EX-10.10

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dex1010.htm

MANUFACTURING AND SUPPLY AGREEMENT

<p>Exhibit 10.10 </p>

<p>\*\*\*Text Omitted and Filed Separately </p>

<p>with the Securities and Exchange

Commission. </p>

<p>Confidential Treatment Requested </p>

<p>Under 17 C.F.R. Sections 200.80(b)(4) </p>

<p>and 230.406. </p>

<p>MANUFACTURING &amp; SUPPLY AGREEMENT </p>

<p>This MANUFACTURING &amp; SUPPLY AGREEMENT (“Agreement”), effective as of 3 August 2007, is entered into between NITEC PHARMA AG, a Swiss corporation having a place of

business at Xxxxxxxxxxxx 00, XX-0000 Xxxxxxx, Xxxxxxxxxxx (hereinafter referred to as “NITEC”), and JAGOTEC AG, a Swiss corporation having a place of business at Xxxxxxxxxxxxxxx 00, XX-0000 Xxxxxxx, Xxxxxxxxxxx

(hereinafter referred to as “JAGOTEC”; (NITEC and JAGOTEC hereinafter sometimes referred to as “Party” or “Parties”). JAGOTEC is a 100% owned subsidiary of SkyePharma plc and SkyePharma AG is a

100% owned subsidiary of SkyePharma plc. </p>

<p>WHEREAS, the Parties and SkyePharma AG signed a Development and Licence Agreement on

20 August 2004 (“DLA”); and </p>

<p>WHEREAS, NITEC is a company engaged directly or through its affiliate Nitec Pharma

GmbH in the manufacture, distribution and licensing of pharmaceutical products, including the Product (as defined below), and is interested in JAGOTEC manufacturing Product for use, marketing, distribution and sale by itself, Nitec Pharma GmbH or a

third party in the Territory (as defined below) under the terms and conditions of this Agreement; and </p>

<p>WHEREAS, JAGOTEC is a

company engaged and specialised directly or through its affiliate SkyePharma SAS - inter alia - in the manufacturing of pharmaceutical products and is interested to manufacture Product for NITEC for use, marketing, distribution and

sale by itself or a third party in the Territory under the terms and conditions of this Agreement. </p>

<p>NOW, THEREFORE, for and in

consideration of the premises, mutual covenants and agreements contained herein, and intending to be legally bound hereby, the Parties hereby agree as follows: </p>

<p> </p>

<table><tbody><tr> <td>1.</td> <td>Definitions </td></tr>

</tbody></table>

<p>For purposes

of this Agreement, the terms defined in this Artide 1 shall have the following meanings: </p>

<p> </p>

<table><tbody><tr> <td>1.1</td> <td>“Active Ingredient” shall mean prednisone in a form meeting the Specifications and the Quality Agreement and ordered by NITEC from a third party

in accordance with Section 5. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.2</td> <td>“Affiliate” shall have the meaning given to it in the DLA. </td></tr>

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<p> </p>

<table><tbody><tr> <td>1.3</td> <td> <p>“Auxiliary Materials” shall mean any and all material, ingredients and components required and/or necessary for the manufacturing of

Product under </p>

</td></tr>

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<p> </p>

<p>1. </p>

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<table><tbody><tr> <td> </td> <td> <p>

and pursuant to the Manufacturing Process and procured by JAGOTEC from third parties in accordance with Section 5, but excluding the Active Ingredient. </p>

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</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.4</td> <td>“Batch” shall mean a production lot containing theoretically […\*\*\*…] units of Product of the same dosage strength (“Theoretical

Quantity”) and, at a lower actual limit, the Lower Quantity. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.5</td> <td>“Business Day” shall mean a day on which commercial banks are open for business in Lyon, France. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.6</td> <td>“Capacity Plan” shall have the meaning given to it in Section 6.1. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.7</td> <td>“Commercially Reasonable Efforts” shall have the meaning given to it in the DLA. </td></tr>

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<p> </p>

<table><tbody><tr> <td>1.8</td> <td>“Committee Members” shall have the meaning given to it in Section 6.1. </td></tr>

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<table><tbody><tr> <td>1.9</td> <td> <p>“Contract Year” shall mean each twelve (12) months period from 1st January through 31st December during the term of this Agreement. </p>

</td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.10</td> <td>“GMP” shall mean Current Good Manufacturing Practice in accordance with rules governing medicinal products in the European Community and the US good

manufacturing practices (CFR 210&amp;211) and/or becoming applicable during the term of this Agreement. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.11</td> <td>“Delivery” shall mean delivery of the Product Ex Works (Incoterms 2000) by JAGOTEC to NITEC in accordance with Section 6.9.

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</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.12</td> <td>“Delivery Day” shall mean the day when the Product is Delivered to NITEC or its nominee. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.13</td> <td>“Effective Date” shall mean the date first written herein above. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.14</td> <td>“Euro” shall mean the single currency of participating members states of the EU. </td></tr>

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<p> </p>

<table><tbody><tr> <td>1.15</td> <td>“Finished Product” shall mean the Product packaged by or on behalf of NITEC for commercial release and sale. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.16</td> <td>“First Launch” shall mean the first commercial sale to a third party customer of the Finished Product in a Major Country.

</td></tr>

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<p> </p>

<table><tbody><tr> <td>1.17</td> <td>“Forecast” shall have the meaning given to it in Section 6.2 </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.18</td> <td>“Joint Product Committee” shall mean a committee established and conducted in accordance with the procedures as set forth in Section 6.1.

</td></tr>

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<p> </p>

<p>\*\*\*Confidential Treatment Requested </p>

<p>2. </p>

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<table><tbody><tr> <td>1.19</td> <td>“Launch Period” shall mean the period of manufacturing Product for First Launch and for the next Contract Year after said First Launch.

</td></tr>

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<table><tbody><tr> <td>1.20</td> <td>“Lower Quantity” shall mean […\*\*\*…] per Batch or if more than one batch is ordered at one time, the average of all such Batches

ordered of the same strength. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.21</td> <td>“Major Capital Expenditure” shall mean the investment by JAGOTEC at the Manufacturing Site including in equipment, zoning and any utilities, totalling

in excess of […\*\*\*…] for the expansion of overall capacity for the manufacture of Product (as opposed to mere replacement). </td></tr>

</tbody></table>

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<table><tbody><tr> <td>1.22</td> <td>“Major Country” shall mean France, Germany, Italy, Spain, the United Kingdom or the United States of America. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.23</td> <td>“Manufacturing Costs” shall mean with respect to Product JAGOTEC’s fully allocated manufacturing costs applied by JAGOTEC to the Product

calculated in accordance with generally accepted accounting principles in Switzerland, and shall include but not be limited to […\*\*\*…]. Manufacturing Costs shall not include costs for Auxiliary Materials and Active Ingredient.

</td></tr>

</tbody></table>

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<table><tbody><tr> <td>1.23</td> <td>“Manufacturing Process” shall mean the process for the manufacturing of Product as submitted in the request for registration of Product to any

Regulatory Authority in the Territory attached hereto as part of the Quality Agreement. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>1.24</td> <td>“Manufacturing Site” shall mean the facilities designated by JAGOTEC for manufacturing Product under this Agreement, which facilities are operated by

JAGOTEC’s Affiliate SkyePharma Production S.A.S. and which are located at 00 xxx xx Xxxxxxxxxx, XX 00, 38291 Saint Xxxxxxx-Fallavier Cedex, France. </td></tr>

</tbody></table>

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<table><tbody><tr> <td>1.25</td> <td>“Marketing Authorization” shall mean with respect to any country that the applicable health authority has approved Finished Product for marketing in

such country. </td></tr>

</tbody></table>

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<table><tbody><tr> <td>1.26</td> <td>“Minimum Commercial Yield” shall mean the minimum yield in % of a Batch manufactured according to the Manufacturing Process for market purposes as set

forth in Section 8. </td></tr>

</tbody></table>

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<table><tbody><tr> <td>1.27</td> <td>“Non-Compliant/Non-Compliance” shall have the meaning given to it in 6.14. </td></tr>

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<table><tbody><tr> <td>1.28</td> <td>“Quality Agreement” shall mean the agreement dated as of the Effective Date on cGMP which agreement shall be attached hereto as Annex 5.

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<p>\*\*\*Confidential Treatment Requested </p>

<p>3. </p>

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<table><tbody><tr> <td>1.29</td> <td>“Price Per Unit” shall mean the price per unit of Product manufactured and supplied hereunder composed of the […\*\*\*…] of the

Manufacturing Costs plus […\*\*\*…] of the costs of the Auxiliary Materials. Costs of the Active Ingredient are not included. The Price per Unit shall be as set out in Annex 4 for the period referred to therein. </td></tr>

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<table><tbody><tr> <td>1.30</td> <td>“Product” shall mean the pharmaceutical formulation named Lodotra containing the Active Ingredient manufactured and supplied hereunder by JAGOTEC in

accordance with the Quality Agreement including the Manufacturing Process and the Specifications, which have been approved for marketing and sale by Regulatory Authorities in the Territory or which are intended to use for commercialisation purposes

or clinical trials. Product is offered in the presentation according to Annex 1. </td></tr>

</tbody></table>

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<table><tbody><tr> <td>1.31</td> <td>“Regulatory Approvals” shall mean all approvals, price approvals or approvals for reimbursements, product and/or establishment licenses, registrations,

permits, or authorizations (including Marketing Authorizations) of any federal, state or local regulatory agency, department, bureau or other governmental entity or Regulatory Authority, necessary for the manufacture, packaging, distribution, use,

storage, importation, export, transport, marketing and sale of the Products and/or Finished Products for therapeutic use in humans in a country of the Territory. </td></tr>

</tbody></table>

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<table><tbody><tr> <td>1.32</td> <td>“Regulatory Authority/(ies)” shall mean any governmental authority in any country or group of countries of the Territory competent to approve

pharmaceutical products for manufacturing, marketing, distribution and sale in any country(ies) of the Territory and/or to approve the price for pharmaceutical products to be sold in any country(ies) of the Territory, including without limitation

the FDA and EMEA, and any successor agency thereof. </td></tr>

</tbody></table>

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<table><tbody><tr> <td>1.33</td> <td>“Regulatory Standards” shall mean all standards, rules and regulations promulgated by a Regulatory Authority and applicable to the product and the

manufacture thereof, including without limitation cGMP. </td></tr>

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<table><tbody><tr> <td>1.34</td> <td>“Release” shall mean release of the Product by the Qualified Person pursuant to the Quality Agreement. </td></tr>

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<table><tbody><tr> <td>1.35</td> <td>“Shelf Life” shall mean in relation to the Product have the meaning given to it in the Quality Agreement/shall mean in respect of each Batch a defined

period of months (“Shelf Life Period”) as per Annex 2a which will be updated from time to time by NITEC) from the date of first contact between the Active Ingredient and Auxiliary Material. </td></tr>

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<table><tbody><tr> <td>1.36</td> <td>“Specifications” shall mean the specifications for the Product as contained in Annex 2. </td></tr>

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<p>\*\*\*Confidential Treatment Requested </p>

<p>4. </p>

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<table><tbody><tr> <td>1.37</td> <td>“Technical Support” shall mean reasonable assistance provided by JAGOTEC to NITEC strictly limited to providing technical support to an alternative

supplier of Product in connection with (a) the training of their staff, (b) cross-validation of the analytical methods and its production of three consecutive validation Batches (of one strength only) complying with the Specifications. All

other technical support, including but not limited to regulatory support, stability programs and any in vivo study work, is specifically excluded. </td></tr>

</tbody></table>

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<table><tbody><tr> <td>1.38</td> <td>“Territory” shall mean collectively each country or group of countries of the world, in which a Regulatory Authority has granted Regulatory Approval.

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<table><tbody><tr> <td>2.</td> <td>Subject Matter and Grant of License </td></tr>

</tbody></table>

<p>NITEC hereby instructs JAGOTEC, and JAGOTEC hereby agrees under the terms and conditions contained in this Agreement, to manufacture at the Manufacturing Site and supply to NITEC Product in bulk form for

use in the Finished Product for sale to the pharmaceutical trade. JAGOTEC shall manufacture and deliver Product exclusively to NITEC. JAGOTEC shall delegate its responsibilities hereunder to its Affiliate SkyePharma SAS, provided that JAGOTEC

remains solely liable to NITEC for the same. The use, marketing, distribution and sale of the Finished Product may at NITEC’s option also be carried out by NITEC’s affiliate Nitec Pharma GmbH and NITEC may delegate any other

responsibilities under this Agreement to Nitec Pharma GmbH so long as NITEC remains solely liable to JAGOTEC for the same. </p>

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<table><tbody><tr> <td>3.</td> <td>Manufacturing of Product </td></tr>

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<table><tbody><tr> <td>3.1</td> <td> <p>JAGOTEC shall manufacture the Product for marketing and sale by NITEC in the Manufacturing Site in strict compliance with the Specifications and the

approved Manufacturing Process and in accordance with the Quality Agreement. Furthermore, JAGOTEC shall only use such equipment and personnel which are appropriate or duly qualified for the manufacturing of Product in accordance with the provisions

of this Agreement and the Quality Agreement. It is acknowledged and agreed between the parties that the final dissolution specification for the Product is not approved by the regulatory authorities at signing this contract but will be approved by

the regulatory authorities during the approval process. Therefore, JAGOTEC shall only be liable for failing to manufacture the Product in accordance with such preliminary dissolution specification (as per annex 2) until agreement of the Joint

Product Committee as set out below. After approval by the regulatory authorities of a final dissolution specification, JAGOTEC shall use Commercially Reasonable Best Efforts to implement such final dissolution specification such that the Product may

be manufactured at the Manufacturing Site in accordance therewith. If, having used such efforts, JAGOTEC is able to manufacture in accordance with such final dissolution specification, it shall notify the Joint Product Committee. Upon the unanimous

agreement of the Joint Product Committee that such final dissolution specification has been implemented, the Specifications and/or the </p>

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<p>5. </p>

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<table><tbody><tr> <td> </td> <td> <p>

Quality Agreement shall be amended to incorporate such final dissolution specification and JAGOTEC agrees that the campaigns following such amendment shall be manufactured in accordance

therewith. If, having used Commercially Reasonable Best Efforts to do so, Jagotec is unable to manufacture Product in accordance with such final dissolution specification within a reasonable period of time following approval, it shall continue to

manufacture in accordance with the Specifications at the date hereof, shall not be in breach of this Agreement and shall have no liability to NITEC in connection with such failure. In this clause, “Commercially Reasonable Best Efforts”

shall mean those efforts and resources that would be used by an established pharmaceutical company in its capacity as a contract manufacturer (taking into all relevant factors including but not limited to product labelling, stage in the relevant

product life, market potential, past performance, availability of resource, economic return, the regulatory environment and competitive market conditions in the therapeutic area), utilizing sound and reasonable scientific and business practice and

judgment and its manufacturing expertise, in a diligent and timely manner, all as measured by the facts and circumstances at the time such efforts are due; it being understood however for the avoidance of any doubt that such efforts shall not

include, nor shall be deemed to include, (a) the commitment by JAGOTEC to any Major Capital Expenditure and (b) any obligation on JAGOTEC to manufacture and supply the Product at less than a reasonable margin. </p>

</td></tr>

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<table><tbody><tr> <td>3.2</td> <td> <p>JAGOTEC shall permit duly authorized representatives of (a) NITEC or (b) any third party contracted by NITEC to have an official

responsibility for the release of the Finished Product to the market according to applicable laws and regulations applying in countries of the Territory (so long as such third party has signed a confidentiality agreement on terms acceptable to

JAGOTEC) during Business Days and hours and upon reasonable prior written notice to inspect once a year (or more often if reasonably requested by NITEC on its own behalf or on behalf of its third party contractor) the Manufacturing Site - including

but not limited to manufacturing, testing, warehousing and/or storing and generation and/or disposal of waste - used for the manufacturing of Product and to inspect and take reasonable quantities of Active Ingredient, Auxiliary Materials,

intermediate product and Product manufactured for examination purposes to verify JAGOTEC’s compliance with the Manufacturing Process, the Specifications and its obligations under this Agreement including the Quality Agreement. Furthermore,

JAGOTEC will supply copies to NITEC (on NITEC’s request and at NITEC’s cost) of any and all records relating to manufacturing and testing of the Product. NITEC shall be promptly informed in writing and by fax or email if and when an

inspection by a Regulatory Authority occurs or is scheduled to occur at the Manufacturing Site which in any way involves inspection of the production of Product or any other feature of JAGOTEC’s actions in connection with Product of the

performance of this Agreement. NITEC shall be entitled to send a representative to attend any such </p>

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<p>6. </p>

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<table><tbody><tr> <td> </td> <td> <p>

inspection of the Manufacturing Site. The findings of any such inspection at the Manufacturing Site or of any other inspections including self inspections carried out in relation to production at

the Manufacturing Site of JAGOTEC for the Product shall promptly be made known in their entirety in writing to NITEC insofar and to the extent that they may potentially impact the commercialization, manufacture (including but not limited to quality

and testing) and Delivery of the Product under this Agreement. </p>

</td></tr>

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<table><tbody><tr> <td>3.3</td> <td>JAGOTEC undertakes to use any and all Active Ingredient exclusively for the performance of its obligations hereunder and JAGOTEC shall, upon receipt of any supply of

Active Ingredient and Auxiliary Materials, promptly perform the quality and quantity control procedures as provided for in the Quality Agreement. In the event that any Active Ingredient and Auxiliary Materials to be used solely in the manufacture of

the Product, or any part thereof, do not meet with the Specifications and/or quality requirements as set forth in the Quality Agreement, then JAGOTEC shall reject such materials and shall promptly notify NITEC thereof in writing - including a

specific description of the deviation from the Specifications—(a) in every case in relation to Active Ingredient and (b) where such rejection is reasonably likely to impact upon the manufacture of the Product in relation to Auxiliary

Materials. The cost of any rejected Auxiliary Materials, the quality control and related rejection for Auxiliary Materials shall be borne by Jagotec or its suppliers subject to the terms of existing supply agreements between Jagotec and its

suppliers of Auxiliary Materials. The cost of any rejected Active Ingredient, quality control and rejection for Active Ingredient shall be borne by NITEC or its selected supplier subject to the terms of any existing supply agreement between NITEC

and the Active Ingredient supplier unless this failure is caused by a failure of JAGOTEC during the quality control process for the Active Ingredient. </td></tr>

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<table><tbody><tr> <td>3.4</td> <td>JAGOTEC shall store all Active Ingredient, Auxiliary Materials, intermediate product and all Product manufactured hereunder, in a suitable warehouse under suitable

conditions as set forth in the Quality Agreement preventing the deterioration, theft or damage of Active Ingredient, Auxiliary Materials, intermediate products and Product until the agreed Delivery Day to NITEC, and JAGOTEC shall insure against such

risks all Active Ingredient, Auxiliary Materials, intermediate products and all Product manufactured hereunder until Delivery. </td></tr>

</tbody></table>

<p>The Active Ingredient ordered by NITEC for the purposes of manufacturing of Product shall remain NITEC property but shall be stored by JAGOTEC under JAGOTEC’s sole responsibility. </p>

<p>JAGOTEC shall report to NITEC at least once a month on the level of stocks of Active Ingredient, and Product manufactured, including a

differentiation of the status of the Product manufactured, such as “under quarantine”, “released”, “rejected”). The report frequency may be modified by decision of the Joint Product Committee. </p>

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<p>7. </p>

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<p>Should Auxiliary Materials ordered exclusively for NITEC need to be re-analysed after being

stored by JAGOTEC in compliance with the Quality Agreement for a period in excess of its intended shelf-life, NITEC shall cover the cost of such analysis. Should Active Ingredient or Auxiliary Materials require re-analysis due to failure to comply

with the storage provisions of the Quality Agreement, or where such re-analysis is carried out by JAGOTEC for its own internal purposes, then JAGOTEC shall cover the cost of such analysis. </p>

<p> </p>

<table><tbody><tr> <td>3.5</td> <td>JAGOTEC hereby agrees to guarantee NITEC, upon two week’s prior written notice, free and full access to any know-how relating to the manufacture of the Product

necessary to enable NITEC to obtain or maintain any Regulatory Approval in the Territory, to perform the Batch release, to ensure that the finished Product is in line with the Regulatory Approval and all other (local) applicable laws and regulations

and to enable qualified NITEC personnel to fulfil NITEC’s legal and regulatory obligations. </td></tr>

</tbody></table>

<p>Each change in

the Product or in the Manufacturing Process proposed by either Party, shall be communicated to the other Party in advance, to enable the other Party to comment on such intended changes before implementation. Any changes proposed by JAGOTEC shall

only be implemented with NITEC’s prior written consent, which consent shall not be unreasonably withheld or delayed. The Joint Product Committee shall discuss any benefit generated by the implementation of changes proposed by JAGOTEC and decide

which party shall bear which proportion of the costs thereof. NITEC shall bear or reimburse JAGOTEC for all of JAGOTEC’s costs (including without limitation any regulatory costs) associated with any change initiated by NITEC or required by a

Regulatory Authority and related specifically to the Product. Further details regarding the change control procedure will be set forth in the separate Quality Agreement. </p>

<p> </p>

<table><tbody><tr> <td>3.6</td> <td>Quality control of Product is under the sole responsibility of NITEC. Therefore JAGOTEC will not analyze the Product in order to determine its suitability for quality

control under this Agreement or applicable requirements of a Regulatory Authority or with any applicable Regulatory Approval. All in-process controls are under the sole responsibility of JAGOTEC. JAGOTEC will not change the in- process controls as

set forth in the Regulatory Approval and the Quality Agreement without the written consent of NITEC. </td></tr>

</tbody></table>

<p>JAGOTEC

shall provide NITEC with the results of the in-process controls after occurrence and with samples of Product to perform the quality control testing within 3 working days of the final press-coating step. NITEC shall inform JAGOTEC on the results of

such analysis also within 3 working days of completion. </p>

<p>In the event that JAGOTEC agrees to the implementation of the

analytical method (quality control)for Product at JAGOTEC, NITEC shall reimburse </p>

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<p>8. </p>

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JAGOTEC for all of JAGOTEC’s reasonable costs associated with such analytical method transfer, to the extent JAGOTEC has notified NITEC in advance of the estimated amount of such costs.

Otherwise, each Party shall bear its own costs related to such analytical method transfer. </p>

<p> </p>

<table><tbody><tr> <td>3.7</td> <td>Without prejudice to Section 3.6, JAGOTEC shall perform all in-process control tests and confirm the GMP-compliant manufacture of the Product pursuant to the terms

of the Quality Agreement. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>3.8</td> <td>JAGOTEC agrees to provide sufficient manufacturing capacity subject to the terms hereof to fulfil NITEC’s requirements for the Product as bulk tablets, to the

extent that these requirements of NITEC are reflected in NITEC’s Forecast per Section 6.2 and in JAGOTEC’s Capacity Plan per Section 6.1. </td></tr>

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<table><tbody><tr> <td>4.</td> <td>Obligations of NITEC </td></tr>

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<p> </p>

<table><tbody><tr> <td>4.1</td> <td>NITEC shall be responsible, at its own cost and expense, for maintaining and updating from time to time, if needed, any and all Regulatory Approvals.

</td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>4.2</td> <td>NITEC shall appoint a supplier of Active Ingredient and shall ensure that such supplier supplies Active Ingredient in a timely manner which meets with the

Specifications and/or quality requirements as set forth in the Quality Agreement. NITEC agrees that for the avoidance of any shortfalls during the Launch Period it will order […\*\*\*…] of the Active Ingredient required for the

manufacturing of Product (as recommended by JAGOTEC pursuant to clause 5.1, firmly ordered by NITEC). </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>4.3</td> <td>NITEC shall be responsible for the qualification of the supplier of the Active Ingredient as set forth in the Quality Agreement. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>4.4</td> <td>NITEC shall contract with such supplier, be responsible for all dealings with, and settle all invoices of such supplier. NITEC shall negotiate with each such qualified

supplier prices, annual amounts and lead times for the supply of the Active Ingredient. NITEC shall inform JAGOTEC in writing of the relevant parts of the agreements between NITEC and the suppliers of the Active Ingredient. </td></tr>

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<table><tbody><tr> <td>4.5</td> <td>NITEC shall ensure that such supply of Active Ingredient shall be in compliance with the Specifications and the requirements set forth in the Quality Agreement, and

shall be delivered DDP (Incoterms 2000 ICC) to the Manufacturing Site. </td></tr>

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<table><tbody><tr> <td>4.6</td> <td>NITEC shall notify JAGOTEC of any matter of which it becomes aware which is reasonably likely to impact upon the delivery or quality of the Active Ingredient to

JAGOTEC. </td></tr>

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<p>\*\*\*Confidential Treatment Requested </p>

<p>9. </p>

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<table><tbody><tr> <td>5.</td> <td>Obligations and Responsibilities of JAGOTEC </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>5.1</td> <td>JAGOTEC undertakes to recommend a supplier of the Auxiliary Materials which JAGOTEC shall contract with and from which JAGOTEC shall order the same for the purposes

hereof. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>5.2</td> <td>JAGOTEC shall be responsible for the qualification of the supplier of the Auxiliary Materials as set forth in the Quality Agreement. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>5.3</td> <td>JAGOTEC shall negotiate with each such qualified supplier prices, annual amounts and lead times for the supply of the Auxiliary Materials. JAGOTEC shall inform NITEC in

writing of the agreements between JAGOTEC and the suppliers of the Auxiliary Materials. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>5.4</td> <td>JAGOTEC shall be responsible for the keeping of the contract with the supplier and the usage of Auxiliary Materials for manufacturing of Product which meet with the

Specifications and/or quality requirements as set forth in the Quality Agreement. </td></tr>

</tbody></table>

<p>For the avoidance of any

shortfalls during the Launch Period JAGOTEC shall order […\*\*\*…] of the Auxiliary Materials required for the manufacturing of Product firmly ordered by NITEC. JAGOTEC shall ensure that such supply of Auxiliary Materials shall be in

compliance with the requirements set forth in the Quality Agreement, and shall be delivered DDP (Incoterms 2000 ICC) to the Manufacturing Site. </p>

<p> </p>

<table><tbody><tr> <td>5.5</td> <td>Any change in the supplier or the specification of the Auxiliary Materials shall require the prior written consent of NITEC. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>5.6</td> <td>JAGOTEC shall notify NITEC of any matter of which it becomes aware which is reasonably likely to impact upon the Delivery Day or otherwise on JAGOTEC’s ability to

fully and timely perform its obligations under this Agreement. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>5.7</td> <td>JAGOTEC may provide support in relation to technology transfer other than Technical Support to NITEC upon agreement by NITEC to the payment of such costs of providing

such support as are agreed. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.</td> <td>Order and Supply of Product </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.1</td> <td> <p>The parties shall establish a “Joint Product Committee” consisting of four (4) individuals (“Committee Members”); two

of whom shall be nominated by JAGOTEC and two of whom shall be nominated by NITEC. The Committee Members may be replaced by notice to the other Party and shall be appropriately qualified and experienced in order to make a meaningful contribution to

the Joint Product Committee meetings. The Joint Product </p>

</td></tr>

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<p>\*\*\*Confidential Treatment Requested </p>

<p>10. </p>

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<table><tbody><tr> <td> </td> <td> <p>

Committee shall meet at least once per quarter to review NITEC’s Forecast (as defined in Section 6.2) for the Product, which shall reflect NITEC’s realistically anticipated up-side

scenario for its requirements for Product. JAGOTEC shall provide to NITEC, at the beginning of each quarter for the following eight quarters with a capacity plan for the Product (“Capacity Plan”). The Joint Production Committee

shall compare the Capacity Plan to NITEC’s Forecast. Each member of the Committee shall have one vote in relation to matters discussed by it and save as otherwise set out herein votes shall be carried by a majority. Initial members of the

Committee shall be set out in Annex 9. </p>

</td></tr>

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<table><tbody><tr> <td>6.2</td> <td>NITEC shall issue, for the first time on the date of signature hereof, and thereafter during the term of this Agreement at the beginning of each quarter in accordance

with Section 6.3, a rolling forecast (“Forecast”) for the upcoming […\*\*\*…] estimating NITEC’s requirements of Product for (a) distribution and sale and (b) for clinical studies in the Territory,

which forecasts shall be used by JAGOTEC for production planning purposes. The submission of each Forecast shall constitute a binding order for the quantity of Product set forth in […\*\*\*…] for Delivery at the latest […\*\*\*…] after

the submission thereof save that the quantities set forth in […\*\*\*…] of the first Forecast issued on the date of signature of this Agreement shall not be binding on the parties unless agreed between them. In each Forecast,

[…\*\*\*…] shall be (i) within +/- […\*\*\*…] of the quantities of the Product set out in […\*\*\*…] in the Forecast immediately preceding the most recent Forecast and (ii) within +/- […\*\*\*…] of the

quantities set out in […\*\*\*…] in the forecast immediately preceding the Forecast referred to in (i). Save as set out herein, it is mutually agreed between the Parties that the Forecast is only a non-binding estimate of NITEC’s

requirements of the Product and that in particular in case of any foreseeable launches in a Major Country such Forecast may be adequately adjusted by mutual agreement of the parties. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.3</td> <td> <p>Any purchase order (to be sent out by NITEC on a monthly basis) shall be confirmed by JAGOTEC within 5 working days and shall be binding upon JAGOTEC,

provided that the requested Delivery Day is not earlier than […\*\*\*…] after the receipt of such purchase order and provided that such order shall correspond with the binding element of the Forecast for the month in question. It is

JAGOTEC’s obligation to negotiate with the Auxiliary Materials supplier lead times for the supply of the Auxiliary Materials in quantities and of quality sufficient for timely manufacturing of Product in accordance with any […\*\*\*…]

Forecast. JAGOTEC shall recommend to NITEC and its Active Ingredient supplier (a) the quantity of Active Ingredient and (b) the dates of delivery of the same which would, in JAGOTEC’s reasonable opinion based on Forecasts, be required

in order for JAGOTEC to timely manufacture Product in accordance with any […\*\*\*…] Forecast. Further JAGOTEC shall inform NITEC at the same time about the existing stock of Active Ingredient held by JAGOTEC. JAGOTEC shall not be responsible

for any other dealings with such </p>

</td></tr>

</tbody></table>

<p> </p>

<p>\*\*\*Confidential Treatment Requested </p>

<p>11. </p>

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<table><tbody><tr> <td> </td> <td> <p>

supplier nor shall it be liable for the failure of such supplier to supply Active Ingredient in a timely manner or that does not meet with the Specifications and/or quality requirements as set

forth in the Quality Agreement. JAGOTEC shall inform NITEC immediately in writing of any deviation from the aforementioned […\*\*\*…] lead time. </p>

</td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.4</td> <td>Notwithstanding anything contained herein, NITEC may always request supply of Product in excess of the quantity set out in Section 6.3 but any such request shall

not be considered a firm order binding upon JAGOTEC unless and to the extent confirmed by JAGOTEC in writing, provided that JAGOTEC shall at all times employ its Commercially Reasonable Efforts to comply with any request of NITEC for Product.

</td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.5</td> <td>If (a) in any three consecutive Forecasts, the quantity forecast in respect of […\*\*\*…] thereof would, in JAGOTEC’s sole opinion, require

Major Capital Expenditure in order for JAGOTEC to manufacture such quantity (JAGOTEC basing such opinion upon it deciding in its sole discretion that the quantity forecast exceeds the quantity that it could provide on the date of each such Forecast

by […\*\*\*…] of the maximum available capacity for NITEC as per Capacity Plan would be required), and (b) in the third such consecutive Forecast, the quantity forecast in respect of […\*\*\*…] thereof would so require Major

Capital Expenditure, JAGOTEC within […\*\*\*…] of receipt of the third such consecutive Forecast shall notify NITEC and decide, whether or not to commence such Major Capital Expenditure. If JAGOTEC commences such Major Capital Expenditure

NITEC agrees and acknowledges that such Major Capital Expenditure is likely to take […\*\*\*…] to complete </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.6</td> <td>If JAGOTEC decides, upon receiving the third such consecutive Forecast as set out in Section 6.5 above, not to commence Major Capital Expenditure it shall notify

NITEC of its decision and any subsequent […\*\*\*…] Forecast shall only become binding as to the quantity that JAGOTEC is able to manufacture without such Major Capital Expenditure. Upon such decision not to commence Major Capital

Expenditure, NITEC shall be entitled to qualify one second manufacturing site on the foregoing conditions. NITEC may, from the date upon which the third consecutive […\*\*\*…] forecast becomes a […\*\*\*…] Forecast, as set out in

Section 6.5, use such second manufacturing site to fulfil in any subsequent quarter only such amount of orders as exceed those which JAGOTEC is unable to manufacture as a result of not commencing Major Capital Expenditure. JAGOTEC shall in such

circumstance provide Technical Support to NITEC at NITEC’s cost. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.7</td> <td> <p>Each order under Section 6.2 above shall consist of not less than […\*\*\*…] Batches of Product covering all dosage strengths (save that in

the first two years following First Launch Jagotec agrees to accept individual orders of less than […\*\*\*…], without prejudice to the minimum order obligation in the following sentence. NITEC shall order the minimum quantities set out and

according to Annex 3 (the “Minimum Quantities”). The firm order for launch </p>

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<p>\*\*\*Confidential Treatment Requested </p>

<p>12. </p>

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stock is at least 1 Batch of Product per dosage strength. NITEC will place orders of Product in units of whole Batches. </p>

</td></tr>

</tbody></table>

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<table><tbody><tr> <td>6.8</td> <td>It is agreed and understood between the parties that the quantities ordered by NITEC shall be based upon the fact that each Batch (or the average of a number of Batches

where more than one Batch is ordered at any one time) may contain […\*\*\*…] of units and such Lower Quantity would be, if Delivered, sufficient to satisfy its requirements and NITEC shall supply Forecasts accordingly.

</td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.9</td> <td>JAGOTEC shall supply Product firmly ordered by NITEC in accordance with this Agreement at the applicable and agreed Delivery Day upon the preceding and following

conditions; (a) Any Batch (or number of Batches on average as set out in Section 6.8) of Product may not fall short of the Lower Quantity; and (b) All Products shall be Delivered to NITEC Ex Works (Incoterms 2000) the Manufacturing

Site. Together with any such shipment of Product, JAGOTEC shall provide NITEC with the documents and samples specified in the Quality Agreement. JAGOTEC shall be responsible for ensuring that each Delivery of Product shall be delivered to NITEC as

soon as possible (and in any event within 3 months) after its manufacture. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.10</td> <td>Delivery performance and failures. Orders are considered as orders fulfilled on time if the Products meet the standards set out in the Quality Agreement and not

properly rejected on the terms hereof and if the Delivery Day set out in an order acceptance is met by […\*\*\*…]. In the case that JAGOTEC does not reach the on time targets above, JAGOTEC shall use all Commercially Reasonable Efforts to

fulfil such orders and NITEC shall, in addition to any other remedy (including under Section 8 in any case in which the Minimum Commercial Yield is not achieved), be entitled to reduce the Price Per Unit of late batches by […\*\*\*…] of

delay but to a maximum of […\*\*\*…] </td></tr>

</tbody></table>

<p>If JAGOTEC produces a Batch or Batches (on average as above)

containing less than the Lower Quantity JAGOTEC shall immediately inform NITEC in writing. NITEC will thereafter be entitled to place an additional order (not defined as or part of any Minimum Orders) and JAGOTEC agrees to use Commercially

Reasonable Efforts to accept and fulfil this order within such a shortened lead time as is reasonably practicable (and to within five days provide NITEC with a Delivery Day therefor) provided that such quantities of Active Ingredient and Auxiliary

Materials are on stock in order to do so. To avoid any shortfalls during the Launch Period the Parties hereby agree (in Sections 4.2 and 5.4) to order […\*\*\*…] of Active Ingredient and Auxiliary Materials respectively of the amount firmly

ordered by NITEC during such Launch Period. </p>

<p> </p>

<p>\*\*\*Confidential Treatment Requested </p>

<p>13. </p>

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<p>NITEC shall then be obliged to pay the following amounts in respect of the additionally

ordered Batches as set out above; </p>

<p> </p>

<table><tbody><tr> <td> </td> <td>(a)</td> <td>in respect of units up to the total Minimum Commercial Yield ordered – the Price Per Unit; </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td> </td> <td>(b)</td> <td>in respect of the balance of supplied units (i.e. in excess of the Minimum Commercial Yield ordered) – the Price Per Unit […\*\*\*…]

</td></tr>

</tbody></table>

<p>JAGOTEC shall not keep Product on stock except for the purpose of retaining samples as defined in the quality

agreement or as required for analysis in case of a dispute pursuant to clause 6.17 or otherwise. </p>

<p> </p>

<table><tbody><tr> <td>6.11</td> <td>JAGOTEC shall notify NITEC of the Delivery Date for a Delivery at least five (5) days prior of the same and NITEC undertakes to accept Delivery of all Product

Delivered by JAGOTEC on such Delivery Date. JAGOTEC will package and label Product in accordance with the provisions of the Quality Agreement including at least code number, name of product, batch number, order number, quantity of supplied Product

per package and date of manufacture. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.12</td> <td>If following completion of Major Capital Expenditure NITEC does not order quantities equal to (a) those in the Forecasts which triggered such Major Capital

Expenditure […\*\*\*…] and (b) that forecast in respect of […\*\*\*…] in the subsequent Forecast, the Price Per Unit of quantities actually ordered will be adjusted as follows; </td></tr>

</tbody></table>

<p>Where the amounts ordered by NITEC are less than […\*\*\*…] but more than […\*\*\*…], of maximum available capacity: Price

Per Unit […\*\*\*…] </p>

<p>Where the amounts ordered by NITEC are […\*\*\*…] or less, but more than […\*\*\*…]

of maximum available capacity: Price Per Unit […\*\*\*…] […\*\*\*…] </p>

<p>Where the amounts ordered by NITEC are

[…\*\*\*…] or less of maximum available capacity: Price Per Unit […\*\*\*…] </p>

<p>The maximum available capacity for

the purposes of this Section 6.12 shall be that available for NITEC as per Capacity Plan at the date upon which JAGOTEC notified NITEC of the need for Major Capital Expenditure under Section 6.5. </p>

<p>Any amounts in respect of an increase in prices due under this Section 6.12 shall be invoiced at the end of the twelve month period

following completion of Major Capital Expenditure. Payment terms shall be as per order to reflect the price adjustment for the previous twelve month; payment term for this invoice will be as per Annex 4. </p>

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<p>\*\*\*Confidential Treatment Requested </p>

<p>14. </p>

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<table><tbody><tr> <td>6.13</td> <td>NITEC shall bear the cost of bulk, quality control and rejection of spoiled, damaged, contaminated or defective Active Ingredient provided that such Active

Ingredient’s damage, contamination or defect could not have been discovered by JAGOTEC with standard sampling or analytical procedures as defined in the Quality Agreement. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.14</td> <td>If any shipment of Product or any portion thereof is spoiled, damaged, contaminated or defective upon Delivery or fails to meet the Specifications or the quality

standards set out in the Quality Agreement (together “Non- Compliant”), then NITEC shall have the right to reject such shipment or the portion affected thereby by giving written notice to JAGOTEC within […\*\*\*…] following

the Delivery of such shipment of Product, sufficiently specifying the alleged Non-Compliance and the quantities affected. Any shipment or portion thereof so rejected by NITEC shall be held at JAGOTEC’s disposal for examination. JAGOTEC shall

investigate such issue and provide a written report to NITEC as soon as possible after notification. JAGOTEC shall not be liable for any Non-Compliance of the Product arising out of the shipment, storage or handling of Product by NITEC or its

representatives, agents or customers. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.15</td> <td>In the event that any shipment of Product or any portion thereof is rightly rejected by NITEC in accordance with Section 6.14 above, then JAGOTEC undertakes to

take back and, at NITEC’s request, destroy such Non-Compliant Product, and to replace such Non-Compliant shipment or portion thereof with an identical quantity of Product as soon as reasonably possible. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.16</td> <td>In any case of Non-Compliance, NITEC shall pay for the Non-Compliant Product, provided that such payment shall not be deemed to be a waiver of NITEC of any of its

rights on account of such Non-Compliance. </td></tr>

</tbody></table>

<p>Should the Non-Compliance be due to JAGOTEC, such replacement shall be

effected at JAGOTEC’s own cost and expense which includes but is not limited the corresponding amount of Active Ingredient and Auxiliary Materials in the Non-Compliant Batch or part thereof and the Manufacturing Costs. </p>

<p>The Non-Compliant Product shall, at JAGOTEC’s cost and expense, be returned to JAGOTEC. </p>

<p>NITEC shall pay for the replacement of Product in accordance with the payment provisions of this Agreement, provided that Product supplied

by JAGOTEC conforms with quality standards as of Annex 5. </p>

<p>Should the Non-Compliance be due to NITEC (including for the

avoidance of doubt in situations where the Active Ingredient is contaminated and such Active Ingredient contamination could not be discovered by JAGOTEC with standard sampling or analytical procedures as defined in the Quality Agreement), NITEC

shall pay for the replacement of Product in accordance with the payment provisions of this Agreement. </p>

<p> </p>

<p>\*\*\*Confidential Treatment Requested </p>

<p>15. </p>

<p>

</p>

<table><tbody><tr> <td>6.17</td> <td>In the event of any dispute between the Parties regarding the question whether a shipment of Product or any part thereof timely rejected by NITEC was actually

Non-Compliant, and/or where responsibility for such Non-Compliance, under the terms hereof, lies the Parties agree to have an independent mutually acceptable (each Party acting reasonably) laboratory or expert perform such tests and analysis on the

rejected Product as deemed necessary and/or required to establish the defect alleged by NITEC and the reasons therefore. The result of such independent laboratory or expert shall be binding upon the Parties, and the cost of such examination shall be

borne by the losing Party. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.18</td> <td>In cases in which the resolution of a dispute or investigations is anticipated to take more than 2 weeks, JAGOTEC shall upon NITEC’s request and as soon as

practicable after notification of the rejection deliver replacement Products for the Products under dispute in order to ensure continuity of supply. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>6.19</td> <td>Together with any shipment of Product, JAGOTEC shall issue a respective invoice for such shipment, applying the then valid Price Per Unit, multiplied by the number of

units of Product actually supplied. NITEC undertakes to pay any and all such invoices within […\*\*\*…] as of the delivery date of the respective shipment of Product (“Payment Date”). In the event of late payment JAGOTEC may

charge interest on the outstanding amount at a rate of […\*\*\*…] and such interest shall be calculated and payable in respect of the period from Payment Date until the date payment in full is received by JAGOTEC. </td></tr>

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<table><tbody><tr> <td>7.</td> <td>Calculation and Adjustment of Price Per Unit </td></tr>

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<p> </p>

<table><tbody><tr> <td>7.1</td> <td>The Price per Unit does not include any Value Added Taxes (VAT), turnover taxes or similar charges in any country, which are to be added and paid by NITEC as

applicable. The Price Per Unit of this Agreement shall remain applicable for all supplies of Product during the term from the Effective Date until 31 Dec 2007. </td></tr>

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<p> </p>

<table><tbody><tr> <td>7.2</td> <td>Thereafter, the Price per Unit contained in Annex 4 hereto may be adjusted by JAGOTEC once each Contract Year in the month of October calculated as follows:

</td></tr>

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<p> </p>

<table><tbody><tr> <td> </td> <td>(a)</td> <td>Adjustments to Manufacturing Costs shall be calculated on the basis of […\*\*\*…]; </td></tr>

</tbody></table>

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<table><tbody><tr> <td> </td> <td>(b)</td> <td>Adjustments to costs of Auxiliary Materials shall be calculated by reference to actual changes to the costs thereof, without any xxxx up added by JAGOTEC

</td></tr>

</tbody></table>

<p>In no Contract Year may any increase be in excess of […\*\*\*…] of the then current Price Per Unit save

by mutual agreement of the parties. Such adjusted Price </p>

<p> </p>

<p>\*\*\*Confidential Treatment Requested </p>

<p>16. </p>

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<p>

per Unit shall be attached hereto as new Annex 3 each year and shall remain in force for supplies of Product during the next Contract Year. </p>

<p> </p>

<table><tbody><tr> <td>7.3</td> <td>NITEC shall have the right, through its employees and/or its independent auditing representatives and upon reasonable notice, to audit, during normal business hours,

all records and accounts of JAGOTEC as may under recognised accounting practices contain information bearing upon the Price per Unit. Such audit shall be carried out at NITEC’s expense unless it reveals that a Price Per Unit quoted by JAGOTEC

to NITEC prior to the audit exceeded the Price per Unit calculated in accordance with this Agreement by […\*\*\*…] or more, in which case JAGOTEC shall, forthwith reimburse NITEC for the cost of audit and an amount equal to the

overpayment. </td></tr>

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<table><tbody><tr> <td>8.</td> <td>Minimum Commercial Yield </td></tr>

</tbody></table>

<p>JAGOTEC commits itself to attaining the Minimum Commercial Yield of the Product as set out in Annex 6 (or as may otherwise be amended on

the terms hereof). The Commercial Yield shall be calculated as follows: </p>

<p>(a +b)/c </p>

<p> </p>

<table><tbody><tr> <td> </td> <td>a    =</td> <td>number of units delivered by JAGOTEC </td></tr>

</tbody></table>

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<table><tbody><tr> <td> </td> <td>b    =</td> <td>number of sample units necessary for control purposes and retaining samples </td></tr>

</tbody></table>

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<table><tbody><tr> <td> </td> <td>c    =</td> <td>theoretical quantity of units per Batch of Product in bulk Tablets </td></tr>

</tbody></table>

<p>If the actual yield of Product, calculated for a maximum of one (1) year, is below the Minimum Commercial Yield, JAGOTEC shall reimburse NITEC for a proportionate amount of the cost of Active

Ingredient. </p>

<p>This Minimum Yield shall be reviewed annually to allow for possible improvements in the Manufacturing Process.

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<p> </p>

<table><tbody><tr> <td>9.</td> <td>Delivery Conditions: </td></tr>

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<p>JAGOTEC will deliver Product packaged and labelled in accordance with the Quality Agreement and the defined “Logistics” under

Annex 7. </p>

<p> </p>

<p>\*\*\*Confidential Treatment Requested </p>

<p>17. </p>

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<table><tbody><tr> <td>10.</td> <td>Term and Termination </td></tr>

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<p> </p>

<table><tbody><tr> <td>10.1</td> <td>According to the DLA this Agreement shall commence as of the Effective Date and shall continue in full force and effect until the end of the 5th year after First Launch

(“Minimum Term”). It shall be automatically extended on a yearly basis unless terminated by one Party by giving to the other at least (subject to the Section 10.2 below) twenty four (24) months’ written notice to

expire not before the end of the Minimum Term. </td></tr>

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<table><tbody><tr> <td>10.2</td> <td>In the event of the payment of Major Capital Expenditure the notice period for any termination by either party to occur within […\*\*\*…] years of such

Major Capital Expenditure shall be […\*\*\*…] months. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>10.3</td> <td>Notwithstanding anything contained in Section 10.1 above, and except as otherwise explicitly provided in this Agreement, this Agreement may be terminated at any

time with immediate effect by giving written notice to that effect, as follows: </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td> </td> <td>a)</td> <td>by either Party, if the other Party is materially in default or in material breach of a term or provision hereof and such default or breach continues “and” if

curable, is not cured or remedied within […\*\*\*…] upon the other Party’s written request to cure or remedy such default or breach; or </td></tr>

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<table><tbody><tr> <td> </td> <td>b)</td> <td>by either Party, if the other Party becomes insolvent or goes into liquidation, voluntarily or otherwise, other than for the sole purpose of reorganisation, or goes

into bankruptcy or makes an assignment for the benefit of creditors, or in the event of a receiver being appointed of the other Party’s property or parts thereof. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>10.4</td> <td>Upon the termination or expiry of this Agreement, regardless of the reason therefor, JAGOTEC shall at NITEC’s written request continue the supply of Product to

NITEC until such time as NITEC has an alternative manufacturing site approved by appropriate Regulatory Authorities for the supply of Product save that it shall be under no obligation to continue such supply for a period exceeding 24 months from the

date of such termination notice. Upon notice of termination or expiry, NITEC shall seek such an alternative manufacturing site with reasonable speed and JAGOTEC shall provide Technical Support to NITEC in relation to technical transfer issues

relating to Product to the alternative manufacturing site chosen by NITEC. If this Agreement is terminated by NITEC for JAGOTEC’s breach of this Agreement, the costs of the Technical Support shall be born by JAGOTEC. In all other circumstances

the costs of the Technical Support shall be borne by NITEC. </td></tr>

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<p>\*\*\*Confidential Treatment Requested </p>

<p>18. </p>

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<table><tbody><tr> <td>11.</td> <td>Effects of Termination </td></tr>

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<p> </p>

<table><tbody><tr> <td>11.1</td> <td>In the event of termination or expiry of this Agreement by either Party, no compensation or indemnity shall be payable to or may be claimed by either Party from the

other Party as a result of such termination other than as set forth in this Agreement. Notwithstanding the preceding sentence, the termination of this Agreement by either Party shall not relieve the Parties of any obligation accruing prior to the

effective date of such termination. </td></tr>

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<p> </p>

<table><tbody><tr> <td>11.2</td> <td>In the event of termination of this Agreement by JAGOTEC under Section 10.2 above, NITEC shall, upon JAGOTEC’s request together with the respective

termination notice take also delivery of any and all Auxiliary Materials in stock and firmly ordered by JAGOTEC on the basis NITEC’s Forecast against payment of the net procurement price for such Auxiliary Materials paid by JAGOTEC to third

party suppliers (plus Value Added Tax, turnover tax or similar charges, as applicable). All such Auxiliary Material and Active Ingredient shall be collected by NITEC from the Manufacturing Site. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>11.3</td> <td>The Parties agree that in the event of termination of this Agreement for whatsoever reason, Sections 11, 12, 13 and 17 shall remain in full force and effect in

accordance with such respective provisions. </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td>11.4</td> <td>Except as otherwise explicitly provided in this Agreement, nothing contained in this Section 10 shall in any way limit, and shall be without any prejudice to, any

other rights or remedies which may be available to either Party. </td></tr>

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<table><tbody><tr> <td>12.</td> <td>Indemnity and Insurance </td></tr>

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<p> </p>

<table><tbody><tr> <td>12.1</td> <td>JAGOTEC does not assume any liability or gives any representation or warranty, whether express nor implied, for the merchantability or fitness for a particular purpose

of Product or Finished Product manufactured and/or supplied hereunder except to the extent that such liability arise from the gross negligence or wilful misconduct of JAGOTEC, its Affiliates or any of its or their respective employees.

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<table><tbody><tr> <td>12.2</td> <td>In no event shall JAGOTEC be liable for any direct, indirect, incidental, commercial or other damage, costs, fees, expenses or costs (“Damages”) caused

by Product and/or the Active Ingredient and/or the Auxiliary Materials to NITEC or any third party except to the extent that such Damages arise from the negligence or wilful misconduct of JAGOTEC, its Affiliates or any of its or their respective

employees. </td></tr>

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<p> </p>

<table><tbody><tr> <td>12.3</td> <td> <p>JAGOTEC assumes no liability vis a vis third parties, including without limitation, product liability, with respect to any and all Product or Finished

Product marketed, distributed, sold or used, directly or indirectly, and the </p>

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<p>19. </p>

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Active Ingredient and Auxiliary Materials contained in any such Product or Finished Product. NITEC shall indemnify JAGOTEC from and against any and all losses, liabilities, damages and expenses

(including reasonable attorney’s fees and reasonable costs) that JAGOTEC suffers as a result of any claim, demand, action or other proceeding by any third party arising from or relating to NITEC’s actions regarding the manufacturing,

marketing, distribution, safe or use of Product, the Active Ingredient and/or Auxiliary Materials and/or Finished Product, or resulting from any breach of any of NITEC’s obligations and/or responsibilities and/or representations and warranties

hereunder, except to the extent that any such losses, liabilities, damages and expenses arise from the gross negligence or wilful misconduct of JAGOTEC. </p>

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<table><tbody><tr> <td>12.4</td> <td>Each of NITEC and JAGOTEC shall maintain, during the term of this Agreement and for a period of not less than five (5) years after its termination for what so ever

reason, liability insurance, including in the case of NITEC, product liability insurance, with respect to and covering their respective obligations contained in this Section 12, in such amount as is customary for companies undertaking similar

activities as the respective Party with products similar to Product. </td></tr>

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<table><tbody><tr> <td>13.</td> <td>Confidentiality </td></tr>

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<p> </p>

<table><tbody><tr> <td>13.1</td> <td>Each Party has disclosed to the other party prior to the Effective Date, and will during the term of this Agreement continue to disclose, proprietary, confidential and

non-public information, including without limitation the Manufacturing Process, price calculations and other business and trade secrets (hereinafter, all collectively referred to as “Confidential Information”). </td></tr>

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<table><tbody><tr> <td>13.2</td> <td>Each Party as recipient (the “Receiving Party”) of Confidential Information of the other Party (the “Disclosing Party”) hereby undertakes to

maintain in confidence all Confidential Information of the Disclosing Party and shall not use, disclose or grant or permit the use of any of the Confidential Information of the Disclosing Party except on a need-to-know basis to its directors,

officers, employees, agents, consultants, clinical investigators or other permitted contractors, to the extent such disclosure is reasonably necessary in connection with the activities of the Receiving Party as expressly authorized by this

Agreement. To the extent that disclosure is authorized by this Agreement, prior to disclosure, the Receiving Party shall obtain agreement in writing of any such person to hold in confidence and not make use of the Confidential Information of the

Disclosing Party for any purpose other than authorized by this Agreement. Each Receiving Party shall notify the Disclosing Party promptly upon the discovery of the unauthorized use or disclosure of any such Confidential Information of the Disclosing

Party. </td></tr>

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<table><tbody><tr> <td>13.3</td> <td> <p>The obligations of confidentiality and non-use contained in Section 13.2 above shall not apply to the extent that (a) a Receiving Party

(i) is required to </p>

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<p>20. </p>

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disclose the Confidential Information by law, regulation or order of a governmental agency or a court of competent jurisdiction, or (ii) is required to disclose Confidential Information of

the Disclosing Party to any Regulatory Authority for purposes of obtaining or maintaining registration for Product and/or Finished Product, provided that the Receiving Party shall request confidential treatment thereof (where available), or

(b) the Receiving Party can demonstrate by written or other tangible evidence that (i) the disclosed information of the Disclosing Party was public knowledge at the time of such disclosure to it, or thereafter became public knowledge,

other than as a result of actions of the Receiving Party, its directors, officers and employees in violation hereof; or (ii) the disclosed information was rightfully known by the Receiving Party (as shown by its written records) prior to the

date of disclosure to it by the Disclosing Party; or (iii) the disclosed information was developed or acquired by the Receiving Party independently of any knowledge or use of the Confidential Information of the Disclosing Party (as shown by its

written records); or (iv) the Confidential Information was previously legally provided to the Receiving Party by a third party without any obligations of confidentiality to the Disclosing Party. </p>

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<table><tbody><tr> <td>13.4</td> <td>The confidentiality obligations under this Section 13 shall be effective during the term of this Agreement and for a period of ten (10) years after the

termination hereof for any reason. Each Disclosing Party shall be entitled to injunctive remedies and relief against the Receiving Party and any third parties for any breach or threatened breach of the confidentiality obligations under this

Section 13 with respect to any of the Confidential Information of the Disclosing Party. </td></tr>

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<table><tbody><tr> <td>14.</td> <td>Exclusivity </td></tr>

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<p>During the

term of this Agreement, JAGOTEC undertakes (a) not to engage in any production of Product for or on behalf of any third party and (b) to supply to NITEC all of NITEC requirements for the Product subject to the terms hereof. NITEC agrees to

order all its requirements for the Product from JAGOTEC (save as is otherwise provided herein). </p>

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<table><tbody><tr> <td>15.</td> <td>Miscellaneous Provisions </td></tr>

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<p> </p>

<table><tbody><tr> <td>15.1</td> <td> <p>Entire Agreement: The terms, covenants, conditions and provisions contained in this Agreement, including the Annexes referred to herein which

are agreed to form an integral part hereof, constitute the total and complete agreement of the Parties regarding the subject matter hereof and supersede all prior understandings and agreements hereto made, and there are no other representations,

understandings or agreements relating to the subject matter hereof. The provisions of this Agreement may not be waived, altered, amended </p>

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<p>21. </p>

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or repealed in whole or in part except by the written consent of both of the Parties to this Agreement. </p>

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<table><tbody><tr> <td>15.2</td> <td>Assignment: Save as set out below, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or

transferred by either Party without the prior written consent of the other Party. Either Party may assign in full all its rights and obligations hereunder to an Affiliate of that party (and only for so long as the assignee remains an Affiliate) and

if the assigning party remains fully liable to the other party for the full and timely performance of this Agreement by the party receiving assignment and any of such parties direct or indirect successors in interest. </td></tr>

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<p>Any permitted assignee shall assume all obligations of its assignor under this Agreement or under the respective rights or obligations

actually assigned. </p>

<p> </p>

<table><tbody><tr> <td>15.3</td> <td>Notices: Any consent, notice or report required or permitted to be given or made under this Agreement by one Party to the other shall be in English and in

writing, delivered personally or by international courier service or by facsimile (promptly confirmed by personal delivery or international courier service) addressed to the other Party at its address indicated below, or to such other address as

shall have been notified in writing to the sending Party by the receiving Party from time to time, and shall take effect upon receipt by the addressee. </td></tr>

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<tr> <td>If to NITEC:</td> <td>  </td> <td>NITEC PHARMA AG</td></tr>

<tr> <td></td> <td>  </td> <td>Xxxxxxxxxxxx 0</td></tr>

<tr> <td></td> <td>  </td> <td>XX 0000 Xxxxxxx</td></tr>

<tr> <td></td> <td>  </td> <td>Xxxxxxxxxxx</td></tr>

<tr> <td></td> <td>  </td> <td>attn.: Xxxxxx Xxxxxx</td></tr>

<tr> <td></td> <td>  </td> <td>Tel: xx 00 00 000.00.00</td></tr>

<tr> <td></td> <td>  </td> <td>Fax: xx 00 00 000.00.00</td></tr>

<tr> <td></td> <td>  </td> <td>Email: xxxxxx.xxxxxx@xxxxxxxxxxx.xxx</td></tr>

<tr> <td></td> <td></td></tr>

<tr> <td>If to JAGOTEC:</td> <td>  </td> <td>JAGOTEC AG</td></tr>

<tr> <td></td> <td>  </td> <td>Xxxxxxxxxxxxxxx 00</td></tr>

<tr> <td></td> <td>  </td> <td>XX-0000 Xxxxxxx,</td></tr>

<tr> <td></td> <td>  </td> <td>Xxxxxxxxxxx</td></tr>

<tr> <td></td> <td>  </td> <td>attn.: Xxxxxxxxx Xxxxxxxx</td></tr>

<tr> <td></td> <td>  </td> <td>Fax No: xx00 00 000 00 00</td></tr>

<tr> <td></td> <td></td></tr>

<tr> <td>With copy to:</td> <td>  </td> <td>SkyePharma Plc</td></tr>

<tr> <td></td> <td>  </td> <td>000 Xxxxxxxxxx</td></tr>

<tr> <td></td> <td>  </td> <td>Xxxxxx X0X 0XX</td></tr>

<tr> <td></td> <td>  </td> <td>Xxxxx Xxxxxxx</td></tr>

<tr> <td></td> <td>  </td> <td>attn.: Group Counsel</td></tr>

<tr> <td></td> <td>  </td> <td>Fax No: xx00 00 0000 0000</td></tr>

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<table><tbody><tr> <td>15.4</td> <td> <p>Independent Contractors: It is expressly agreed that the Parties shall be independent contractors and that the relationship between the Parties

shall not </p>

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<p>22. </p>

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constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be

binding on the other Party, without the prior written consent of the other Party to do so. </p>

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<table><tbody><tr> <td>15.5</td> <td>NITEC warranty: NITEC warrants that it owns one hundred percent of the shares of Nitec Pharma GmbH. </td></tr>

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<table><tbody><tr> <td>15.6</td> <td>Severability: Each Party hereby acknowledges that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or

decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties hereto shall substitute, by mutual consent, valid

provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid

provisions. </td></tr>

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<table><tbody><tr> <td>15.7</td> <td>Force Majeure: Neither Party hereto shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for

failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including but not limited to fire, floods, embargoes, war,

acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labour disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party hereto.

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<table><tbody><tr> <td>15.8</td> <td>Headings: The titles and headings used in this Agreement are intended for convenience only and shall not in any way affect the meaning or construction of any

provision of this Agreement. </td></tr>

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<table><tbody><tr> <td>15.9</td> <td>Waiver: The waiver by either Party hereto of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any

other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise. </td></tr>

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<table><tbody><tr> <td>16.</td> <td>Dispute Resolution and Jurisdiction </td></tr>

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<table><tbody><tr> <td>16.1</td> <td>In the event of any dispute arising between the Parties concerning this Agreement, the Parties agree that in the first place they shall meet for good faith discussions

in an attempt to negotiate an amicable solution. </td></tr>

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<table><tbody><tr> <td>16.2</td> <td> <p>For any dispute arising between the Parties out of or in connection with this Agreement, or the interpretation, breach or enforcement thereof, which

cannot be amicably resolved pursuant to Section 16.1 above within two (2) months as from the first appearance of such dispute, the Parties agree and irrevocably </p>

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<p>23. </p>

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submit to arbitration under the Rules of Arbitration of the International Chamber of Commerce (the “Rules”) by three (3) arbitrators appointed in accordance with the Rules. The

seat of arbitration shall be Basel, Switzerland, and any such arbitration shall be conducted in the English language. Any judgment upon the award rendered by the arbitrators shall be final and binding upon the parties and may be entered in any court

having jurisdiction thereof. </p>

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<table><tbody><tr> <td>16.3</td> <td>Notwithstanding anything contained in this Section 16, either Party may seek preliminary or injunctive measures or relief in any competent court having

jurisdiction. </td></tr>

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<table><tbody><tr> <td>17.</td> <td>Applicable Law </td></tr>

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<p>The

Parties hereto agree that this Agreement shall be construed under and be governed by the laws of Switzerland, without reference to the principles of conflict of laws thereof, and shall not be governed by the United Nations Convention on Contracts

for the International Sale of Goods (the Vienna Convention of April 11, 1980). </p>

<p>IN WITNESS WHEREOF, the Parties have executed this

Agreement effective as of the Effective Date. </p>

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<table><tbody><tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td></tr>

<tr> <td> <p>For and on behalf of</p>

<p>JAGOTEC AG</p>

</td> <td> </td> <td></td> <td> </td> <td></td> <td> </td> <td></td></tr>

<tr> <td></td> <td></td> <td></td></tr>

<tr> <td> <p>/s/ Xxxxxxxxx XXXXXXXX</p>

</td> <td> </td> <td></td> <td> </td> <td> <p>[Illegible Signature]</p>

</td></tr>

<tr> <td>by:</td> <td> </td> <td>Xxxxxxxxx XXXXXXXX</td> <td> </td> <td></td> <td> </td> <td>by:</td> <td> </td> <td></td></tr>

<tr> <td>its:</td> <td> </td> <td>Director ,3 Aug 07</td> <td> </td> <td></td> <td> </td> <td>its:</td> <td> </td> <td>Director 3 Aug 07</td></tr>

<tr> <td></td> <td></td> <td></td> <td></td></tr>

<tr> <td> <p>For and on behalf of</p>

<p>NITEC PHARMA AG</p>

</td> <td> </td> <td></td> <td> </td> <td></td> <td> </td> <td></td></tr>

<tr> <td></td> <td></td> <td></td></tr>

<tr> <td> <p>/s/ Xxxxxx Xxxxxx 3.8.07</p>

</td> <td> </td> <td></td> <td> </td> <td> <p>3 Aug 2007 /s/ Xx. Xxxxx Xxxxxxxxx</p>

</td></tr>

<tr> <td>by:</td> <td> </td> <td>Xxxxxx Xxxxxx</td> <td> </td> <td></td> <td> </td> <td>by:</td> <td> </td> <td>Xx. Xxxxx Xxxxxxxxx</td></tr>

<tr> <td>its:</td> <td> </td> <td>Managing Director</td> <td> </td> <td></td> <td> </td> <td>its:</td> <td> </td> <td>EVP RD and Manufacturing</td></tr>

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<p>24. </p>

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<p>List of Annexes: </p>

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<tr> <td>Annex 1:</td> <td> </td> <td>Presentations</td></tr>

<tr> <td></td> <td></td></tr>

<tr> <td>Annex 2:</td> <td> </td> <td>Specifications</td></tr>

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<tr> <td>Annex 2a:</td> <td> </td> <td>Shelf Life Period</td></tr>

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<tr> <td>Annex 3:</td> <td> </td> <td>Minimum Orders</td></tr>

<tr> <td></td> <td></td></tr>

<tr> <td>Annex 4:</td> <td> </td> <td>Prices</td></tr>

<tr> <td></td> <td></td></tr>

<tr> <td>Annex 5:</td> <td> </td> <td>Quality Agreement</td></tr>

<tr> <td></td> <td></td></tr>

<tr> <td>Annex 6:</td> <td> </td> <td>Commercial Yield</td></tr>

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<tr> <td>Annex 7:</td> <td> </td> <td>Logistics</td></tr>

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<tr> <td>Annex 8:</td> <td> </td> <td>Hygiene, Safety and Working conditions and Protection of the environment</td></tr>

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<tr> <td>Annex 9:</td> <td> </td> <td>Initial Members of the Committee</td></tr>

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<tr> <td>Annex 10:</td> <td> </td> <td>Statement of Storage Conditions</td></tr>

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<p>25. </p>

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<p>MANUFACTURING &amp; SUPPLY AGREEMENT </p>

<p>BETWEEN NITEC and JAGOTEC </p>

<p>Annex 1 </p>

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<tr> <td>PRESENTATION </td> <td> </td> <td></td> <td> </td> <td></td> <td> </td> <td></td> <td> </td> <td></td> <td> </td> <td></td></tr>

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<table><tbody><tr> <td>–</td> <td>Lodotra </td></tr>

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<table><tbody><tr> <td>–</td> <td>DOSAGE : 1,2,5 mg </td></tr>

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<table><tbody><tr> <td>–</td> <td>Bulk tablets stored 30 L plastic drum </td></tr>

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<p>MANUFACTURING &amp; SUPPLY AGREEMENT </p>

<p>BETWEEN NITEC and JAGOTEC </p>

<p>Annex 2a </p>

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<table><tbody><tr> <td></td></tr>

<tr> <td>Shelf Life Period</td></tr>

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<p>[…\*\*\*…] </p>

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<p>\*\*\*Confidential Treatment Requested </p>

<p>27. </p>

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</p>

<p>MANUFACTURING &amp; SUPPLY AGREEMENT </p>

<p>BETWEEN NITEC and JAGOTEC </p>

<p>Annex 2 </p>

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<table><tbody><tr> <td></td></tr>

<tr> <td>Specifications</td></tr>

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<p>\*\*\*Confidential Treatment Requested </p>

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<tr> <td>[…\*\*\*…]</td> <td>  </td> <td>[…\*\*\*…]</td> <td>  </td> <td></td> <td>  </td> <td></td></tr>

<tr> <td> <p>[…\*\*\*…]</p>

</td> <td>  </td> <td>[…\*\*\*…]</td> <td>  </td> <td>[…\*\*\*…]</td> <td>  </td> <td>[…\*\*\*…]</td></tr>

<tr> <td> <p>[…\*\*\*…]</p>

</td> <td>  </td> <td>[…\*\*\*…]</td> <td>  </td> <td></td> <td>  </td> <td></td></tr>

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<p>\*\*\*Confidential Treatment Requested </p>

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<table><tbody><tr> <td></td> <td></td> <td></td></tr>

<tr> <td>[…\*\*…]</td> <td> </td> <td>[…\*\*\*…]</td></tr>

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<p> </p>

<p>\*\*\*Confidential Treatment Requested </p>

<p>30. </p>

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<p>MANUFACTURING &amp; SUPPLY AGREEMENT </p>

<p>BETWEEN NITEC and JAGOTEC </p>

<p>Annex 3 </p>

<p> </p>

<table><tbody><tr> <td></td></tr>

<tr> <td>MINIMUM ORDERS- for the 1st calendar year after Product approval and launch in the first Major Country</td></tr>

</tbody></table>

<p>[…\*\*\*…] </p>

<p> </p>

<table><tbody><tr> <td></td></tr>

<tr> <td>MINIMUM ORDERS- starting from the second calendar year after Product approval and launch in 3 out of 5 Major

Countries</td></tr>

</tbody></table>

<p>[…\*\*\*…] </p>

<p> </p>

<p>\*\*\*Confidential Treatment Requested </p>

<p>31. </p>

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<p>MANUFACTURING &amp; SUPPLY AGREEMENT </p>

<p>BETWEEN NITEC and JAGOTEC </p>

<p>Annex 4 </p>

<p> </p>

<table><tbody><tr> <td></td></tr>

<tr> <td> <p>PRICES</p>

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<p> </p>

<table><tbody><tr> <td>1.</td> <td>The following prices relate to the packaged Product delivered Ex Works by JAGOTEC </td></tr>

</tbody></table>

<p>                […\*\*\*…] </p>

<p> </p>

<p> </p>

<table><tbody><tr> <td>2.</td> <td>Payment shall be made in Euros by bank transfer within […\*\*\*…] of the invoice date, unless otherwise agreed between the parties. Bank transfer shall be made

to such account as Jagotec shall notify to Nitec. </td></tr>

</tbody></table>

<p> </p>

<p>\*\*\*Confidential Treatment Requested </p>

<p>32. </p>

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<p>MANUFACTURING &amp; SUPPLY AGREEMENT </p>

<p>BETWEEN NITEC and JAGOTEC </p>

<p>Annex 5 </p>

<p> </p>

<table><tbody><tr> <td></td></tr>

<tr> <td> <p>QUALITY

AGREEMENT</p>

</td></tr>

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<p>A Quality Agreement will be signed at the latest after manufacturing of the first campaign of the Product.

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<p>MANUFACTURING &amp; SUPPLY AGREEMENT </p>

<p>BETWEEN NITEC and JAGOTEC </p>

<p>Annex 6 </p>

<p> </p>

<table><tbody><tr> <td></td></tr>

<tr> <td>MINIMUM COMMERCIAL YIELD</td></tr>

</tbody></table>

<p>For active ingredient ordered by JAGOTEC on behalf of NITEC, the minimum commercial yield is as follows: </p>

<p> </p>

<table><tbody><tr> <td></td></tr>

<tr> <td>[…\*\*\*…]            </td></tr>

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<p>composed of yield […\*\*\*…] </p>

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<p>\*\*\*Confidential Treatment Requested </p>

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<p>MANUFACTURING &amp; SUPPLY AGREEMENT </p>

<p>BETWEEN NITEC and JAGOTEC </p>

<p>Annex 7 </p>

<p>Distribution Specifications </p>

<p> </p>

<table><tbody><tr> <td></td></tr>

<tr> <td>LOGISTICS</td></tr>

</tbody></table>

<p>Introduction: </p>

<p>In order to facilitate transfer, storage, distribution and shipment of

products which are the subject of the present contract, the following recommendations must be applied as from delivery of the first batch, failing this, JAGOTEC undertakes to apply these recommendations within a period agreed with NITEC. </p>

<p>1 - Packaging: </p>

<p>Tablets of Product are

packed as bulk tablets for shipment in containers of 20(±3) kg in drums with PE in-liner. The packaging material is defined in the Quality Agreement. For printing batch number and the expiration date ink based technique must be used instead

of embossing which is less readable. </p>

<p>2 - Grouping cartons: </p>

<p>The quantity shall be defined in the Quality Agreement (see annex 5). </p>

<p>This quantity will be

defined by NITEC in agreement with JAGOTEC. </p>

<p>Identification of each drum will be carried out according to the provisions in the Quality

Agreement (see annex 5). </p>

<p>3 - Pallets: </p>

<p>Type 1’200 x 800, five tiers, total high including pallet must not exceed 1’250 mm. </p>

<p>Any variation from this norm must be agreed in writing by NITEC. </p>

<p>Consigned pallets are not accepted. NITEC can supply pallets to JAGOTEC if necessary. </p>

<p>It is

recommended to identify each pallet with similar label to those stuck on the drums. </p>

<p>Pallets will be wrapped in a transparent film. A cover

must be placed on incomplete pallets before wrapping. </p>

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<p>4 - Transport: </p>

<p>If product delivery to NITEC is paid by JAGOTEC, it must use a carrier agreed by itself and only use sheet metal trailers. The carrier must be designed for transporting medicines. </p>

<p>Documents necessary for a good reception must be joined: delivery notes, analysis certificates… </p>

<p>JAGOTEC shall inform NITEC and NITEC’s partner for packaging by fax of all details concerning the load as soon as possible before the truck

departure. </p>

<p>5 - Modifications: </p>

<p>Any modifications of points one to four above must be agreed by NITEC Distribution. At the very least the NITEC Distribution must be informed at the time

of the start up of the first Batch concerned, if it relates to a modification of regulations. </p>

<p>Each pallet of the modified first Batch must

undergo a supplementary special identification mentioning the type of modification. </p>

<p>6 - Detailed log book: </p>

<p>NITEC can provide by simple request JAGOTEC a detailed log book. </p>

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<p>MANUFACTURING &amp; SUPPLY AGREEMENT </p>

<p>BETWEEN NITEC and JAGOTEC </p>

<p>Annex 8 </p>

<p>Hygiene, Safety and Working conditions and Protection of

the environment </p>

<p> </p>

<table><tbody><tr> <td>1.</td> <td>Hygiene, Safety and Working conditions: </td></tr>

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<p> </p>

<table><tbody><tr> <td>1.1</td> <td>JAGOTEC is held to know all the relevant legislative, regulatory or conventional requirements relating to hygiene, safety and working conditions, which it is required

to satisfy by reason of its activities hereunder. It undertakes to comply strictly with these at all times with regard to the provisions foreseen in the present contract. </td></tr>

</tbody></table>

<p>To this effect, JAGOTEC declares that it has received from NITEC the information which the latter has available concerning: </p>

<p> </p>

<table><tbody><tr> <td> </td> <td>–</td> <td>The particular hazards of the Active Ingredient or preparations thereof which are the subject of the present contract, as well as the procedures necessary for their use

or their manufacture </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td> </td> <td>–</td> <td>The provisions to take to provide against these hazards, notably the particular precautions necessary to take with regard to handling, use and, should the case arise,

storage </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td> </td> <td>–</td> <td>The rules for packaging and labelling which are applicable to them </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td> </td> <td>–</td> <td>The action to take in case of an accident </td></tr>

</tbody></table>

<p>This information is founded on existing scientific and technical knowledge, to which NITEC may have had reasonable access. </p>

<p> </p>

<table><tbody><tr> <td>1.2</td> <td>JAGOTEC must, with the least delay and by all means at its disposal, keep NITEC informed of: </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td> </td> <td>–</td> <td>All incidents or accidents occurring on the occasion of carrying out the provisions foreseen in the present contract, which causes harm to, or may cause harm to the

health and safety of workers </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td> </td> <td>–</td> <td>The emergency measures which, should the case arise, have been taken by itself or by the competent administrative authority </td></tr>

</tbody></table>

<p>According to the same terms JAGOTEC will bring to the knowledge of NITEC: </p>

<p>All new facts in its actual knowledge concerning: </p>

<p> </p>

<p>37. </p>

<p>

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<table><tbody><tr> <td> </td> <td>–</td> <td>the hazardous properties of substances or dangerous preparations which are the subject of the present contract, which result from the improvement of scientific or

technical understanding, or result from the observation of the effects of these products on the health of workers or the environment; </td></tr>

</tbody></table>

<p> </p>

<table><tbody><tr> <td> </td> <td>–</td> <td>The possible modification of physicochemical or toxicological properties of these same substances or preparations, by reason notably of a change in the nature or

concentration of the impurities which they contain; </td></tr>

</tbody></table>

<p>in each case having applied reasonable care to become aware

of developments and changes to the same. </p>

<p>In a reciprocal fashion NITEC will, with the least delay and by all means at its

disposal bring to the knowledge of JAGOTEC all information of the same type of which comes to be in possession </p>

<p> </p>

<table><tbody><tr> <td>1.3</td> <td>The parties will meet as often as necessary to examine together the conditions, and possibly the difficulties in the application of: </td></tr>

</tbody></table>

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<table><tbody><tr> <td> </td> <td>–</td> <td>The legislative, regulatory or conventional dispositions relating to hygiene, safety and working conditions to which the provisions of the present contract are

subjected </td></tr>

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<p> </p>

<table><tbody><tr> <td> </td> <td>–</td> <td>The procedure for reciprocal exchange of information instituted in section 1.2 above </td></tr>

</tbody></table>

<p>Furthermore, each party will have the right to request of the other the holding of an ad hoc technical meeting in order to resolve all

questions that particularly relate to hygiene or to industrial safety, or to deal with an emergency situation, whatever the cause. The date and duration of this ad hoc technical meeting will be agreed jointly. </p>

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<table><tbody><tr> <td>2.</td> <td>Protection of the environment </td></tr>

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<table><tbody><tr> <td>2.1</td> <td>JAGOTEC recognises expressly that, in order to have been duly authorised by the competent administrative authority or to have been so declared to it, all the

installations necessary for the execution of the provisions foreseen in the present contract comply with the legislative or regulatory dispositions to which they are subject with regard to the protection of the environment. </td></tr>

</tbody></table>

<p>In consequence, it undertakes to maintain this situation during the full duration of the contract and to be in a position to justify this

at any time to NITEC. </p>

<p> </p>

<table><tbody><tr> <td>2.2</td> <td>JAGOTEC will comply strictly, for all the provisions foreseen in the present contract, with all the legislative or regulatory dispositions relating to the disposal of

waste, the term “disposal” describing the operations of collection, transport, storage, sorting and treatment so as to avoid all harm to the environment, including in the long term. </td></tr>

</tbody></table>

<p>In particular JAGOTEC undertakes that it will ensure or get assurance that the waste which results from the provisions foreseen in the

present contract is treated only in installations duly authorised or accepted to this effect by the </p>

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competent administrative authority. It will be in a position to justify this at any time to NITEC. </p>

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<p>ANNEX 9

</p>

<p>INITIAL MEMBERS OF THE COMMITTEE </p>

<p>NITEC </p>

<p>Xxxxx Xxxxxxxxx </p>

<p>Xxxxxx Xxxxxx </p>

<p>JAGOTEC </p>

<p>Xxx Xxxxxxxxxx </p>

<p>Xxxx-Xxxx Xxxxxxxxx </p>

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<p>\*\*\*Confidential Treatment Requested </p>

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<p>ANNEX 10 </p>

<p>Statement on the storage condition of Lodotra® tablets </p>

<p>This statement clarifies the requirements of temperature-sensitive materials involved in the production of Lodotra bulk tablets (manufacturing site: SkyePharma Production SAS, France), with regard to

in-house storage and handling and shall prevail over any contrary provision in this Agreement </p>

<p>For all batches of Product manufactured up to

September 2007, the agreed storage conditions are and shall be at room temperature in accordance with USP. </p>

<p>For all batches of Product

manufactured after September 2007, the nominal storage condition of temperature-sensitive materials, i.e. </p>

<p>–

[…\*\*\*…], </p>

<p>including samples of these materials (e.g. batch release samples), shall be between […\*\*\*…] Compliance with this

temperature range (subject to the following) has to be ensured continuously throughout the presence of the above mentioned materials at the manufacturing site (Monitoring). Proof of this compliance has to be provided by SkyePharma (e.g. temperature

curves). Deviations from the nominal temperature range always require written documentation. </p>

<p>After September 2007 the nominal storage

condition will not be exceeded by more than […\*\*\*…] </p>

<p>The exceptions in the foregoing paragraph do not render temperature monitoring

and documentation of deviations from the nominal storage condition unnecessary. Correspondingly, Certificates of Compliance have to be supplemented by deviation reports and temperature monitoring data, if deviations occur. </p>

<p>Nitec proposes the following measures to ensure and/or prove appropriate storage of the materials at the manufacturing site: </p>

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<table><tbody><tr> <td> </td> <td>–</td> <td>attachment of temperature loggers to the temperature-sensitive materials </td></tr>

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<table><tbody><tr> <td> </td> <td>–</td> <td>use of mobile (validated) temperature container for storage </td></tr>

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<p>\*\*\*Confidential Treatment Requested </p>

<p>41. </p>