1.3 Limitations, if any, on a Subcontractor's overhead and profit for increases in the cost of its portion of the Work:

§ 5.1.4 Rental rates for Construction Manager-owned equipment shall not exceed [\*\*] percent [\*\*] of the standard rate paid at the place of the Project.

##### § 5.1.5 Unit prices, if any:

(Identify and state the unit price; state the quantity limitations, if any, to which the unit price will be applicable.)

Item	Units and Limitations	Price per Unit (\$0.00)
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#### § 5.2 Guaranteed Maximum Price

§ 5.2.1 The Construction Manager guarantees that the Contract Sum shall not exceed the Guaranteed Maximum Price set forth in the Guaranteed Maximum Price Amendment, as it is amended from time to time. To the extent the Cost of the Work exceeds the Guaranteed Maximum Price, the Construction Manager shall bear such costs in excess of the Guaranteed Maximum Price without reimbursement or additional compensation from the Owner.  
(Insert specific provisions if the Construction Manager is to participate in any savings.)

§ 5.2.2 The Guaranteed Maximum Price is subject to additions and deductions by Change Order as provided in the Contract Documents and the Date of Substantial Completion shall be subject to adjustment as provided in the Contract Documents.

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### § 5.3 Changes in the Work

§ 5.3.1 The Owner may, without invalidating the Contract, order changes in the Work within the general scope of the Contract consisting of additions, deletions or other revisions. The Owner shall issue such changes in writing. The Architect may make minor changes in the Work as provided in Section 7.4 of AIA Document A201-2007, General Conditions of the Contract for Construction. The Construction Manager shall be entitled to an equitable adjustment in the Contract Time as a result of changes in the Work.

§ 5.3.2 Adjustments to the Guaranteed Maximum Price on account of changes in the Work subsequent to the execution of the Guaranteed Maximum Price Amendment may be determined by any of the methods listed in Section 7.3.3 of AIA Document A201-2007, General Conditions of the Contract for Construction.

§ 5.3.3 In calculating adjustments to subcontracts (except those awarded with the Owner's prior consent on the basis of cost plus a fee), the terms "cost" and "fee" as used in Section 7.3.3.3 of AIA Document A201-2007 and the term "costs" as used in Section 7.3.7 of AIA Document A201-2007 shall have the meanings assigned to them in AIA Document A201-2007 and shall not be modified by Sections 5.1 and 5.2, Sections 6.1 through 6.7, and Section 6.8 of this Agreement. Adjustments to subcontracts awarded with the Owner's prior consent on the basis of cost plus a fee shall be calculated in accordance with the terms of those subcontracts.

§ 5.3.4 In calculating adjustments to the Guaranteed Maximum Price, the terms "cost" and "costs" as used in the above-referenced provisions of AIA Document A201-2007 shall mean the Cost of the Work as defined in Sections 6.1 to 6.7 of this Agreement and the term "fee" shall mean the Construction Manager's Fee as defined in Section 5.1 of this Agreement.

§ 5.3.5 If no specific provision is made in Section 5.1.2 for adjustment of the Construction Manager's Fee in the case of changes in the Work, or if the extent of such changes is such, in the aggregate, that application of the adjustment provisions of Section 5.1.2 will cause substantial inequity to the Owner or Construction Manager, the Construction Manager's Fee shall be equitably adjusted on the same basis that was used to establish the Fee for the original Work, and the Guaranteed Maximum Price shall be adjusted accordingly.

## ARTICLE 6 COST OF THE WORK FOR CONSTRUCTION PHASE

### § 6.1 Costs to Be Reimbursed

§ 6.1.1 The term Cost of the Work shall mean costs necessarily incurred by the Construction Manager in the proper performance of the Work. Such costs shall be at rates not higher than the standard paid at the place of the Project except with prior consent of the Owner. The Cost of the Work shall include only the items set forth in Sections 6.1 through 6.7.

§ 6.1.2 Where any cost is subject to the Owner's prior approval, the Construction Manager shall obtain this approval prior to incurring the cost. The parties shall endeavor to identify any such costs prior to executing Guaranteed Maximum Price Amendment.

### § 6.2 Labor Costs

§ 6.2.1 Wages of construction workers directly employed by the Construction Manager to perform the construction of the Work at the site or, with the Owner's prior approval, at off-site workshops.

§ 6.2.2 Wages or salaries of the Construction Manager's supervisory and administrative personnel when stationed at the site with the Owner's prior approval.

*(If it is intended that the wages or salaries of certain personnel stationed at the Construction Manager's principal or other offices shall be included in the Cost of the Work, identify in Section 11.5, the personnel to be included, whether for all or only part of their time, and the rates at which their time will be charged to the Work.)*

§ 6.2.3 Wages and salaries of the Construction Manager's supervisory or administrative personnel engaged at factories, workshops or on the road, in expediting the production or transportation of materials or equipment required for the Work, but only for that portion of their time required for the Work.

§ 6.2.4 Costs paid or incurred by the Construction Manager for taxes, insurance, contributions, assessments and benefits required by law or collective bargaining agreements and, for personnel not covered by such agreements,

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customary benefits such as sick leave, medical and health benefits, holidays, vacations and pensions, provided such costs are based on wages and salaries included in the Cost of the Work under Sections 6.2.1 through 6.2.3.

**§ 6.2.5 Bonuses, profit sharing, incentive compensation and any other discretionary payments paid to anyone hired by the Construction Manager or paid to any Subcontractor or vendor, with the Owner's prior approval.**

**§ 6.3 Subcontract Costs**

Payments made by the Construction Manager to Subcontractors in accordance with the requirements of the subcontracts.

**§ 6.4 Costs of Materials and Equipment Incorporated in the Completed Construction**

**§ 6.4.1 Costs, including transportation and storage, of materials and equipment incorporated or to be incorporated in the completed construction.**

**§ 6.4.2 Costs of materials described in the preceding Section 6.4.1 in excess of those actually installed to allow for reasonable waste and spoilage. Unused excess materials, if any, shall become the Owner's property at the completion of the Work or, at the Owner's option, shall be sold by the Construction Manager. Any amounts realized from such sales shall be credited to the Owner as a deduction from the Cost of the Work.**

**§ 6.5 Costs of Other Materials and Equipment, Temporary Facilities and Related Items**

**§ 6.5.1 Costs of transportation, storage, installation, maintenance, dismantling and removal of materials, supplies, temporary facilities, machinery, equipment and hand tools not customarily owned by construction workers that are provided by the Construction Manager at the site and fully consumed in the performance of the Work. Costs of materials, supplies, temporary facilities, machinery, equipment and tools that are not fully consumed shall be based on the cost or value of the item at the time it is first used on the Project site less the value of the item when it is no longer used at the Project site. Costs for items not fully consumed by the Construction Manager shall mean fair market value.**

**§ 6.5.2 Rental charges for temporary facilities, machinery, equipment and hand tools not customarily owned by construction workers that are provided by the Construction Manager at the site and costs of transportation, installation, minor repairs, dismantling and removal. The total rental cost of any Construction Manager-owned item may not exceed the purchase price of any comparable item. Rates of Construction Manager-owned equipment and quantities of equipment shall be subject to the Owner's prior approval.**

**§ 6.5.3 Costs of removal of debris from the site of the Work and its proper and legal disposal.**

**§ 6.5.4 Costs of document reproductions, facsimile transmissions and long-distance telephone calls, postage and parcel delivery charges, telephone service at the site and reasonable petty cash expenses of the site office.**

**§ 6.5.5 That portion of the reasonable expenses of the Construction Manager's supervisory or administrative personnel incurred while traveling in discharge of duties connected with the Work.**

**§ 6.5.6 Costs of materials and equipment suitably stored off the site at a mutually acceptable location, subject to the Owner's prior approval.**

**§ 6.6 Miscellaneous Costs**

**§ 6.6.1 Premiums for that portion of insurance and bonds required by the Contract Documents that can be directly attributed to this Contract. Self-insurance for either full or partial amounts of the coverages required by the Contract Documents, with the Owner's prior approval.**

**§ 6.6.2 Sales, use or similar taxes imposed by a governmental authority that are related to the Work and for which the Construction Manager is liable.**

**§ 6.6.3 Fees and assessments for the building permit and for other permits, licenses and inspections for which the Construction Manager is required by the Contract Documents to pay.**

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§ 6.6.4 Fees of laboratories for tests required by the Contract Documents, except those related to defective or nonconforming Work for which reimbursement is excluded by Section 13.5.3 of AIA Document A201-2007 or by other provisions of the Contract Documents, and which do not fall within the scope of Section 6.7.3.

§ 6.6.5 Royalties and license fees paid for the use of a particular design, process or product required by the Contract Documents; the cost of defending suits or claims for infringement of patent rights arising from such requirement of the Contract Documents; and payments made in accordance with legal judgments against the Construction Manager resulting from such suits or claims and payments of settlements made with the Owner's consent. However, such costs of legal defenses, judgments and settlements shall not be included in the calculation of the Construction Manager's Fee or subject to the Guaranteed Maximum Price. If such royalties, fees and costs are excluded by the last sentence of Section 3.17 of AIA Document A201-2007 or other provisions of the Contract Documents, then they shall not be included in the Cost of the Work.

§ 6.6.6 Costs for electronic equipment and software, directly related to the Work with the Owner's prior approval.

§ 6.6.7 Deposits lost for causes other than the Construction Manager's negligence or failure to fulfill a specific responsibility in the Contract Documents.

§ 6.6.8 Legal, mediation and arbitration costs, including attorneys' fees, other than those arising from disputes between the Owner and Construction Manager, reasonably incurred by the Construction Manager after the execution of this Agreement in the performance of the Work and with the Owner's prior approval, which shall not be unreasonably withheld.

§ 6.6.9 Subject to the Owner's prior approval, expenses incurred in accordance with the Construction Manager's standard written personnel policy for relocation and temporary living allowances of the Construction Manager's personnel required for the Work.

#### § 6.7 Other Costs and Emergencies

§ 6.7.1 Other costs incurred in the performance of the Work if, and to the extent, approved in advance in writing by the Owner.

§ 6.7.2 Costs incurred in taking action to prevent threatened damage, injury or loss in case of an emergency affecting the safety of persons and property, as provided in Section 10.4 of AIA Document A201-2007.

§ 6.7.3 Costs of repairing or correcting damaged or nonconforming Work executed by the Construction Manager, Subcontractors or suppliers, provided that such damaged or nonconforming Work was not caused by negligence or failure to fulfill a specific responsibility of the Construction Manager and only to the extent that the cost of repair or correction is not recovered by the Construction Manager from insurance, sureties, Subcontractors, suppliers, or others.

§ 6.7.4 The costs described in Sections 6.1 through 6.7 shall be included in the Cost of the Work, notwithstanding any provision of AIA Document A201-2007 or other Conditions of the Contract which may require the Construction Manager to pay such costs, unless such costs are excluded by the provisions of Section 6.8.

#### § 6.8 Costs Not To Be Reimbursed

§ 6.8.1 The Cost of the Work shall not include the items listed below:

- .1 Salaries and other compensation of the Construction Manager's personnel stationed at the Construction Manager's principal office or offices other than the site office, except as specifically provided in Section 6.2, or as may be provided in Article 11;
- .2 Expenses of the Construction Manager's principal office and offices other than the site office;
- .3 Overhead and general expenses, except as may be expressly included in Sections 6.1 to 6.7;
- .4 The Construction Manager's capital expenses, including interest on the Construction Manager's capital employed for the Work;
- .5 Except as provided in Section 6.7.3 of this Agreement, costs due to the negligence or failure of the Construction Manager, Subcontractors and suppliers or anyone directly or indirectly employed by any of them or for whose acts any of them may be liable to fulfill a specific responsibility of the Contract;
- .6 Any cost not specifically and expressly described in Sections 6.1 to 6.7;

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- .7 Costs, other than costs included in Change Orders approved by the Owner, that would cause the Guaranteed Maximum Price to be exceeded; and
- .8 Costs for services incurred during the Preconstruction Phase.

#### § 6.9 Discounts, Rebates and Refunds

§ 6.9.1 Cash discounts obtained on payments made by the Construction Manager shall accrue to the Owner if (1) before making the payment, the Construction Manager included them in an Application for Payment and received payment from the Owner, or (2) the Owner has deposited funds with the Construction Manager with which to make payments; otherwise, cash discounts shall accrue to the Construction Manager. Trade discounts, rebates, refunds and amounts received from sales of surplus materials and equipment shall accrue to the Owner, and the Construction Manager shall make provisions so that they can be obtained.

§ 6.9.2 Amounts that accrue to the Owner in accordance with the provisions of Section 6.9.1 shall be credited to the Owner as a deduction from the Cost of the Work.

#### § 6.10 Related Party Transactions

§ 6.10.1 For purposes of Section 6.10, the term "related party" shall mean a parent, subsidiary, affiliate or other entity having common ownership or management with the Construction Manager; any entity in which any stockholder in, or management employee of, the Construction Manager owns any interest in excess of ten percent in the aggregate; or any person or entity which has the right to control the business or affairs of the Construction Manager. The term "related party" includes any member of the immediate family of any person identified above.

§ 6.10.2 If any of the costs to be reimbursed arise from a transaction between the Construction Manager and a related party, the Construction Manager shall notify the Owner of the specific nature of the contemplated transaction, including the identity of the related party and the anticipated cost to be incurred, before any such transaction is consummated or cost incurred. If the Owner, after such notification, authorizes the proposed transaction, then the cost incurred shall be included as a cost to be reimbursed, and the Construction Manager shall procure the Work, equipment, goods or service from the related party, as a Subcontractor, according to the terms of Sections 2.3.2.1, 2.3.2.2 and 2.3.2.3. If the Owner fails to authorize the transaction, the Construction Manager shall procure the Work, equipment, goods or service from some person or entity other than a related party according to the terms of Sections 2.3.2.1, 2.3.2.2 and 2.3.2.3.

#### § 6.11 Accounting Records

The Construction Manager shall keep full and detailed records and accounts related to the cost of the Work and exercise such controls as may be necessary for proper financial management under this Contract and to substantiate all costs incurred. The accounting and control systems shall be satisfactory to the Owner. The Owner and the Owner's auditors shall, during regular business hours and upon reasonable notice, be afforded access to, and shall be permitted to audit and copy, the Construction Manager's records and accounts, including complete documentation supporting accounting entries, books, correspondence, instructions, drawings, receipts, subcontracts, Subcontractor's proposals, purchase orders, vouchers, memoranda and other data relating to this Contract. The Construction Manager shall preserve these records for a period of three years after final payment, or for such longer period as may be required by law.

### ARTICLE 7 PAYMENTS FOR CONSTRUCTION PHASE SERVICES

#### § 7.1 Progress Payments

§ 7.1.1 Based upon Applications for Payment submitted to the Architect by the Construction Manager and Certificates for Payment issued by the Architect, the Owner shall make progress payments on account of the Contract Sum to the Construction Manager as provided below and elsewhere in the Contract Documents.

§ 7.1.2 The period covered by each Application for Payment shall be one calendar month ending on the last day of the month, or as follows:

§ 7.1.3 Provided that an Application for Payment is received by the Architect not later than the [\*\*] day of a month, the Owner shall make payment of the certified amount to the Construction Manager not later than the [\*\*] day of the same month. If an Application for Payment is received by the Architect after the application date fixed above,

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*(Federal, state or local laws may require payment within a certain period of time.)*

**§ 7.1.5** Each Application for Payment shall be based on the most recent schedule of values submitted by the Construction Manager in accordance with the Contract Documents. The schedule of values shall allocate the entire Guaranteed Maximum Price among the various portions of the Work, except that the Construction Manager's Fee shall be shown as a single separate item. The schedule of values shall be prepared in such form and supported by such data to substantiate its accuracy as the Architect may require. This schedule, unless objected to by the Architect, shall be used as a basis for reviewing the Construction Manager's Applications for Payment.

**§ 7.1.7** Subject to other provisions of the Contract Documents, the amount of each progress payment shall be computed as follows:

- .4 Subtract retainage of [ ] percent [ ] from that portion of the Work that the Construction Manager self-performs;
- .5 Subtract the aggregate of previous payments made by the Owner;
- .6 Subtract the shortfall, if any, indicated by the Construction Manager in the documentation required by Section 7.1.4 to substantiate prior Applications for Payment, or resulting from errors subsequently discovered by the Owner's auditors in such documentation; and
- .7 Subtract amounts, if any, for which the Architect has withheld or nullified a Certificate for Payment as provided in Section 9.5 of AIA Document A201-2007.

**§ 7.1.9** Except with the Owner's prior approval, the Construction Manager shall not make advance payments to suppliers for materials or equipment which have not been delivered and stored at the site.

§ 7.1.10 In taking action on the Construction Manager's Applications for Payment, the Architect shall be entitled to rely on the accuracy and completeness of the information furnished by the Construction Manager and shall not be deemed to represent that the Architect has made a detailed examination, audit or arithmetic verification of the documentation submitted in accordance with Section 7.1.4 or other supporting data; that the Architect has made exhaustive or continuous on-site inspections; or that the Architect has made examinations to ascertain how or for what purposes the Construction Manager has used amounts previously paid on account of the Contract. Such examinations, audits and verifications, if required by the Owner, will be performed by the Owner's auditors acting in the sole interest of the Owner.

## § 7.2 Final Payment

§ 7.2.1 Final payment, constituting the entire unpaid balance of the Contract Sum, shall be made by the Owner to the Construction Manager when

- .1 the Construction Manager has fully performed the Contract except for the Construction Manager's responsibility to correct Work as provided in Section 12.2.2 of AIA Document A201-2007, and to satisfy other requirements, if any, which extend beyond final payment;
- .2 the Construction Manager has submitted a final accounting for the Cost of the Work and a final Application for Payment; and
- .3 a final Certificate for Payment has been issued by the Architect.

The Owner's final payment to the Construction Manager shall be made no later than 30 days after the issuance of the Architect's final Certificate for Payment, or as follows:

§ 7.2.2 The Owner's auditors will review and report in writing on the Construction Manager's final accounting within 30 days after delivery of the final accounting to the Architect by the Construction Manager. Based upon such Cost of the Work as the Owner's auditors report to be substantiated by the Construction Manager's final accounting, and provided the other conditions of Section 7.2.1 have been met, the Architect will, within seven days after receipt of the written report of the Owner's auditors, either issue to the Owner a final Certificate for Payment with a copy to the Construction Manager, or notify the Construction Manager and Owner in writing of the Architect's reasons for withholding a certificate as provided in Section 9.5.1 of the AIA Document A201-2007. The time periods stated in this Section supersede those stated in Section 9.4.1 of the AIA Document A201-2007. The Architect is not responsible for verifying the accuracy of the Construction Manager's final accounting.

§ 7.2.3 If the Owner's auditors report the Cost of the Work as substantiated by the Construction Manager's final accounting to be less than claimed by the Construction Manager, the Construction Manager shall be entitled to request mediation of the disputed amount without seeking an initial decision pursuant to Section 15.2 of A201-2007. A request for mediation shall be made by the Construction Manager within 30 days after the Construction Manager's receipt of a copy of the Architect's final Certificate for Payment. Failure to request mediation within this 30-day period shall result in the substantiated amount reported by the Owner's auditors becoming binding on the Construction Manager. Pending a final resolution of the disputed amount, the Owner shall pay the Construction Manager the amount certified in the Architect's final Certificate for Payment.

§ 7.2.4 If, subsequent to final payment and at the Owner's request, the Construction Manager incurs costs described in Section 6.1.1 and not excluded by Section 6.8 to correct defective or nonconforming Work, the Owner shall reimburse the Construction Manager such costs and the Construction Manager's Fee applicable thereto on the same basis as if such costs had been incurred prior to final payment, but not in excess of the Guaranteed Maximum Price. If the Construction Manager has participated in savings as provided in Section 5.2.1, the amount of such savings shall be recalculated and appropriate credit given to the Owner in determining the net amount to be paid by the Owner to the Construction Manager.

## ARTICLE 8 INSURANCE AND BONDS

For all phases of the Project, the Construction Manager and the Owner shall purchase and maintain insurance, and the Construction Manager shall provide bonds as set forth in Article 11 of AIA Document A201-2007.

*(State bonding requirements, if any, and limits of liability for insurance required in Article 11 of AIA Document A201-2007.)*

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Type of Insurance or Bond

Limit of Liability or Bond Amount (\$0.00)

Contractor's Liability Insurance  
Contractor's Liability Insurance  
Contractor's Liability Insurance  
Contractor's Liability Insurance  
Automobile Liability (owned, non-owned  
and hired vehicles) for bodily injury and  
property damage

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ARTICLE 9 DISPUTE RESOLUTION

§ 9.1 Any Claim between the Owner and Construction Manager shall be resolved in accordance with the provisions set forth in this Article 9 and Article 15 of A201-2007. However, for Claims arising from or relating to the Construction Manager's Preconstruction Phase services, no decision by the Initial Decision Maker shall be required as a condition precedent to mediation or binding dispute resolution, and Section 9.3 of this Agreement shall not apply.

§ 9.2 For any Claim subject to, but not resolved by mediation pursuant to Section 15.3 of AIA Document A201-2007, the method of binding dispute resolution shall be as follows:

*(Check the appropriate box. If the Owner and Construction Manager do not select a method of binding dispute resolution below, or do not subsequently agree in writing to a binding dispute resolution method other than litigation, Claims will be resolved by litigation in a court of competent jurisdiction.)*

- ☐ Arbitration pursuant to Section 15.4 of AIA Document A201-2007
- ☐ Litigation in a court of competent jurisdiction
- ☐ Other: *(Specify)*

§ 9.3 Initial Decision Maker

The Architect will serve as the Initial Decision Maker pursuant to Section 15.2 of AIA Document A201-2007 for Claims arising from or relating to the Construction Manager's Construction Phase services, unless the parties appoint below another individual, not a party to the Agreement, to serve as the Initial Decision Maker.  
*(If the parties mutually agree, insert the name, address and other contact information of the Initial Decision Maker, if other than the Architect.)*

ARTICLE 10 TERMINATION OR SUSPENSION

§ 10.1 Termination Prior to Establishment of the Guaranteed Maximum Price

§ 10.1.1 Prior to the execution of the Guaranteed Maximum Price Amendment, the Owner may terminate this Agreement upon not less than seven days' written notice to the Construction Manager for the Owner's convenience and without cause, and the Construction Manager may terminate this Agreement, upon not less than seven days' written notice to the Owner, for the reasons set forth in Section 14.1.1 of A201-2007.

§ 10.1.2 In the event of termination of this Agreement pursuant to Section 10.1.1, the Construction Manager shall be equitably compensated for Preconstruction Phase services performed prior to receipt of a notice of termination. In no event shall the Construction Manager's compensation under this Section exceed the compensation set forth in Section 4.1.

§ 10.1.3 If the Owner terminates the Contract pursuant to Section 10.1.1 after the commencement of the Construction Phase but prior to the execution of the Guaranteed Maximum Price Amendment, the Owner shall pay to the

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Construction Manager an amount calculated as follows, which amount shall be in addition to any compensation paid to the Construction Manager under Section 10.1.2:

- .1 Take the Cost of the Work incurred by the Construction Manager to the date of termination;
- .2 Add the Construction Manager's Fee computed upon the Cost of the Work to the date of termination at the rate stated in Section 5.1 or, if the Construction Manager's Fee is stated as a fixed sum in that Section, an amount that bears the same ratio to that fixed-sum Fee as the Cost of the Work at the time of termination bears to a reasonable estimate of the probable Cost of the Work upon its completion; and
- .3 Subtract the aggregate of previous payments made by the Owner for Construction Phase services.

The Owner shall also pay the Construction Manager fair compensation, either by purchase or rental at the election of the Owner, for any equipment owned by the Construction Manager which the Owner elects to retain and which is not otherwise included in the Cost of the Work under Section 10.1.3.1. To the extent that the Owner elects to take legal assignment of subcontracts and purchase orders (including rental agreements), the Construction Manager shall, as a condition of receiving the payments referred to in this Article 10, execute and deliver all such papers and take all such steps, including the legal assignment of such subcontracts and other contractual rights of the Construction Manager, as the Owner may require for the purpose of fully vesting in the Owner the rights and benefits of the Construction Manager under such subcontracts or purchase orders. All Subcontracts, purchase orders and rental agreements entered into by the Construction Manager will contain provisions allowing for assignment to the Owner as described above.

If the Owner accepts assignment of subcontracts, purchase orders or rental agreements as described above, the Owner will reimburse or indemnify the Construction Manager for all costs arising under the subcontract, purchase order or rental agreement, if those costs would have been reimbursable as Cost of the Work if the contract had not been terminated. If the Owner chooses not to accept assignment of any subcontract, purchase order or rental agreement that would have constituted a Cost of the Work had this agreement not been terminated, the Construction Manager will terminate the subcontract, purchase order or rental agreement and the Owner will pay the Construction Manager the costs necessarily incurred by the Construction Manager because of such termination.

#### § 10.2 Termination Subsequent to Establishing Guaranteed Maximum Price

Following execution of the Guaranteed Maximum Price Amendment and subject to the provisions of Section 10.2.1 and 10.2.2 below, the Contract may be terminated as provided in Article 14 of AIA Document A201-2007.

§ 10.2.1 If the Owner terminates the Contract after execution of the Guaranteed Price Amendment, the amount payable to the Construction Manager pursuant to Sections 14.2 and 14.4 of A201-2007 shall not exceed the amount the Construction Manager would otherwise have received pursuant to Sections 10.1.2 and 10.1.3 of this Agreement.

§ 10.2.2 If the Construction Manager terminates the Contract after execution of the Guaranteed Maximum Price Amendment, the amount payable to the Construction Manager under Section 14.1.3 of A201-2007 shall not exceed the amount the Construction Manager would otherwise have received under Sections 10.1.2 and 10.1.3 above, except that the Construction Manager's Fee shall be calculated as if the Work had been fully completed by the Construction Manager, utilizing as necessary a reasonable estimate of the Cost of the Work for Work not actually completed.

#### § 10.3 Suspension

The Work may be suspended by the Owner as provided in Article 14 of AIA Document A201-2007. In such case, the Guaranteed Maximum Price and Contract Time shall be increased as provided in Section 14.3.2 of AIA Document A201-2007, except that the term "profit" shall be understood to mean the Construction Manager's Fee as described in Sections 5.1 and 5.3.5 of this Agreement.

### ARTICLE 11 MISCELLANEOUS PROVISIONS

§ 11.1 Terms in this Agreement shall have the same meaning as those in A201-2007.

#### § 11.2 Ownership and Use of Documents

Section 1.5 of A201-2007 shall apply to both the Preconstruction and Construction Phases.

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**§ 11.3 Governing Law**

Section 13.1 of A201-2007 shall apply to both the Preconstruction and Construction Phases.

**§ 11.4 Assignment**

The Owner and Construction Manager, respectively, bind themselves, their agents, successors, assigns and legal representatives to this Agreement. Neither the Owner nor the Construction Manager shall assign this Agreement without the written consent of the other, except that the Owner may assign this Agreement to a lender providing financing for the Project if the lender agrees to assume the Owner's rights and obligations under this Agreement. Except as provided in Section 13.2.2 of A201-2007, neither party to the Contract shall assign the Contract as a whole without written consent of the other. If either party attempts to make such an assignment without such consent, that party shall nevertheless remain legally responsible for all obligations under the Contract.

**§ 11.5 Other provisions:**

11.5 Supplementary Conditions Exhibit A are made as part of this agreement.

11.6 Section 15.1.6 of A201<sup>TM</sup>-2007 is amended to exclude

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**ARTICLE 12 SCOPE OF THE AGREEMENT**

**§ 12.1** This Agreement represents the entire and integrated agreement between the Owner and the Construction Manager and supersedes all prior negotiations, representations or agreements, either written or oral. This Agreement may be amended only by written instrument signed by both Owner and Construction Manager.

**§ 12.2** The following documents comprise the Agreement:

- .1 AIA Document A133-2009, Standard Form of Agreement Between Owner and Construction Manager as Constructor where the basis of payment is the Cost of the Work Plus a Fee with a Guaranteed Maximum Price
- .2 AIA Document A201-2007, General Conditions of the Contract for Construction
- .3 AIA Document E201<sup>TM</sup>-2007, Digital Data Protocol Exhibit, if completed, or the following:
- .4 AIA Document E202<sup>TM</sup>-2008, Building Information Modeling Protocol Exhibit, if completed, or the following:
- .5 Other documents:  
(List other documents, if any, forming part of the Agreement.)

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This Agreement is entered into as of the day and year first written above.

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OWNER (Signature)

CONSTRUCTION MANAGER (Signature)

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ROBERT W. DUGGAN  
(Printed name and title)

(Printed name and title)

Chairman & CEO



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11.5

Supplementary Conditions Exhibit A

2.2.10 The guaranteed maximum price shall be [\*\*]  
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6.2 Labor Costs

.2 Wages and salaries of the Construction Manager's supervisory or administrative personnel engaged, at the home office, in managing, estimating, purchasing, administration, of the work with the Owner's agreement.

Wages of the Construction Management will be reimbursed based upon classifications for the project as follows:

Project Executive [\*\*]

Project Manager [\*\*]

Project Superintendent [\*\*]

Project Estimator [\*\*]

Assistant Superintendent [\*\*]

Project Engineer [\*\*]

Administrator [\*\*]

7.1.4. Strike "receipted invoices or invoices with check vouchers" and insert "receipted subcontractor invoices and log of all minor invoices".

ATTACHMENT F

## API Procurement Tracking Report

API Procurement Tracking Report							
<i>Example</i>							
WuXi STA							
Ordered Date for [**] Material	Manufacture Lot #	QTY	Ship Date	Arrival Date at [**]	Tracking RYG	Comments	
[**]	[**]	[**]	[**]	[**]		[**]	
	[**]	[**]	[**]	[**]		[**]	
[**]	[**]	[**]				[**]	
[**]							
Ordered Date of API	Manufacture Lot #	QTY	Ship Date	Date [**]	Arrival Date at [**]	Tracking RYG	Comments
[**]	[**]	[**]	[**]	[**]	[**]		[**]
	[**]	[**]	[**]	[**]	[**]		[**]
[**]	[**]	[**]					[**]
[**]							
Ordered Date of API	Manufacture Lot #	QTY	Ship Date	Arrival Date at [**]	Tracking RYG	Comments	
[**]	[**]	[**]	[**]	[**]		[**]	
	[**]	[**]	[**]	[**]			
[**]	[**]	[**]				[**]	