

AZELASTINE COMBINATION PRODUCT AGREEMENT

This AZELASTINE COMBINATION PRODUCT AGREEMENT ("Agreement") is entered into as of the 13th day of November, 2006 (the "Effective Date") by and between MedPointe Healthcare Inc., a corporation organized under the laws of Delaware with its principal place of business at 265 Davidson Avenue, Suite 300, Somerset, New Jersey 08873-4120 ("MedPointe"), and CIPLA Ltd., a limited company organized under the laws of India and having a place of business at Mumbai Central, Mumbai 400 008, India ("Cipla"). MedPointe and Cipla are sometimes referred to individually as a "Party" and collectively as the "Parties."

WHEREAS, Cipla is the owner of an Existing Formulation (as hereinafter defined) and related Product Intellectual Property (as hereinafter defined);

WHEREAS, Cipla wishes to develop a Product (as hereinafter defined) for commercialization in the Territory (as hereinafter defined) based on the Existing Formulation;

WHEREAS, MedPointe wishes to exclusively license the Product Intellectual Property (as hereinafter defined) for the Territory to manufacture and have manufactured the Product anywhere in the world and market, sell, import and distribute the Product in the Territory for the term of this Agreement and as per the terms of this Agreement;

WHEREAS, Cipla wishes to grant MedPointe such a license for the term of this Agreement for the Territory, as well as a right of first refusal to acquire an exclusive license to market, sell, import and distribute the Product in certain Markets (as hereinafter defined); and

WHEREAS, Cipla wishes to supply, and MedPointe wishes to purchase from Cipla eighty percent (80%) of its requirements of the Product in the Territory.

NOW, THEREFORE, in consideration of the rights and obligations set forth in this Agreement, and intending to be legally bound, the Parties agree as follows:

ARTICLE I - DEFINITIONS

The following capitalized terms shall have the following meanings when used in this Agreement, and all terms defined in the singular shall have the same meanings when used in the plural (and vice versa, as appropriate), unless otherwise specified:

1.1 "Affiliate" shall mean with respect to a Party a corporation, partnership, entity, person, trust, limited liability company or other business entity that controls, is controlled by, or is under common control with the referenced Party. For the purposes of this definition the word "control" (including, with correlative meaning, the terms "controlled by" or "is under the common control with") means the possession, directly or indirectly, of the power to direct the management or policies of the applicable entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance or otherwise.

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HIGHLY CONFIDENTIAL -
SUBJECT TO STIPULATED PROTECTIVE ORDER

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Argentum Pharmaceuticals LLC v. Cipla Ltd.
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1.2 "Applicable Law" shall mean any applicable federal, state, local or foreign statute, law, ordinance, rule or regulation, judicial order or industry standard imposed by regulation or law, including without limitation the laws of, and regulations promulgated under, the FDCA.

1.3 "Calendar Year" shall mean each successive twelve (12) month period commencing on January 1 and ending on December 31; provided that the first Calendar Year of this Agreement shall begin on the Effective Date and end on December 31, 2006. In the event that the termination of this Agreement does not fall on the last day of a Calendar Year, the "Final Calendar Year" shall mean the period from the first day of the then-current Calendar Year through the applicable date of termination of this Agreement.

1.4 "Certificate of Analysis" shall have the meaning set forth in Section 6.3(c).

1.5 "cGMP" shall mean all laws, guidelines and regulations applicable to the manufacturing, testing, labeling and packaging of the Product including current Good Manufacturing Practice regulations as promulgated under the applicable sections of 21 CFR (Chapters 210 and 211), as the same may be amended or re-enacted from time to time.

1.6 "Confidential Information" shall mean the existence and contents of this Agreement and any information, in whatever form (and whether tangible or intangible), disclosed by a Party (the "Disclosing Party") to the other Party (the "Receiving Party") in connection with the discussions, performance or implementation of this Agreement including, without limitation, non-public Intellectual Property, any pending unpublished patent applications, patent office correspondence, new drug applications and NDA submissions, FDA or other Regulatory Authority correspondence, drug master files, batch records, quality control records, technical or clinical data, Trade Secrets, know-how, research, product plans, products, services, suppliers, customer lists, prices and costs, software, developments, ideas, techniques, business methods, photographs, sound recordings, algorithms, inventions, laboratory notebooks, processes, formulas, technology, specifications, test results, designs, drawings, engineering, marketing, finances, budgets and other actual or anticipated business, research or development information which is disclosed by the Disclosing Party to the Receiving Party and whether or not specifically designated as confidential. Confidential Information shall not include:

- (a) information which at the time of disclosure is publicly known;
- (b) information which, after the time of disclosure, becomes publicly known, other than by breach of an agreement between the Disclosing Party and the Receiving Party or any Third Party;
- (c) information which is or was in the possession of the Receiving Party at the time of disclosure by the Disclosing Party and was not acquired directly or indirectly from the Disclosing Party or from any other party under an obligation of confidentiality to the Disclosing Party; and
- (d) information which is independently developed by or for the Receiving Party without reference to or reliance upon any Confidential Information of the Disclosing Party as demonstrated by credible written documentation.

- 1.7 “Defaulting Party” shall have the meaning set forth in Section 12.2.
- 1.8 “Dispute” shall have the meaning set forth in Section 16.6.
- 1.9 “Existing Formulation” shall mean Cipla’s existing formulation, for the nasal spray combination product containing azelastine hydrochloride and fluticasone propionate that is currently sold in India under the “Duonase” trademark.
- 1.10 “FDA” shall mean the United States Food and Drug Administration, or any successor entity thereto.
- 1.11 “FDCA” shall mean the Federal Food, Drug & Cosmetics Act, 21 U.S.C. 321 *et seq.*, any amendments or supplements thereto, or any regulations promulgated or adopted thereunder.
- 1.12 “Goa Facility” shall mean Cipla’s manufacturing facility in Goa, India.
- 1.13 “Improvements” shall mean, with respect to a particular technology, all discoveries, innovations, improvements, enhancements, derivative works or modifications based upon such particular technology if and to the extent that the legal right to make, use, sell, copy, distribute and perform such discoveries, innovations, improvements, enhancements, derivative works or modifications would necessarily require a license (*i.e.*, a license would necessarily be required assuming that the improver of such technology is not also the owner of such technology) to such particular technology.
- 1.14 “indemnitee” shall have the meaning set forth in Section 14.3.
- 1.15 “indemnitor” shall have the meaning set forth in Section 14.3.
- 1.16 “Intellectual Property” shall mean: (i) patents and applications therefor, including all continuations, divisionals and continuations-in-part thereof and patents issuing thereon, along with all reissues, reexaminations and extensions thereof (collectively, “Patents”); (ii) trademarks, service marks, trade names, service names, brand names, trade dress rights, logos, corporate names, trade styles, logos and other source or business identifiers and general intangibles of a like nature, together with the goodwill associated with any of the foregoing, along with all applications, registrations, renewals and extensions thereof (collectively, “Trademarks”); (iii) copyrights whether or not registered or published, all registrations and recordings thereof and all applications in connection therewith, along with all reversions, extensions and renewals thereof (collectively, “Copyrights”); and (iv) confidential and proprietary discoveries, concepts, ideas, research and development, know-how, formulae, inventions, compositions, manufacturing and production processes and techniques, technical data, procedures, designs, drawings, batch and quality records, specifications, and databases (collectively, “Trade Secrets”).
- 1.17 “Launch” shall mean, for each country within the Territory, the first date when the Product becomes commercially available to consumers.
- 1.18 “Markets” shall have the meaning set forth in Section 2.2

1.19 "Market Product" shall have the meaning set forth in Section 2.2

1.20 "MedPointe Intellectual Property" shall mean all Intellectual Property relating to azelastine, alone and/or in combination with other ingredients, as set forth on Schedule B1 for the Territory, in each case that MedPointe owns or under which MedPointe has the right to grant licenses.

1.21 "Net Sales" shall mean the gross amount invoiced to Third Parties for sale of the Product, in finished packaged form, in the Territory, less, to the extent deducted from or on such invoice consistent with generally accepted accounting principles, consistently applied, the following items: (i) quantity, trade or case discounts, chargebacks, returns, allowances, rebates (including without limitation any and all federal, state or local government rebates, such as Medicaid rebates) and price adjustments, to the extent actually allowed; (ii) sales, customs, and other excise taxes and duties or similar governmental charges directly related to such sale, to the extent such items are included in the gross invoice price; (iii) amounts actually refunded due to rejected, spoiled, damaged, outdated or returned Product; and (iv) freight, shipment and insurance costs actually incurred in transporting Product to a Third Party purchaser and separately invoiced. In the case of any sale of Product for consideration other than monetary consideration, such as barter or countertrade, such Product shall be deemed to be sold at the average sales price during the applicable reporting period generally achieved for such Product in the applicable country in the Territory when such Product is sold alone and not with other products.

1.22 "NDA" shall mean a New Drug Application, including any amendments or supplements thereto, in accordance with the requirements of the FDA.

1.21 "Non-Defaulting Party" shall have the meaning set forth in Section 12.2.

1.22 "Notice of Breach" shall have the meaning set forth in Section 12.2.

1.23 "Product" shall mean a nasal spray combination product containing azelastine hydrochloride (137 mcg) and fluticasone propionate (50 mcg) which will be developed by Cipla for MedPointe as per the terms of this Agreement.

1.24 "Product Intellectual Property" shall mean all Intellectual Property relating to the Existing Formulation and the Product, as set forth on Schedule B2, in each case that Cipla owns or under which Cipla has the right to grant licenses.

1.25 "Raw Materials" shall mean azelastine hydrochloride, fluticasone propionate and all excipients, components and other materials required to manufacture the Product, excluding packaging, labeling and inserts.

1.26 "Regulatory Authorities" shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities, including without limitation the FDA, regulating or otherwise exercising authority with respect to the development and approval of the Products in the Territory.

1.27 “Target Formulation” shall be the nasal spray combination product containing azelastine hydrochloride and fluticasone propionate that shall serve as the basis for the formulation development work to be conducted pursuant to this Agreement as set forth in Schedule A attached hereto and made a part hereof.

1.28 “Tech Transfer” shall mean cooperation between the Cipla and MedPointe in effecting an orderly transition of manufacturing matters with respect to the Product, including transferring copies of reasonably necessary information and files, disclosing all reasonably necessary Product Intellectual Property and granting all necessary rights of reference with respect to the FDA or other applicable Regulatory Authority to MedPointe towards qualifying either MedPointe or a secondary supplier to supply twenty percent (20%) of MedPointe’s commercial requirement or to supply the Product during force majeure conditions. To the extent Applicable Law requires MedPointe to control original documents, such original documents will be provided to MedPointe as part of the Tech Transfer.

1.29 “Term” shall have the meaning set forth in Section 12.1.

1.30 “Territory” shall mean the United States of America and its territories and possessions, Canada and Mexico.

1.31 “Third Party” shall mean any person or entity other than Cipla or MedPointe, or an Affiliate of either of them.

ARTICLE II - GRANT OF RIGHTS

2.1 Grant. Subject to the terms and conditions of this Agreement, Cipla hereby grants MedPointe an exclusive license, with the right to sublicense, under the Product Intellectual Property to use, have used, market, sell, import and distribute the Product in the Territory for the term of this Agreement and a non-exclusive license, with the right to sublicense, to manufacture and have manufactured the Product anywhere in the world towards manufacturing twenty percent (20%) of the Territories requirement. This license shall also include the right of MedPointe to use all of Cipla’s scientific and other data relating to the Product for the Term of this Agreement. For the avoidance of doubt, for the Term of this Agreement, (a) neither Cipla nor any of its agents, licensees or Third Party distributors shall be permitted to market, sell, import or distribute the Product or any other combination azelastine hydrochloride and fluticasone propionate nasal spray product in or into the Territory other than through MedPointe; and (b) Cipla agrees not to infringe any MedPointe Intellectual Property anywhere in the Territory by manufacturing, having manufactured, using, selling, offering for sale, importing or exporting any goods or services; provided MedPointe informs Cipla of its existing MedPointe Intellectual Property.. Schedule B1 attached hereto shall serve as notice to Cipla of MedPointe Intellectual Property within the Territory, as of the Effective Date and MedPointe agrees that it shall update Schedule B1 from time to time to reflect any changes to MedPointe Intellectual Property. Notwithstanding the foregoing, Cipla has notified MedPointe that it has two existing contracts with unidentified parties, one contract for supply of a finished azelastine hydrochloride product in Canada. and the other contract for supply of a finished azelastine hydrochloride product in the U.S. and Canada, the existence of which may violate the covenant in subsection (b) by Cipla. The parties agree that actions taken by Cipla solely to carry out its obligations

under the above-referenced agreements shall be exempt from the covenant set forth in subsection (b) but there will be no other permitted exceptions during the Term of this Agreement. The parties further agree that Cipla does not have any license, covenant not to sue or other authority from MedPointe in connection with the above-referenced agreements and that this Agreement does not affect in any way any rights MedPointe has or may have in the future to sue Cipla for patent infringement in connection with any activities relating to the above-referenced agreements. Any sublicensees of MedPointe and its Affiliates hereunder must agree to be bound by the terms and conditions of this Agreement as they apply to MedPointe. MedPointe will be responsible for any breach committed by its sublicensees provided MedPointe has notice of such breach and right to cure pursuant to Section 12.2 herein.

2.2 Right of First Refusal. Cipla hereby grants MedPointe a right of first refusal to enter into an exclusive license with Cipla to market, sell, import and distribute a nasal spray combination product containing azelastine hydrochloride and fluticasone propionate (the "Market Product") or the Product in the following countries: Germany, Spain, Portugal, the United Kingdom, Italy, France, Japan, Korea and Australia (individually, a "Market" and collectively, the "Markets"). Should MedPointe desire to launch the Product or the Market Product in one of the Markets, it will request that Cipla develop a Market Product for such Market or grant MedPointe the rights to the Product for such Market, and such request shall not be unreasonably denied subject to a commercial Agreement to be reached between MedPointe and Cipla on the said proposal. Should Cipla independently choose to launch the Product in the Market or develop a Market Product for one of the Markets, or agree to develop a Market Product at MedPointe's request, it shall grant MedPointe the right of first refusal to market, sell, import and distribute the Product or the Market Product within its respective Market.

(a) Cipla shall, in its discretion, select the Markets for which it develops a Market Product; provided, however, Cipla shall in good faith take MedPointe's requests to develop Market Products for particular Markets into consideration.

(b) Each time Cipla decides to launch the Product in a Market or develops a Market Product for a Market, it shall first approach MedPointe in writing with an offer to enter into an exclusive licensing arrangement for that particular Market. MedPointe shall provide Cipla with a written confirmation of its interest within four (4) weeks of Cipla's written offer. If MedPointe fails to respond within four (4) weeks of Cipla's written offer, it shall be deemed a forfeiture of MedPointe's rights with respect to that particular Market. The terms and conditions of the exclusive licenses for the Markets shall be the subject of separate written commercial agreements between the Parties; provided, however, that MedPointe agrees to source one hundred percent (100%) of its requirement of the Product or the Market Product for each relevant Market from Cipla, and that such agreements will include provisions for alternate sourcing in the event of a force majeure or other situation where Cipla is unable to supply MedPointe's entire requirements.

(c) If MedPointe declines Cipla's offer with respect to the Product or a particular Market Product under Section 2.2(b), but delivers Cipla a written counter-offer within four (4) weeks of Cipla's offer, then Cipla shall be free to solicit Third Party offers and enter into related agreements relating to the Product or that particular Market Product so long as the terms

finally agreed upon with the Third Party are commercially more favorable in the aggregate to Cipla than MedPointe's counter-offer.

2.3 Cipla's Use of MedPointe Data. MedPointe hereby grants Cipla the right to use any clinical data relating to the Product that is generated by MedPointe during the Term of this Agreement solely for countries outside the Territory. Cipla can use the clinical data in the Markets (as defined in Section 2.2) provided MedPointe confirms within four weeks of Cipla's written notice that MedPointe is not interested in developing the Market Product or Launching the Product in the Markets. Cipla may choose to launch the Product in countries outside the Territory and the Markets, in which case, Cipla may use MedPointe's clinical data subject to the following conditions :Cipla must enter into a separate formal written agreement with MedPointe setting forth the terms and conditions of use (which would cover any combination of azelastine and fluticasone) with such agreement including a provision requiring Cipla to pay MedPointe a royalty of ten percent (10%) of any net sales of the Product for the first five (5) years of commercialization in each country outside the Territory..

2.4 Express Reservation of Rights. The Parties expressly reserve all rights under their respective Intellectual Property that are not expressly licensed and/or granted to the other Party under this Agreement.

2.5 Anti-diversion. Cipla shall exercise commercially reasonable efforts to prevent and/or stop any diversion of Products made or sold by or for Cipla or any of its Affiliates into the Territory, including via the internet. Cipla shall notify MedPointe of any diversion of Products made or sold by or for Cipla or any of its Affiliates into the Territory, including without limitation tracking down the source of such diverted Products, discontinuing any contractual or other relationship it or its Affiliate has with such Third Party with respect to the diverted Products, and keeping MedPointe apprised of any such efforts.

ARTICLE III - PAYMENTS

3.1 Upfront Fee. MedPointe shall pay Cipla a one-time fee of seven hundred and fifty thousand dollars (\$750,000) upon execution of this Agreement.

3.2 Milestone Fees. MedPointe shall pay Cipla the following one-time fees within thirty (30) days of the achievement of the following milestone events:

MILESTONE EVENT	MILESTONE FEE
Cipla's transfer of the Product manufacturing technology to the Goa Facility	US \$300,000
Cipla's manufacture of the Phase I clinical batches of the Product	US \$300,000
MedPointe's submission of an NDA for the Product in the United States	US \$150,000

3.3 Payments.

(a) U.S. Dollars. All payments to be made under this Agreement shall be made in United States Dollars in immediately available funds by wire transfer as designated by Cipla or by such other method as Cipla shall reasonably notify MedPointe from time to time. MedPointe will endeavor to make all payments within 15 days of receipt by MedPointe of a valid invoice from Cipla but in any event shall ensure payments are made within 21 days of receipt of such valid invoice.

(b) Development Batches. MedPointe shall also pay Cipla for all development batches manufactured prior to the commercialization of the Product. Cipla shall invoice at the supply price agreed between the Parties for the Product for these batches.

(c) Interest. Cipla shall charge interest of 1% per month for any late payment whether it is related to development or commercialization.

ARTICLE IV - FORMULATION DEVELOPMENT

4.1 Formulation Development. Cipla shall be responsible for developing the Product for the Territory based upon the Target Formulation, which the parties acknowledge may involve making possible modifications, provided such modifications are agreed upon prior to implementation by MedPointe. Cipla shall also manufacture all regulatory batches, conduct stability testing and carry out process validation and analytical method validations reasonably required by MedPointe in connection with the regulatory approval process for the Product in the Territory.

ARTICLE V - REGULATORY MATTERS AND PATENT COOPERATION

5.1 Regulatory Filings. MedPointe shall be responsible for (a) conducting and funding all clinical studies whether pilot or pivotal studies which are required in order to obtain regulatory approval to Launch the Product within the Territory, and (b) compiling and filing the NDA with the FDA and analogous agencies outside the U.S. within the Territory. Based on a commercial assessment of the market opportunities, MedPointe shall in its sole discretion determine the optimal timing and strategy for seeking and obtaining regulatory approval for the Product in the countries within the Territory. Cipla agrees to provide MedPointe access to all data, analyses, documentation or other assistance reasonably required to by MedPointe to conduct clinical studies and file an NDA or other applications for regulatory approval with the appropriate Regulatory Authorities.

5.2 Ownership. MedPointe shall be the owner of all data, analyses and documentation it generates in its clinical studies relating to the Product during the Term of this Agreement, and shall also own all regulatory filings and approvals, including NDAs, it submits within the Territory.

5.3 Compliance with the Federal Food Drug & Cosmetic Act. MedPointe warrants that all Product sold or promoted by it under this Agreement will, at the time of such sale or promotion, not be adulterated (after transfer from Cipla to MedPointe or while under MedPointe's control) or misbranded within the meaning of the FDCA. Cipla warrants that all

Product sold or promoted by it under this Agreement will, at the time of such sale or promotion, not be adulterated (prior to transfer to MedPointe or while under Cipla's control) or misbranded within the meaning of the FDCA.

5.4 Expenses. MedPointe shall be responsible for all expenses associated with filing and obtaining regulatory approval of the Product within the Territory.

5.5 Quality Agreement. The parties agree that prior to commercial sale of the Product in the Territory they will enter into a quality agreement substantially in the form attached hereto as Exhibit 5.5.

5.6 Patent Cooperation. The parties agree that they shall fully cooperate with one another and provide each other with all information and assistance necessary for the prosecution of U.S. Patent Application No. 10/518,016, filed June 13, 2003 (published as US20060025391-A1 on February 2, 2006), any continuation, divisional, continuation-in-part, reissue, reexamination or interference thereof, and the patent applications in Canada and Mexico that correspond to and are the Canadian and Mexican equivalents of such U.S. patent applications (collectively referred to herein as "the Patent Applications"). Cipla shall instruct its patent counsel to keep MedPointe fully informed of the substance and status of the prosecution of the Patent Applications and shall obtain MedPointe's comments and suggestions prior to taking any material actions in the prosecution of the Patent Applications. The parties also agree that Cipla and/or its counsel will take all actions in the prosecution of the Patent Applications that are reasonably recommended and/or requested by MedPointe that would expand and/or maximize the scope of the rights sought-- provided if Cipla incurs any additional expense towards this exercise then MedPointe will reimburse the same to Cipla.

ARTICLE VI - PURCHASE AND DELIVERY

6.1 General Obligation to Purchase. During the Term and subject to the terms and conditions of this Agreement, MedPointe shall purchase eighty percent (80%) of its requirements of the Product for the Territory from Cipla, and Cipla shall manufacture, test, sell and deliver to MedPointe, eighty percent (80%) of MedPointe's requirements of the Product for the Territory.

6.2 Purchase Orders and Forecasts.

(a) MedPointe shall place orders ("Purchase Orders") specifying the quantity of the Product it wishes to purchase and such other commercially reasonable terms agreed upon by the Parties. Cipla shall accept all conforming Purchase Orders submitted by MedPointe pursuant hereto within five (5) days of Cipla's receipt of such Purchase Order. The terms of this Agreement shall prevail over any inconsistent terms in any Purchase Order, acknowledgment or invoice. Cipla shall fill all conforming Purchase Orders within ten (10) days of receipt and will achieve a quarterly fill rate of ninety percent (90%), subject to the limitations otherwise established by Section 6.2(c) hereof.

(b) Cipla shall package and label the Product with packaging and labeling artwork approved by MedPointe in the quantities and configurations specified by MedPointe and in conformity with cGMP and industry practices.

(c) Cipla and MedPointe shall work together to minimize waste and maximize shelf life of the Product by coordinating production, inventory maintenance levels, Purchase Orders and shipments as follows:

(i) Prior to the beginning of each calendar quarter, (A) MedPointe shall provide Cipla a forecast of its orders for the Product for the following four (4) full calendar quarters, and (B) Cipla shall provide MedPointe with a tentative schedule for the production of bulk batches over the same period. MedPointe shall provide Cipla with its first forecast and Purchase Order for the Product three (3) full calendar month(s) prior to the date for first the anticipated Launch within the Territory, as determined by MedPointe.

(ii) The first quarterly period in each four (4)-calendar-quarter estimate provided by MedPointe under Section 6.2(c)(i) hereof shall constitute a binding commitment to issue Purchase Orders for the Product during that quarter in an amount equal to the forecast amount, and MedPointe shall issue conforming Purchase Orders from time to time specifying quantities and delivery dates during such calendar quarter. Cipla shall use its commercially reasonable efforts to meet MedPointe's requested delivery dates, which shall be within ten (10) days after the date Cipla receives each applicable conforming Purchase Order. For avoidance of any doubt, if the PO quantities are less than the binding forecast provided by Medpointe and Cipla has completed manufacturing as per the binding forecast, then MedPointe will pay for the quantities manufactured by Cipla as per the binding forecast.

(iii) Cipla shall not be required to accept Purchase Orders for quantities of Product in excess of one hundred and fifty percent (150%) of the amount specified in the forecast for the relevant calendar quarter, but shall use commercially reasonable efforts to fill any relevant excess Purchase Order(s). MedPointe shall place Purchase Orders in quantities in increments equal to Cipla's minimum batch size with the understanding that Cipla will supply the yield of the batch.

6.3 Delivery.

(a) All sales shall be FOB Mumbai, India, and title and risk of loss to all Products shall pass to MedPointe upon tender to a qualified carrier. Cipla shall use MedPointe designated carriers whenever possible. In the event that a MedPointe designated carrier is not available, Cipla may use a qualified carrier of its choice, with prior approval from MedPointe.

(b) Cipla shall furnish MedPointe a certificate of analysis ("Certificate of Analysis") for every batch produced with each shipment of the Product, and a copy of the complete batch record (including raw material, intermediate and final Product testing results) for the first batch of Product produced after the Effective Date. At MedPointe's request, Cipla shall additionally provide a complete batch record for all other batches of Product produced after the

Effective Date. The Certificate of Analysis shall include, at a minimum, the Product name, batch number, date of manufacture, analytical test results, specifications, microbiological test results, if applicable, and certification by Cipla that all specifications have been met and that the Product was produced and tested in accordance with cGMP requirements.

(c) Within thirty (30) days of receipt of each shipment, MedPointe shall perform: (i) a visual damage and/or loss inspection of that shipment relating to product count, packaging and appearance, and (ii) review the Certificate of Analysis test results against the specifications. If such inspection of any shipment and the review of any Certificate of Analysis reveals any non-conformities that should be revealed by the foregoing inspection and review, MedPointe shall promptly notify Cipla that such shipment of Product does not conform to the specifications and MedPointe may return the non-conforming Products to Cipla at Cipla's expense. At MedPointe's request, Cipla shall promptly either furnish replacement Products at no cost to MedPointe or provide MedPointe a credit for the returned Product. If the Parties disagree regarding the failure of any shipment of Product to meet specifications relating to product appearance, the Parties shall refer the disagreement to a mutually-agreed independent Third Party for resolution. The cost of such independent Third Party shall be paid for by the Party who is determined to be incorrect with respect to such Product. If Cipla's results have been endorsed by the Independent lab and Cipla has already supplied the replacement batch or provided MedPointe with a credit, MedPointe will pay for such batches or return the credit to Cipla, as the case may be. For avoidance of any doubt, MedPointe will be responsible for any non-conforming Product if the same is solely due to improper storage and transportation by MedPointe.

6.4 Capacity. If Cipla, upon receiving a forecast or a Purchase Order under Section 6.2 in excess of the quantities allowed by Section 6.2(c)(iii), is, or anticipates that it shall be, unable to meet such forecast or Purchase Order, either in whole or in part, due to any reason, Cipla shall give written notice of such inability to MedPointe promptly upon becoming aware of such fact. If such fact results in a partial inability to meet any forecast or Purchase Order, Cipla shall fulfill Purchase Orders with such quantities of the Product as are available. Cipla shall use its commercially reasonable efforts to ensure that Purchase Orders are supplied in full on a timely basis.

6.5 Second Source.

(a) MedPointe may select and qualify one additional sources (including MedPointe itself) for the supply of twenty percent (20%) of the Product requirement for the Territory, at its own cost. Cipla shall cooperate with MedPointe and the applicable Regulatory Authorities in the qualification of any additional sources under this Section 6.5, at MedPointe's expense.

(b) At MedPointe's reasonable request, Cipla shall promptly work with MedPointe to effectuate a Tech Transfer to enable MedPointe's second source supplier to manufacture the Product, as authorized hereunder. Cipla will grant access to its Goa facility for technical staff from the second source supplier, in order for them to witness the actual manufacture of the product. MedPointe's second source supplier shall not acquire any ownership rights in such transferred technology or know-how by virtue of this Agreement, shall be subject to confidentiality obligations at least as stringent as those contained in this Agreement, and shall be

expressly contractually prohibited from using such technology or know-how for any purposes other than supplying Product to MedPointe for the Territory or the Markets as per the terms of this Agreement, should Cipla not be able to supply these countries. MedPointe shall bear all costs in connection with any Tech Transfer.

6.6 Product Supply Fees. MedPointe shall pay Cipla a fixed price per unit of \$3.25 for each unit of Product sold by Cipla to MedPointe as commercial trade product. MedPointe shall pay Cipla a fixed price per unit of \$2.00 for each unit of Product sold by Cipla to MedPointe used as a physician sample. These prices are on FOB, Mumbai basis. For avoidance of doubt, these prices do not include the cost of Azelastine API which will be supplied by MedPointe to Cipla as per the terms of this Agreement.

6.7 MedPointe Pricing. MedPointe shall have sole discretion over establishing the price at which it sells the Product to Third Parties in the Territory.

6.8 Inventory. During the term of this agreement, Cipla shall use commercially reasonable efforts to maintain a six (6) month supply of Raw Materials and components except Azelastine. MedPointe will be responsible to ensure that Cipla has 6 months supply of Azelastine in its inventory.

ARTICLE VII - MANUFACTURE AND QUALITY

7.1 Manufacturing. Cipla shall manufacture commercial batches of the Product for the Territory at the Goa Facility. Cipla shall maintain such facility in compliance with cGMP at its own cost and shall remain fully responsible for its workforce and compliance with Applicable Laws.

7.2 Equipment and Raw Materials. Except for azelastine hydrochloride, Cipla shall be solely responsible for obtaining all other Raw Materials and obtaining and maintaining all equipment necessary for the manufacture, packaging, testing, analysis and shipment of the Product consistent with the specifications and Applicable Law, including cGMP. During the Term of this Agreement, Cipla shall obtain its entire requirements of azelastine hydrochloride for use in formulating and manufacturing the Product from MedPointe, and MedPointe shall provide, at MedPointe's cost, Cipla with its entire requirements of azelastine hydrochloride for the Product. Promptly after the Effective Date, Cipla shall provide MedPointe with samples of azelastine hydrochloride for which it has manufactured validation batches and prepared a drug master file that is ready to be filed, so that MedPointe may analyze such sample and determine its usability as a second source. At MedPointe's sole discretion it may choose to use azelastine hydrochloride manufactured by Cipla during the Term of the Agreement.

7.3 Packaging and Labeling. MedPointe shall provide Cipla with all necessary packaging and labeling artwork for the Product, giving due consideration to MedPointe's forecasts and Purchase Orders and lead time required by Cipla to satisfy its obligations under such Purchase Orders, in a timely manner. Notwithstanding anything herein to the contrary, Cipla shall not be responsible for any delay, breach or default hereunder resulting from MedPointe's failure to furnish Cipla with sufficient packaging and labeling artwork for the Product in a timely manner.

7.4 Changes to Specifications. Cipla shall not change the specifications, source of Raw Materials, components, suppliers, packaging materials, analytical test procedures and Third Party testing laboratories, or any manufacturing conditions or manufacturing equipment used in the manufacture of the Product in a manner that would initiate the Cipla change control process, or require any approval or filing with Regulatory Authorities, without the prior written consent of MedPointe, which consent shall not to be unreasonably withheld or delayed. If changes to the specifications or manufacturing processes are requested by MedPointe or MedPointe's consultants then Cipla and MedPointe shall cooperate in making such changes and obtaining necessary approvals in a timely manner. In this case, MedPointe will bear all the internal and external costs for making such changes. If changes to the specifications or manufacturing processes are required by Applicable Laws ("Manufacturing Changes") then Cipla and MedPointe shall cooperate in making such changes, and obtaining all necessary approvals, in a timely manner. In this instance, all internal and external costs associated with Manufacturing Changes shall be borne by Cipla.

7.5 Stability Testing. Cipla shall manage, at MedPointe's cost and expense, the stability program and provide testing for Product lots. The stability program (including storage and testing) shall meet applicable the International Conference on Harmonization (ICH) FDA, any other applicable Regulatory Authority guidelines and cGMP. MedPointe shall pay Cipla \$2,000 per complete analysis, per testing point, per strength, per pack, per stability condition (where applicable), per orientation (where applicable), per batch whether it is Cipla product or any reference sample. These charges are applicable for analysis in general whether it is for Stability Analysis or any other analysis.

7.6 Other Testing. MedPointe shall pay the cost of any necessary extractables/leachables testing, filter validations or other similar testing. For any additional testing not specified in this section 7.6, Cipla shall provide MedPointe a written quote for all work to be done and MedPointe shall decide whether to proceed with the Cipla quote or obtain other quotes to complete the testing. Should MedPointe determine the tests are necessary and Cipla performs them, this work shall be at MedPointe's cost.

ARTICLE VIII - RECORDS, ACCESS AND COMPLIANCE

8.1 Records. Each Party shall maintain any other manufacturing, packaging, analytical and stability records, records of shipment, and validation data relating to the Product to the extent and for the time periods required by Applicable Laws.

8.2 Compliance.

(a) MedPointe shall be responsible for (and bear all costs of) compliance with all Applicable Laws, rules and regulations with respect to the sale, labeling and advertising of the Product.

(b) Cipla shall provide reasonable support to MedPointe for all Product regulatory filings dealing with manufacturing, testing, labeling, packaging and storage of the Product, Raw Materials and components. Cipla shall provide MedPointe with a reasonably detailed report of all changes (manufacturing, testing and storage of the Product and Raw

Materials, components, vendors and equipment) associated with the Product that have occurred since the end of the previous annual FDA, or other applicable Regulatory Authority, Product reporting period.

(c) Prior to final commercial sale of the Product Cipla and MedPointe will sign a Quality Agreement.

8.2 Access to Facilities. MedPointe shall, upon reasonable request and with at least thirty (30) days notice, have the right to inspect those portions of the manufacturing, storage and testing facilities of Cipla where Products are being manufactured, stored or tested, as the case may be, during regular business hours and without undue interference to Cipla's business operations, to ascertain compliance with cGMP and the specifications. If the FDA or other applicable Regulatory Authority asserts any notice to the effect that Cipla has failed to comply with any Applicable Law in connection with the manufacture of the Product, then MedPointe shall have the right to inspect such portions of the manufacturing facilities of Cipla that relate to the manufacture and testing of such the Product upon reasonable notice and during normal business hours.

ARTICLE IX - ADVERSE EVENT AND RECALL REPORTING

9.1 Product Inquiries and Complaints. Each Party shall promptly submit to the other Party all safety and efficacy inquiries, quality complaints and adverse drug event reports received by such Party relating to the Product, together with all available evidence and other information relating thereto. MedPointe shall be responsible for investigating and responding to all medical, health and safety inquiries, complaints and adverse events regarding the Product in the Territory. In addition, MedPointe shall be responsible for complying with all applicable national, federal, state and local governmental reporting requirements regarding adverse drug events and Product quality matters in the Territory.

9.2 Response to Complaints and/or Adverse Drug Events. Cipla shall, at MedPointe's request, conduct analytical testing of corresponding retention samples and provide the results thereto to Cipla as soon as reasonably practicable after a product inquiry, complaint or adverse drug event. MedPointe shall be responsible for reporting any and all results to the FDA or other applicable Regulatory Authority in the Territory.

9.3 Recalls. MedPointe shall be responsible for any Product recalls in the Territory and Cipla shall assist MedPointe in complying with product recall policies of the applicable Regulatory Authority relating to the Product. The Parties shall cooperate in taking all appropriate corrective actions.

(a) Cipla shall bear the expenses of any recall in the Territory resulting from (i) Cipla's negligence or willful misconduct; (ii) damages to or defects in the Product occurring prior to Cipla's shipment of the Product from Mumbai; or (iii) Cipla's failure to manufacture and supply Product in accordance with cGMP and approved specifications.

(b) MedPointe shall bear the expenses for recalls resulting from (i) MedPointe's negligence or willful misconduct; or (ii) sterility, packaging, quality control; or (iii)

other manufacturing defects not within the control of Cipla. (iii) or any other reason not relating to manufacturing.

(c) For purposes of this Agreement, expenses of recall include, without limitation, the value of the recalled Product, expenses of notification and destruction or return of the recalled Product.

9.4 Product Liability Claims. As soon as it becomes aware of any pending or threatened product liability matter, each Party will give the other prompt written notice of any alleged defect in the Product, any injury alleged to have occurred as a result of the use or application of the Product, and any circumstances that may give rise to litigation or recall of the Product or regulatory action that may affect the sale or manufacture of the Product, specifying, to the extent the Party has such information, the time, place and circumstances thereof and the names and addresses of the persons involved. Each Party will also furnish to the other copies of all papers received in respect of any claim, action or suit arising out of such alleged defect, injury or regulatory action.

ARTICLE X - INSURANCE

10.1 Insurance. Upon the Launch of the Product in the Territory, MedPointe shall obtain and maintain in effect, for the term of this Agreement and for a period of five (5) years thereafter, Commercial General Liability insurance and Product Liability coverage including coverage for contractual liability with policy limits no less than Ten Million Dollars (\$10,000,000) for each occurrence and Ten Million Dollars (\$10,000,000) in the aggregate. Such policy limits may be obtained through an umbrella policy. Each such policy shall name Cipla as an additional insured. MedPointe shall ensure that its insurer should waive the right of subrogation it may have against Cipla related to each claim in the event that it can be proven through competent evidence that Cipla has manufactured the product in accordance with all applicable specifications and laws and regulations, including without limitation cGMP.

ARTICLE XI - INTELLECTUAL PROPERTY

11.1 Intellectual Property. Each Party shall retain all right, title and interest in and to Intellectual Property made, conceived, reduced to practice or generated by its employees, agents, or other persons acting under its authority in the course of or as a result of this Agreement. Cipla shall grant MedPointe a royalty-free license to any Improvements made by Cipla during the Term to the Product in the Territory for the term of this Agreement provided however that such license shall be exclusive, royalty-free, perpetual and irrevocable to MedPointe automatically in the event this Agreement is terminated due to breach by Cipla as per Section 12.2.

11.2 Infringement Suit by Third Parties. If a Third Party sues MedPointe and/or Cipla for infringement or misappropriation of Intellectual Property arising out of or relating to the Product in the Territory, the Party receiving such suit shall immediately notify the other Party in writing. MedPointe shall defend such lawsuit on behalf of the two companies and indemnify Cipla per Article XIV herein, provided that Cipla gives MedPointe, at Cipla's expense, all reasonable assistance, which shall include internal time and travel costs of Cipla employees and agents in connection therewith.

11.3 Third Party Infringement of Intellectual Property. If MedPointe or Cipla becomes aware of actual or threatened infringement or misappropriation of any Product Intellectual Property in the Territory, that Party shall immediately notify the other Party in writing. MedPointe shall have the first right, but not the obligation, to bring, at its own expense, an infringement or misappropriation action against any such Third Party, provided there is prior notification to and consultation with Cipla, and to use Cipla's name in connection therewith and to name Cipla as a party thereto. If MedPointe brings such an action, it shall retain all amounts obtained in successful prosecution of such legal action. If MedPointe does not commence a particular infringement action within ninety (90) days of receipt of the notice of infringement, then Cipla, after notifying MedPointe in writing, shall be entitled to bring such infringement action at its own expense and shall retain all amounts obtained in successful prosecution of such legal action. The Party conducting such action shall have full control over its conduct, provided, however, any party may not engage in a settlement without the other party's prior written consent. In any event, MedPointe and Cipla shall assist one another and cooperate in any such litigation at the other Party's request without expense to the requesting Party.

ARTICLE XII - TERM AND TERMINATION

12.1 Term. The term of this Agreement shall be, for each country within the Territory, from the Effective date to fifteen (15) years from the date of Launch within that particular country ("Term").

12.2 Termination for Breach. This Agreement may be terminated by either Party for material breach of this Agreement by the other Party where the breach was not the result of the acts or omissions of the Party seeking termination. The Party not in breach ("Non-Defaulting Party") shall have the right to give the other Party ("Defaulting Party") written notice thereof ("Notice of Breach"), which notice must state the nature of the breach in reasonable detail and must request the Defaulting Party to cure such breach within one-hundred twenty (120) days, with all rights and obligations remaining in full force and effect during such one-hundred twenty (120) day period. If the Defaulting Party shall dispute the existence, extent or nature of any breach set forth in a Notice of Breach, the Parties shall use good faith efforts to resolve the dispute. If the Defaulting Party shall not have cured the breach within that) one-hundred twenty (120) day period, the Non-Defaulting Party, at its option and in addition to any other remedies it may have, may terminate this Agreement.

12.3 Termination by Cipla. Cipla may terminate this Agreement if (a) MedPointe or any of its successors does not Launch the Product by December 31, 2013 through no fault of Cipla and has not launched another combination azelastine hydrochloride and fluticasone propionate nasal spray product in the Territory; or (b) MedPointe does not Launch the Product in the Territory by December 31, 2013 but has launched a non-Cipla (not formulated by Cipla) combination azelastine hydrochloride and fluticasone propionate nasal spray product in the Territory by such date; or (c) MedPointe has received a full, final approval of the NDA for the Product by the FDA but has not Launched the Product within eighteen (18) months of such approval date; provided however that such delay is not due to (i) fault of Cipla, (ii) failure to obtain adequate supplies of any component of the Product, including without limitation bottles, pumps, seals, labels, active, inactive and excipient ingredients; (iii) governmental, regulatory or court action, decree or regulation that puts significant restrictions or difficulties on Launch . If

Cipla terminates this Agreement under Section 12.2 or Section 12.3 (a) above, then MedPointe shall transfer the NDA free of charge to Cipla promptly upon receiving notice of termination by Cipla. If Cipla terminates this agreement under 12.3(b), then MedPointe shall have no obligation to transfer the NDA back to Cipla but instead shall pay Cipla a royalty on Net Sales of the first launched non-Cipla product in the Territory (and no subsequent product) equal to 5% of Net Sales generated by MedPointe or any of its successors, partners, licensees or sublicensees for the first 5 years immediately following launch. Notwithstanding the foregoing, the royalty for each of the 5 years shall bear a maximum annual amount of U.S.\$5,000,000 (USD 5 Million). If Cipla terminates this Agreement under 12.3(c) above, then MedPointe shall transfer the NDA to Cipla provided that the transfer shall be conditioned on the parties entering into a written binding agreement providing that Cipla shall pay MedPointe 50% of all profits generated by Cipla or any of its successors, partners, licensees or sublicensees on the Product once the NDA is transferred back to Cipla. It is understood and agreed that in the event the Agreement is terminated by Cipla due to MedPointe breach per Section 12.2, the transfer of the NDA from MedPointe to Cipla shall serve as liquidated damages and not a penalty; MedPointe shall have no further liability to Cipla with respect to the default giving rise to the termination. If the termination occurs prior to MedPointe filing an NDA with the FDA for the Product, MedPointe shall pay Cipla all unpaid monies due to Cipla under this Agreement at such time including charges for milestone payments, stability studies/extractables, leachables etc as liquidated damages and not a penalty and MedPointe hereby grants Cipla an exclusive, perpetual, irrevocable, fully paid, royalty free license to all clinical trial reports generated whether pilot or pivotal; MedPointe shall have no further liability to Cipla with respect to the default giving rise to the termination.

12.4 Termination by MedPointe. If MedPointe terminates this Agreement under Section 12.2 above, then (a) Cipla hereby grants MedPointe an exclusive, perpetual, irrevocable, fully paid and royalty-free license under the Product Intellectual Property to use, have used, market, sell, import and distribute the Product in the Territory and a perpetual, non-exclusive, irrevocable, fully paid and royalty-free license, with the right to sublicense, to manufacture and have manufactured the Product anywhere in the world; (b) in addition to the clauses referenced in 12.6 below, Section 5.6 above shall survive such termination; (c) if the termination occurs prior to MedPointe filing an NDA with the FDA for the Product, Cipla shall refund MedPointe all monies paid by MedPointe to Cipla including charges for milestone payments, stability studies/extractables, leachables etc up to a cap of U.S. \$4,000,000 (USD 4 million). as liquidated damages and not a penalty; Cipla shall have no further liability to MedPointe with respect to the default giving rise to the termination other than liability relating to infringement of MedPointe's Intellectual Property (for which Cipla's liability shall not be limited); and (d) If the termination occurs after MedPointe has filed an NDA with the FDA for the Product, Cipla shall pay MedPointe U.S.\$4,000,000 (USD 4 million) as liquidated damages and not a penalty; Cipla shall have no further liability to MedPointe with respect to the default giving rise to the termination other than liability relating to infringement of MedPointe's Intellectual Property (for which Cipla's liability shall not be limited).

12.5 Termination by Mutual Consent. In the event the parties mutually agree to terminate this Agreement, and such termination is not for a breach by either party pursuant to Section 12.2, Cipla and MedPointe acknowledge and agree that neither party shall owe the other the monetary payments specified as liquidated damages and they further agree that they would at such time negotiate such other terms as would apply in such situation.

12.6 Survival. The following provisions shall survive the termination of this Agreement for any reason in accordance with their respective terms: Article I, VIII, IX, XIII, XIV, XV, XVI and Sections 11.1, 12.3 12.4, 12.5 and 12.6.

ARTICLE XIII - REPRESENTATIONS AND WARRANTIES

13.1 Cipla Representations and Warranties. Cipla hereby represents and warrants to MedPointe that:

(a) Power and Authority. It has the corporate power, authority and legal right to enter into this Agreement and perform its obligations hereunder and has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.

(b) Binding Agreement. This Agreement has been duly executed and delivered on behalf of Cipla and constitutes a legal, valid and binding obligation of Cipla that is enforceable against it in accordance with its terms.

(c) No Conflict. The execution, delivery and performance of this Agreement does not conflict with, and would not result in a breach of, any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound.

(d) Validity. It is aware of no action, suit, inquiry or investigation instituted by any Third Party that questions or threatens the validity of this Agreement.

(e) Corporate Existence. It is a corporation duly organized and validly existing, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement.

(f) Debarment. Neither Cipla nor any of its Affiliates has been debarred or is subject to debarment and neither Cipla nor any of its Affiliates will knowingly use in any capacity, in connection with the services to be performed under this Agreement, any entity who has been debarred pursuant to Section 306 of the FDCA, or who is the subject of a conviction described in such section. Cipla agrees to immediately inform MedPointe in writing if it or any person or entity who is performing services hereunder is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of Cipla's knowledge, is threatened, relating to the debarment or conviction of Cipla or any person or entity performing services hereunder.

(g) Product Rights. It has not granted, and shall not during the Term grant, any right, license, covenant, consent or privilege with respect to the Product in the Territory to any Third Party or otherwise undertake any action which would conflict with the rights granted to MedPointe as set forth in this Agreement.

(h) Ownership. Cipla is the exclusive owner of all right, title and interest in the Product and to the Product Intellectual Property, and such rights are not subject to any encumbrance, lien or claim of ownership by any Third Party.

(i) Status of Product Intellectual Property.

(i) To the knowledge of Cipla, the conception, development and reduction to practice of the subject matter claimed and/or disclosed in the Product Intellectual Property existing as of the Effective Date have not constituted or involved the misappropriation of trade secrets or other rights or property of any Third Party. There are no judgments or settlements against Cipla or amounts owed by Cipla (other than amounts owed in the ordinary course of business) with respect to the Product Intellectual Property. No litigation has been brought or threatened, by any person or entity alleging that the Product Intellectual Property is invalid or unenforceable.

(ii) Except for the license grant in Section 2.1, neither Cipla nor any of its Affiliates has, directly or indirectly, expressly or by implication, by action or omission or otherwise (A) assigned, transferred, conveyed or otherwise encumbered any right, title or interest in or to the Product Intellectual Property, or (B) agreed to or is otherwise bound by any covenant not to sue for any infringement, misuse or otherwise with respect to the Product Intellectual Property.

13.2 Representations of MedPointe. MedPointe hereby represents and warrants to Cipla that:

(a) Power and Authority. It has the corporate power, authority and legal right to enter into this Agreement and perform its obligations hereunder and has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.

(b) Binding Agreement. This Agreement has been duly executed and delivered on behalf of MedPointe and constitutes a legal, valid and binding obligation of MedPointe that is enforceable against it in accordance with its terms.

(c) No Conflict. The execution, delivery and performance of this Agreement does not conflict with, and would not result in a breach of, any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound.

(d) Validity. It is aware of no action, suit, inquiry or investigation instituted by any Third Party that questions or threatens the validity of this Agreement, or which successful, would have a material adverse effect on the rights granted to Cipla under this Agreement.

(e) Corporate Existence. It is a corporation duly organized and validly existing, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement.

(f) Debarment. Neither MedPointe nor any of its Affiliates has been debarred or is subject to debarment and neither MedPointe nor any of its Affiliates will knowingly use in any capacity, in connection with the services to be performed under this Agreement, any entity who has been debarred pursuant to Section 306 of the FDCA, or who is the subject of a conviction described in such section. MedPointe agrees to immediately inform Cipla in writing if it or any

person or entity who is performing services hereunder is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of MedPointe's knowledge, is threatened, relating to the debarment or conviction of MedPointe or any person or entity performing services hereunder.

ARTICLE XIV - INDEMNIFICATION

14.1 Indemnification by Cipla. Cipla shall defend, hold harmless and indemnify MedPointe and its Affiliates, agents, directors, officers and employees and assigns from and against any and all damages (including reasonable attorney's fees and court costs), as well as liabilities resulting directly or indirectly from any Third Party claims, suits, actions or demands arising out of or relating to: (i) Cipla's negligent or willful misconduct; (ii) claims of death or injury due to the proven manufacturing defect in the Product or (iii) packaging, quality control or other manufacturing defects in the Product not within the control of MedPointe.

14.2 Indemnification by MedPointe. MedPointe hereby agrees to defend, hold harmless and indemnify Cipla and its Affiliates, agents, directors, officers and employees and assigns from and against any and all liabilities resulting directly or indirectly from any Third Party claims, suits, actions or demands arising out of or relating to: (i) MedPointe's negligent and willful misconduct; (ii) sterility, packaging, quality control or other manufacturing defects not within the control of Cipla; or (iii) infringement of Third Party Intellectual Property in the Territory by the making, supply, using, marketing, importation distribution or sale of the Product

14.3 Procedures for Indemnification for Third-Party Claims. A party (the "indemnatee") that intends to claim indemnification under this Article XIV shall notify the indemnifying party (the "indemnitor") within a reasonable time in writing of any action, claim, or liability in respect of which the indemnatee believes it is entitled to claim indemnification; provided that the failure to give timely notice to the indemnitor will not release the indemnitor from any liability to the indemnatee except to the extent the indemnitor is actually prejudiced thereby. The indemnitor will have the right, by notice to the indemnatee, to assume the defense of any such action or claim within the fifteen (15) day period after the indemnitor's receipt of notice of any action or claim with counsel of the indemnitor's choice and at the sole cost of the indemnitor. If the indemnitor does not so assume the defense of such Third Party claim, the indemnatee may assume such defense with counsel of its choice and at the sole cost of the indemnitor. If the indemnitor so assumes such defense, the indemnatee may participate therein through counsel of its choice, but at the sole cost of the indemnitor. The party not assuming the defense of any such claim will render all reasonable assistance to the party assuming such defense, and all reasonable out-of-pocket costs of such assistance will be for the account of the indemnitor. No such claim will be settled other than by the party defending the same, and then only with the consent of the other party, which shall not be unreasonably withheld; provided that the indemnatee shall have no obligation to consent to any settlement of any such action or claim that imposes on the indemnatee any liability or obligation that cannot be assumed and performed in full by the indemnitor, and the indemnatee will have no right to withhold its consent to any settlement of any such action or claim if the settlement involves only the payment of money by the indemnitor or its insurer.

14.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE FOR INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE INCURRED BY THE OTHER PARTY IN CONNECTION WITH THIS AGREEMENT REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. DAMAGES PAYABLE TO THIRD PARTIES THAT ARE SUBJECT TO INDEMNIFICATION HEREUNDER SHALL NOT BE CONSIDERED INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES FOR PURPOSES OF THE FOREGOING SENTENCE, EVEN IF THE UNDERLYING DAMAGES ARE SO CHARACTERIZED.

14.5 Exclusive Remedy. The Parties acknowledge and agree that the indemnification provisions of Sections 14.1 and Section 14.2 shall be the sole and exclusive remedies of the Parties for any breach by the other Party of the representations and warranties in this Agreement and for any failure by the other Party to perform and comply with any covenants and agreements in this Agreement.

ARTICLE XV - CONFIDENTIALITY

15.1 Confidentiality. All Confidential Information provided by the Disclosing Party to the Receiving Party in connection with this Agreement is proprietary to the Disclosing Party and shall be maintained in strict confidence by the Receiving Party. Such Confidential Information shall remain the property of the Disclosing Party, and the Receiving Party shall not use the same for any purposes other than exercising its rights and performing its obligations under this Agreement. At the termination of this Agreement, the Parties shall promptly return to the Disclosing Party any physical embodiments (including copies) of any such Confidential Information or, at the Disclosing Party's sole election, destroy the same under the Disclosing Party's supervision.

15.2 Disclosure. Nothing in this Agreement shall be construed as preventing or in any way inhibiting either Party from disclosing Confidential Information necessary to comply with Applicable Laws. In the event a Party shall deem it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to this Section 15.2, the Disclosing Party shall to the extent possible give reasonable advance notice of such disclosure to the other Party, and shall consider in good faith the other Party's objections to such disclosure, including suggestions to redact Confidential Information, and take reasonable measures to ensure confidential treatment of such information.

15.3 Period of Obligation. This Article shall survive for a period of ten (10) years after expiration or termination of this Agreement.

15.4 Equitable Relief. The Parties each acknowledge that a breach by it of this Article XV cannot reasonably or adequately be compensated in damages in an action at law and that such a breach may cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party may be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of this Article XV by the other Party; provided, however,

that no specification in this Agreement of a specific legal or equitable remedy shall be construed as a waiver or prohibition against the pursuing of other legal or equitable remedies in the event of such a breach. Each Party agrees that the existence of any claim, demand, or cause of action of it against the other Party, whether predicated upon this Agreement, or otherwise, shall not constitute a defense to the enforcement by the other Party, or its successors or assigns, of the covenants contained in this Article XV.

ARTICLE XVI - MISCELLANEOUS

16.1 Public Announcements. Neither Party shall make any publicity releases, interviews, or other dissemination of information concerning this Agreement or its terms, or either Party's performance hereunder, to communication media, financial analysts, or others without the approval of the other Party, which approval shall not unreasonably be withheld. Either Party may upon notice to the other Party make any disclosure in filings with regulatory agencies as required by law, rules of a self-regulatory organization or securities exchange, or applicable court order; provided that the other Party shall have the opportunity to consult in advance on such disclosures and filings.

16.2 Force Majeure. Neither Party shall be liable for any default or delay in such Party's performance if such default or delay is caused by an event beyond the reasonable control of such Party, including, but not limited to: act of God; war or insurrection; civil commotion; destruction of essential facilities or materials by earthquake, fire, flood or storm; labor disturbance; epidemic; terrorist act or threat of terrorist act or other similar event; provided, however, that the Party so affected will give prompt notice of such event, and shall use its Commercially Reasonable Efforts to avoid, remove or alleviate such causes of nonperformance and shall continue performance hereunder with the utmost dispatch whenever such causes are removed.

16.3 Entire Agreement. This Agreement and the documents referred to herein constitute the entire agreement between the Parties pertaining to the subject matter hereof, and this Agreement supersedes, on its Effective Date, any other agreements, understandings, promises and representation, whether written or oral, between the Parties relating to the same subject matter save for where otherwise expressed in this Agreement. No agent of either Party is authorized to make any representation, promise, or warranty not contained in this Agreement.

16.4 Amendment and Waiver. This Agreement may only be amended by the Parties in writing, making specific reference to this Agreement, provided that the same is signed by all Parties. No course of dealing between the Parties or failure by either Party to exercise any right or remedy hereunder shall constitute an amendment to this Agreement or a waiver of any right or remedy or the later exercise of any right or remedy.

16.5 Governing Law. This Agreement shall be construed in accordance with the Laws of the United Kingdom without regard to any choice of law provisions.

16.6 Dispute Resolution. Any controversy, claim, or dispute arising out of or relating to this Agreement (collectively "Dispute") shall be attempted to be settled by the Parties in good faith. In the event that there is no resolution of such Dispute, any action arising out of this

Agreement shall be brought exclusively to the courts of London, U.K.. MedPointe and Cipla consent to the venue of and to the exercise of such jurisdiction by the courts of London, U.K. and waive any defense of lack of personal jurisdiction.

16.7 Assignment. Neither Party may assign any right or obligation hereunder without the written consent of the other Party, such consent not to be unreasonably withheld; provided, however, that either Party may assign this Agreement to any affiliate or to any corporation with which it may merge or consolidate, or to which it may transfer all or substantially all of its assets to which this Agreement relates, without obtaining the consent of the other Party. The Agreement will be binding on the successors of either Party and other permitted assigns.

16.8 Nature of Agreement. In operating under the Agreement, each Party shall act independently and this Agreement shall not be construed as creating any partnership, joint venture or incorporated business entity. No Party shall have any authority to incur any liability or obligation whatsoever on behalf of any other Party.

16.9 Notice. Any notice, demand, waiver, consent, approval or other communication which is required or permitted to be given to any Party under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be effective on receipt, as evidenced in writing, when given by registered airmail or certified mail, postage prepaid, or overnight courier, and addressed, unless otherwise specified in writing, to the addresses of the Parties described below, and effective upon sending if sent by facsimile confirmed by a written transmission report:

If to MEDPOINTE:

265 Davidson Ave., Suite 300
Somerset, NJ 08873-4120
Tel: (732) 564-2200
Fax: (732) 564-2210

Attention: Beth Hecht, Esq.

with a copy to:

Weil, Gotshal & Manges LLP
767 Fifth Avenue
New York, NY 10153-0119
Tel: (212) 310-8000
Fax: (212) 310-8007

Attention: Jeffrey Osterman, Esq.

If to CIPLA:

Cipla Ltd.
Mumbai Central,

Confidential

Mumbai. 400008.
India.
Phone:91-22-23070399
Fax: 91-22-23070385

Attention: Mr. Amar Lulla

16.10 Separability.

(a) In the event any portion of this Agreement shall be held illegal, void or ineffective, the remaining portions hereof shall remain in full force and effect.

(b) If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to conform with such statute or rule of law, and the remaining portions hereof shall remain in full force and effect.

(c) In the event that the terms and conditions of this Agreement are materially altered as a result of Sections 16.10(a) or 16.10(b), the Parties will renegotiate the terms and conditions of this Agreement to effectuate their original intent as closely as possible while remaining valid and enforceable.

16.11 Execution in Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be an original and all of which shall constitute together the same instrument.

16.12 Compliance with Law. Each Party shall discharge its obligations as set forth in this Agreement in a professional manner and in compliance in all material respects with the requirements of Applicable Law. Each Party agrees to commit qualified and experienced personnel, facilities, equipment, expertise and other resources necessary to perform its obligations hereunder, and to monitor and oversee its personnel, facilities, equipment and operations in all material respects as required under Applicable Law.

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IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed on the date first written above by their respective duly authorized officers, on the date first written above.

MEDPOINTE HEALTHCARE INC.

By: Corey Fishman (signature)

Name: Corey Fishman

Title: EVP + CFO

CIPLA LTD.

By: Amar Lulla (signature)

Name: AMAR LULLA

Title: JT. M.D.

Schedule A – Target Formulation**Target Product Profile**

Parameter	Target Profile
Formulation	Azelastine HCL 137mcg/spray (0.1 % w/v) + Fluticasone Propionate 50mcg/spray (0.0365%w/v) ¹ , BAC (0.01% w/v), Phenyl Ethyl alcohol (0.25% v/v)
Dose Form	Nasal Spray
Dosage and Administration	1 spray/nostril twice daily

Physical Product Parameters

Parameter	Target Profile
Desired Commercial Batch	200 liters (8,695 bottles) ²
Active Pharmaceutical Ingredients	Azelastine: Meda, Fluticasone: Cipla
Pump	Valois 140µL VP3. Crimp on to match bottle (with cover)
Bottle-Trade	US DMF Amber Glass Bottle from Nuova Ompi 25R DIN std; OFC 30.5cc USP Type 1
Bottle-Sample	US DMF Amber Glass Bottle from Nuova Ompi 10R DIN std; 10 mL USP Type 1
Target Fill Volume 1. Trade	120 Metered Doses-30 Day Supply (22-23 mLs)
2. Sample	28 Metered Doses-7 Day Supply (5 mLs)
Spray Volume	137µL
Expiration Dating (Trade & Sample)	24-months (File with 12-months)
Storage	Store at Controlled Room Temperature 20°- 25° C (do not refrigerate). Protect from light
Packaging Configurations Trade: 30-Day Supply	Single 30.5 mL Amber Glass Bottle with Valois VP3 Pump attached in box. Primary colors of container label and box-TBD. No cellophane overwrap. Each box contains package insert and patient instructions
Sample: 7 day Supply	Single 10 mL Amber Glass Bottle with Valois VP3 Pump attached in box. Primary colors of container label and box-TBD. No cellophane overwrap. Each box contains package insert and patient instructions

¹ 50 mcg Fluticasone propionate to be delivered per spray (137mcg of product).

² The proposed fill volume per bottle is 23mL. Hence, no. of bottles per batch of 200 liters would be approximately 8,695.

Schedule B1

MedPointe Intellectual Property
Azelastine in Territory

1. **U.S. Patents:**
 - a) U.S. 5,086,050
 - b) U.S. 5,110,814
 - c) U.S. 5,164,194
 - d) U.S. 5,232,919
 - e) U.S. 5,271,946
 - f) U.S. 5,760,221
2. **U.S. Patent Applications:**
 - a) U.S. App 60/370,274
 - b) U.S. App 11/284,109 published as US 2006-0110331-A1 on 5/26/06
 - c) U.S. App 11/486,454
3. **Canadian Patents:**
 - a) CA 2016089
 - b) CA 2007480
 - c) CA 1319322
 - d) CA 1317595
 - e) CA 1325976
 - f) CA 2138308
4. **International Patent Applications designating US, CA, MX**
 - a) PCT/US2005/042362, filed 11/22/05, publ. as WO 2006/058022 6/01/06
 - b) PCT/US2006/027435, filed 7/14/06

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Schedule B2- Product Intellectual Property

Canada

National phase entry date-24/2/05

Application No.- 2489427

Mexico

National phase entry date- 14/12/04

Application No.- PA/a/2004/012666

USA

National phase entry date-14/12/04

Application Nos.-10/518016

Priority Appin: 0213739.6 filed at GB patent office on 14/6/02

Pct appln no PCT/GB2003/002557 filed on 13/6/2003

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Exhibit 5.5

Quality Agreement

QUALITY AGREEMENT

BETWEEN

MEDPOINTE HEALTHCARE INC.

AND

Cipla Ltd.

NY1: 1460507.02\N@XN02\DOC\62641.0013

29

**HIGHLY CONFIDENTIAL -
SUBJECT TO STIPULATED PROTECTIVE ORDER**

MEDA_APTX03490412

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PTX1016-00029

DATED AS OF October 24, 2006

TABLE OF CONTENTS

- I. Annual Product Reviews and Annual Reports
- II. Document and Reserve Sample Retention
- III. Deviations and Failure Investigations
- IV. Complaint and Adverse Event Handling
- V. Recalls
- VI. NDA Field Alerts
- VII. Control Documents and Change Control Implementation
- VIII. Label Copy Approval
- IX. Regulatory Contacts
- X. Audits by MedPointe
- XI. Dispute Resolution
- XII. Specifications
- XIII. Testing
- XIV. Disposition of Material/Component/Product
- XV. Validation/Qualification
- XVI. Sub-Contractors
- XVII. Contact List

PRODUCT: Azelastine Hydrochloride Combination Nasal Spray

CONTRACTOR: MedPointe Healthcare Inc. ("MedPointe")

CONTRACT FACILITY: Cipla Ltd. ("Cipla")
PLOT NO. L-139 AND L-140A, VERNA INDUSTRIAL ESTATE
VERNA, SALCETTE, GOA-403 722 INDIA

MedPointe and Cipla hereby agree to the following terms relating to key quality and regulatory systems involved in the manufacture and/or packaging of the above-noted "Product". Non-commercial Product manufacturing/packaging will require an approved protocol to address MedPointe special requirements and/or deviations from this agreement.

I. ANNUAL PRODUCT REVIEWS AND ANNUAL REPORTS

Cipla shall prepare an Annual Product Review ("APR") for each Product as required by current Good Manufacturing Practices and applicable regulations, including 21 CFR 211.180(e). A copy of the Cipla APR must be forwarded to MedPointe Corporate Quality Assurance within 10 business days after completion of the APR. The APR shall be provided to MedPointe within 60 days of the NDA Anniversary date. Annual Retain inspection 21 CFR 211.170(b) results shall be included in the APR report.

For MedPointe NDA Product, MedPointe shall be responsible for preparing the Annual Report as required by applicable regulations, including 21 CFR 314.70(d) and 314.81(b) (2), and/or 601.12(d), (f) (3). At least 90 business days before the Annual Report due date (i.e., the Product anniversary date), MedPointe shall request in writing from Cipla the chemistry, manufacturing and controls data required for submission of the Annual Report. Cipla shall provide the information to MedPointe no later than 60 business days after the request.

II. DOCUMENT AND RESERVE SAMPLE RETENTION

All documents, records, and reports associated with the manufacture, holding, storage, packaging, or testing of any Product lot, including investigation reports, shall be retained by Cipla for at least 1 year beyond the expiration date of the finished Product lot, or as otherwise required by applicable law. Validation records will be maintained for the life of the Product. Cipla shall retain the stability data for the life of the product. All such documents, records, and reports must be maintained by Cipla in such a manner that they are (i) readily retrievable and (ii)

stored in an environment suitable to prevent damage or loss. Cipla shall provide copies of all such documents and information to MedPointe.

Cipla shall retain samples from each incoming lot of active ingredient and excipient used in the manufacture of any Product in an amount sufficient to perform two complete repetitions of full analytical testing. Cipla shall also retain samples of the packaged finished Product for each lot of Product in an amount sufficient to perform two complete repetitions of full finished Product analytical testing. Cipla shall store retain samples under conditions consistent with the labeling for a minimum of 1 year after the expiration of the finished Product.

III. DEVIATIONS AND FAILURE INVESTIGATIONS

Except as provided in Sections IV, Cipla must notify MedPointe Corporate Quality Assurance within 3 business days of the occurrence of a confirmed out-of specification result or major process deviation relating to the Product in accordance to Cipla SOP on incident investigations. MedPointe in consultation with Cipla shall make all Quality decisions regarding any such out-of-specification result or major process deviation that may impact the quality, efficacy, purity of the Product and/or is a deviation from the approved NDA. Any additional processing that may be needed as part of the investigation is to be reviewed and approved by MedPointe prior to the initiation.

All investigations must be completed, documented, and approved by Cipla prior to issuance of a Certificate of Compliance or a Certificate of Analysis pursuant to Section XIV.

IV. COMPLAINT AND ADVERSE EVENT HANDLING

All Adverse Event reports shall be forwarded to MedPointe Medical Affairs who has sole responsibility for handling Adverse Events. Cipla shall investigate Product complaints forwarded to Cipla by MedPointe. Cipla shall comply with all reasonable MedPointe requests in connection with the investigation of any Product complaint. Cipla must provide MedPointe with information regarding any Product complaint investigation as reasonably requested by MedPointe.

Cipla shall complete and document each Product complaint investigation within 30 business days after initial receipt of the complaint by Cipla, unless otherwise agreed by MedPointe, whose consent shall not be unreasonably withheld or delayed. If the investigation will exceed 30 business days, Cipla must provide MedPointe Corporate Quality Assurance with an interim report, including test results to date and a target completion date, on or before the 30th business day of the investigation. Cipla shall complete the complaint investigation within 60 business days after initial receipt of the complaint by Cipla. Cipla shall forward a copy of the final

investigation report to MedPointe Corporate Quality Assurance within 5 business days after the completion of the investigation. MedPointe shall be responsible for determining, in its reasonable discretion, when a complaint investigation has been completed and shall have sole responsibility for responding to the complainant (if applicable).

Cipla shall notify MedPointe Corporate Quality Assurance of a confirmed out-of-specification result pertaining to a complaint sample within 1 business day of the occurrence of the out-of-specification result.

Any out-of-specification results relating to a Product complaint sample shall be investigated as follows;

Cipla shall report any confirmed out-of-specification results relating to a Product lot to MedPointe corporate Quality Assurance within 1 business day of the occurrence. Cipla shall use its best efforts to complete and document an investigation with regard to any such out-of-specification result within 30 business days of the initial out-of-specification result. If the investigation will exceed 30 business days, Cipla shall provide MedPointe Corporate Quality Assurance with an interim report, including test investigation. A copy of the final investigation report shall be forwarded to MedPointe within 5 business days of completion of the investigation. Cipla shall provide MedPointe with information regarding any investigation as reasonably requested by MedPointe. Retain samples may be analyzed as part of the investigation to confirm any complaint sample out-of-specification result.

Cipla shall retain unused Product complaint samples at their labeled storage conditions for a minimum of 90 business days after a copy of the complaint investigation report has been sent to MedPointe.

V. RECALLS

MedPointe shall have sole responsibility for initiating and managing any Recall of the Product, provided that MedPointe shall consult with Cipla prior to initiating any Recall. Upon receiving from any governmental or Regulatory Authority having jurisdiction any direction to Recall any Product from the market, the receiving party shall immediately notify the other party.

VI. NDA FIELD ALERTS

MedPointe shall be responsible for determining the need for, and for filing, any NDA Field Alert Report and/or follow-up reports relating to a Product. MedPointe Corporate Quality Assurance shall notify Cipla of any NDA Field Alert Report or follow-up report relating to a Product prior to its filing.

VII. CONTROL DOCUMENTS AND CHANGE CONTROL IMPLEMENTATION

Any change(s) made to the Specifications of raw materials, packaging components, API, labeling, including but not limited to the manufacturing process (i.e. equipment, facility modifications, location, etc.) and/or analytical methods which may affect the quality, validated state of the systems, performance of the Product, or commitments made in regulatory filings must be approved by MedPointe, in writing, prior to implementation. MedPointe shall be notified of any changes to documentation not requiring MedPointe approval. Cipla shall be responsible to evaluate and notify MedPointe of any USP required changes in accordance with this Section of the agreement. The aforementioned changes may be initiated by Cipla in accordance to Section VII of this agreement. Documents referenced in this Section must be amended as required by the Product Application or license or as required by applicable laws, rules, regulations or regulatory agencies.

VIII. LABEL COPY APPROVAL

In the packaging of the Product, Cipla shall use only labels and labeling approved in compliance with standards/specifications provided by MedPointe. All labeling changes, including mechanicals and final proofs, shall be reviewed/approved by MedPointe Regulatory Affairs prior to implementation.

IV. REGULATORY CONTACTS

MedPointe shall be solely responsible for all contacts and communications with any regulatory agency with respect to all matters relating to the Product.

Unless required by law or a regulatory agency, Cipla shall have no contacts or communication with any regulatory agency regarding any Product without the consent of MedPointe, which consent shall not be unreasonably withheld or delayed. Cipla shall notify MedPointe Corporate Quality Assurance promptly, preferably no later than 1 business day, after Cipla receives any contact or communication from any regulatory agency regarding a Product.

Cipla shall provide MedPointe Corporate Quality Assurance with copies of all communications received from or sent to any regulatory agency with respect to MedPointe Product within 1 business day after receipt or sending of the communication, as the case may be.

Cipla and MedPointe shall inform the other party of any inquiry from a regulatory agency specifically relating to the Product. Cipla shall allow a MedPointe representative at its discretion to participate in any further contacts or communications relating to a Product if reasonably practicable. MedPointe shall, at its discretion, participate in any agency inspection specific to MedPointe product. Cipla will secure agreement from MedPointe, which shall not be unreasonably withheld or delayed, prior to making commitment to a regulatory agency regarding the Product. Cipla shall comply with all reasonable requests and comments by MedPointe with respect to all contacts and communications with a regulatory agency relating to a Product.

Cipla shall make available to MedPointe any data and/or information, including samples, required to ensure MedPointe's compliance with its regulatory filings. MedPointe reserves the

right to submit such data to regulatory agencies as required maintaining compliance with its regulatory filings.

X. AUDITS BY MEDPOINTE

MedPointe shall have access to Cipla's facilities at a mutually agreeable time for the sole purpose of auditing Cipla's compliance with cGMPs and the content of this Agreement. At mutually agreeable times, MedPointe shall be permitted to review Cipla's facilities, equipment, process, and records associated with the Product, or as follow-up to failure investigations, deviations, non-conformances to approved specifications, and/or quality audit observations.

XI. DISPUTE RESOLUTION

In the event that a dispute arises between Cipla and MedPointe in the analysis of the Product, the resolution will proceed in stages. The first stage requires direct communication between analysts from both parties to determine that the methods of analysis are the same and are being executed in the same manner at both sites. Second, carefully controlled, split samples should be sent from one site to the other for analysis in an attempt to reach agreement. Should there be a failure to achieve resolution; analysts from both parties will be required to communicate to work through the analysis of a mutually agreeable sample. If these actions fail to achieve resolution, and only after these avenues have been exhausted, a qualified referee laboratory will be used by MedPointe to achieve resolution. The results from this referee laboratory will be used to determine resolution, but whatever the outcome MedPointe retains the right to determine Product release status. Cipla is responsible for product release for shipping to MedPointe and MedPointe is responsible for product release for distribution.

XII. SPECIFICATIONS

Cipla shall comply with the approved MedPointe Specifications and protocols (e.g. Validation, Stability, etc.). Any non-conformances to the MedPointe approved Specifications shall be investigated in accordance to Section III of this agreement and referred to MedPointe Corporate Quality Assurance for final disposition.

XIII. TESTING

Cipla shall perform raw material, packaging component, API, Finished Product and secondary packaging component, testing using the MedPointe approved analytical methods and

specifications for the Product. Any material supplied by MedPointe shall be manufactured, held, stored, packaged, and tested in accordance with current Good Manufacturing Practices, MedPointe specifications, and applicable laws, rules, and regulations. MedPointe is responsible for auditing the vendor of any material/component that is specific to the MedPointe Product. MedPointe shall provide Cipla with a copy of the quality audit reports.

XIV. DISPOSITION OF MATERIAL/COMPONENT/PRODUCT

Subject to the terms of this Agreement, Cipla shall be responsible for determining whether to release or reject any Product lot to MedPointe. At the time of shipment by Cipla to MedPointe of any Product lot, Cipla shall provide MedPointe Corporate Quality Assurance with copies of a Certificate of Compliance/Certificate of Analysis and reference all investigation reports relating to the Product lot.

A Certificate of Analysis includes a listing of all finished product specifications and test results corresponding to an individual lot of Product. To be provided by Cipla

A Certificate of Compliance is a certification that the Product was processed, packaged and stored in accordance with cGMPs, specifications and Cipla's SOPs. Additionally, the certification states that the Product meets all specifications, no investigations remain unresolved and all reconciliations and accountability have been satisfactorily completed. The certificate must include the Product identification, lot number, expiration date and final Product yield. To be provided by Cipla.

Disposition of any excess, expired or rejected materials shall be in accordance to Cipla's procedures for destruction. Cipla shall make documentation or completion of disposition available to MedPointe upon reasonable request.

XV. VALIDATION/QUALIFICATION

MedPointe and Cipla agree to the following Validation/Qualification Policies

1. Qualification/Validation shall be performed for manufacturing/packaging equipment, facilities/utilities, process, packaging, analytical methods, cleaning, and computerized systems. All Process and Packaging protocols/reports require MedPointe written approval.

2. Process Validation shall consist of prospective performance on at least three consecutive Production batches. Validation must be conducted with commercial Production processes and equipment.
3. Cipla shall ensure on an ongoing basis that systems and processes used to support the manufacturing, packaging, and holding of the Product are maintained in a validated state and in compliance to all applicable laws, regulations, and MedPointe Specifications. Subsequent to the initial agreed validation program, if additional validation is required then the costs of such validations will be mutually agreed before implementation of the additional validations program.
4. MedPointe colleagues shall have the right to be present during the manufacture of validation and launch batches.

5 **Cleaning Validation**

Cipla is responsible to ensure that a successful cleaning validation has been performed for all shared equipment where the Product is manufactured/packaged. Cipla shall ensure that all shared equipment, including Product contact parts, are cleaned to acceptable levels of API, previous Product residue, and/or detergent residue in compliance with applicable regulations. Cipla shall inform MedPointe QA of the type of products that are manufactured/packaged in shared equipment, including all Product contact parts, and allow MedPointe QA to evaluate the adequacy of the cleaning validation.

Revalidation

MedPointe shall have the right to require full or partial revalidation for changes made to the validated Product. Cipla will notify MedPointe of any planned changes to a validated process or associated procedures sufficiently in advance to allow MedPointe an opportunity to assess the change (s) and any ramifications. Such changes will require prior written consent from MedPointe.

XVI. SUB-CONTRACTORS

Cipla will not use sub-contracted service providers for manufacturing, packaging, testing, storage or distribution of the Product without prior written notice and concurrence of MedPointe, which concurrence shall not be unreasonably withheld or delayed.

XVII. CONTACT LIST

MedPointe Healthcare Inc.

Vice President, Supply Chain	Dennis Fuge	Phone: 732-564-2357
------------------------------	-------------	---------------------

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Regulatory Affairs	Ajay Chawla	E-mail: dfuge@medpointepharm.com Phone: 732-564-2363 E-mail: Achawla@medpointepharm.com
Vice President, Medical Affairs	Harry Sax	Phone: 732-564-2375 E-mail: hsax@medpointepharm.com
Vice President, Pharmaceutical Product Development	Alex D'Addio	Phone: 732-564-2348 E-mail: adaddio@medpointepharm.com
Director, Corporate Quality Assurance	Walter Cespedes	Phone: 732-564-2374 E-mail: weespedes@medpointepharm.com

Cipla Ltd.

Manager, Formulation Development	Geena Malhortra	Phone: (9122) 2578 1878 E-mail: geena@cipla.com
Production Services	Mr. Sanjay Singh	Phone: 91 832 2782581/82/83 E-mail: sanjaysingh@cipla.com
Unit Quality Assurance	Ashwin Upasane	Phone: 91 832 2782581/82/83 E-mail: ashwin.upsane@cipla.com
Unit Quality Control	Sunil Rane	Phone: 91 832 2889110 E-mail: goaqc1@cipla.com

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In Witness Whereof, the parties have caused this Agreement to be duly executed in their respective names and on their behalf, as of the date first above written.

MedPointe Healthcare Inc.

By: Amy Freshman

Title: VP + CFO

By: _____

Title: _____

Cipla Ltd.

By: D.S.

Title: DAVID DOURADO
QUALITY ASSURANCE
MANAGER.

By: _____

Title: _____
