

## **TERMS & CONDITIONS**

### **Manufacture of API, Intermediates and/or Fine Chemicals**

1. **AGREEMENT AND ACCEPTANCE:** These Terms and Conditions govern the manufacture, supply and sale of Product (as defined below) by Supplier (as defined below) to Customer (as defined below). These Terms and Conditions, along with the Supplier form to which these Terms and Conditions are incorporated by reference, constitute a binding contract between Customer and Supplier and are referred to herein as the "Agreement." The terms and conditions of the manufacture, supply and sale of Product are limited to those contained in this Agreement and any additional or different terms or conditions in any form delivered by Customer are hereby deemed to be material alterations and notice of objection to them and rejection of them is hereby given. By engaging Supplier to supply Product, Customer agrees to be bound by and accepts these Terms and Conditions unless Customer and Supplier have entered into a separate Supply Agreement, in which case the Supply Agreement will govern over these Terms and Conditions. For purposes of this Agreement, any active pharmaceutical ingredient, intermediate, fine chemical and/or any other drug substance manufactured by Supplier and supplied to Customer in the performance of this Agreement shall be referred to as a "Product" or "Products." For purposes of this Agreement, "Supplier" refers to Prime European Therapeutics S.p.A. (Euticals S.p.A) and/or any of its direct or indirect subsidiaries who are manufacturing and supplying the Products hereunder, and "Customer" refers to the entity contracting for such Products.

Customer may issue a purchase order for administrative purposes only. Additional or different terms and conditions contained in any such purchase order will be null and void. No course of prior dealings between the parties and no usage of trade will be relevant to determine the meaning of these Terms and Conditions. This Agreement contains the entire understanding of the parties with respect to the matters contained herein and supersedes and replaces in its entirety any and all prior communications and contemporaneous agreements and understandings, whether oral, written, electronic or implied, if any, between the parties with respect to the subject matter hereof.

2. **MANUFACTURE OF PRODUCT:** (I) Time is not of the essence with respect to Supplier's supply of Product. (II) All orders for Products shall be made in full batch sizes. (III) With respect to all batches of Product manufactured prior to the establishment of a validated manufacturing process ("Development Product"), Customer acknowledges and agrees that specific results for Development Product are unable to be guaranteed, and until a manufacturing process is optimized and validated under cGMP conditions, there is no assurance that the results, specifications or yield of a given batch of material (collectively, "Specifications") will be exactly as set forth in the Agreement. With respect to Development Product, Customer is obligated to pay for, and Supplier shall have no liability for, all Development Product even if the Product produced does not conform to Specifications, unless such failure to conform is caused by Supplier's gross negligence or willful misconduct. In the event of such a failure due to Supplier's gross negligence or willful misconduct, Supplier shall have, in its sole discretion, the right to either re-manufacture the relevant Development Product at no further cost to Customer or to refund/credit to Customer the amount paid by Customer for such Development Product. The foregoing remedy shall be Customer's sole and exclusive remedy for any failure of Development Product to conform to Specifications. (IV) With respect to all batches of Product manufactured after the establishment of a validated manufacturing process, If Supplier exclusively manufactures the Product for Customer then, if there is a quantitative discrepancy between the actual yield of Product delivered by Supplier and the yield of Product indicated in the Agreement and/or any purchase order issued by Customer, the parties acknowledge and agree that (1) the delivered quantity of Product shall be deemed to satisfy the quantity indicated in the Agreement and/or purchase order, and (2) Customer shall pay for, and the applicable invoice shall reflect, the actual quantity of Product delivered. (V) Supplier's standard quality practices will govern the manufacture of Product unless the parties have entered into a specific quality agreement, in which case that quality agreement will apply. If the parties have entered into a specific quality agreement for the manufacture of Product, the terms of this Agreement shall govern in the event of a conflict between the provisions hereof and any provision in the quality agreement, except to the extent that such provision relates to compliance with cGMP requirements and/or applicable regulatory laws and regulations, in which case the quality agreement's provision shall govern.

3. **DELIVERY; STORAGE:** Title to and risk of loss of each batch of Product shall transfer from Supplier to Customer upon delivery of the batch EXW Supplier's facility (Incoterms 2015) ("Delivery"). Evidence of Delivery will be through the issuance of the completed certificate of analysis to Customer. Customer is responsible for transportation of the batch to Customer's final destination, at the sole risk and expense of Customer. For avoidance of doubt, Customer is responsible for arranging pick up by the carrier and all shipping costs and risks. Should Customer request Supplier to assist with any arrangements with the carrier, such arrangements will be made by Supplier on behalf of Customer in accordance with Customer's applicable instructions and at the sole risk and expense of Customer. If Customer does not pick up Product upon Delivery by Supplier, Supplier shall store such Batch at Supplier's facilities or third party storage location at a monthly storage charge to Customer for the duration of storage, billed at Supplier's (or third party's as applicable) then current standard monthly storage fees and minimums, pro-rated for any partial month. For all Product stored by Supplier, Customer agrees that: (i) Customer has title and risk of ownership; (ii) Customer has made a fixed commitment to purchase such Product; (iii) Customer is responsible for any decrease in market value of such Product that relates to factors and circumstances outside of Supplier's control; (iv) Customer is responsible for obtaining insurance of such Product during the storage period, if desired; and (v) Customer is responsible for transportation of the Product to the Customer's final destination, at the sole risk and expense of Customer.

4. **RESCHEDULING AND CANCELLATION:** Customer may not cancel or reschedule any Service.

5. **ANCILLARY SERVICES:** The pricing set forth in this Agreement applies only to the services expressly identified herein. Any increase or change to the scope of these services, including, without limitation, analytical testing beyond regulatory requirements, supply of reference standards, technology transfer to third parties, regulatory consulting and support, re-drafting/re-formatting of reports, and out-of-specifications investigations, will require a price change and must be memorialized in a written change order executed by both parties ("Change Order"). Notwithstanding anything to the contrary herein, Supplier shall not be in breach of this Agreement in the event Supplier stops performance pending approval and signature of such Change Order by Customer. Supplier shall invoice Customer, and Customer shall pay Supplier, as such charges are incurred for any ancillary services at Supplier's then-current rates for such services.

6. **PRICING/ PAYMENT:** Customer shall pay to Supplier the price for Product as set forth in the Supplier form to which these Terms and Conditions are incorporated by reference. Supplier shall invoice Customer for each batch of Product upon Delivery thereof. Customer shall pay all invoices in full, within ten (10) days of the date of such invoice. In the event payment is not received by Supplier on its bank account by the due date for such payment, then such unpaid amount shall accrue interest at the rate of one percent (1%) per month (or the maximum amount allowed by applicable law at location of Supplier if less than 1% per month) compounded monthly until paid in full. Any taxes, duties or fees applicable to the sale, export or import of Customer Materials or Product or otherwise related to the performance of work under this Agreement (other than taxes based upon Supplier's income)

shall be borne solely by Customer, and Customer shall reimburse Supplier for any such taxes, duties or other fees paid by Supplier.

7. CONFIDENTIAL INFORMATION: Supplier and Customer agree that they 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, however, 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 employees, representatives or affiliates under this Agreement that (A) need to know such confidential information for the purpose of performing under this Agreement, and (B) agree to be bound by written confidentiality obligations no less stringent than those set forth in this Agreement. Each party agrees that it shall not use the other party's confidential information except for purposes of fulfilling its obligations under this Agreement. Notwithstanding anything to the contrary herein, the obligations of confidentiality and non-use under this Agreement will not apply to confidential information that (i) 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, or (ii) is already known by the receiving party at the time of disclosure as evidenced by the receiving party's written records, or (iii) 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 (iv) was or is independently developed by or for the receiving party without use of the disclosing party's confidential information. Upon termination of this Agreement, the receiving party shall, upon request, promptly return, within 30 days, all confidential information, received or accessed, including any copies thereof, and cease its use or, promptly destroy the same and certify such destruction to the disclosing party; 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. The obligations of this Section 7 will terminate five (5) years from the expiration of this Agreement; provided that Customer's confidentiality obligations under this Agreement with respect to Supplier IP (as defined below) shall survive for an indefinite term.

8. INTELLECTUAL PROPERTY/ CUSTOMER MATERIALS: Supplier has, and shall retain, sole and exclusive rights of ownership in and to any of Supplier's intellectual property ("Supplier IP"), and Customer does not acquire any license or other right to Supplier IP except to the extent necessary for the limited purpose of using Product manufactured and supplied under this Agreement. Customer shall at all times retain all right, title and risk of loss to any and all products, materials and processes supplied by or on behalf of Customer to Supplier in connection with this Agreement ("Customer Materials").

9. EQUIPMENT: In the event any Customer-owned or Customer-dedicated equipment is required to be utilized to manufacture Product, Customer shall bear the costs of any maintenance and/or repair of such equipment.

10. AUDITS: During the term of this Agreement, Supplier will permit Customer to audit Supplier's relevant non-financial records with reasonable advance prior notice, during normal business hours, no more than once per calendar year solely to permit Customer to confirm that Product is or has been manufactured in compliance with applicable laws and regulations. Supplier shall invoice Customer, and Customer shall pay Supplier, for inspections and/or audits, including, without limitation, any EHS audits, supply chain audits and/or any pre-approval inspections by the FDA or other regulatory authority, at five thousand Euro (5.000,00 EUR) per day and auditor/inspector, provided any such additional audits shall not exceed one per calendar year.

11. WARRANTIES; DISCLAIMER: Customer represents and warrants that (I) any and all Customer Materials will not infringe on any third party's intellectual property rights; and (II) Customer will comply with all applicable laws in relation to its use of the Product. SUPPLIER MAKES NO REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, QUALITY, NON-INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES OR FITNESS FOR A PARTICULAR PURPOSE.

12. LIMITATION OF LIABILITY: IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR LOST PROFITS OR ANY SPECIAL, CONSEQUENTIAL, PUNITIVE OR INDIRECT OR INCIDENTAL DAMAGES OF THE OTHER PARTY OR ITS RELATED INDEMNIFIED PARTIES, INCLUDING ANY LOST PROFITS OR ANY LOST REVENUES RELATING TO THE PERFORMANCE OF THIS AGREEMENT WHETHER SUCH LIABILITY IS IN CONTRACT, TORT (INCLUDING NEGLIGENCE OR BREACH OF STATUTORY DUTY) OR OTHERWISE. THE FOREGOING WAIVER SHALL IN NO EVENT LIMIT CUSTOMER'S INDEMNITY OBLIGATIONS HEREUNDER. SUPPLIER'S AGGREGATE LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED THE TOTAL FEES PAID BY CUSTOMER TO SUPPLIER FOR THE BATCH OF PRODUCT GIVING RISE TO SUCH LIABILITIES, CLAIMS OR OBLIGATIONS.

13. INDEMNIFICATION: Customer shall indemnify, defend and hold harmless Supplier and its affiliates and their respective directors, officers and employees from and against any and all losses, liabilities, damages, costs and expenses (including reasonable attorneys' fees) resulting from or arising out of any suit, demand, claim or action by any third party ("Losses") to the extent arising out of (i) the marketing, sale, distribution, further development of or use of the Product, including, but not limited to, use in human subjects, or any side effects, contraindications, illness, and/or death resulting from use of the Product (whether based on strict liability, inherent design defect, negligence, failure to warn, breach of contracts or any other theory of liability); (ii) infringement of third party intellectual property by Customer's intellectual property, Product or Customer Materials; or (iii) Customer's negligence or willful misconduct.

14. LITIGATION SUPPORT: In the event a subpoena or other court order requiring personal appearance or production of documents is received by Supplier in respect of litigation that Customer is involved in and to which Supplier is not a party, Customer agrees that Supplier shall obtain its own counsel and Customer agrees to indemnify Supplier from and against any and all costs and expenses (including reasonable legal fees and expenses) reasonably relating to responding to such subpoena and any required internal investigations. In the event Customer requests Supplier's assistance in any litigation that Customer is involved in and to which Supplier is not a party (which assistance may include, without limitation, production of documents), Customer shall pay Supplier for any agreed-to assistance at Supplier's then-current rates as determined based on timing of the request, resource demand, and any business disruption that may be caused by such request.

15. RECALLS: In the event any regulatory authority issues, or Customer voluntarily undertakes, a recall of any Product or any finished dosage form pharmaceutical product containing any Product, Supplier and Customer shall fully cooperate with each other in connection therewith. Supplier shall comply with such a request, directive, order or determination and all expense, fees and services by Supplier associated with such compliance shall be borne by Customer. Notwithstanding the foregoing, Customer shall bear the expenses of any recall of any Product or any finished dosage form pharmaceutical product containing Product, and in no event shall Supplier or its affiliates be financially responsible for the costs of, or associated with,

any such recall.

16. **INSURANCE:** Each party shall procure and maintain at its own expense appropriate product and commercial liability insurance with respect to the conduct and performance of the work under this Agreement and use or sale of the Product, as each party customarily maintains with respect to similar activities. Customer is responsible for maintaining insurance on all materials that it has, or retains, title to, if insurance coverage of such materials is desired by Customer.

17. **SUCCESSORS AND ASSIGNS:** This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns, and any entity that acquires rights to the Product that is the subject hereof. Customer may not transfer or assign, by operation of law or otherwise, its rights or obligations under this Agreement, in whole or in part, without Supplier's written consent, which consent shall not be unreasonably withheld. Supplier may transfer or assign its rights or obligations under this Agreement, in whole or in part, without Customer's written consent in the event of (i) a merger or consolidation of Supplier, (ii) a transaction or series of related transactions in which a third party becomes the beneficial owner of 50% or more of the combined voting power of the outstanding securities of Supplier, or (iii) the sale of all or substantially all of the assets of Supplier.

18. **TERMINATION BY SUPPLIER:** Each of the following shall constitute a default by Customer for purposes of this Agreement (a) the insolvency of Customer, (b) any assignment for the benefit of creditors of Customer, (c) the voluntary or involuntary filing of a petition order or other decree in bankruptcy by or against Customer, (d) the commencement of any proceeding, under court supervision or otherwise, for liquidation of, reorganization of, or the composition, extension, arrangement or readjustment of the obligations of Customer, and (e) failure by Customer to comply with any of the provisions of this Agreement. In the event of a default by Customer which is not cured within 30 days of receiving a notice thereof, Supplier may terminate this Agreement immediately upon written notice. Notwithstanding the foregoing, Supplier may, at any time upon 30 days' prior written notice, terminate this Agreement in whole or in part regardless of whether there is a default by Customer.

19. **EFFECT OF TERMINATION:** Upon termination of this Agreement as set forth in Section 18, Supplier shall invoice Customer for, and Customer shall pay (a) the price for Products previously Delivered and not yet paid, (b) the price of completed or in-process Product not yet delivered, and (c) other actual costs and expenses, including, without limitation, labor, incurred by Supplier and relating to decommissioning activities or otherwise attributable to the Products. Without limiting the foregoing, upon termination of this Agreement, Supplier shall, in its sole discretion, either dispose of or ship to Customer all Customer Materials and Product in Supplier's possession and Customer shall pay all costs associated therewith.

20. **WAIVER; SEVERABILITY:** Failure by Supplier to insist upon strict compliance with any terms of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon strict compliance with respect to any subsequent failure. 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. **BRIBERY AND CORRUPT PRACTICES:** Supplier is committed to complying with all applicable anti-corruption laws, regulations and policies worldwide. Supplier expects its customers, suppliers and business partners to comply with all such laws that prohibit the making, offering or promise of any payment or anything of value, directly or indirectly, to a government official or a government agency ("Officials"), when the payment is intended to influence an act or decision or the retention of business. Accordingly, Customer represents, warrants and covenants that it shall comply with all applicable anti-corruption laws, rules and regulations, including but not limited to the United States Foreign Corrupt Practices Act and the UK Bribery Act, and that it shall not make any payment of money, gifts, services or anything of value either directly or indirectly, to an Official, when the payment is intended to influence an act or decision or the retention of business.

22. **PERSONAL DATA PROTECTION:** Each party acknowledges and agrees, and hereby expressly consents, as follows: (A) in the performance of this Agreement, and the delivery of any documentation hereunder, Personal Data (as defined below) may be generated, disclosed to a party to this Agreement, and may be incorporated into files processed by either party or by the affiliates of either party; (B) Personal Data will be stored as long as such data is necessary for the performance of this Agreement, as well as for maintaining historical records; (C) it represents and warrants that it has all legal right and authority to disclose any Personal Data of any third party it discloses to the other party to this Agreement, and that it has obtained the necessary consents from the relevant third party data subjects to so disclose such Personal Data; (D) it has been informed of the existence of its right to request access to, removal of or restriction on the processing of its Personal Data, as well as to withdraw consent at any time; and (E) it acknowledges its right to file a complaint with the Personal Data supervisory authority in the relevant jurisdiction. As used herein, "Personal Data" shall be as defined in Article 4 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) or any other applicable data protection legislation.

23. **FORCE MAJEURE:** Supplier shall not be liable in damages for, nor shall this Agreement be terminable or cancellable by reason of, any delay or default in Supplier's performance hereunder if such default or delay is caused by events beyond Supplier's reasonable control including, but not limited to, acts of God, regulation or law 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 storm, labor disturbances, epidemic, or failure of suppliers, public utilities or common carriers; provided, however that Supplier shall promptly notify Customer of such cause(s) beyond its reasonable control, and Supplier shall use all reasonable endeavors to reinstate its ongoing obligations to Customer. If the cause(s) shall continue unabated for 180 days, then both parties shall discuss and negotiate in good faith any required modification to this Agreement.

24. **GOVERNING LAW; ARBITRATION:** This Agreement shall be governed by and construed under the laws of Italy, without regard to its principles of conflicts of law; provided that if a court or arbitral tribunal of competent jurisdiction that is presiding over a dispute arising from or related to this Agreement rejects said choice of law, then this Agreement shall be governed by, interpreted and construed in accordance with the laws of the jurisdiction where Supplier is incorporated or formed, without regard to its principles of conflicts of law. All disputes arising from or related to this Agreement may be submitted to the ordinary courts in the city and country where Supplier is located.