#### MANUFACTURING CONTRACT

By and Among

**AVICANNA LATAM S.A.S.** 

**AVICANNA INC.** 

And

ALTEA FARMACÉUTICA S.A.

Date: December 11, 2018



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#### MANUFACTURING CONTRACT

Manufacturing Contract (the "Contract"), dated December 11, 2018 (Execution Date), entered into by and between the following parties:

- (i) AVICANNA LATAM S.A.S., a company incorporated and existing under the laws of the Republic of Colombia, domiciled in Santa Marta, Colombia ("Avicanna"), identified by the tributary number identification No. represented for purposes of this Contract by Lucas Nosiglia, acting in his capacity as legal representative, pursuant to the Certificate of Existence and Legal Representation issued by the Chamber of Commerce of Bogotá, enclosed hereto as Annex A, duly authorized by Avicanna's Board of Directors; and is a fully approved Affiliate of Avicanna Inc., a company incorporated under the laws of Ontario, Canada, based in Toronto, Canada;,
- (ii) AVICANNA INC., a company incorporated and existing in accordance with the laws of Canada, domiciled in 510 King Street East, Suite 323, Toronto, Ontario, Canada M5A 1M1, duly represented by Setu Nimish Purohit, of legal age, identified as it appears next to his signature, acting in his capacity as General Counsel, as evidenced in the documents attached hereto as Annex I, ("Avicanna Inc."); and
- (iii) Altea Farmacéutica S.A., a company incorporated and existing under the laws of Colombia, domiciled in Bogotá D.C. ("Altea" or the "Manufacturer"), identified by de tributary number identification No. represented for purposes of this Contract by Olga Lucía Cadena, acting in her capacity as legal representative, pursuant to the Certificate of Existence and Legal Representation issued by the Chamber of Commerce of Bogotá, enclosed hereto as Annex 2, duly authorized by Altea Farmacéutica's Board of Directors.

Herein, Avicanna and Altea will be individually referred to as a "Party" and, collectively, as the "Parties".

#### **RECITALS**

1. Whereas Avicanna Inc. has developed the Products (as defined hereunder) and owns the Intellectual Property (as defined hereunder) thereof.



- 2. Whereas Avicanna Inc. is the owner of the Intellectual Property related to the Products.
- Whereas Avicanna is registered as the owner in trust, seller, and manufacturer under the Products'
  marketing authorizations, granted by INVIMA (as defined hereunder) or certain authorities in the
  markets where Avicanna exports its products.
- 4. Whereas SMGH (as defined hereunder) is the owner of all the permitted licenses for medical cannabis, under Colombian law.
- 5. Whereas Altea has the capacity and experience necessary to manufacture the Products for Avicanna.
- 6. Whereas Avicanna wishes to engage Altea to manufacture the Products and Altea agrees to manufacture the Products pursuant to such terms and conditions.
- 7. Whereas Altea has the necessary Governmental Approval (as defined hereunder) required to comply with this Contract.

THEREFORE, the Parties hereby agree as follows:

#### 1. DEFINITIONS

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Unless otherwise expressly stated or required given the context, the words and expressions below, whenever used in this Contract, including this first clause, shall have the meanings attributed thereto by the parties, as follows:

- 1.1 ACC: means the Arbitration and Conciliation Center of the Chamber of Commerce of Bogotá;
- 1.2 Additional Period: has the definition assigned in clause 2.1.3;
- 1.3 Affiliate: means, with respect to each Party, any corporation, company, partnership, or other legal entity directly or indirectly controlled by, controlling, or is under common control with such Party. For purposes of this definition, control means, with respect to such entity, the direct or indirect ownership of more than fifty percent (50%) of the interest with voting rights in such entity or the power to, directly or indirectly, direct such entity's management or policies;
- 1.4 Altea (or the Manufacturer): means Altea Farmacéutica S.A., a company incorporated under the laws of Colombia;
- 1.5 Annex: means an additional document to the body of this Contract and that is an integral part of it;
- 1.6 Avicanna: means Avicanna LATAM S.A.S., a company incorporated under the laws of Colombia;
- 1.7 Avicanna Materials: means the raw materials (active ingredients and excipients) and bulk product, established in Annex 3; delivered by SMGH to Avicanna before its delivery to Altea.
- 1.8 Binding Forecast: has the definition assigned in clause 5.1.1;
- 1.9 Business Days: means Mondays through Fridays, except holidays in Colombia;



- **1.10 Certificate of Analysis:** means a document issued by a manufacturer verifying the adherence and compliance to product specifications and standards of production of the products manufacturing process, it includes the actual test results performed on the product batch.
- 1.11 Change of Control: has the meaning assigned in clause 18.3;
- 1.12 Chosen Address: means Calle 10 No. 65 28, Bogotá D.C., Colombia;
- 1.13 Confidential Information: means any information, whatever its nature (oral, written, electronic, or otherwise), including data, manufacturing processes and systems, Formulas, standard operating procedures, product samples, software techniques, procedures, financial statements, and unpublished information, licenses, prices, price lists, pricing policies, customers and suppliers lists, customers and suppliers names, and any other information related to customers and suppliers, marketing techniques and tactics, marketing development plans, and any other containing or consisting of technical, operational, administrative, economic, marketing, planning, business, or financial materials or that is an Intellectual Property, which a Party or any of its Affiliates discloses to the other Party and/or any employee or advisor contracted or designated by such other Party, respectively.
- 1.14 Consumption Report: This is a report prepared by Altea which details the amount of raw materials (materials, active ingredients, excipients, etc.) that have been used for manufacturing of Avicanna products at a defined point in time.
- **1.15 Contract:** means this Manufacturing Contract, including its Annexes and amendments, modifications, restatements, substitutions, or supplements made from time to time;
- 1.16 Control: has the meaning assigned in clause 18.3;
- 1.17 COP: means Colombian pesos;
- **1.18 Current GMP:** means the laws, rules, regulations, and guidelines applicable in Colombia that govern pharmaceutical products' good manufacturing practices and the World Health Organization's good manufacturing practices guidelines applicable to the Contract, as updated from time to time;
- **1.19 Current GMP Certificate:** means a legal document issued by a health authority, authorizing manufacturing operations in accordance with current GMP standards;
- 1.20 EUR: means Euros.
- 1.21 Execution Date: means this Contract's execution date;
- **1.22 Facilities:** means Altea's pharmaceutical production facilities, located at Calle 10 No. 65 28 and Calle 10 No. 65 75, Bogotá D.C., Colombia;
- **1.23 Finished Product:** means the Products subject matter of this Contract that has gone through all production and quality control stages and has been released for delivery to Avicanna.
- **1.24 Finished Product Specifications:** means the set of parameters describing the quality attributes that the finished product shall fulfill according to that registered with the relevant authority. These parameters are part of the document called Quality Specifications for Finished Product.
- 1.25 Forecast: has the definition assigned in clause 5.1.1;
- **1.26 Formula:** means the technical document provided by Avicanna, describing the product's composition in terms of its ingredients and their quantities;
- 1.27 Government Approval: means any approval, waiver, exemption, divergence, permit, authorization, license, registration, or similar approval by any government authority in Colombia or in the world, necessary for the Products' manufacturing, analysis, labeling, packing, storage, or transport;
- **1.28 Government Authority:** means any regulatory authority at the national, regional, departmental, district, or local level, as well as any other government entity, department, office, commission, council, in any part of the world.
- 1.29 Infringed Party: has the definition assigned in clause 19.1;
- 1.30 Infringing Party: has the definition assigned in clause 19.1;

- 1.31 Intellectual Property: means: (i) the copyrights, trademarks, trade secrets, patent rights, supplementary patent certificates, patent extensions, know-how, formulas, notions, Confidential Information, rights on databases and trademark rights, trade secrets and commercial designs (whether registered or not) Specifications, Finished Product Specifications, Formula, Product Technical Information, Products, Avicanna Materials, standard operating procedures and the Product Manufacturing Process; (ii) the applications for registration and the right to apply for registrations of any of them; (iii) any other intellectual property rights and equivalent or similar forms of protection, existing anywhere in the world; (iv) any improvement and invention in connection with the above and, in each case, associated or related to the Products; and any data or information that arises or results from this contract, including but not limited to the Certificate of Analysis
- **1.32 INVIMA:** means the *Instituto Nacional de Vigilancia de Medicamentos y Alimentos* (INVIMA) [National Institute for Drugs and Foods Monitoring] of Colombia;
- 1.33 Initial Period: has the definition assigned in clause 2.1.2;
- **1.34 Intermediate Product:** means the materials resulting from certain raw materials' transformation, which in turn will be later used to manufacture a Finished Product;
- **1.35 Market Withdrawal**: means any action by Avicanna to recover the title or possession or to prevent the distribution, prescription, consumption, or release of a Product sold or delivered to third parties.
- 1.36 Master Documents' Index: This is referred to the various technical documents (Products' formulas, methods of manufacturing, quality specification, analytical techniques, etc.) that are provided by Avicanna for Altea to follow and manufacture and perform quality testing on the products they manufacture for Avicanna.
- **1.37 Minimum Order Quantity (MOQ)**: means the requirement from the Manufacturer that specifies the lowest quantity of a certain product that a supplier is willing to produce on a single production batch.
- 1.38 Notice: has the definition assigned in clause 25.1;
- **1.39 Other Materials**: means any material or component used for the manufacturing, analysis, packaging, labeling, or storage of Products not included in the definition of Avicanna Materials.
- 1.40 Products: means the Products that are included in Annex 4;
- **1.41 Product Manufacturing Process:** Means the manufacturing process of the Products, according to the instructions provided by Avicanna.
- 1.42 Product's Technical Information: means all technical documents necessary for the Products' manufacturing, analysis, packaging, labeling, release, and storage. These technical documents are documents controlled, either by Avicanna or Altea and may be updated from time to time or whenever necessary. The Product's technical information consists of the manufacturing instructions, the finished product's analytical method, the active principle and excipients' analytical methods, the conditioning material's specifications, the package final designs, data for conditioning, list of materials (finished product) for each SKU, print sheet and marketing authorization. Such documents' management and control are described in Annex 6 (Technical Agreement);
- **1.43 Production Term:** means the delivery term required to manufacture each Product as established in such period in Annex 4;
- 1.44 Purchase Order: has the definition assigned in clause 5.2.1;
- **1.45 Purchase Order (PO)**: means a commercial document and first official request for production issued by Avicanna to Altea, indicating types, quantities, and agreed prices for products.
- 1.46 Recalled Product: means the Products subject to Market Withdrawal;
- 1.47 Release Notice: has the meaning assigned in clause 8.1
- 1.48 Requested Delivery Date: means the ordered Product's delivery date, indicated under a Purchase Order, provided that such date is not prior to the Purchase Order date plus the relevant Production Term.

- **1.49 Shelf Life:** means the period established in the Product's Technical Information. This period is approved by the regulatory authority, for the products where the regulation requires it, and based on the stability studies provided by Avicanna and/or tested at Altea. For raw materials, shelf life is that asserted by the material's manufacturer.
- 1.50 SMGH: means Santa Marta Golden Hemp S.A.S. a company incorporated and existing under the laws of the Republic of Colombia, domiciled in Santa Marta, Colombia and Affiliate of Avicanna Inc., that will provide Avicanna the Avicanna Materials before its delivery to Altea.
- **1.51 Specifications:** means the quality criteria indicated in the dossier and the Product's applicable technical information describing its quality attributes included in this Contract as Annex 3;
- 1.52 Taxes: has the definition assigned in clause 7.2.1;
- **1.53 Technical Agreement**: means the document establishing the technical responsibilities of the Parties, as referenced in Annex 6. The Technical Agreement may be modified from time to time by decision of the parties, without affecting the contents of this Manufacturing Contract;
- 1.54 USD: means United States of America Dollars.

#### 2. COMMENCEMENT AND TERMINATION OF THE CONTRACT.

- 2.1. This Contract:
- 2.1.1. Will commence on the Execution Date;
- 2.1.2. Will continue for an initial five (5) years-period (the "<u>Initial Period</u>"), unless terminated earlier as provided hereunder; and,
- 2.1.3. After the Initial Period, the contract shall be renewed automatically for successive three (3) year periods (each, an "Additional Period"), unless terminated earlier as provided for hereunder.
- 2.2. Either Party shall have the right to terminate this Agreement upon the end of the Initial Period or the Additional Period, through written notice provided to the other Party at least twelve (12) months in advance to such termination.

#### 3. MANUFACTURING.

Altea shall manufacture, analyze, label, pack, store, release, and deliver the cannabinoid-containing products described on annex 4 exclusively for and to Avicanna at the Facilities, in accordance with Avicanna's requirements, the terms and conditions set forth in this Contract (including the Technical Agreement), and strictly complying with:

- 3.1. All applicable laws and regulations;
- 3.2. Current GMP;
- 3.3. The Finished Product Specifications; and
- 3.4. Avicanna's policies and instructions in connection with the manufacturing, analysis, packaging labeling, storage, and transportation of the Products, delivered to Altea from time to time.

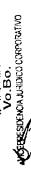
The Parties agree that Altea will not manufacture, analyze, label, pack, store, release, and deliver any cannabinoid-containing product for any person, company or trust other than Avicanna or its Affiliates. The Parties also agree that Altea will be the sole manufacturer of the Products. If any new product is developed during the performance of this Contract, Altea will have the exclusive right i for its manufacture under the same terms hereof. If Altea is not capable of manufacturing the new Product, or does not have the technical expertise for its manufacture, Avicanna will be free to contract with a third party its manufacturing.

In exchange for the exclusivity set forth in this clause, Avicanna agrees to request from Altea services or products, under this Contract or any other agreement to which Avicanna and/or Avicanna Inc and Altea are parties, for a total value of at least USD\$750.000 during the first year of performance of this Contract (the "Minimum Order Amount"). The value of the Minimum Order Amount will increase at least 10% for each year of execution of this Contract.

If this Minimum Order Amount is not met by Avicanna at the anniversary of the first year of this Contract, and each calendar year thereafter, the exclusive rights granted to Avicanna by Altea will terminate unless Avicanna, at its discretion, elects to satisfy the outstanding amount of the Minimum Order Amount within the following six months by requesting Purchase Orders, paying in cash, or a combination of both.

#### 4. DELIVERY OF AVICANNA MATERIALS AND OTHER MATERIALS.

- 4.1. Avicanna shall deliver or cause delivery to Altea, to the Facilities and at no cost for Altea, of the quantities of Avicanna Materials established in Annex 3. All Avicanna Materials, shall be delivered to the Facilities with their freight, insurance, and taxes paid.
- 4.2. Avicanna Materials shall be in accordance with the Specifications established by Avicanna. Avicanna shall provide or cause the provision of a Certificate of Analysis for each lot of Avicanna Materials delivered to Altea.
- 4.3. Altea shall acknowledge receipt and conformity of the Avicanna Materials in the form submitted by the Avicanna's representative or carrier delivering the Avicanna Materials within the five Business Days following its receipt. Altea shall record the number of boxes received, external conditions of the boxes, any visible physical damage of the packaging, the number of missing boxes or packaging (if any), and any other circumstance that may be noticed at the time of delivery. Altea shall provide Avicanna photographic evidence\_of any damage or deficiencies of the delivery. Altea shall quarantine the damaged Avicanna Materials, until they are returned to Avicanna. Avicanna shall assume the costs associated with replacing any Avicanna Materials. If Altea does not report any damages or deficiencies of Avicanna Materials upon receipt or within the five Business Days following its receipt, as per the terms set forth herein, Avicanna shall not assume the costs of providing replacement Avicanna Materials to Altea. If Avicanna does not timely deliver or cause the delivery of the replacement of the damaged Avicanna Materials, the Parties will agree on the necessary corrective measures, and a new Delivery Date.
- 4.4. Avicanna shall bear the costs to remedy any shortfall in the amount of Avicanna Materials received by Altea. If Avicanna does not timely deliver or cause delivery of the replacement of Avicanna Materials. Altea's obligations to deliver the Products on the Requested Delivery Date, which are contingent on the receipt of such Avicanna Materials, shall be temporarily suspended until Altea receives all the Avicanna



Materials required. Upon Avicanna's replacement of the missing Avicanna Materials, a new Requested Delivery Date shall be discussed and agreed upon in writing by the Parties.

- 4.5. Upon the receipt of the Avicanna Materials at the Facilities, Altea assumes the custody, risk, and responsibility thereon. If there is any loss or damage of Avicanna Materials under Altea's custody, Altea shall immediately inform Avicanna so that Avicanna may arrange to replace the Avicanna Materials at the current prices in force. By virtue of the offset principle, Avicanna may offset the amounts that Altea owes to Avicanna in such connection, from the amounts that Avicanna owes to Altea in connection with the services subject matter of this Contract.
- 4.6. Altea will ensure having at all times a system guaranteeing the traceability and allowing periodical determination of the quantity and location of Avicanna Materials. Altea shall use this inventory in accordance with the "first expiring/first out" principle (FEFO) of Products' manufacture. With one (1) months notice to Altea, Avicanna may request to review any inventory of Avicanna Materials in Altea's possession.
- 4.7. Altea will not offer for sale, assign, mortgage, deposit as pledge, or allow any type of retention right to be imposed on Avicanna Materials or in Avicanna's name, the Products in process, or the finished Products. All Avicanna Materials or those supplied on behalf of Avicanna hereunder, shall be exclusively used to manufacture the Products.
- 4.8. Altea shall take samples and analyze the Avicanna Materials, if so agreed, in accordance with the Technical Agreement and the Current GMP standards. Altea shall inspect each entry of Avicanna Materials in order to verify compliance with the Specifications. Altea will carry out this inspection by performing identification and analytical tests, using the analysis methods established in the Product's Technical Information and the relevant Master Documents' Index. Any deviation of the Avicanna Materials from the Specifications shall be investigated and notified to Avicanna within thirty (30) days. The tests material and retention samples' costs, which shall be borne by Avicanna, will be included in the [Consumption Report].
- 4.9. If Altea considers that the Avicanna Materials do not comply with the Specifications, Altea shall send to Avicanna the technical analysis of the Avicanna Materials as soon as reasonably possible, indicating the technical reasons of the non-conformity. If Avicanna agrees with the above reasons, or the analysis made by SMGH, as explained below, establishes the non-conformity of the Specifications, Avicanna shall assume the costs arising from and related to the return of the non-conforming Avicanna Materials. If Avicanna does not timely replace the Avicanna Materials, Altea's obligations to deliver the Products on the Requested Delivery Date will be temporarily suspended and a new Requested Delivery Date shall be discussed and agreed upon in writing by the Parties. In the event that Avicanna does not agree with the analysis of Altea, a sample of the Avicanna Materials will be sent to an independent laboratory agreed by the Parties, for further testing and the result of the testing will be final.
- 4.10. Avicanna will provide Altea with the final package designs to be used for the labels, packaging material, and other printed materials of the Products. Altea will guarantee its suppliers' printing of the relevant material as specified in the Product's Technical Information and Master Documents' Index. For materials during the Products first production. If Avicanna requests modifications to the final package Page 9 of 28 new Products (including new SKUs of existing Products) or changes in the final package designs, Altea will

designs, Altea will implement such modifications within the terms required for the change under the process established in clause 9, which includes the control change process, the material's analysis, and the material's internal specifications updating and approval. Avicanna will reimburse Altea for the costs derived from the modifications requested; however, Avicanna will not bear the costs associated with the packaging, labels, or other printed materials, exceeding the materials Binding Forecast except for materials purchased in excess due to the Minimum Order Quantity.

- 4.11. Altea will timely provide at its own cost and expense all Other Materials, labor, facilities, including all premises, equipment, machinery, heating, electricity, and energy, sufficient for the manufacturing, analysis, labeling, packaging, and storage of the Products. Altea will purchase such Other Materials from suppliers authorized or approved by Avicanna, if Avicanna requests such authorization or approval or if the Colombian Government Authorities or any other authority or market to which Avicanna exports its Products, requires such authorization or approval. The Other Materials shall comply with the specifications agreed to by the Parties. Altea will analyze and assess the Other Materials. Altea may have at least one alternative source for the supply of the critical materials and components identified and approved by Avicanna.
- 4.12. Altea will acquire the Other Materials in accordance with the minimum quantities of the orders established by the suppliers, prior written approval by Avicanna. Should the minimum quantities of the suppliers exceed the required amount and the remaining amount expires, Avicanna will bear the materials corresponding cost and destruction cost.
- 4.13. Altea agrees not to include the deductible taxes ("deducibles y descontables") charged by third parties to Altea on any of the Other Materials.
- 4.14. Upon request, Avicanna shall promptly deliver to Altea the certificates or any other document required for the Other Materials tax exemption; otherwise, Avicanna will bear any tax that may be charged to Altea as a result promptly delivering such certificates or other documents.
- 4.15. Altea will do everything possible to avoid any seizure or confiscation of Avicanna Materials, the Product in process, or the Finished Product. In case of such seizure or confiscation, the Parties will analyze the particular case to establish the responsibilities and possible solutions. Should Avicanna Materials, the Intermediate Product, or the Finished Product be seized or confiscated, Altea shall: (i) immediately inform Avicanna of the existence, terms, and circumstances surrounding such seizure or confiscation; and (ii) cooperate with Avicanna to exercise any legal measures available to stop or minimize such seizure or confiscation.
- 4.16. Avicanna shall bear the storage cost of those Avicanna Materials which have been in the inventory without any turnover for a period exceeding 90 calendar days, under the Price List in Force (Annex 7).
- 4.17. In the case of Products for export, Avicanna shall promptly deliver to Altea the information required for the certificate of origin's issuance (accreditation percentages for different countries, harmonized code, trade and technical name, presentations, and FOB price of the Products to be declared). Once the certificate is issued, Avicanna will be responsible for making the decision on its applicability.

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#### 5. FORECAST AND PURCHASE ORDERS.

#### 5.1. Forecast.

- 5.1.1. Not later than on the second (2nd) Business Day of each calendar month, Avicanna will provide Altea with a written, rolling and non-binding forecast of the estimated orders of its Products for the following twenty-four (24) months ("Forecast"). The first three (3) months will be deemed binding, will not be subject to changes, and will be recorded in the relevant Purchase Orders (as defined below), unless the Parties agree otherwise ("Binding Forecast").
- 5.1.2. Not later than on the tenth (10th) Business Day of each calendar month, Altea will confirm acceptance of Purchase Orders and delivery dates to Avicanna. Products shall be delivered to Avicanna or its representative in a maximum of 90 calendar days.
- 5.1.3. If a plant closing is scheduled for end-of-year maintenance, which shall be informed by Altea to Avicanna at least sixty (60) days before such closing, Avicanna shall deliver in September the Purchase Orders corresponding to January and February of the following year, and in November, the Purchase Orders corresponding to March of the following year. Should any cancellations and/or changes affecting Other Materials purchased under this assumption take place, Avicanna shall assume such materials cost.

#### 5.2. Purchase Orders.

- 5.2.1. Not later than on the second (2nd) Business Day of each calendar month, Avicanna will order Product through written purchase orders issued from time to time and submitted by mail, email, or fax ("<u>Purchase Order</u>"). Purchase Orders will replace any prior verbal agreement between the Parties.
- 5.2.2. Avicanna shall submit the Purchase Orders according to the Minimum Order Quantity included in the Price List in Force, guaranteeing complete distribution of the bulks in their equivalent in units; otherwise, the Purchase Order shall not be included in the master planning calendar.
- 5.2.3. Each Purchase Order will state its number, the Products' code, the Requested Delivery Date, the delivery address, the quantity, and the price in Colombian pesos (COP).
- 5.2.4. Altea will acknowledge and confirm each Purchase Order no later than on the tenth (10th) Business Day of each calendar month following the relevant Purchase Order's receipt.
- 5.2.5. If Avicanna requires an early delivery to the Requested Delivery Date, which may cause additional costs that Altea, acting reasonably, deems non-absorbable, Altea shall inform the relevant cost to Avicanna, before initiating any process. The additional costs shall have Avicanna's prior approval and Avicanna will bear them accordingly.
- 5.2.6. In case that Avicanna decides to participate in a public biddings for large volumes of product, the Parties will negotiate, on a case-by-case basis, the conditions regarding the applicable price, quantities, and Requested Delivery Dates.
- 5.2.7. If Avicanna needs to cancel a Purchase Order and the Other Materials available in the inventory cannot be used to manufacture the Other Products, Altea will deliver to Avicanna a report on the

appraised inventories, along with their cost and the storage costs until their destruction, so that Avicanna can decide, at its discretion, whether to destroy or purchase the Other Materials.

#### 6. DELIVERY.

- 6.1. Delivery.
- 6.1.1. The Product's delivery will take place at the Facilities.
- 6.1.3. Altea will release each Product lot in accordance with the Current GMP and requirements under the Technical Agreement. All Products delivered to Avicanna by virtue of this document, shall have at least an eighty-five percent (85%) useful remaining Shelf Life at the time of delivery.
- 6.1.4. Altea will guarantee that each Product's lot release comes along with: (i) a Certificate of Analysis; (ii) a certificate of conformity certifying that the Product was manufactured, analyzed, packaged, labeled, stored, released, and delivered in accordance with the Product Specifications and the Technical Agreement; (iii) any other certificate required by the authorities of the country that the Product will be shipped to and the requirements and documents established under the applicable legal provisions, particularly, but not limited to, those in Article 3 of Resolution 2892 of 2017 and any rules modifying or replacing it; and (iv) a report on the Consumption Report.
- 6.1.5. Altea will provide, together with each Product delivery, a delivery note referring to the Purchase Order's number, the Product's code, quantity, the delivery date, and the delivery address.
- 6.1.6. Avicanna, or its authorized representative, shall withdraw the Products and all the required documents (as provided for in clause 6.1.4.) from the Facilities, within the ten (10) Business Days following the Release Notice as described in clause 8.1, date. Storage of the Finished Products following the aforementioned period's lapse will accrue storage charges to Avicanna pursuant to Annex 7, subject to the relevant annual increments.
- 6.1.7. Altea will timely notify any eventual delay in connection with the Purchase Order's satisfaction.
- 6.1.8. Altea agrees to satisfy each Purchase Order on the Requested Delivery Date, in accordance with a minimum 95% yield, except in those cases where such yield has been actually demonstrated to be not achievable. The actual yield will be deemed the quantity of Products delivered to Avicanna, as well as the samples retained for whatever reason such as retention samples, reference or comparison samples, stability tests samples, quality control samples, validation samples, etc. Such retained samples will be invoiced as Products delivered, in accordance with the Prices in force. Altea will provide an inform of the use of these samples including, if needed, a certificate of destruction.

#### 7. PRICE.

- 7.1 Price.
- 7.1.1. The prices that Avicanna will pay to Altea for its services will be calculated per Product, as follows:

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- a. The cost per Product for 2018, this Contract's year of execution, will be those indicated in Annex 7 the Price List in Force.
- b. The cost per Product, as indicated in Annex 7, will be adjusted on January first (1st) of each year, as follows:
- (i) The labor cost per Product will increase with the official adjustment of the minimum wage for the relevant year as determined by the Government of Colombia;
- (ii) The cost of Other Materials that are locally purchased, will increase with the CPI (consumer price index) for the previous year, as certified by the *Departamento Administrativo Nacional de Estadística* (DANE) [National Administrative Department of Statistics].
- (iii) The costs of Other Materials imported will be adjusted with the COP/USD or COP/EUR exchange rate variation, as applicable, calculated as the difference between the average exchange rate for the immediately preceding semester and the average exchange rate for the semester prior to that, whenever such change (up or down) exceeds five percent (5%). The average exchange rate for each semester will be calculated based on the daily exchange rates, the representative exchange rate certified by the Bank of the Republic of Colombia and the Financial Superintendence, beginning on January 1 and ending on June 30; and beginning on July 1 and ending on December 31. The adjustment, if applicable, will be reflected in an updated cost per product (Annex 7);
- (iv) Up to three (3) percentage points may be added to the result of the calculation described Annex 7.1.1 (b) (iv) This percentage will not be added if the condition of at least 10% growth as set forth on clause 3.4 are met by Avicanna.
- 7.1.2. In the case of new Products, the price established in Annex 7, will remain final only after the first three lots are manufactured in full scale, so that this is considered a standardized process in terms of time.
- 7.1.3. Regarding any Additional Period, the Parties will agree, according to Annex 7.1.1 (b)(iv), the price of Altea's services in connection with each Product, six (6) months in advance to the start of each Additional Period The Products requested under Purchase Orders issued during such Additional Period, provided that the Parties have not reached an agreement, will be invoiced in the terms established in section 7.1.1. b.

#### 7.2. Taxes.

- 7.2.1. Except as expressly indicated in any other clause of this Contract, each Party shall bear its own taxes and other costs and expenses incurred in regarding: (i) this Contract; and (ii) the transactions contemplated herein.
- 7.2.2. Altea will be responsible for, and will pay all fees, expenses, charges, costs, and taxes established by a government authority (including, without limitation, sales, use, special, added value services, services, excise, and other taxes and obligations), new taxes accrued before Avicanna's receipt of the Product's ownership ("Taxes"), in addition to import and export duties, levies or charges, or custom duties related to the manufacturing expenses, in accordance with the applicable tax laws.



7.2.3. Altea's invoices shall indicate, separately, the Tax amount charged to Avicanna, as applicable, in accordance with the applicable tax and fiscal legislation. Altea will provide and make available to Avicanna any resale certificates, information related to any sale abroad or equipment, materials, or services' use, and any other exemption certificates or information previously requested by Avicanna.

#### 8. INVOICES AND PAYMENT.

- 8.1. Altea will invoice separately each order delivered under this Contract. Invoices will not be issued before the date when the lot's release date is notified to Avicanna ("Release Notice").
- 8.2. The invoices shall include the Purchase Order's number, the Product's code, the quantity, the unit price, the total price in COP, and will be delivered to Avicanna's Finance Department.
- 8.3. Avicanna shall pay the relevant amounts within the thirty (30) days following the invoice's receipt. Payment will be made in COP by means of a bank transfer.

#### 9. MANAGEMENT OF TECHNICAL MODIFICATIONS.

- 9.1. Avicanna may modify the Product Manufacturing Process at its discretion, from time to time, provided that such modification complies with the Current GMP standards. If the modifications to the Product Manufacturing Process cause any cost increase, Altea will report such costs within the five (5) following Business Days and, Avicanna, at its sole discretion, will determine whether it: (i) bears the relevant price increase; (ii) proposes an increment in the current price or (iii) does not implement the modification.
- 9.2. Each Party shall promptly notify the other one of any request it receives from the government authorities to change the analytical methods, the Finished Product Specifications, and/or the Product Manufacturing Process. If the modifications to the Product Manufacturing Process lead to a cost increase, Altea will notify such costs within the following five (5) Business Days and Avicanna, at its sole discretion, will determine whether it: (i) bears the relevant price increase; or (ii) recalls the Product from the market. Following Avicanna's written approval, Altea shall implement, as soon as possible, any change to the Finished Product Specifications and/or Product Manufacturing Process that the government authorities may request, informing the implementation terms to Avicanna, within the 5 Business Days following Avicanna's written approval. Altea will provide to Avicanna the documentation required to evidence such changes and support the government authorities' approval.
- 9.3. Both Parties may propose modifications to improve the Products' quality, costs, performance, processes, etc.

If such changes lead to the Products' costs increases or require investments, both Parties shall reach an agreement on the payment of such costs, in accordance with the benefits to be achieved. Altea shall not begin the implementation of any improvement it proposes without Avicanna's prior written approval and once the impact on the costs has been agreed.

- 9.4. To determine how the costs of any given change will be borne, the parties will review that provided for in Annex 5 (List of Modifications), and if necessary, will discuss the situation in good faith.
- 9.5. Any modification whatsoever will automatically be assigned to Avicanna Inc. and any rights of any kind to the modification will belong solely to Avicanna Inc.

#### 10. REGULATORY AND QUALITY MATTERS.

- 10.1. Altea shall ensure and maintain in order, and at its own cost, all government approvals, licenses, and consents as requested by any government authority, in order to comply with the obligations hereunder. If a particular license related to cannabis must be obtained to perform this Contract, the Parties will agree how the costs of obtaining and maintaining the license will be allocated among them.
- 10.2. Altea will not deliver or invoice any Finished Product not complying with the Finished Product Specifications and the guarantees established hereunder.
- 10.3. Altea will immediately notify Avicanna of any Finished Product's non-conformity with the Finished Product Specifications. If Avicanna confirms the non-conformity and requests the non-conforming Finished Product's lot destruction in writing, the Product will be destroyed in accordance with the applicable local laws and regulations and the Manufacturer will deliver evidence to Avicanna documenting such destruction. The destruction's cost shall be borne by the Party deemed responsible for the Product's non-conformity.
- 10.4. Delivery of any additional technical information by Altea not corresponding to manufacturing and quality control activities of the commercial lots manufactured for Avicanna (for example: manufacturing of pilot lots, manufacturing of test lots, technology transfer processes, stability studies, f tests (similarity factor), additional analysis, adjustments tests in connection with the manufacturing processes, large-scale trials, process validations, analytical methods validations, annual product reviews, etc.), will be agreed upon in writing between both Parties and will be subject to Avicanna's approval of a proposal in terms of price and execution time. That is, the above described or any other similar activities, are not included in the Product prices subject matter of this Contract.
- 10.5. In no case may Altea: (i) submit an application to INVIMA, any other Colombian authority, or any governmental authority abroad, for the marketing authorization of Products manufactured with the same Formulas manufactured for Avicanna; (ii) attempt to be registered as the Products' marketing authorization titleholder; or (iii) use any Intellectual Property or other technical information related to the Products to manufacture any product for third parties or Altea in Colombia or abroad.

#### 11. PRODUCT CLAIMS.

The process to handle any claims between the Parties is described in the Technical Agreement.

#### 12. MARKET WITHDRAWAL.

12.1. In case of any market withdrawal arising or resulting from any Altea's flaw in the manufacturing, analysis, packaging, labeling, storage, release, and/or delivery of the Product in accordance with Current



GMP standards, the Finished Product Specifications, or the guarantees established in this contract and its annexes, Altea shall supply the Product, at its own expense, within the sixty (60) days following the withdrawal's commencement date, in a quantity sufficient to replace the quantity of Product withdrawn from the market. In this case, Altea will not be entitled to the reimbursement of any expenses in which it incurred in order to deliver to Avicanna the Finished Products complying with the Current GMP standard, the Finished Product Specifications, or the guarantees provided in this Contract and its Annexes.

- 12.2. Should any withdrawal arise or result from any Avicanna's flaw in the manufacturing, analysis, packaging, labeling, storage, release, and delivery of the Product in accordance with Current GMP standard, the Finished Product Specifications, or the guarantees established hereunder, Avicanna shall pay to Altea all reasonable and duly documented expenses directly incurred by Altea in connection with such withdrawal. Such expenses shall include all reasonable labor costs or expenses.
- 12.3. Should any withdrawal arise or result from a flaw in the manufacturing, analysis, packaging, labeling, storage, release, and delivery of the Finished Product in accordance with Current GMP stanards, the Finished Product Specifications, or the guarantees established hereunder by a flaw not fully attributable to one Party the Parties will negotiate in good faith the appropriate allocation of the costs and expenses directly related to the withdrawal. Such expenses shall include all reasonable labor and out-of-pocket costs.

#### 13. INSURANCE.

13.1 As of the day of the execution of this contract, Altea has in full force and effect the insurance policies that are enclosed to this Contract as Annex 8. Altea shall maintain at its expense, in full force and effect, the insurance policies listed on Annex 8, or will obtain from another insurer equivalent covers to those covered in these policies, during the term of this Contract and the three following years. Altea will send each year, during the term of the Contract, to Avicanna copy of the policies and a receipt of the payment of its premia.

#### 14. MANUFACTURER'S WARRANTY.

- 14.1. Altea represents and warrants to Avicanna, with respect to each Finished Product's delivery, that:
- 14.1.1. The Product is manufactured, analyzed, labeled, packed, stored, released, and delivered in accordance with this Contract and its Annexes (including the Technical Agreement), the Current GMPs, and all Colombian laws and regulations;
- 14.1.2. The Product complies with the Finished Product Specifications;
- 14.1.3. The Finished Product have at least eighty-five percent (85%) of its remaining Shelf Life at the time of delivery, except for those Finished Products with different terms and conditions as agreed to by the Parties.
- 14.2. Altea also represents and guarantees as an ongoing guarantee for the term of this Contract that:



#### Manufacturing Contract

14.2.1. Its resources do not have any illicit origin and its legal representatives or shareholders have not been sentenced or investigated for corruption, money laundering, and terrorism financing-related crimes (AL/TF), nor are they included in international restrictive lists binding for Colombia under international law (United Nations

lists), OFAC lists, or other lists of criminals and terrorists that, due to their nature, generate a high risk for money laundering and terrorism financing.

- 14.2.2. It has received and complies with each and every one of the government approvals required to manufacture, analyze, pack, label, store, release, and deliver the Product to Avicanna in accordance with this Agreement.
- 14.2.3. With respect to any applications filed by Altea to obtain government approvals, it represents that its data and information are free of any fraud or material falsehood, that the government approvals will not be obtained through bribes or the payment of illegal rewards, that the data and information in the applications that Altea files are and will be accurate and reliable in order to support their approval, and that the government approvals were and will be obtained without any illegal or unethical conduct of any kind.
- 14.2.4. Altea's compliance with the terms and conditions that it is required to under this Agreement is not in conflict with, neither infringes or violates any other agreement that it is a party to, nor its regulations, operational documents, or bylaws;
- 14.2.5. The Product and any part thereof, and Avicanna and/or its Affiliates' use, sale, offer for sale, and/or import of such Products or parts thereof, does not infringe any third party's copyrights, patents, trademarks, trade secrets, or intellectual property rights and, on the Execution Date, there are no ongoing claims or pending or threatened action against Altea or any third party arguing that the Product or parts thereof allegedly infringe, violate, or have misappropriated the intellectual property rights of third parties. Altea shall immediate notify Avicanna of such claims or actions should they arise.
- 14.3. If Altea and/or Avicanna do not agree that a Product complies with the warranties established in clause 14.1 or if any breach of such warranties is attributable to defective Avicanna Materials, the matter will be submitted to an independent laboratory analysis, acceptable to both Parties, in order to determine whether the Product meets the Product Specifications and the results of the laboratory's tests shall be final and binding for both Parties. Such analysis fees and expenses shall be borne by the Party that, according to a final and unappealable judgement, is decided to have incorrectly determined that the Product complied with the warranties established in clause 14.1.

#### 15. INDEMNITY.

15.1. Avicanna will indemnify and hold Altea, its officers, directors, agents, and employees harmless from all losses, damages (including any person's injuries or death, or any property's damage or destruction), liabilities, and expenses and Costs resulting from third-party claims, Government Authorities, actions, orders, or other pending or threatened proceedings ("Indemnification Costs"), to the extent that they derive from: (i) Avicanna's breach of any of its representations, warranties, or covenants hereunder; (ii) Avicanna, its Affiliates, officers, directors, agents, and employees' negligence, errors, omissions, or willful misconduct; (iii) any defect in the Avicanna Materials in accordance with the Specifications, when

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delivered to Altea; (iv) the written instructions by an Avicanna's duly authorized officer and accepted in writing by Altea; and (v) any infringement by Avicanna of third parties' intellectual property rights and, in general, violation of any applicable law. Altea may compensate from any payment owed to Avicanna, any fines, penalties, payments, damages, and costs derived from Avicanna's indemnity obligations.

- 15.2. Altea will indemnify and hold Avicanna, its Affiliates and their respective officers, directors, agents, and employees harmless from any Indemnification Costs to the extent that they derive from: (i) Altea's breach of any of its representations, warranties, or covenants hereunder; (ii) Altea, its Affiliates, officers, directors, agents, and employees' negligence, errors, omissions, or willful misconduct; (iii) any non-compliance in connection with the manufacture, analysis, packaging, labeling, storage, release, and/or delivery of the Products in accordance with the applicable government approvals, the Product Specifications, or the warranties provided for hereunder, except where such breach results from the implementation of the written instructions of an Avicanna's duly authorized officer and accepted in writing by Altea; and (iv) any infringement by Altea of third parties' intellectual property rights and, in general, violation of any applicable law. Avicanna may withhold and deduct from any payment owed to Altea, any fines, penalties, payments, damages, and costs derived from Altea's indemnity obligations.
- 15.3. In no case will any of the Parties be liable to the other for any consequential, incidental, indirect, punitive, exemplary damages or lost profits arising from or related to this Contract, including any loss of profits or business opportunities suffered by Avicanna or Altea.

#### 16. INTELLECTUAL PROPERTY.

- 16.1. Avicanna and/or its Affiliates will own and have the exclusive right, title, and interest in relation to the *know-how*, trademarks, patents, technical and pharmaceutical formulations, and all documentation and information related to the Products and the Intellectual Property. Except as required by this Contract, Altea will not be entitled to use Avicanna's Intellectual Property without a prior written consent. The Intellectual Property will be deemed Avicanna's Confidential Information hereunder.
- 16.2. From time to time, Avicanna will provide formulas, instructions, Finished Product Specifications, and the know-how, as well as other forms of Intellectual Property, that Altea may require to manufacture the Products. The Formulas and Product's Technical Information shall be Avicanna's sole and exclusive property. Such formulas may only be used by Altea to the extent necessary to give effect to the provisions hereunder. In no case may Avicanna's Intellectual Property be used to manufacture any third parties' product. In no case may Altea apply for the registration of any Intellectual Property on the Products or for similar Intellectual Property rights before any Government Authority in Colombia or abroad, or claim any right on such Intellectual Property.
- 16.3. No improvements, modifications, or changes may be incorporated or implemented in connection with the Formulas or the manufacture of the Products without Avicanna's prior written consent; any improvement, modification, or change enures directly to Avicanna's benefit and this Contract confers an automatic assignment of any improvement to Avicanna Inc. In no case may Altea apply for the registration of or claim any rights on any improvement before any government authority.



- 16.4. The Products may be advertised, promoted, marketed, or sold, either separately or as part of other Products, under any trademark, trade name, domain name, copyright, or logo, either registered or not, selected by Avicanna and its affiliates at their entire discretion.
- 16.5. Any use for research and development purposes, as well as any commercial use of Avicanna's Intellectual Property shall be for Avicanna's exclusive benefit and belongs to Avicanna.
- 16.6. Altea may not use or market the Avicanna Products for purposes other than those set forth in this Contract.

#### 17. SUBCONTRACTING.

- 17.1. Altea may not subcontract any part of the services subject matter of this Contract, without Avicanna's prior written consent.
- 17.2. Subject to clause 17.1, Altea will be liable to Avicanna for any of its subcontractors' acts or omissions in connection with this Contract, as if such acts or omissions were directly performed by Altea. Subcontracting of any obligations hereunder shall not exempt Altea from its obligations to Avicanna regarding their due and appropriate performance as further described in the Technical Agreement.

#### 18. ASSIGNMENT.

- 18.1. Altea may not assign any of its rights under this Agreement without Avicanna's prior written consent, which shall not be unreasonably denied.
- 18.2. Avicanna may assign this Contract in whole or in part by means of a written notice to Altea, delivered within the forty-five (45) days following the delivery of: i) any transfer of assets; ii) any change on a marketing authorization titleholder; and/or (iii) any change of ownership of the trademarks of the Products subject matter of this Contract.
- 18.3. Altea shall notify Avicanna in writing, at least forty-five (45) days in advance, of (i) any change of control of Altea; or ii) Altea's sale, transfer, or disposal of all or substantially all of its assets used in any manner to comply with its obligations hereunder (each, a "Change of Control"). Within forty-five (45) days following receipt of the Change of Control notice, Avicanna shall notify Altea in writing whether it consents or not to terminate the Contract following a Change of Control, which shall be to Avicanna's discretion. For the purposes of clause 18.3 "Control" shall mean the ownership (direct or indirect) of more than fifty percent (50%) of the capital stock with voting rights or otherwise with the power to direct Altea's affairs.
- 18.4. Except as provided for in clause 18.3, in case of a Change of Control of the Manufacturer, Avicanna may, at its exclusive discretion: (i) request Altea to assign this Contract in its entirety to the acquirer and cause the acquirer to assume this Contract in writing; or (ii) immediately terminate this Agreement, in whole or in part, without any further penalty, liability, or obligation.

#### 19. TERMINATION.

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19.1. If any of the Parties (the "Infringing Party") breaches any provision hereunder and remains in breach for forty-five (45) days following receipt of a written notice delivered by the other Party (the "Infringed" by

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- <u>Party</u>"), such Infringed Party shall be entitled, at its discretion and notwithstanding any other rights the Infringed Party may have under this contract or the law, to the following:
- 19.1.1. Maintain this Contract against the Infringing Party and claim the specific performance of the Infringing Party's obligations hereunder, with or without claiming damages;
- 19.1.2. Maintain this Contract and claim damages; and/or
- 19.1.3. Terminate this Contract and claim damages, in which case the Infringed Party shall deliver a written notice of the termination to the Infringing Party and the termination will take effect immediately upon receipt of the notice.
- 19.2. Avicanna may terminate this Agreement at any time in its entirety or regarding any Product:
- 19.2.1. Through a written notice delivered sixty (60) calendar days in advance to Altea, if Avicanna, at its entire discretion, determines that it will no longer market such Product in Colombia or any other export market. In this case, Avicanna will reimburse Altea the costs of both the Intermediate Product (if applicable) and the inventory of the Other Materials exclusively used for the Product that will not be used by Altea in any way.
- 19.2.2. Through written notice to Altea, if any Government Authority: (a) revokes, suspends or withdraws a government approval for the manufacture or commercialization of such Product; or (b) takes any action whose result is to prohibit or impose a significant restriction to the manufacturing, packaging, labeling, storage, import, sale, or use of such Product or Avicanna Materials used for such Product. Avicanna will reimburse Altea the costs corresponding to both the Product in process (if applicable) and the inventory of Other Materials exclusively used in the Product that will be discontinued.
- 19.3. Any of the Parties may terminate this Contract at any time and immediately, if:
- 19.3.1. If either of the Parties or any of their directors, or officers, is or becomes included in the Specially Designated Nationals and Blocked Persons List issued by the Office
- of Foreign Assets Control of the US Treasury Department of the United of America ("OFAC") and/or in any similar list issued by the OFAC, international restrictive lists binding to Colombia under international law (United Nations lists) or other lists of criminals and terrorists that, by their nature, generate a high risk for money laundering and terrorism financing.
- 19.3.2. Whenever there are reasonable indications that Altea or Avicanna's resources originate from any illegal activities under the criminal legislation or that they have engaged in transactions or operations for purposes of such activities or in favor of persons related thereto.

#### 20. EFFECTS OF TERMINATION.

20.1. If Altea terminates this Agreement in accordance with clause 2.2 or if Avicanna terminates the agreement in accordance with clauses 2.2, 18.4, or 19.1, and 19.2.:



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- 20.1.1. Altea will be required to comply with all pending Purchase Orders and Avicanna will be required to pay to Altea the price of the product supplied in response to pending Purchase Orders.
- 20.1.2. Avicanna will be entitled to request and purchase all or part of the Products projected for delivery in the six (6) months following the current Forecast. Altea will deliver and Avicanna will pay for the Products so required.
- 20.2. If this Contract is terminated by Altea pursuant to clause 2.2 or by Avicanna pursuant to clauses 2.2, 18.4, or 19.1 and 19.2.1, upon Avicanna's request Altea will continue to supply the Products complying with Avicanna's requirements following this Contract's termination date, if Avicanna fails to fully identify to or register with the competent Government Authorities in Colombia or any other market where Avicanna exports its Products, a new manufacturer of the Product. Such Altea's obligation will continue until Avicanna notifies that a new manufacturer of the Products has been identified and duly registered with the competent government authorities in Colombia or any other market where it exports its Products, provided that Avicanna does everything possible to identify to and get the government's approval of this new manufacturer. Once this condition takes place, the Parties will agree, by means of a separate document, on the term during which the supply will be made and Avicanna will pay to Altea the value of the Products delivered, in accordance with the fees in force as of the termination date.
- 20.3. Upon termination of this Contract for whatever reason, each Party shall promptly return to the other one, within a maximum five (5)-days term, all Confidential Information received therefrom. In addition, Altea will immediately make available to Avicanna all Avicanna Materials in its power. Avicanna will withdraw these materials, at its expense, from the Facilities.
- 20.4. Likewise, Avicanna will reimburse Altea the value of the Other Materials acquired by Altea, based on the Products manufacturing forecast received from Avicanna. This obligation shall not apply in those cases where Avicanna terminates this Agreement pursuant to clauses 19.1 and 19.3.
- 20.5. The Parties' aforementioned rights and remedies shall be notwithstanding the other rights and remedies available thereto under this Agreement or the applicable legislation.

#### 21. DISPUTE RESOLUTION.

#### 21.1. ARBITRATION.

Any and all disputes or controversies related to this Contract shall be resolved by an Arbitration Tribunal managed by the Chamber of Commerce of Bogota's Center of Arbitration and Conciliation, which shall be governed by its regulations and procedures, in accordance with the following rules:

- 21.1. The Tribunal shall be comprised by three arbitrators to be jointly appointed by the parties. If this appointment does not take place, the arbitrators must be assigned by the Center of Arbitration and Conciliation, upon request from either party.
- 21.2. The Tribunal's decision will be in accordance with the rule of law.



- 21.3. The Tribunal will be held at the Chamber of Commerce of Bogota's Center of Arbitration and Conciliation facilities.
- 21.4. The secretary of the tribunal will be appointed from the lists of official secretaries of the Chamber of Commerce of Bogota.

#### 22. ACTS OF GOD OR FORCE MAJEURE.

- 22.1. Neither Party shall be liable to the other for its failure or delay to comply with its obligations hereunder, provided that such breach is the result of an act of god or force majeure, <u>duly proven</u> in accordance with the provisions under the Colombian Civil Code and the other laws and regulations governing acts of god and force majeure in Colombia.
- 22.2. Following any act of god or force majeure circumstance, the Infringing Party:
- 22.2.1. Shall notify the other Party promptly upon becoming aware of the occurrence of such an event;
- 22.2.2. Shall use its best efforts to resume compliance; and
- 22.2.3. Shall cooperate with the other Party in the application of those contingency measures that such other Party may reasonably suggest.
- 22.3. The Party not applying this provision shall be entitled to terminate this Contract immediately following a written notice of an act of god or force majeure, duly evidenced, that has not ceased after three (3) months from its occurrence.
- 22.4. Altea will, at all times, maintain the appropriate insurance that includes the replacement value of the Avicanna Material, Intermediate Products, or Finished Products in Altea's possession, in the event of a force majeure circumstance.

#### 23. CONFIDENTIALITY.

- 23.1. From the Execution Date and after the expiration or termination of this Contract, the Parties:
- 23.1.1. Shall keep the Confidential Information confidential;
- 23.1.2. Shall refrain from disclosing the Confidential Information to any person, unless with the prior written consent of the other Party; and
- 23.1.3. Shall refrain from using the Confidential Information for any purpose other than complying with their obligations under this Agreement.
- 23.2. During the term of this Agreement, a Party may disclose the Confidential Information to its employees, provided that it is necessary for the purposes of this Contract. The Party disclosing the information to its employees shall ensure that each employee is aware of and complies with the Party's confidentiality obligations hereunder.

- 23.3. Considering that Avicanna's Confidential Information is sensitive information, the measures adopted by Altea when disclosing such information to its employees, in order to comply with the purpose of this Contract, shall contemplate, among other aspects: (i) assignation of passwords; (ii) instructions on documentation filing under security conditions; (iii) video surveillance cameras for production environments, and all those that aimed at ensuring full confidentiality.
- 23.4. The obligations under this clause 23 will not apply to any Confidential Information:
- 23.4.1. That is or becomes public, provided that is not as a result of a breach of this Contract; or
- 23.4.2. Whose disclosure is required by the applicable law, a government regulation, or a judicial or administrative authority's valid order, provided that the receiving Party promptly notifies the disclosing Party of such disclosure requirement, takes reasonable and legal action to avoid or minimize the extent of such disclosure, provides confidential treatment to any Confidential Information disclosed, and fully cooperates with the disclosing Party in connection with the Disclosing Party's efforts to apply for a protection order or take any other relevant measures to restrict the Confidential Information's disclosure.

#### 24. APPLICABLE LEGISLATION.

This Contract shall be governed, interpreted, and applied in accordance with the laws of Colombia.

#### 25. NOTICES AND LEGAL PROCEEDING.

25.1. Each Party chooses as its address, for all purposes of this Contract ("Chosen Address"), either to respond to any judicial proceeding or documents, deliver notices or any other communications, and for any other purpose arising hereunder ("Notice"), the following:

**AVICANNA and AVICANNA INC:** 

Avicanna's Representative: Lucas Nosiglia

Carrera 1 # 22 - 58 Of: 903

Ed. Bahía Centro Santa Marta Magdalena Colombia

Email: lucas.nosiglia@avicanna.com

**ALTEA FARMACÉUTICA S.A.:** 

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Altea's Representative: Olga Lucía Cadena

Calle 10 # 65-28 Bogotá D.C. Colombia

Email: altea@alteafarma.com.co

25.2. Any Notice required or permitted under this Agreement will be valid and effective only if it is in writing.

- 25.3. Any Party may, through Notice delivered to the other Party, change its Chosen Address to another physical address in Colombia and such modification shall take effect five (5) Business Days following receipt of the relevant communication.
- 25.4. Any Notice delivered to a Party's Chosen Address or recorded in its Certificate of Existence and Legal Representation, will be considered valid and received on its delivery date.
- 25.5. Notices received at the emails indicated in section 25.1, will be valid notifications under this Contract.

#### **26. PENALTIES AND FINES**

- 26.1. In case of unjustified delay in the delivery of the Products, with respect to the Requested Delivery Date, for causes attributable to Altea, Avicanna may impose fines to Altea equivalent to zero point five percent (0.5%) per week of delay up to a maximum of five percent (5%) of the value of the delayed quantity. In these events, the application of penalty does not retroact to the original Delivery Date but starting to count on the sixteenth (16) day since the expiration of the date requested in the Purchase Order. Altea will not be responsible for the delays attributable to Avicanna.
- 26.2. If the Products do not meet the Finished Product Specifications, current GMPs, applicable laws and regulations and, in general, the conditions established in this Contract and its annexes, for causes attributable to Altea, Avicanna may impose fines to Altea equivalent to zero point five percent (0.5%) per week of delay up to a maximum of ten percent (10%) of the value of the delayed quantity.
- 26.3. Through the execution of this Contract, Altea authorizes Avicanna to deduct any amounts owed in this connection, from the invoices owed by Avicanna to Altea hereunder.
- 26.4. To impose the fines established in this clause, the following procedure shall be followed:
- 26.4.1. Avicanna will <u>notify</u> Altea of the breach, which Altea may answer to within the following five (5) Business Days, <u>proving that</u> the breach is not attributable to Altea and submitting the relevant evidence.
- 26.4.2. If Altea does not answer within the above term, such lack of answer shall be deemed a confession of Altea's breach and Avicanna will proceed to impose the fines contemplated in this clause.
- 26.4.3. If Altea answers within the term established herein and submits reasonable evidence to Avicanna showing that the breach is not attributable to Altea, the fines will not apply. Otherwise, Avicanna will proceed to apply such fines and Altea will have to pay such fine within the following 15 business days.
- 26.4.3. The fines will be imposed up to 20 days of delay, after which, the delay will be deemed a material breach of the Contract, and thus Avicanna, at its sole discretion, can terminate the Contract or request its specific performance. In both cases, Avicanna will be entitled to charge Altea, in addition to the relevant fines, the Penalty Clause (as outlined in Clause 26.5) and the damages suffered not fully indemnified by the Penalty Clause.
- 26.5. Penalty Clause:

- 26.5.1. In case of any material or definitive breach by any of the Parties, the Infringing Party shall pay to the Infringed Party, as penalty, an amount equivalent to 20% of sum of the value of all the Purchase Orders under the Contract as of the date in which Avicanna delivers the notice of section 26.4. Contract's value, amount that shall be charged to the amount of the damages suffered by the Infringed Party, and which shall be deducted from the outstanding balances in favor of the Infringing Party.
- 26.5.2. Before applying the penalty, the procedure established in the section 26.4. shall be applied.
- 26.5.3. If the damages suffered by a Party exceed the amount of the penalty, that Party will be allowed to commence proceeding against the Infringing Party for the outstanding not indemnified balance. Application of the penalty clause does not exclude any legal actions against the Infringing Party for the compensation of the damages caused, if in the Infringed Party's exclusive opinion such damages exceed the amount of the penalty.
- 26.5.4. As the payment of the penalty does entail that the Infringing Party's principal obligation to compensate the total damages caused to the Infringed Party as a result of the Contract's breach becomes extinct, the Infringed Party may enforce the penalty clause as indicated above, as well as demand the specific performance of the Contract, and/or demand payment of the compensation for the damages caused as a result of the Contract's breach.
- 26.5.5. The agreed to penalty clause will arise with the mere breach and will not require any prior judicial decision.
- 26.5.6. The Infringing Party irrevocably authorizes the Infringed Party to withhold and deduct any amount in such connection. In any case, the sums thus withheld by the Infringed Party shall not accrue any interest in favor of the Infringing Party, even if any dispute in relation to the Infringing Party's payment obligation to the Infringed Party exists. The parties agree that any withholdings by the Infringed Party hereunder, will not be deemed a breach of contract, but rather actions that are part of the contract's enforcement.
- 26.6.7. If the penalty clause in charge of the Infringing Party and in favor of the Infringed Party cannot be paid through the deduction or withholding of any amount of money because there are no amounts pending payment in favor of the Infringing Party, this Contract will be executable for those amounts owed by the Infringing Party to the Infringed Party.

#### 27. INTERPRETATION.

- 27.1. Titles and subtitles are only for reference and should not be used for interpretation purposes.
- 27.2. Unless the context clearly indicates the contrary, any word implying:
- 27.2.1. Any gender, includes both genders;
- 27.2.2. The singular, includes the plural and vice versa;
- 27.2.3. Individuals include legal entities and vice versa;

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#### Manufacturing Contract

- 27.2.4. Insolvency includes provisional or permanent measures on assets or the debtor's administration, judicial liquidation, or reorganization.
- 27.3. Any reference to a Business Day is a reference to any calendar day excluding Saturdays, Sundays, and holidays in Colombia.
- 27.4. When any number is established in days, such number will refer to calendar days, unless business days are expressly referred to, and will exclude the first and include the last day unless the last day corresponds to a Saturday, Sunday, or holiday in Colombia, case in which the last day will be the next business day.
- 27.5. Any reference to a regulation or Law is a reference to such regulation or Law on this Contract's Execution Date, with any amendments or new promulgations thereof, made from time to time.
- 27.6. No rule of interpretation will apply against the person preparing this document, regarding the interpretation or performance of this Contract, because this Contract is the product of the Parties' negotiation and both Parties were advised by a lawyer.
- 27.7. If any provision under a definition is a material provision granting rights or imposing obligations on any of the Parties, regardless of merely being included in the definitions clause, will have the effects of a material provision under this Contract.
- 27.8. Provided a provision is followed by the words "even", "including", and specific examples, such examples shall not be construed so as to limit the scope of the relevant provision.
- 27.9. Whenever a term is defined in the context of a particular clause hereunder, unless it is clear from the relevant clause that the term thus defined has an application limited to the such clause, the term thus defined shall have the meaning attributed thereof for all purposes hereunder, despite such term is not defined in the definitions clause.
- 27.10. In case of conflict or contradiction between this Contract and an Annex, the provisions hereunder shall prevail, except in case of technical or quality-related conflicts or contradictions, case in which the Technical Annex shall prevail.

#### 28. GENERAL AND MISCELLANEOUS PROVISIONS.

#### 28.1. NO AMENDMENT EXCEPT IN WRITING.

No agreed addition, amendment, variation, or cancellation of this Contract shall be valid or effective unless in writing and executed by or on behalf of the parties by their duly authorized representatives.

#### 28.2. OTHER WARRANTIES.

The Parties will: (a) mutually execute and deliver documents to each other; and (b) do the acts and things  $\frac{\omega}{2\pi}$  that a Party may reasonably request in order to comply with the purpose of this Contract and the documents to be delivered hereunder.

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#### 28.3. **WAIVERS**.

Unless stated otherwise in this document, any failure of either Party to enforce at any time any provision of this Contract shall not be construed as a waiver to such provision or in any way affect its validity or any part thereof, nor any Party's right to enforce each of those provisions. A waiver to a breach under this Contract shall not be deemed a waiver to any other subsequent breach that may arise.

#### 28.4. SURVIVAL OF OBLIGATIONS.

28.4.1. Any provision hereunder, providing compliance or observance following this Contract's termination shall survive such termination and continue to be in full force and effect, including, without limitation, clauses 13 to 18 (inclusive), 22, 23, 24, 25, 28 and this clause 28.4.

28.4.2. Altea's representations, warranties, and agreements in clause 14.1 will terminate and expire with respect to each delivery of the Product at the end of the relevant Product's Shelf Life, provided that the Product has been properly stored or handled. In case of a latent defect in the Product, Altea's representations and warranties shall terminate and expire one (1) year following the date when Avicanna discovered or was notified of such defects, whichever occurs first. Notwithstanding the foregoing, the indemnity obligations shall be maintained until the statute of limitations operates in connection with any third parties' actions or competent authority's sanctioning power.

#### 28.5. APPROVALS AND CONSENTS.

Any approval or consent granted by one of the Parties hereunder will only be valid if it is in writing and does not relieve the other Party's responsibility to comply with its obligations under this Contract; and shall not be construed as a waiver of rights, except as and to the extent expressly provided for otherwise in such approval or consent, or elsewhere in this Contract.

#### 28.6. INDEPENDENT CONTRACTORS.

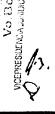
Nothing in this Contract shall be construed as one of the Parties being an agent or representative for the other Party, nor the Parties being partners or parties to a joint venture. Each Party represents itself and acts on its own behalf. Neither Party shall be liable for the other Party's acts or omissions, nor shall it have the authority to speak or act on behalf of the other Party or bind such Party in any way, without the latter's prior written consent.

#### 28.7. ENTIRE AGREEMENT.

. !

This Contract and its Annexes comprise the entire agreement between the Parties in connection with the subject matter hereof and supersede all prior commitments, communications, and representations, either oral or written between the Parties, regarding its subject matter.

28.8. **COUNTERPARTS**. This Contract may be delivered in a number of counterparts, each of which will be deemed an original following its execution, but all counterparts together will constitute a single document.



#### Manufacturing Contract

28.9. **UN CONVENTION.** The Parties agree that the United Nations Convention on Contracts for the Purchase and Sale of International Goods (2000) will not apply to this Contract and is expressly excluded thereof.

28.10. **LANGUAGE**. This Contract is written in both English and Spanish and shall be interpreted in accordance with its Spanish version, which shall prevail upon the English version in case of any conflict or doubt as to its interpretation.

28.11. **SEPARABILITY**. If any competent court or administrative authority finds that any provision under this Contract is not valid or enforceable, such invalidity or unenforceability shall not affect the other provisions hereunder, which shall remain in full force and effect.

IN WITNESS WHEREOF, the Parties have duly executed and delivered this Agreement on the date mentioned in its first page.

ALTEA FARMACÉUTICA S.A.

Legal Representative

. !

Olga Lucía Cadena
Legal Representative

AVICANNA LATAM S.A.S.

(signed) "Lucas Nosiglia"

Lucas Nosiglia
Legal Representative

AVICANNA INC

(signed) "Setu Purohit"

Setu Purohit



## ANNEX 1 CERTIFICATE OF EXISTENCE AND LEGAL REPRESENTATION OF AVICANNA

# ANNEX 2 CERTIFICATE OF EXISTENCE AND LEGAL REPRESENTATION OF THE MANUFACTURER

# ANNEX 3 RAW MATERIALS OF AVICANNA AND OTHERS RAW MATERIALS

#### **ANNEX 4**

#### LIST OF PRODUCTS

# ANNEX 5 LIST OF MODIFICATIONS

# ANNEX 6 TECHNICAL AGREEMENT



### TECHNICAL AGREEMENT BETWEEN AVICANNA LATAM S.A.S, AVICANNA INC. AND ALTEA FARMACÉUTICA S.A.

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# TECHNICAL AGREEMENT BETWEEN AVICANNA LATAM S.A.S, AVICANNA INC. AND ALTEA FARMACÉUTICA S.A.

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Between AVICANNA LATAM SAS, a company legally organized under the laws of Colombia, based in Bogotá, and, AVICANNA Inc., a company legally organized under the laws of Ontario, Canada, who henceforth "AVICANNA" will be called, on the one hand and on the other, "ALTEA FARMACÉUTICA S.A.", company legally organized under the laws of Colombia, based in Bogota, who henceforth "ALTEA" is called, has entered into a Quality Agreement shall be governed by the Articles set out after the following considerations:

- AVICANNA and ALTEA will be referred hereinafter to herein as the "Parties"
- ALTEA owns the Product Records of the products listed in Annex A.
- ALTEA has given AVICANNA, according to the Supply Contract Product signed with AVICANNA, the manufacture of the products listed in Annex A to the Colombian market and export, which AVICANNA accepted.
- ALTEA states that has the equipment, facilities and regulatory approvals, required by the Colombian/or Local authorities to manufacture and supply products and has taken appropriate measures to ensure product quality and compliance with the principles and rules of the Guide measures technical report of the WHO (World Health Organization) 823, report 37 "establish principles and standards for Good Manufacturing Practices for medicinal products for human use and for medicinal investigational products for human use" and AVICANNA quality requirements that have been reported to ALTEA.

#### 1 ARTICLE 1 – DEFINITIONS

- 1.1 Manufacture All operations of purchase of materials, Production, Quality Control, release, storage, of medicinal products and the related controls.
- 1.2 Compliance File -A Compliance file is a versioned document comprised of parts the registered CMC dossier and/or the detailed Manufacturing and Packaging instructions, analytical specifications of Raw material, In-process and finished products with effective date. Compliance File contains given standards, in compliance with the registered dossiers, provided by AVICANNA to the ALTEA as well as a classification for the cGMP documents drawn up by the ALTEA on the

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basis of such standards approved by AVICANNA for the manufacture, testing, packaging, labeling, release and storage of products.

- 1.3 Starting materials- For the purposes of this Technical Agreement, starting materials are all raw materials for the manufacture, of the medicinal and cosmetic product bulk form in the form of raw materials and active pharmaceutical ingredients.
- 1.4 **Materials**-For the purposes of this Technical Agreement, materials are all starting materials, packaging materials and medicinal or cosmetic product bulk forms.
- 1.5 **Reworking** For the purposes of this Technical Agreement, reworking is defined as subjecting an intermediate that does not conform to standards or specifications to one or more processing steps that are different from the established production process to obtain intermediate of acceptable quality.
- 1.6 Reprocessing Repeating a processing step of the established process applied to a processed material or product that did not conform to specification or is defective or was not performed as expected.
- 1.7 Changes-For the purposes of this agreement, changes are variations to the content of this agreement and its relevant Attachments, including the Compliance File, in their actual versions and /or any initiation, Any prospective modification (including discontinuation)of material, supplier, services, Product, Manufacturing/Packaging/supply Process, method, equipment, specifications, Facility and/or responsibility for performing and/or documenting a GMP related activity that has an effect on the overall quality, purity, efficacy, or safety of the Products as well as variations relevant to application of cGMP.
- 1.8 Certificate of Analysis (CoA) Controlled and signed document listing actual test results and Specification to be met for a batch of Material or Product, stating its final disposition.
- 1.9 Certificate of Compliance (CoC) Certificate/Confirmation of Compliance as defined in Annex C.
- 1.10 **Products** the products listed in annex



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- GMP- Applicable laws, rules, regulations and guidelines in Colombia and all 1.11 countries where ALTEA is supplying Products for AVICANNA governing Good Manufacturing Practice for pharmaceutical manufactures and the World Health Organization's current Good Manufacturing Practice guidelines, in each case as updated from time to time.
- Product Quality Review / Annual product review-Documented review performed 1.12 on a yearly basis to comply with the GMP standards.
- Regulatory Affairs Manager A person in charge of keeping the Regulatory 1.13 Compliance of the product by means of compliance check of master documentation with the current regulatory submission file, technical writing, compilation of Quality Overall Summaries, processing of variations, renewals and handling of deficiency letters
- Equipment raw data -Any piece of information obtained from manufacturing and 1.14 testing equipment. This includes for example, charts, graphs, electronic records, spreadsheet information.
- Specification-Quality criteria stated in the applicable dossier or regulatory 1.15 compendium or other document describing quality attributes.
- Critical Deviation -or High Deviation: A deviation that has potential serious impact 1.16 on product quality and patient, safety, registration files and GMP compliance.
- Major Deviation or Medium Deviation: A deviation that has possible effect on 1.17 product quality and patient safety, registration files and GMP compliance.
- High-priority (critical) complaints-Complains that may have immediate impact on the 1.18 product's identity, strength, safety, quality, purity and medical or technical and regulatory specifications.
- Adverse Event (AE): Means any untoward medical occurrence in a patient or 1.19 Clinical Trial subject administered a Medicinal Product which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a Medicinal Product, whether or not considered related to the Medicinal Product. In addition to the foregoing, in the



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context of Clinical Trials an AE will also mean events associated with and/or possibly attributable to the Clinical Trial protocol design or Clinical Trial procedures. For Medical Devices this also includes Reportable Incidents for Cosmetic Products, this also includes Undesirable Effects.

## 2 ARTICLE 2 - PURPOSE OF THE AGREEMENT

- 2.1 The purpose of the Agreement is to specify quality requirements, responsibilities and commitments of the parties and manufacturing operations and quality to be met by ALTEA.
- 2.2 This agreement applies to products listed in Annex A.

## 3 ARTICLE 3 – DOCUMENTATION

- 3.1 ALTEA provide when applying any identification and tracking information (tracking characteristics) that should appear on the packaging material, to allow AVICANNA or its authorized representative to draw up the final artwork.
- 3.2 ALTEA, monitor and review the Batch Record of each batch of product manufactured, such documentation must be available for review by AVICANNA, if required.
- 3.3 AVICANNA or its authorized representative has the right to ask ALTEA, via e-mail, airmail or fax, all technical information such as: test results, research reports and records, reports validations, batch record and balance of finished product.
- From each batch of finished product, ALTEA store for all technical information,

  Batch Record manufactured and a sufficient number of samples for at least two (2)

  complete analysis for 1 year after expiry of shelflife.
- In the event of conceptual differences between corporate policies AVICANNA against corporate policies ALTEA with respect to issues such as Assurance and Quality Control, manufacture, packaging and / or storage of finished products and / or supplies, these issues will be reviewed jointly by the "Parties" to reach agreement

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in which uniformity in the criteria established for products distributed by AVICANNA is guaranteed.

## 4 ARTICLE 4 – PRODUCTION

- ALTEA verify processing of products, strict compliance with the guidelines of AVICANNA as well as Good Manufacturing Practices (GMP), both in manufacturing and packaging, storage and quality control of products and inputs. In addition it will apply the regulations of WHO and regulation and legal provisions on the subject in Colombia.
- 4.2 Any change, improvement or modification of the production process or product specification shall be first approved by AVICANNA.
- 4.3 ALTEA will manufacture the products in ALTEA production plant located in Bogotá.

### 5 ARTICLE 5 – QUALITY

- 5.1 AVICANNA is responsible to the health authorities, legal authorities, customers, of the quality of the finished products and the processes included in the contract.

  ALTEA must provide the support when necessary.
- 5.2 ALTEA will verify that data and batch records are complete; in compliance with Good Manufacturing Practices and quality requirements of AVICANNA.
- ALTEA will perform quality controls during the manufacturing process for each of the products in accordance with the agreed specifications. In this sense, ALTEA make the appropriate analysis, approve and authorize the delivery of the finished product to AVICANNA. The Certificate of Analysis will include specifications of the tests performed, test results, date of manufacture and expiry of the product. This document must be approved by the Head of Quality Control or its delegate. In the event of a claim or complaint submitted by a client, this will be handled directly by AVICANNA taking in to account the provisions of the preceding paragraph 5.1.

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AVICANNA INC

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- All deviations related to quality, including deviations that do not affect the agreed 5.4 specifications, will be investigated and documented by ALTEA. The documentation will be kept on file as part of the batch record from the affected lot. When presented with a deviation related to quality and classified as high impact, which could affect agreed specifications or departure that affect product quality and / or the agreed specifications, before taking any decision, ALTEA will provide AVICANNA notice in writing of such deviation (preliminary information), within seventy-two (72) hours after the event.
- AVICANNA may authorize in writing the approval of a product or a batch of material 5.5 for use or marketing agreement with ALTEA.
- On the occurrence of high impact deviations ALTEA and AVICANNA will have the 5.6 ultimate responsibility to determine the significance of the impact of these deviations on the product, the determination on the future disposition of the affected lots should be made jointly between ALTEA and AVICANNA. Responsibility towards to the customers, regulatory agencies and patients is AVICANNA's. responsible for reporting any critical deviation and define together with AVICANNA about the approval or rejection of the lot affected.
  - When a production lot is rejected by ALTEA and does not meet AVICANNA's specifications and/or Good Manufacturing Practices, a certificate of rejection shall be issued, which must be authorized by the Head of Quality Assurance of ALTEA. For the destruction of a batch that is rejected, ALTEA inform to AVICANNA the date
    - and time of destruction and this should be done in the presence of an authorized representative of AVICANNA when is required. Or failing to deliver the corresponding certificate of destruction in support of the destruction made the rejected product.
- Any change in the record or in the process of manufacturing the products subject to 5.9 the prior written consent of the parties.
- ALTEA inform in writing to AVICANNA, of any changes in facilities and / or 5.10 equipment that could compromise the quality of products. Prior agreement between the parties, the change will be implemented by ALTEA.

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- 5.11 ALTEA shall not subcontract the production, packaging or quality control without prior written consent of AVICANNA.
- 5.12 AVICANNA shall be entitled to perform tests for their products through a laboratory of their choice to confirm the data obtained from analyzes previously made.
- 5.13 ALTEA is responsible for coordinating the development of studies of natural and accelerated stability, after approval of quotation and signature of PO. (See Annex B Responsibilities).

## 6 ARTICLE 6 - STORAGE

- 6.1 ALTEA store inputs and outputs, according to the Good Storage Practices.
- 6.2 AVICANNA store inputs and outputs, according to the Good Storage Practices.
- The supplies taken in production will be taken from stocks using the FEFO method.

  First Expired, First Out.

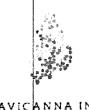
## 7 ARTICLE 7 – ARCHIVES

7.1 ALTEA archived at least five (5) years, documents related to production, such as Quality Control Log books, ledgers, log books and Control Verification and / or calibration of equipment. Validation documents shall be retained for ten (10) years after the change of equipment or process.

### 8 ARTICLE 8 – CLAIMS

- 8.1 If AVICANNA receives a complaint from a "third party", AVICANNA shall report the claim within twenty-four (24) hours to ALTEA who will initiate the investigation.
- 8.2 If ALTEA receives a complaint from a "third party" that relates or could be related to AVICANNA product, ALTEA FARMACEUTICA S.A. communicate it to AVICANNA within five (5) working days of receiving the claim and / or defective sample if of being a minor and within 24 hours in case of complaints critical or major complaint.

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For complaints critical and Major, ALTEA must send to AVICANNA a preliminary 8.3 investigation report on the complaint within 5 working days.

> In the event an investigation by ALTEA take longer than agreed, ALTEA inform AVICANNA and "THE PARTIES" agree on a reasonable period of time, taking into account the interests of each of the parties involved (customer, regulatory agency etc.).

## ARTICLE 9 - RECALL OF BATCHES

AVICANNA, promptly notify in writing to ALTEA any real or potential recall of a batch 9.1 of the Product due to manufacturing operations, materials, conditions of storage or analysis by ALTEA and AVICANNA.

> ALTEA investigate and provide a quick initial response as soon as possible and a full report within ten (10) working days and in any case soon enough for AVICANNA comply with the terms established by the regulatory agency.

> ALTEA will inform AVICANNA, within a period no longer than 3 business days, if there is an objection to the recall of the product from the market, sending support to AVICANNA to support its considerations.

> After discussing it with ALTEA, the Parties will decide whether the recall of a batch of product is needed. The Parties will cooperate to respond to the authorities.

> AVICANNA will be responsible for coordinating activities related product recall in the territory where "products" have been sold.

"Parties" define the responsibility for the cause of recall from the market and the parties agree on the management of associated costs.

#### 10 **ARTICLE 10 - ADVERSE EVENTS**

In case of an adverse event, this will be notified to Altea only if it is suspected that the cause is related to a process developed by ALTEA. AVICANNA must clearly specify the investigation requirement that requires ALTEA to verify. Responsibility



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for the handling, management or communication of the adverse event with the authority or the Patient is solely of AVICANNA and will be responsible for responding and monitoring through its pharmacovigilance program.

### 11 ARTICLE 11 -INSPECTIONS/ AUDITS -

- 11.1 ALTEA will cooperate with AVICANNA in carrying out inspections subject to prior notification of at least 6 months to ALTEA and, within the scope of the inspections, will grant access to representatives designated by AVICANNA and the authorities, to all manufacturing facilities, analysis and storage and will allow them to inspect all documentation to the extent that the facilities and documents in question are related to the manufacture of the contractual products.
- AVICANNA shall fulfill its obligation to audit the ALTEA's documentation and facilities regularly in order to ensure compliance with the agreement and the current GMP requirements. Prior to the audit the dates and the length of the audit are agreed between AVICANNA and ALTEA and an audit agenda with objectives and scope will be provided. An audit agenda with objectives and scope must be communicated to the ALTEA.
- In addition to the regular audit AVICANNA has the right to carry out at any time, but upon prior notice, "for cause audit" at the ALTEA's site.
- The ALTEA shall remedy all substantial defects that are discovered within the scope of inspections/audits.
- ALTEA responds with corrective/preventive action plans. A plan of corrective and preventive activities with compliance dates will be provided within thirty (30) calendar days.

### 12 ARTICLE 12 – CONFIDENTIALITY

12.1 "Parties" undertake to keep confidential all production processes, quality standards and technical information provided by each of the Parties.





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ARTICLE 12 - CONFIDENTIALITY 12

12.1 "Parties" undertake to keep confidential all production processes, quality standards Parties. technical information provided by each of the and

> This article "11", will apply during the term of the agreement quality and Ten (10) years after its termination. Whatever the origin.

#### 13 **ARTICLE 13 - DURATION**

- The Quality Agreement is valid for the period of the Supply Contract Product is in 13.1 effect provided, however, that the obligations of Articles 7 (Archives), 9 (Recall of Batches) and 12 (Confidentiality) shall survive terminating the prescribed period.
- Any changes in this contract must be updated and approved by the parties. 13.2

#### **ARTICLE 14 - MISCELLANEOUS** 14

- Quality Agreement shall be governed by and construed in accordance with the 14.1 laws of Colombia.
- Quality Agreement, shall not affect, replace or cancel any of the provisions of the 14.2 **Product Supply Contract.**
- In the event of any discrepancy or inconsistency between this Agreement and 14.3 Quality Product Supply Contract arise, prevail Product Supply Contract.



Date of Signature

# TECHNICAL AGREEMENT BETWEEN AVICANNA LATAM S.A.S, AVICANNA INC. AND ALTEA FARMACÉUTICA S.A.

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AVICANNA LÂTAM SAS	ALTEA FARMACEUTICA S.A.	
(signed) "Roland Alvarez F"	(signed) "Yaneth Gutierrez" Signature	
Signature		
Roland Alvarez F	Yaneth Gutiérrez	
Name	Name	
VP Regulatory Affairs	Quality Director	
Title	Title	
	20181203	
Date of Signature	Date of Signature	
AVICANNATING	ALTEA FARMACEUTICA S.A.	
(signed) "Janeth Mora"	(signed) "Daniel Carreno"	
Signature	Signature	
Janeth Mora	Daniel Carreño	
Name	Name	
EVP Commercial Development	Quality Assurance Head	
Title	Title	
December 4, 2018	2016-12-09	

Date of Signature



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## **LIST OF ANNEXES**

- A. List of Finished products
- B. Responsibilities: Summary Table/Detailed Responsibilities
- C: Certificate of Compliance
- D: Change Notifications NOT requiring (AVICANNA) review
- E. Contact list

## **REVISION HISTORY**

Revision N°	Effective Date	Description of revisions
00	03/12/2018	Creation of new Technical Agreement.





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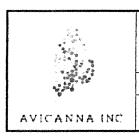
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**ANNEX A** 

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**ANNEX B** 

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**ANNEX C** 

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### ANNEX D

## Change Notifications NOT requiring (AVICANNA) review

Typographical errors and formatting in batch documentation, specifications and analytical methods including spelling correction, punctuation or change in typeface (i.e., bolding or font size.)

Revision of master batch records concerning waste treatment and safety provisions.

Clarification of process details for operator instruction.

Computer hardware/software/programming (unless the change would impact the GXP).

Routine equipment repair, maintenance, calibration, and/or replacement (like for like) of auxiliary equipment (i.e. equipment that is not in direct contact with the Product) which does not impact the validated state. EXCEPTION: All changes in equipment for sterile products and Vaccines must be reviewed.

Maintenance, replacement (like for like), repair and/or calibration of lab equipment, unless the change would impact the equipment qualification, method validation, column (chromatography) and/or test method.

Routine maintenance and repair of utilities, services and support systems. Archiving of obsolete documentation.

Non-GMP changes to plant areas such as area layout or establishing sample preparation rooms provided they do not change the environmental quality of utilities/services.

Changes of Contractor and/or Manufacturer and/or material for tertiary packaging materials as long as it meets specifications.

Changes to raw materials for APIs, unless they are part of the regulatory filing or critical raw materials for the process.

Changes to GMP service providers (e.g. calibration providers, pest control, GMP documentation storage providers, and preventive maintenances providers).

Changes to Contractor part numbers provided they are not specifically referred to in batch records.





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AVICANNA INC

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Change of same-supplier manufacturing site for compendial raw materials or excipients, provided the raw material or excipient is not of animal origin and the specifications remain as currently approved:

Decommissioning of facilities, equipment or utilities.

Changes to facility and equipment cleaning/sanitization procedures and cycles.

Engineering modifications that do not impact the manufacturing process.

Changes in Suppliers or brokers of raw materials

Changes in specifications or packaging, and raw materials, if they are pharmacopeics.





 Revision:
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 03/12/2018

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## **ANNEX E**

## **CONTACT LIST**

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# ANNEX 7 COST PER PRODUCT – CONTRACT MANUFACTURING

[Redacted - Commercially Sensitive Information]

# ANNEX 8 INSURANCE POLICIES

[Redacted - Commercially Sensitive Information]