Catalent Standard Commercial Terms and Conditions

- A. <u>Expiration</u>. The pricing in the Agreement (as defined below) to which these Standard Commercial Terms and Conditions (the "Terms and Conditions") are attached is valid for thirty (30) days from the date hereof, and becomes binding if signed and delivered by both parties during that period.
- B. <u>Audits</u>. Client may conduct one quality assurance facility audit every other year at no cost. Additional audits will be invoiced separately at the current rate for such services unless such audit is for cause.
- C. <u>Regulatory Inspections</u>. Catalent will promptly notify Client of any regulatory inspections directly relating to the services performed under the Agreement (the "Project"). Client shall reimburse Catalent for reasonable and documented costs associated with such regulatory inspections that are directly related to the Product.
- D. <u>Changes</u>. Catalent may revise the prices provided in the Agreement (i) if Client's requirements or any Client-provided information is inaccurate or incomplete (including, but not limited to, as a result of changes to the specifications of components (including size, stock or copy of printed components), whether to the components themselves or the assumptions on which the pricing for components is based, and changes to order quantities or lot size); (ii) if Client revises Catalent's responsibilities or the Project specifications, instructions, procedures, assumptions, processes, test protocols, test methods or analytical requirements; or (iii) for such other reasons set forth in the Agreement. Any revision to the Agreement shall be set forth in a written agreement signed by both parties in accordance with Section W.
- E. <u>Payments</u>. Catalent will invoice Client as set forth in the Agreement. Catalent charges a late payment fee of eight percentage points (8%) above the base rate for payments not received by the date specified in the Agreement (or if no date is specified, within 30 days of invoice date). Failure to bill for interest due shall not be a waiver of Catalent's right to charge interest.
- F. <u>Taxes</u>. All sales, use, gross receipts, compensating, value-added or other taxes, duties, licenses or fees (excluding Catalent's net income and franchise taxes) assessed by any tax jurisdiction arising from the Project are the responsibility of Client, whether paid by Catalent or Client.
- G. <u>Hazardous Materials</u>. Client warrants to Catalent that no specific safe handling instructions are applicable to any Client-supplied materials, except as disclosed to Catalent in writing by the Client in sufficient time for review and training by Catalent prior to delivery. Where appropriate or required by law, Client will provide a Material Safety Data Sheet for all Client-supplied materials and finished product.
- H. <u>Delivery</u>. (i) Catalent shall deliver all Products and other materials EXW (Incoterms 2010) Catalent's facilities. To the extent not already held by Client, title shall pass to Client upon such tender of delivery. If Catalent provides storage services, title and risk of loss shall pass to Client upon transfer to storage.
- (ii) In the event Catalent arranges shipping or performs similar loading and/or logistics services for Client at Client's request, such services are performed by Catalent at Client's expense and on Client's behalf as a convenience to Client only and does not alter subsection (i) above.
- I. <u>Discrepant Test Results.</u> In the event of a disagreement between the parties regarding whether the Product meets specifications, 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 Product alleged to be nonconforming. The independent party's results 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 the party found responsible, and by Client when the third party cannot determine responsibility.
- J. <u>Defective Product</u>. Catalent will, at its option, either replace non-conforming Product or credit any payments made by Client for any such batch of non-conforming Product due solely to Catalent's gross negligence or willful misconduct ("Defective Product"). Client shall supply, at its cost, any Client-supplied materials necessary for replacing such non-conforming Product. The obligation of Catalent to replace Defective Product or credit payments made by Client for Defective Product, shall be Client's sole and exclusive remedy under these Terms and Conditions for Defective Product and is in lieu of any other warranty, express or implied.
- K. <u>Limitations of Liability</u>. CATALENT'S TOTAL LIABILITY UNDER THE AGREEMENT SHALL IN NO EVENT EXCEED THE TOTAL FEES PAID FOR THE BATCH OF PRODUCT GIVING RISE TO THE CLAIM. CATALENT SHALL

HAVE NO LIABILITY UNDER THIS AGREEMENT FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED CLIENT-SUPPLIED MATERIALS, WHETHER OR NOT INCORPORATED INTO FINISHED PRODUCT. UNLESS IT HAS CAUSED SUCH DAMAGES INTENTIONALLY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES OR LOSS OF REVENUES, PROFITS OR DATA, ARISING OUT OF PERFORMANCE UNDER THIS PRICING LETTER, WHETHER IN CONTRACT, IN CIVIL LIABILITY OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. OTHER THAN AS SET OUT ABOVE, IN CASE OF ORDINARY NEGLIGENCE, CATALENT SHALL ONLY BE LIABLE FOR THE BREACH OF OBLIGATIONS THE FULFILMENT OF WHICH IS OF PARTICULAR SIGNIFICANCE TO ATTAIN THE CONTRACTUAL PURPOSE AND ON WHICH CLIENT COULD THEREFORE STRICTLY RELY (MAJOR OBLIGATION/KARDINALPFLICHT), LIMITED IN EXTENT TO THE DAMAGES THAT ARE TYPICAL AND FORESEEABLE WITH REGARD TO THE AGREED SERVICE. THIS APPLIES MUTATIS MUTANDIS FOR ANY CLAIM UNDER THE LAW OF TORTS. NOTHING IN THIS CLAUSE J AND IN THIS AGREEMENT SHALL BE INTERPRETED AS REVERSING THE STATUTORY BURDEN OF PROOF OR ANY ESTABLISHED RULES ON THE BURDEN OF PROOF SET OUT BY GERMAN CASE LAW WITH REGARD TO CATALENT'S OR CLIENT'S LIABILITY. Nothing in this Agreement shall, to the extent applicable, limit the liability of Catalent for (i) death or personal injury arising from Catalent's or any of its affiliates' negligence; (ii) willful misconduct, gross negligence, the fraud or fraudulent misrepresentation of Catalent, any of its affiliates or any of their respective employees or representatives; (iii) express warranties or claims made against Catalent pursuant to the German Product Liability Act or (iv) for any matter for which it would be illegal for Catalent or any of its affiliates to exclude or to attempt to exclude liability.

L. <u>Confidentiality</u>. All information disclosed by a party in connection with the Agreement shall be confidential information, unless such information is (i) already known to the receiving party, on a non-confidential basis, as evidenced by written records; (ii) independently developed or discovered by the receiving party without the use of the disclosing party's confidential information, as evidenced by written records; (iii) in the public domain, other than through the fault of the receiving party; or (iv) disclosed to the receiving party by a third party not in breach of a duty of confidentiality owed to the disclosing party. Neither party shall, without the other party's prior written consent, use the confidential information of the other party or disclose such information except (a) to provide to employees of the receiving party or its affiliated entities who require such information to perform such party's obligations under the Agreement, or (b) as required to be disclosed by law, or court or administrative order; <u>provided</u> that the receiving party first gives prompt written notice thereof to the disclosing party. This undertaking shall survive for 7 years following the date of the Agreement.

M. 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 the Project; "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 the Project; "Invention" means any intellectual property developed by either party in connection with the Project; "Client 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 Client Invention, that relates exclusively to the Catalent IP or relates to developing, formulating, manufacturing, filling, processing, packaging, analyzing or testing pharmaceutical products generally. All Client IP and Client Inventions shall be owned solely by Client and no right therein is granted to Catalent under the Agreement except for use in performing the Project. All Catalent IP and Process Inventions shall be owned solely by Catalent and no right therein is granted to Client under the Agreement. All Inventions to generic API (other than Client Inventions and Process Inventions), if any, shall be owned jointly by Catalent and Client 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.

N. <u>Warranties</u>. Client represents and warrants to Catalent that:

- the Client-supplied materials will comply with all applicable specifications, will have been produced in compliance with the applicable laws, and will be provided in accordance with these terms and conditions;
- it has all necessary authority and all right, title and interest in and to any intellectual property related to the Client-supplied materials;
- no specific safe handling instructions are applicable to the Product or to and any Client-supplied materials, except as disclosed to Catalent in writing by the Client in sufficient time for review and training by Catalent prior to delivery;
- all Product delivered to Client by Catalent will be held, used and/or disposed of by the Client in accordance with all Applicable Laws;
- Client will comply with all laws, rules, regulations and guidelines applicable to Client's performance hereunder and its use of Products provided by Catalent hereunder;
- Client will not release any batch of Product if the required Certificates of Analysis indicate that the Product does not comply with the Specifications;
- the content of all artwork provided to Catalent complies with all Applicable Laws;
- Client has all necessary authority and right, title and interest in and to any copyrights, trademarks, trade secrets, patents, inventions and developments related to the Product, the Processing thereof, and any Product artwork;
- the work to be performed by Catalent hereunder will not violate or infringe upon any trademark, tradename, copyright, patent or other rights held by any person or entity; and
- 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 the Product is safe and effective for its intended purpose or any other purpose for which such Product might reasonably be utilized. Client will be solely responsible for and will obtain all governmental approvals, permits and licenses necessary or desirable in connection with the testing, marketing, sale, advertising or distribution of the Product.
- Client shall have obtained all applicable licenses, permits, and registrations required for the transport and distribution of Client-supplied materials and supplies to Catalent.

Catalent represents and warrants to Client that at the time of delivery of the Product as provided in Section I, such Product will conform to and will have been Processed in conformance with the specifications and applicable laws. THE WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE WARRANTIES MADE BY CATALENT TO CLIENT, AND CATALENT MAKES NO OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING ANY EXPRESS, LEGAL OR IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT, QUALITY, DURABILITY, TITLE OR FITNESS FOR A PARTICULAR PURPOSE.

- O. <u>Client Obligations</u>. Unless otherwise agreed to by the parties in writing, Client is solely responsible at its cost and expense to (i) provide complete and accurate scientific data regarding the Project; (ii) deliver to Catalent all Client-supplied materials; (iii) prepare all submissions to regulatory authorities and obtain Catalent's prior written consent (which will not be unreasonably withheld) before identifying Catalent in such regulatory submissions; (iv) if applicable, review and approve all in-process and finished Product test results to ensure conformity of such results with the Product specifications, regardless of which party is responsible for finished Product release; and (v) perform such other obligations of Client set forth in the Agreement.
- P. <u>Regulatory Compliance</u>. Catalent shall obtain and maintain all permits and licenses with respect to general facility operations in the jurisdiction in which Catalent performs the services. Client shall be responsible at its cost to obtain and maintain all other regulatory approvals, authorizations, certifications and permits relating to Client-supplied materials and Client Product, including without limitation those relating to the import, export, use, distribution and sale of Client-supplied materials and Client Product. Client shall reimburse Catalent for any payments Catalent is required to make to any regulatory authority resulting directly from Catalent's formulation, development, manufacturing, processing, filling, packaging, storing or testing of

Client's Product or Client-supplied materials (including without limitation any payments or fees Catalent is required to make pursuant to the United States Generic Drug User Fee Amendments of 2012, if applicable). Client shall not identify Catalent in any regulatory filing or submission without Catalent's prior written consent. Such consent shall not be unreasonably withheld and shall be memorialized in a writing signed by authorized representatives of both parties. Upon written request, Client shall provide Catalent with a copy of any regulatory approvals required to distribute, market and sell Product in any territories where the parties have agreed that Client will distribute, market or sell the Product. If Client is unable to provide such information, Catalent shall have no obligation to deliver Product to Client, notwithstanding anything to the contrary in this Agreement. Catalent shall not be obligated to perform any services which would involve any countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom or United States.

- Q. <u>Indemnification</u>. Client will indemnify, defend and hold harmless Catalent, its affiliates and their respective directors, officers, employees and agents from and against any losses, damages, costs and expenses, including reasonable attorneys' fees, resulting from any third-party claim arising directly or indirectly from (i) the manufacture, promotion, marketing, distribution or sale of, or use of or exposure to, the Product, API and Client-supplied materials that are the subject of the Project, (ii) the negligence or willful misconduct of Client (iii) the breach of the Agreement by Client, or (iv) the use of any intellectual property, materials or other information provided by Client to Catalent; in each case, including but not limited to costs associated with responding to subpoenas and giving testimony relating to disputes between Client and third parties. Catalent will indemnify, defend and hold harmless Client from and against any losses, damages, costs and expenses, including reasonable attorneys' fees, resulting from any third-party claim arising directly or indirectly from the negligence or willful misconduct of Catalent or the breach of the Agreement by Catalent.
- R. <u>Right to Dispose and Settle</u>. If Catalent requests in writing from Client direction with respect to disposal of products, materials, equipment, samples or other items belonging to Client and is unable to obtain a response from Client within a reasonable time period after making reasonable efforts to do so, Catalent may in its sole discretion (i) dispose of all such items and (ii) set-off any and all amounts due to Catalent or any of its affiliates from Client against any credits Client may hold with Catalent or any of its affiliates.
- S. <u>Force Majeure</u>. Neither party will be liable for any failure to perform or for delay in performance resulting from any cause beyond its reasonable control, including without limitation acts of God, fires, floods or weather, strikes or lockouts, factory shutdowns, embargoes, wars, hostilities or riots, or shortages in transportation. If the cause continues unabated for 90 days, then both parties shall meet to discuss and negotiate in good faith what modifications to the Agreement should result from such cause.
- T. <u>Record Retention</u>. Unless the parties otherwise agree in writing, Catalent will retain batch, laboratory and other technical records for the minimum period required by applicable law.
- U. <u>Independent Contractor</u>. The relationship of the parties is that of independent contractors and not of joint venturers, co-partners, employer/employee or principal/agent.
- V. <u>Publicity</u>. Neither party will make any press release or other public disclosure regarding the Agreement or the transactions contemplated hereby without the other party's express prior written consent, except as required by applicable law, 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 public disclosure.
- W. <u>Amendment & Precedence</u>. These Terms and Conditions constitute a part of the agreement or pricing letter to which they are attached (collectively, the "Agreement"); <u>provided</u>, that these Terms and Conditions supersede any conflicting terms and conditions set forth in the Agreement to which they are attached or any other document, including Client Purchase Order. This 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 Project. No term of the Agreement may be amended except upon written agreement signed by both parties.

- X. <u>Dispute Resolution</u>. If a dispute arises between the parties in connection with the Agreement, the respective presidents or Senior Executives of Catalent and Client shall first attempt to resolve the dispute. If such parties cannot resolve the dispute, such dispute shall be arbitrated and finally resolved by arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce (ICC) of Berlin by three (3) arbitrators appointed in accordance with the said Rules. The place of the arbitration shall be Frankfurt, Germany. The language of arbitration shall be English.
- Y. <u>Survival</u>. Subject to execution, the rights and obligations of Client and Catalent in Sections E, F, K, L, M, N, O, Q, T, V, X, Y, Z, and CC of these Terms and Conditions shall survive termination or expiration of the Agreement.
- Z. <u>Governing Law</u>. The Agreement shall be governed by and construed under the laws of Germany, excluding its conflict of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the Agreement.
- AA <u>Successors and Assigns</u>. This Quotation will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Client may not assign Client's rights or obligations under the Agreement, in whole or in part, without the prior written consent of Catalent. Catalent may assign the Agreement, in whole or in part at any time during the term without the prior written consent of Client.
- BB. <u>Recall</u>. If Client believes a recall, field alert, product withdrawal or field correction ("Recall") may be necessary with respect to any Product supplied by Catalent under the Agreement, Client shall promptly notify Catalent of such. Client will not initiate a Recall without providing prior written notice to Catalent. If Catalent believes a Recall may be necessary with respect to any Product supplied under the Agreement, Catalent shall promptly notify Client and Client shall provide all necessary cooperation and assistance to Catalent. Client will be responsible for all costs of a Recall, in each case reduced to the extent such expenses are caused solely by Catalent's negligence or willful misconduct, for which Catalent shall be responsible for the direct, reasonable, administrative costs of such Recall.
- CC. Insurance. Each party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term in US dollars or foreign currency equivalent the following: (A) Commercial General Liability Insurance with a per-occurrence limit of not less than \$1,000,000; (B) Products and Completed Operations Liability Insurance with a per-occurrence limit of not less than \$10,000,000; (C) Workers' Compensation Insurance with statutory limits and Employers Liability Insurance with limits of not less than \$1,000,000 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 \$100 million or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than \$75 million. Each required insurance policy, other than selfinsurance, 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 3 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.
- DD. <u>Quality Agreement</u>. The parties shall negotiate in good faith and enter into a quality agreement on Catalent's standard template (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.

- EE. <u>Advance Payment</u>. if at any time Catalent determines that Client's credit is impaired, Catalent may require payment in advance before performing any further services or making any further shipment of Product.
- FF. <u>Specifications</u>. 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. No change in the specifications shall be implemented by Catalent 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 pricing).
- GG. <u>Pricing Increase</u>. The pricing shall be adjusted on an annual basis upon sixty (60) days' prior written notice from Catalent to Client. Catalent shall pass through to Client any price changes due to exchange rate fluctuations, as applicable. In addition, price increases for raw materials, labor, utilities and components shall be passed through to Client.
- HH. <u>Storage Fees</u>. If Client fails to take delivery of any Product on any scheduled delivery date, Catalent shall store such Product and Client shall be invoiced on the first day of each month following such scheduled delivery for reasonable administration and storage costs.
- II. <u>Artwork and Labeling</u>. Client shall provide or approve, prior to the procurement of applicable raw material, all artwork, advertising and labeling information necessary for processing, if any. Such artwork, advertising and labeling information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising and labeling information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder.
- JJ. <u>Purchase Orders and Acknowledgements</u>. From time to time, Client shall submit to Catalent a binding, non-cancelable purchase order for Product, specifying the number of batches to be processed, pricing, the batch size (to the extent the specifications permit batches of different sizes) and the requested delivery date for each batch (a "Purchase Order"). Promptly following receipt of a Purchase Order, Catalent shall issue a written acknowledgement ("Acknowledgement") that it accepts or rejects 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.

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