PART E

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA,

Plaintiff,

vs.

(1) PURDUE PHARMA L.P.;
(2) PURDUE PHARMA, INC.;
(3) THE PURDUE FREDERICK COMPANY,
(4) TEVA PHARMACEUTICALS USA, INC.;
(5) CEPHALON, INC.;
(6) JOHNSON & JOHNSON;
(7) JANSSEN PHARMACEUTICALS, INC,
(8) ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS;
(9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;
(11) WATSON LABORATORIES, INC.;
(12) ACTAVIS LLC; and
(13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,

Defendants.

Case No. CJ-2017-816
Honorable Thad Balkman

William C. Hetherington
Special Discovery Master

CONFIDENTIAL
FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER DATED APRIL 16, 2018

DEFENDANTS TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, AND ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.'S MOTION FOR PROTECTIVE ORDER AND TO MAINTAIN CONFIDENTIALITY OF CERTAIN DOCUMENTS AT TRIAL

DOCUMENTS SEALED PER COURT ORDER DATED APRIL 16, 2018

CONFIDENTIAL—TO BE FILED UNDER SEAL

EXHIBIT 13

35790

FINAL VERSION
PRIVILEGED AND CONFIDENTIAL

SUPPLY AGREEMENT

THIS AGREEMENT is made as of January 1, 2009, ("Effective Date") by and between Noramco Inc. with its principal office at 500 Swedes Landing Road, Wilmington, Delaware 19801 and its Affiliates ("NORAMCO") and Actavis Elizabeth LLC, having an office at 200 Elmora Avenue, Elizabeth, New Jersey 07207 and its Affiliates ("ACTAVIS").

WITNESSETH

WHEREAS, ACTAVIS is a manufacturer and distributor of finished drug products, and

WHEREAS, NORAMCO is a manufacturer of bulk pharmaceuticals, including, morphine sulfate for use in finished pharmaceutical products, and

WHEREAS, ACTAVIS wishes to purchase bulk active ingredients from NORAMCO to use in the manufacture of finished drug products containing said active ingredient for distribution and sale throughout the United States.

NOW, THEREFORE, in consideration of these promises and the mutual covenants contained herein, the parties agree as follows:

ARTICLE 1.0 DEFINITIONS

1.1 "Affiliate" of a party to this Agreement shall mean any corporation or partnership or other entity which directly or indirectly controls, is controlled by or is under common control with such party. "Control" shall mean the legal power to direct or cause the direction of the general management or partners of such entity whether through the ownership of voting securities, by contract or otherwise.

1.2 "Commercial Requirements" shall be the total purchases of Product during a calendar year.

1.3 "DMF" as used herein shall mean the file maintained by the U.S. Food and Drug Administration ("FDA"), which contains information submitted by NORAMCO with respect to morphine sulfate, its composition, manufacture, and packaging.

1.4 "Forecasted Requirements" shall be ACTAVIS' expected requirements for Product during the periods defined in Article 4.

1.5 "Product" as used herein shall mean morphine sulfate in bulk form and meeting the Specifications.

1.6 "Specifications" as used herein shall mean the material specifications set forth in Exhibit A, attached hereto and made a part hereof.

1.7 "Territory" as used herein shall mean the United States.

ARTICLE 2.0 MANUFACTURE, PURCHASE AND SALE

2.1 NORAMCO shall manufacture, supply, and sell Product to ACTAVIS and ACTAVIS shall order and purchase Product from NORAMCO, all in accordance with the terms and conditions of this Agreement.

2.2 ACTAVIS shall purchase and NORAMCO shall supply at least sixty percent (60%) of ACTAVIS' Commercial Requirements for Product during the term of this Agreement.

2.3 NORAMCO shall manufacture, process, test, label and package the Product in accordance with applicable national, state, and local laws and regulations, including, but not limited to, United States law, local laws, and regulations.

ARTICLE 3.0 TERMS OF PURCHASE

3.1 The Base Price to be paid by ACTAVIS to NORAMCO for Product shall be $950 per kilogram.

3.2 NORAMCO and ACTAVIS shall meet during the fourth quarter of each calendar year during the term of this Agreement to discuss significant changes in market prices for the Product and NORAMCO's cost to produce said Product that have occurred since the Effective Date. If significant changes are identified, the Parties shall negotiate in good faith appropriate adjustments to the price of the Product.

3.3 Should NORAMCO be unable to supply ACTAVIS' requirements for Product during any period during the term of this Agreement, ACTAVIS shall be permitted to purchase its requirements of Product during such period from third parties without violating this Agreement.

3.4 NORAMCO shall pay the freight charges from the place of shipment to ACTAVIS.

3.5 NORAMCO shall bill ACTAVIS for each order of Product delivered. ACTAVIS shall pay each invoice via electronic transfer, or by other means acceptable to NORAMCO, no later than sixty (60) days after receipt. NORAMCO reserves the right to refuse orders and hold shipments of any Product should ACTAVIS' account be in arrears greater than fifteen (15) days.

ARTICLE 4.0 FORECASTS

4.1 Within sixty (60) days of the Effective Date, ACTAVIS shall notify NORAMCO of its Forecasted Requirements for the upcoming calendar year.

4.2 ACTAVIS shall also furnish to NORAMCO during the first calendar month of each subsequent quarter of the term of this Agreement, a written projection of its Forecasted Requirements of Product for each of the next twelve (12) months.

4.3 The parties acknowledge that the foregoing forecasts are estimates and shall not be binding upon ACTAVIS unless and until confirmed in ACTAVIS' written purchase order.

ARTICLE 5.0 PRODUCT ORDERS

5.1 Product shall be ordered on ACTAVIS' standard purchase order form accompanied by the associated Drug Enforcement Administration ("DEA") Form 222, which shall specifically reference this Agreement. The terms and conditions contained in the purchase order, to the extent that they are inconsistent or in conflict with the provisions of this Agreement, are hereby superseded.

5.2 ACTAVIS shall issue written purchase orders to NORAMCO at least forty-five (45) days prior to the requested delivery date. ACTAVIS' purchase orders shall be firm orders and shall designate the desired quantity of Product, the delivery date, and any special shipping instructions. NORAMCO shall be required to supply such quantities ordered, provided said quantities for any calendar quarter are no greater than thirty-five percent (35%) of the Forecasted Requirements for the next twelve (12) months per Article 4.0.

ARTICLE 6.0 DELIVERY

6.1 NORAMCO shall cause the Product to be shipped to ACTAVIS or its designate in the quantities specified in ACTAVIS' purchase orders. Delivery shall be F.O.B. the place of shipment. NORAMCO shall bear the expense and cost of putting each order of Product into the possession of the carrier. Risk of loss shall pass to ACTAVIS upon receipt by ACTAVIS.

6.2 Prior to shipment, NORAMCO shall cause each lot of Product comprising the shipment to be tested for conformance with the Specifications and shall furnish to ACTAVIS the results of such testing including, but not limited to, a Certificates of Analysis with each shipment.

6.3 NORAMCO shall also furnish ACTAVIS with a Material Safety Data Sheet for the Product and shall timely furnish material updates to the Material Safety Data Sheet as they occur.

ARTICLE 7.0 INSPECTION

7.1 Upon receipt of each order of Product, ACTAVIS shall inspect the order to ascertain that the shipment conforms to the order and that it contains the designated quantity of Product.

7.2 ACTAVIS shall notify NORAMCO in writing within ninety (90) days after receipt of the shipment whether it accepts or rejects the Product. ACTAVIS' failure to reject Product within such period shall constitute acceptance thereof; provided, however, that nothing contained herein shall prevent ACTAVIS from rejecting Product for latent defects discovered by ACTAVIS after such stipulated period has expired and which could not reasonably be discovered within ninety (90) days of receipt of Product (provided that ACTAVIS notifies NORAMCO within thirty (30) days after it discovers or reasonably should have discovered such latent defect).

7.3 Without limitation to any other rights specifically set forth in this Agreement, if ACTAVIS rejects Product under Section 7.2 as non-conforming to Specifications, NORAMCO shall promptly replace, at no additional cost to ACTAVIS, and as ACTAVIS' sole and exclusive remedy, any Product which fails to meet Specifications as to which a timely notification pursuant to this paragraph is provided to NORAMCO.

ARTICLE 8.0 REGULATORY MATTERS

8.1 ACTAVIS shall be responsible for obtaining and maintaining during the term of this Agreement all necessary governmental registrations or approvals, including all appropriate state, province or local registrations or approvals as required, for the manufacture and marketing within the Territory of finished drug products incorporating Product supplied by NORAMCO hereunder.

8.2 NORAMCO shall maintain updated DMFs in the Territory with the appropriate governmental authorities. NORAMCO shall grant to ACTAVIS a right of reference to the DMFs on file in the Territory and shall provide information to ACTAVIS concerning the composition, manufacture and packaging of Product as may be required by governmental authorities to enable ACTAVIS to obtain and

maintain governmental registrations or approvals for the manufacture and marketing in the Territory of finished drug products incorporating Product supplied by NORAMCO hereunder. Further, NORAMCO will notify ACTAVIS of any material changes in the DMF process prior to implementation as required by the FDA "Guidelines for Drug Master Files" Section VIIA and applicable FDA regulations. Such changes may include, but are not limited to, modifications in production, testing or packaging procedures.

8.3 ACTAVIS shall have the right, upon reasonable notice to NORAMCO and during regular business hours, to inspect and audit the facilities being used by NORAMCO for production of Product to assure compliance by NORAMCO with applicable rules and regulations and with other provisions of this Agreement. ACTAVIS will provide NORAMCO written observations. NORAMCO will respond in writing to these observations.

8.4 NORAMCO shall notify ACTAVIS of the following within three (3) business days:

a) Initiation of an inspection by the DEA or the FDA when the inspection scope includes the Product.

b) Receipt of notice from the DEA or FDA of formal agency regulatory actions.

ARTICLE 9.0 PRODUCT COMPLAINTS, ADVERSE EXPERIENCES, AND RECALLS

9.1 The parties will notify each other by facsimile (and confirm receipt of same) of all complaints related to Product that were sold by ACTAVIS without undue delay, but no later than three (3) business days of receipt. ACTAVIS will correspond with complainants on all complaints associated with Product sold by ACTAVIS. ACTAVIS shall investigate all Product complaints with respect to the Product, shall maintain a complaint file and shall forward completed complaint reports relating to the Product to ACTAVIS within two (2) business days after completion of a complaint investigation. As needed, ACTAVIS shall provide interim status reports to NORAMCO of complaint investigations if the investigation exceeds thirty (30) calendar days from the day of receipt of a complaint. If NORAMCO, in its reasonable discretion, determines that any physical, chemical, biological or other evaluation should be conducted in relation to a Product complaint, ACTAVIS will conduct the evaluation and provide NORAMCO with a written report of such evaluation. ACTAVIS will notify NORAMCO within twenty-four (24) hours if any such Product evaluation determines that the Product fails to meet Specifications. Evaluations requested by NORAMCO that are not required by regulation and not typically carried out by ACTAVIS in the usual course of its investigations will be at the expense of NORAMCO. NORAMCO shall maintain a complaint file and shall immediately notify ACTAVIS of any complaints relating to the Product, which may be the result of, or have an effect on, the manufacturing performed by NORAMCO.

9.2 The parties shall notify each other without undue delay, but in any event within three (3) business days, regarding any adverse drug events ("ADEs"). ACTAVIS will file any ADEs required under 21 CFR 314.80 and 21 CFR 314.81 concerning the Product to FDA. ACTAVIS shall provide NORAMCO a copy of its quarterly report of all ADEs for the Product within thirty (30) business days after submission to the FDA.

9.3 The parties shall cooperate fully with one another in connection with: (i) any field actions related to the Product including, but not limited to, a recall, field or safety alert, Product market withdrawal, stock recovery or field correction and related press releases and communications ("Recall") required by any regulatory authority or court; and (ii) any Recall requested by either party. In the event either party believes a Recall may be necessary with respect to any Product provided under this Agreement, such Party shall immediately notify the other in writing. In the event it is determined that a Recall is necessary or appropriate, ACTAVIS be responsible for coordinating such Recall, including all contacts with the FDA, and NORAMCO shall provide all necessary cooperation, information and assistance requested by ACTAVIS.

9.4 ACTAVIS shall be responsible for all Recall Costs (as defined below), and shall reimburse NORAMCO for its applicable Recall Costs, except in the event that a Recall is due to NORAMCO's breach of its representations and warranties, or obligations under this Agreement, applicable laws or its negligence or willful misconduct, in which event NORAMCO shall reimburse ACTAVIS for its Recall Costs to the extent attributable to NORAMCO and in accordance with its relative responsibility for the Recall. If a Recall is due to the acts or omissions of both parties, the parties shall share the Recall Costs in accordance with their relative responsibility for the Recall. For purposes of this Article 9.4, Recall Costs shall mean the expenses of notification and destruction or return of the recalled Product, and, in the case of NORAMCO, Recall Costs shall also include the Base Price paid by ACTAVIS for such recalled Product and the cost of manufacture of associated finished product, including any additional costs related thereto pursuant to this Agreement. Each of the parties shall use commercially reasonable efforts to minimize the Recall Costs, which it incurs and shall provide to the other, upon request, reasonable evidence of the out-of-pocket expenses being claimed by it.

9.5 This Section 9 and the obligations contained herein shall survive the expiration or termination of this Agreement for the period of time that a Recall may be required by applicable laws.

ARTICLE 10.0 WARRANTIES AND INDEMNIFICATION; LIMITATION OF LIABILITY

10.1 NORAMCO warrants that the Product at the time of delivery to the carrier shall:

a) Conform to the Specifications.

b) Not be adulterated within the meaning of the U.S. Federal Food, Drug and Cosmetic Act or any other applicable law.

c) Be in compliance with all applicable federal, state, provincial, and local laws and regulations.

10.2 NORAMCO warrants that it will manufacture Product in compliance with all applicable federal, state, provincial, and local laws including, but not limited to, cGMPs as applied to bulk pharmaceutical chemicals as regulated by the FDA as well as all applicable NORAMCO Standard Operating Procedures during the term of this Agreement.

10.3 Indemnification by ACTAVIS. Subject to Section 10.4 of this Agreement, ACTAVIS shall indemnify, defend and hold harmless NORAMCO, its directors, officers, and employees ("Noramco Indemnified Parties") against any and all liability, loss, damage, loss, cost, or expense (including, without limitation, reasonable attorneys' fees) resulting from any third party claim made or suit ("Liability") brought against NORAMCO to the extent arising or resulting from: (i) the breach by ACTAVIS of its representations, warranties or obligations set forth in this Agreement; (ii) the marketing, sale, handling, transportation or storage of finished product(s) which incorporate Product; or (iii) its negligence or willful misconduct, except that any of the foregoing arises out of or results from NORAMCO's obligations or the negligence or willful misconduct of any Noramco Indemnified Party.

Indemnification by NORAMCO. Subject to Section 10.4 of this Agreement, NORAMCO shall indemnify, defend and hold harmless ACTAVIS, its directors, officers, and employees ("Actavis Indemnified Parties") against any and all Liability brought against ACTAVIS to the extent arising or resulting from: (i) a claim of infringement of any patent or the unauthorized use of a trade secret resulting from the manufacture or sale of the Product; (ii) the breach by NORAMCO of its representations, warranties or obligations set forth in this Agreement or resulting from the breach of its obligations to deliver Product in full conformity to the Specifications and all applicable laws; or (iii) its negligence or willful misconduct, except that any of the foregoing arises out of or results from ACTAVIS' obligations or the negligence or willful misconduct of any Actavis Indemnified Party.

Indemnity Process. Each party agrees, to the extent reasonably practicable, to cooperate with the indemnifying party in the defense of any claims made by third party(ies) to which this Section 10 applies, including, but not limited to, (i) promptly notifying the indemnifying party and its applicable insurance carrier of the Liability to be indemnified; (ii) allowing the indemnifying party to conduct and control (at the cost and expense of such indemnifying party), at its option, the defense of such a claim and any related settlement negotiations, with the exception of a settlement which includes any admission of liability by the indemnified party, which admission may only be granted to the indemnifying party by the indemnified party in writing; and (iii) affording all reasonable assistance to the indemnifying party (at the cost and expense of such indemnifying party) and making no admission prejudicial to the defense of such a claim. Subject to other provisions of this Section 10, the indemnified party may, at its sole cost and expense, participate in the defense of any claim hereunder with counsel of its own choice.

10.4 Limitations of Liability. NO PARTY SHALL BE LIABLE TO THE OTHER FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL DAMAGES, INCLUDING (WITHOUT LIMITATION) BUSINESS INTERRUPTION DAMAGES OR LOST PROFITS OR REVENUES, WHETHER IN CONTRACT OR TORT, EVEN IF SUCH PARTY HAS BEEN MADE AWARE OF THE POSSIBILITY OF ANY SUCH DAMAGES AND WHETHER OR NOT, UNDER ANY APPLICABLE CIRCUMSTANCES, ANY SUCH DAMAGES ARE REASONABLY FORESEEABLE. THIS LIMITATION OF LIABILITY SHALL NOT EXTEND TO A PARTY'S INDEMNIFICATION OBLIGATION UNDER ARTICLE 10; PROVIDED HOWEVER, THAT NEITHER PARTY SHALL BE RESPONSIBLE FOR THE PAYMENT OF CONSEQUENTIAL OR INDIRECT DAMAGES AWARDED BY A COURT OF LAW ARISING OR RESULTING FROM A CONTRACT CLAIM BROUGHT BY A THIRD PARTY. NOTWITHSTANDING THE FOREGOING, A PARTY'S INDEMNIFICATION OBLIGATION SHALL COVER THE DEFENSE OF SUCH CONTRACT CLAIM.

ARTICLE 11.0 INSURANCE

11.1 The parties shall each, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the term of this Agreement: (a) Commercial General Liability Insurance with per-occurrence and general aggregate limits of not less than $10,000,000; and (b) Product and Completed Operations Liability Insurance with per-occurrence and general aggregate limits of not less than $10,000,000. In the event that any of the required policies of insurance are written on a claims-made basis, then such policies shall be maintained during the entire term of this Agreement and for a period of not less than three (3) years following the termination or expiration of this Agreement plus twelve (12) months of discovery. Each policy shall provide that not less than thirty (30) days' prior written notice shall be given to the other party in the event of the cancellation, termination or non-renewal thereof. Each party shall name the other party as an additional insured on both the Commercial Liability and Products/Completed Operations Liability Insurance policies.

ARTICLE 12.0 CONFIDENTIAL INFORMATION

12.1 In carrying out the terms of this Agreement it may be necessary that one party disclose to the other certain information which is considered by the disclosing party to be proprietary and of a confidential nature. As used herein "Confidential Information" shall mean any and all information, know-how and data, technical or non-technical concerning any finished drug product or bulk active pharmaceutical ingredient, its manufacture, marketing and sale, which is disclosed and reduced to writing under this Agreement as set forth below and which ACTAVIS or NORAMCO identify as proprietary and confidential. Confidential Information shall include, but shall not be limited to plans, processes, compositions, formulations, specifications, samples, systems, techniques, analyses, production and quality control data, testing data, marketing and financial data, and such other information or data relating to any finished drug product or bulk active pharmaceutical ingredient or its manufacture, marketing or

sale.

12.2 The receiving party shall not use the Confidential Information for any purpose other than for purposes of performing its obligations under this Agreement and shall divulge the information only to those of its employees who have a need to know it as a part of the receiving party's obligations hereunder and said employees shall hold the information in confidence pursuant to this Agreement. The receiving party shall not disclose Confidential Information to any third party without the written consent of the disclosing party.

12.3 The obligations of confidentiality as provided herein shall terminate five (5) years from the expiration or termination of this Agreement and shall impose no obligation upon the receiving party with respect to any portion of the received information which (i) was known to or in the possession of the receiving party prior to the disclosure; or (ii) is or becomes publicly known through no fault attributable to the receiving party; or (iii) is provided to the receiving party from a source independent of the disclosing party which is not subject to a confidential or fiduciary relationship with the disclosing party concerning the information; or (iv) is generated by the receiving party independently of any disclosure from the disclosing party; or (v) is required by law to be disclosed to government officials who shall be informed of the confidential nature of such information (provided however, in such event the receiving party will give the disclosing party prompt notice thereof so that the disclosing party may seek an appropriate protective order prior to such required disclosure. The receiving party will reasonably cooperate with the disclosing party in its efforts to seek such protective order).

12.4 Upon expiration or earlier termination of this Agreement, the receiving party shall, as the disclosing party may direct in writing, either destroy or return to the disclosing party all Confidential Information disclosed together with all copies thereof, provided, however, the receiving party may retain one archival copy thereof for the purpose of determining any continuing obligations of confidentiality.

ARTICLE 13.0 TERM AND TERMINATION

13.1 This Agreement shall commence on January 1, 2009 ("Effective Date") and shall continue for an initial term of three (3) years. Thereafter, this Agreement shall be automatically renewed for successive terms of one (1) year each unless terminated as of the end of the initial term or any renewal term by written notice from either party to the other given at least one (1) year prior to the expiration of such initial term or renewal term.

13.2 Either party may terminate this Agreement for material breach if such material breach is not cured by the breaching party within thirty (30) days following written notice of such breach from the non-breaching party or the breaching party is not continuing to make all reasonable efforts, with due diligence, to remedy such breach beyond said thirty (30) days. Any termination of this Agreement in accordance with this provision shall be effective as of the date of receipt by the breaching party of a written notice of termination from the non-breaching party.

13.3 ACTAVIS shall have the right on sixty (60) days' prior written notice to terminate this Agreement, without penalty, in the event, in its sole discretion, the sale of Product manufactured pursuant to this Agreement becomes commercially non-viable, if any intellectual property of any third party may be infringed, misappropriated or otherwise violated by the manufacture, import, use, sale or distribution of the Product or if there is an unacceptable risk from a product liability perspective, or if ACTAVIS acquires or merges with another entity, which renders the Product non-viable, or any Regulatory Authority requires ACTAVIS to cease production on Product.

13.4 The rights and obligations with respect to indemnification as provided in Article 10.0 and of confidentiality as provided in Article 12.0 shall survive the expiration or termination of this Agreement.

13.5 Termination of this Agreement for any reason shall not release either party hereto from any liability which at such time has already accrued or which thereafter accrues from a breach or default prior to such expiration or termination, nor affect in any way the survival of any other right, duty or obligation of either party hereto which is expressly stated elsewhere in this Agreement to survive such termination.

ARTICLE 14.0 NOTICES

14.1 Any notice required or permitted to be given herein shall be deemed to have been sufficiently delivered to either party if given by telephone, telex, or cable and confirmed by registered mail, postage prepaid, addressed as follows:

If to ACTAVIS	Actavis Elizabeth LLC 200 Elmora Avenue Elizabeth, New Jersey 07207 Attention: Tejendra Rao
With a copy to:	Actavis Elizabeth LLC 60 Columbia Rd., Building B Morristown, New Jersey 07960 Attn: Legal Department Facsimile: 973-993-4306
If to NORAMCO:	Noramco Inc. 500 Swedes Landing Road Wilmington, DE 19801 Attention: Vice President Worldwide Bulk Analgesics

14.2 Either party may from time to time by notice served as set forth above designate a different address or a different or additional person to which all such notices or communications hereafter are to be given.

ARTICLE 15.0 LEGAL REQUIREMENTS

15.1 All actions to be taken by the parties under this Agreement shall be taken in full compliance with all applicable laws and governmental regulations and the provisions of this Agreement shall be so construed to effectuate such compliance.

15.2 Anything herein to the contrary notwithstanding, neither party hereto shall be obligated to do any act pursuant to any provisions of this Agreement, when to do so would be inconsistent with any law, rule, ruling, regulation or order of any duly constituted governmental body having jurisdiction over either party.

15.3 If any provision of this Agreement is determined to be illegal or unenforceable or incapable of construction consistent with legal or regulatory requirements, the enforceability of the other provisions of this Agreement shall not be affected and the parties will cooperate in agreeing upon some other method of performance which is consistent with the purposes and intents of this Agreement.

ARTICLE 16.0 RELATIONSHIP OF THE PARTIES

16.1 Nothing contained in this Agreement shall be deemed to create a partnership or joint venture between the parties, and each of the parties shall be an independent contractor in all matters connected herewith. Except as expressly provided herein, neither of the parties hereto shall hold itself out as the agent of the other, nor shall either of the parties incur any indebtedness or obligation to the name of, or shall be binding on the other, without the prior written consent of the other.

ARTICLE 17.0 DISPUTE RESOLUTION

17.1 The parties shall amicably discuss and negotiate any issues that are not specifically set forth herein. If any dispute should arise between the parties with respect to this Agreement, the parties shall first negotiate in good faith in an attempt to resolve such dispute prior to bringing any legal action.

17.2 In the event that a controversy or claim arising out of or relating to this Agreement cannot be amicably resolved by good faith negotiation between the parties, it shall be resolved by arbitration before a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") then pertaining (available at www.adr.org), except where those rules conflict with this provision, in which case this provision controls. Any court with jurisdiction shall enforce this clause and enter judgment on any award. The arbitrator shall be selected within twenty (20) business days from commencement of the arbitration from the AAA's National Roster of Arbitrators pursuant to agreement or through selection procedures administered by the AAA. Within forty-five (45) days of initiation of arbitration, the parties shall reach agreement upon and thereafter follow procedures, including limits on discovery, assuring that the arbitration will be concluded and the award rendered within no more than eight (8) months from selection of the arbitrator or, failing agreement, procedures meeting such time limits will be designed by the AAA and adhered to by the parties. The arbitration shall be held in New Jersey and the arbitrator shall apply the substantive law of New Jersey, except that the interpretation and enforcement of this arbitration provision shall be governed by the Federal Arbitration Act. Prior to commencement of arbitration, emergency relief is available from any court to avoid irreparable harm. Subject to Section 10.4 of this Agreement, the arbitrator shall not award either party punitive, exemplary, multiplied or consequential damages (including but not limited to lost profits) or attorney's fees or costs.

17.3 Prior to commencement of arbitration, the parties must attempt to mediate their dispute using a professional mediator from AAA, the CPR Institute for Dispute Resolution, or like organization selected by agreement or, absent agreement, through selection procedures administered by the AAA. Within a period of forty-five (45) days after the request for mediation, the parties agree to convene with the mediator, with business representatives present, for at least one (1) session to attempt to resolve the matter. In no event will mediation delay commencement of the arbitration for more than forty-five (45) days absent agreement of the parties or interfere with the availability of emergency relief.

ARTICLE 18.0 FORCE MAJEURE

18.1 Neither party shall be considered in default or be liable to the other for any delay or failure in performance of any of its obligations hereunder if caused by circumstances beyond the control of the party, including but not limited to Acts of God, fire, civil unrest, strike, disruption utilities or other public services, flood, war, order of any court, or other causes which cannot be controlled by the party who failed to perform. Each party shall promptly notify the other should such circumstances occur and shall promptly take steps to remedy any delay or failure in performance upon removal of the circumstances causing such delay or failure.

ARTICLE 19.0 WAIVER

19.1 The waiver by either party of a breach of any provisions of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

ARTICLE 20.0 ASSIGNMENT

20.1 This Agreement may not be assigned by either party without the prior written consent of the other which consent shall not be unreasonably withheld. Notwithstanding the foregoing, either NORAMCO or ACTAVIS may assign its rights and/or obligations hereunder to any of its Affiliates or in connection with any sale of the business to which this Agreement relates.

ARTICLE 21.0 AMENDMENTS

21.1 No changes in or additions to this Agreement shall be binding unless specifically agreed to in writing and signed by the duly authorized representatives of the parties.

ARTICLE 22.0 GOVERNING LAW

22.1 This Agreement and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the internal substantive laws of the State of New Jersey, USA without giving effect to choice of law principles.

ARTICLE 23.0 ENTIRE AGREEMENT

23.1 This Agreement constitutes the complete and exclusive statement of the agreement between the parties and supersedes all proposals, oral or written, and all other communications between the parties relating to the subject matter of this Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the day and year first above written.

Noramco Inc.

By: _____

Name: Michael Kindergan

Title: Global Vice President, Marketing & Business Development

Actavis Elizabeth LLC

By: Kevin Bain

Name: KEVIN M. BAIN

Title: V.P. FINANCE & OPERATION

EXHIBIT A

SPECIFICATIONS

(Attached)

NORAMCO INC

DOC TYPE: PRODUCT SPECIFICATION

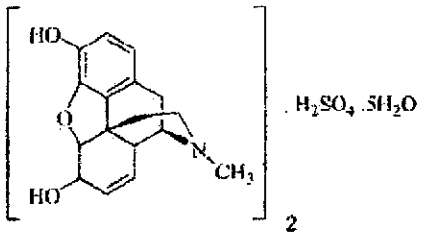
TITLE: MORPHINE SULFATE, USP (FINE GRADE)

LOCATION(S): ATHENS; WILMINGTON

Supersedes: PR0026

VERSION	DESCRIPTION
1.0	Legacy document PR0026.7 migrated to EDMS.
2.0	Updated Header and Legacy document numbers throughout. Updated description section (1.0). Updated specifications according to 08-COC-055. (A. Gaulding).
3.0	Changed the title of section 3.16 from "Organic Volatile Impurities" to "Residual Solvents" and updated to address USP <467> residual solvent requirements. Added Athens as a location for testing (08COC182 and 08COC183, A. Gaulding).

1.0 PRODUCT DESCRIPTION



Morphine Sulfate

$C_{34}H_{50}N_2O_{15}S$
Mol. Wt.: 758.83

7,8-Didehydro-4,5α-Epoxy-17-methylmorphinan-3,6α-diol Sulfate (2:1) (Salt) Pentahydrate

2.0 ITEM NUMBER

Item No.: 770096
SAP No.: 51634001701

3.0 PROPERTIES & REQUIREMENTS

3.1 Description

White to off-white crystalline solid

3.2 Identification – IR Absorption (Current USP <197 A>)

Matches IR of USP Morphine Sulfate Reference Standard
(dried @ 145° for 1 hour)

3.3 Identification – Spot Test (Current USP)

Purple, then blue-violet

3.4 Identification – Color Test (Current USP)

Blue then dark red-brown

CONFIDENTIAL

3.5 Identification – Sulfate Test (Current USP <191>)

- Barium Chloride TS: A white precipitate should form that is insoluble in either Hydrochloric acid or Nitric acid.
- Hydrochloric Acid: No precipitate should form.
- Lead Acetate TS: A white precipitate should form with a neutralized solution of sulfate that is soluble in Ammonium Acetate TS.

3.6 Specific Rotation (Current USP <781S>)

+107° to –109.5° (Anhydrous Basis)

3.7 Acidity (Current USP)

NMT 0.50 mL is required to produce a yellow color

3.8 Water (Current USP Method I <921>)

Between 10.4% and 13.4%

3.9 Residue on Ignition (Current USP <281>)

Not more than 0.1%, from 500 mg

3.10 Chloride (Current USP)

No precipitate or turbidity is produced immediately

3.11 Ammonium Salts (Current USP)

No odor of ammonia is perceptible

3.12 Limit of Foreign Alkaloids (Current USP)

Not less than 7.5 mL is required (1.5%)

3.13 Residual Ethanol by GC (SOP-NOR-1443)

Not more than 5000 ppm

3.14 Assay by HPLC (SOP-NOR-1443)

98.0 – 102.0% (Calculated on the anhydrous basis)

3.15 Impurities by *HPLC* (*SOP-NOR-1443*)

Morphine N-Oxide:	NMT 0.15% w/w
Morphinone Sulfate:	NMT 0.15% w/w
Pseudomorphine Sulfate:	NMT 0.15% w/w
Codeine Sulfate:	NMT 0.20% w/w
Individual Unspecified Impurities:	NMT 0.10% w/w
Total Impurities:	*NMT 1.0% w/w*

3.16 Residual Solvents (Current USP <467>)

To be included on Certificate of Analysis:

Noramco's compliance with the current USP <467> residual solvent requirements has been demonstrated through the use of a validated test method to measure solvents likely to be present in the Morphine Sulfate drug substance. Only the Class 3 solvent ethanol is likely to be present. Residual Class 2 solvents are below the Option 1 limit and residual Class 3 solvents are below 0.5% (5000 ppm). Therefore, *Noramco certifies that this material*, if tested, will comply with the established residual organic solvent specifications of USP <467>.

4.0 IN-HOUSE PROPERTIES & REQUIREMENTS

4.1 Color by UV/VIS (Au/g @400 nm) (SOP-NOR-1443)

Informative

4.2 Density (SOP-NOR-1443)

Untapped:	Informative
Tapped:	Informative
Volume occupied by 10 grams (untapped):	Informative

4.3 Insoluble Matter (SOP-NOR-1443)

Passes test

4.4 Impurities by HPLC (SOP-NOR-1443)

Oripavine Sulfate:	NMT 0.10% w/w
Apomorphine Sulfate:	NMT 0.10% w/w
Thebaine Sulfate:	NMT 0.10% w/w

4.5 Particle Size by Airjet Analyzer (SOP-NOR-1443)

#100 Mesh: Informative

#450 Mesh: NLT 80% passing through

4.6 Particle Size by Malvern Mastersizer (SOP-NOR-1443)

Median Diameter:	12 - 25 µm
Percent Greater than 50 µm:	NMT 10%
Percent Less than 8.5 µm:	NMT 30%

5.0 RETEST DATE

5 Years from date of manufacture

6.0 PACKAGING, LABELING & STORAGE

6.1 Packaging

Packaged in double polyethylene liners in high-density polyethylene (HDPE) drums. The polyethylene liners are twisted and tied with locking tie wraps and the drums are secured.

6.2 Labeling

Each container shall be clearly marked with at least the following:

- Contents Name
- Batch/Lot Number
- Quantity

6.3 **Storage**

Store between 15-40°C as supported by product stability.

7.0 SAMPLING REQUIREMENTS

Analytical: Obtain approximately 100g of sample from a representative source of each batch in a large polyethylene bag or plastic container.

Retain: Obtain approximately 80g of sample from a representative source of each batch in a large polyethylene bag or plastic container.

8.0 TESTING FREQUENCIES

Characteristic	TP	New Lot	Retest
IR Absorption	Current USP	1/lot	N/R
Identity – Spot Test	Current USP	1/lot	N/R
Identity – Color Test	Current USP	1/lot	N/R
Identity – Sulfate Test	Current USP	1/lot	N/R
Specific Rotation	Current USP	1/lot	N/R
Acidity	Current USP	1/lot	N/R
Water	Current USP	1/lot	1/lot
Residue on Ignition	Current USP	1/lot	N/R
Chloride	Current USP	1/lot	N/R
Ammonium Salts	Current USP	1/lot	N/R
Limit of Foreign Alkaloids	Current USP	1/lot	N/R
Assay by HPLC	SOP-NOR-1443	1/lot	1/lot
Residual Solvents	Current USP	N/R	N/R
Color by UV/VIS	SOP-NOR-1443	1/lot	N/R
Density	SOP-NOR-1443	1/lot	N/R
Insoluble Matter	SOP-NOR-1443	1/lot	N/R
Impurities by HPLC	SOP-NOR-1443	1/lot	1/lot
Ethanol by GC	SOP-NOR-1443	1/lot	N/R
Particle Size	SOP-NOR-1443	1/lot	N/R

N/R: Not Required

EXHIBIT 14

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT, effective January 1, 2015 (the "Effective Date"), by and between Noramco, Inc., a Georgia corporation, with offices at 500 Swedes Landing Road, Wilmington, Delaware 19801 ("Noramco") and Actavis, Inc., a Delaware limited liability company located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054 and each of its Affiliates set forth in Appendix D and made a party to this Agreement (hereinafter referred to as "Buyer"). Noramco and Buyer may be referred to herein as a "Party" or "Parties" as the context may require.

WHEREAS, for the API listed in Appendix B, this Agreement supersedes the Amended and Restated Active Ingredient Supply Agreement between Noramco and Watson Laboratories, Inc., dated July 18, 2008, and as amended on the following dates: December 21, 2009, January 1, 2011, January 4, 2012 and March 1, 2013.

WHEREAS, this Agreement supersedes all pre-existing supply agreements and amendments between Noramco, on one hand, and each of Actavis LLC, Actavis Totowa, LLC and Actavis Elizabeth LLC (DE), on the other, including the Supply Agreement between Noramco, Inc. and Amide Pharmaceutical, Inc. (to become Actavis Totowa, LLC) dated September 7, 2004, and as amended on the following dates: June 15, 2005, January 31, 2007 and December 21, 2007 and the Supply Agreement between Noramco Inc. and Actavis Elizabeth, LLC dated January 1, 2009.

WHEREAS, Noramco is engaged in the business of manufacturing and selling active pharmaceutical ingredients;

WHEREAS, Buyer is engaged, inter alia, in the business of manufacturing and/or selling finished pharmaceutical products; and

WHEREAS, Buyer wishes to purchase the active pharmaceutical ingredient(s) for its use in the manufacture of the Product (as defined below) and Noramco is willing to supply the active pharmaceutical ingredient(s) to Buyer on the terms and conditions of this Agreement.

NOW THEREFORE, INTENDING TO BE LEGALLY BOUND HEREBY AND IN CONSIDERATION OF THE MUTUAL REPRESENTATIONS, WARRANTIES AND COVENANTS SET FORTH IN THIS AGREEMENT AND OTHER GOOD AND VALUABLE CONSIDERATION THE RECEIPT AND SUFFICIENCY OF WHICH IS HEREBY ACKNOWLEDGED, THE PARTIES AGREE AS FOLLOWS:

DEFINITIONS

For purposes of this Agreement, the following words or expressions have the meanings provided below:

"Affiliate"- means with respect to either Party, any individual, partnership, association, corporation, limited liability company, trust or other legal person or entity that is controlled by, controls or is under common control with that Party. As used herein, "control" of a corporation or other business entity means direct or indirect beneficial or legal ownership of fifty percent (50%) or more of the voting interest in, or more than fifty percent (50%) of the equity of or the right to appoint fifty percent (50%) or more of the directors or managers of that corporation or other business entity.

"ANDA" means an Abbreviated New Drug Application filed with the FDA.

"API(s)" - means the active pharmaceutical ingredient(s) listed in Appendix A.

"cGMP" - means current good manufacturing practices as required by the rules and regulations of the FDA, as applicable to the manufacturing, packaging, handling, storage and control of API.

"DEA" – means the Drug Enforcement Administration of the US Department of Justice or any successor organization.

"DMF" - means the Drug Master File as filed with the FDA by Noramco or its Affiliates.

"FDA" – means the United States Food and Drug Administration or any successor organization.

"Manufacturing Interruptions" – shall have the meaning set forth in Section 8.1.

"Manufacturing Quota" – means the amount of an API allotted to Noramco by the DEA pursuant to applicable DEA regulations so that Noramco may manufacture API.

"Manufacturing Quota Restrictions" – shall have the meaning set forth in Section 8.

"Procurement Quota" – means the quota allotted to Buyer by the DEA pursuant to applicable DEA regulations so as to permit shipment of API from Noramco to Buyer.

"Product(s)" - means the finished pharmaceutical product containing the API(s) in all dosage forms manufactured by or for Buyer for commercial sale world-wide, pursuant to an ANDA approved by the FDA or similar marketing authorization.

"Purchase Order" means an order from Buyer given in accordance with the provisions of this Agreement specifying a delivery date(s) and quantities of the API(s) to be manufactured by Noramco.

"Quality Agreement" - means the agreement related to quality assurance and control to be entered into between the Parties in the form attached hereto as **Appendix C**.

"Regulatory Authority" - means any and all governmental bodies and organizations regulating the manufacture, importation, distribution, use and/or sale of Product.

"Specification(s)" - means the API specification(s) contained in **Appendix A** except as may be agreed in writing by Buyer and Noramco as an amendment to this Agreement.

1 SUPPLY

1.1 (a) Buyer shall use commercially reasonable efforts to qualify Noramco's API for use in sufficient SKU's of its Product(s) to meet the requirements of Article 1.2.

(b) Within 3 months of Noramco obtaining FDA approval of any new active pharmaceutical ingredient not produced by Noramco as of the Effective Date ("New API"), Buyer shall, for all Products that Buyer has filed with FDA that incorporate such New API, discuss in good faith with Noramco the possibility of qualifying such New API and filing appropriate notices to FDA to obtain approval to use such New API in its Products; provided, that such qualification is not specifically prohibited by any existing Buyer agreement at the time of the approval of the New API by FDA.

1.2 Subject to the terms and conditions of this Agreement, for use in connection with the manufacture of Product(s) by Buyer, Noramco shall supply to Buyer and Buyer shall purchase from Noramco a minimum percentage of Buyer's total annual commercial requirements of the API(s) as listed in Appendix B for Products. Buyer will keep accurate records of its annual commercial requirements of API(s), and, upon the request of Noramco, will permit an independent third party mutually agreed upon by the parties to examine such records during normal business hours and upon reasonable notice, but not more than once per calendar year, for the purpose of verifying the correctness of all such calculations.

1.3 In addition to supplying Actavis, Inc. with the APIs in accordance with this Agreement, Noramco shall likewise provide APIs ordered by Buyer's Affiliates set forth in Appendix D and made a party to this Agreement in accordance with the terms and conditions of this Agreement. In connection with such supply, Actavis, Inc. shall be responsible for its Affiliates' compliance with the terms and conditions of this Agreement.

2 PERMITS; DMF(S) AND cGMP

2.1 Noramco shall obtain, at its expense, any licenses or permits, and any regulatory and government approvals necessary for the manufacture of the API(s) except as otherwise set forth herein.

2.2 Noramco, at its sole cost and expense, has filed or will file and shall maintain a valid DMF covering the API(s) for and during the term of this Agreement, all in accordance with all applicable laws, rules and regulations of the FDA or any other Regulatory Authority.

2.3 Noramco shall provide Buyer with an access or right of reference letter entitling Buyer to make continuing reference to the Noramco DMFs in connection with any regulatory filings made with the FDA by Buyer with respect to Product.

2.4 Noramco shall provide a certificate of analysis with each shipment of API. All API sold to Buyer under this Agreement will be manufactured in accordance with cGMP and conform to the Specifications and the Quality Agreement.

3. FORECASTS AND PURCHASE ORDERS FOR API

3.1 On the first day of the month preceding each consecutive calendar quarter (e.g. December 1, March 1, June 1, and September 1) throughout the term of this Agreement, Buyer shall provide to Noramco a twelve (12) month rolling (e.g. January 1st to December 31st, April 1st to March 30th, July 1st to June 30th, and October 1st to September 30th), non-binding (except as set forth below) forecast (each a "Quarterly Forecast") of the anticipated purchases of API(s) under this Agreement. This forecast will include quantities for planned regulatory filings. Subject to the second paragraph of 3.3 below and Section 8, the first three months of each Quarterly Forecast shall be binding on the parties and shall constitute a firm commitment to issue a purchase order for and provide supply of the API indicated for such months except that Noramco may modify binding volumes according to final weights of available batches at time of shipment with the written approval of Buyer.

3.2 With respect to any Quarterly Forecast submitted hereunder, the quantity of API(s) forecast with respect to each of the first (1st) through sixth (6th) months in such Forecast may not deviate by more than twenty-five percent (25%) from the quantity of API(s) forecast in the immediately prior Quarterly Forecast (so for example, the quantity for the fourth month shall not vary by more than 25% from the quantity set forth for the seventh month in the immediately prior Quarterly Forecast, the quantity for the first month shall not vary by more than 25% from the quantity set forth for the fourth month in the immediately prior Quarterly Forecast, etc.).

In addition, with respect to each Quarterly Forecast, Noramco may within twenty (20) days of receipt thereof, notify Buyer that it will not be able to meet Buyer's anticipated demand as reflected for any of months seven through twelve month for any API. In such event, the Parties shall promptly meet to discuss in good faith to revise such Quarterly Forecast which shall be resubmitted by Buyer to Noramco with amounts mutually acceptable to both Parties.

3.3 Buyer shall place Purchase Orders for the API(s) with Noramco, specifying quantities in kilograms and delivery dates that are not less than sixty (60) days nor more than one hundred twenty (120) days from the date of Noramco's receipt of the purchase order. Subject to the paragraph below and

Section 8, Noramco shall supply and deliver such quantities to Buyer as set forth in each Purchase Order provided that each purchase order is consistent with the quantity set forth in the applicable binding portion of the applicable Quarterly Forecast provided in accordance with Section 3.2 and the delivery date restrictions set forth above.

Each Purchase Order must be submitted with a certificate of available Procurement Quota or a completed DEA Form 222 on an API by API basis which evidences that Buyer shall be able to take delivery of the API(s) subject to the Purchase Order; provided however that Noramco, in its reasonable discretion, may agree to accept a Purchase Order which specifies on an API by API basis the amounts that are contingent upon future receipt of Procurement Quota. In the event that Noramco accepts any Purchase Order which specifies that all or a portion of any API is contingent upon receipt of Procurement Quota, the supply and purchase thereof shall be subject to Section 8.

4. CONSIDERATION FOR SUPPLY OF API

4.1 The price of API(s) to be sold to Buyer is as set forth in **Appendix B**.

4.2 Buyer shall pay Noramco for all supplied quantities of API within forty-five (45) days from the date of invoice; provided that pending resolution of any dispute under Article 6, Buyer is not obligated for any payment payable with respect to API for which Buyer has delivered a written objection pursuant to Article 6.

4.3 All payments payable for the purchase of API will be made by electronic transfer of United States Dollars to an account designated in writing by Noramco.

4.4 Noramco will not be obligated to honor orders or shipments to Buyer should Buyer's account with Noramco fall greater than sixty (60) days in arrears after notice thereof to Buyer.

4.5 In addition to the price, Buyer shall pay Noramco any and all governmental taxes, charges or duties of every kind (excluding any tax based upon Noramco's net income) that Noramco may be required to collect or pay upon sale, transfer or shipment of API(s).

5. SHIPMENT OF API

5.1 Noramco shall make deliveries of API to Buyer or its designate DAP Incoterms 2010 (Buyer's designated facility).

5.2 If at any time the financial status of Buyer, or the credit risk involved, shall become unsatisfactory to Noramco in its reasonable discretion, or in the event that a Purchase Order is delivered where delivery of any API thereunder is contingent upon Buyer securing Procurement Quota, Noramco may require cash or satisfactory security prior to accepting such Purchase Order or shipments or deliveries of API hereunder. The election by Noramco to require such cash or security shall not affect the obligation of Buyer to take and pay for the contracted API. Noramco shall be entitled to charge interest on any overdue sum at the maximum rate of eight percent (8%) per annum.

6. INSPECTION AND REJECTION

6.1 All API may be inspected by Buyer and rejected if the API does not meet the Specifications or has not been manufactured in accordance with cGMP(s) (any such API, "Nonconforming API"). API will be deemed accepted if Noramco does not receive written notice from Buyer to the contrary, setting forth in reasonable detail the claimed nonconformity, within forty-five (45) days after delivery to Buyer of such API; provided, however, that in the case of Nonconforming API

containing non-conformance(s) that are discovered by Buyer more than forty-five (45) days after delivery, Buyer shall notify Noramco of any such non-conformance (each a "Latent Defect") promptly following discovery thereof. Notwithstanding anything to the contrary contained herein, in the case of Latent Defects, Buyer shall have thirty (30) days from the earlier of: (i) date of discovery of such Latent Defect, or (ii) expiration of the Product containing the Nonconforming API, to notify Noramco of such Latent Defect.

6.2 Upon receipt of notification as set forth above of Nonconforming API (including API exhibiting any Latent Defect), Noramco will have thirty (30) days to inspect the affected API and make a reasonable assessment of the alleged nonconformance. At Noramco's request, Buyer must promptly supply samples of the API that are allegedly Nonconforming API or some other evidence of deficiency that Noramco may reasonably specify. If the Parties agree, or there is a determination under Section 6.3, that there is a nonconformance, Noramco, at its sole cost and expense shall promptly replace any Nonconforming API, to be shipped at Noramco's cost. This shall be Buyer's sole remedy other than as provided for in Section 7.3 (Recalls) and Section 9.5 (Indemnification). Nonconforming API will be returned to Noramco at its expense.

6.3 Any dispute between the Parties concerning the rejection of any API which the Parties are unable to resolve within a sixty (60) day period will be investigated in accordance with the Quality Agreement. If the Parties cannot agree after such investigation whether the API is in fact Nonconforming API, samples will be submitted to a qualified independent laboratory mutually agreed to by Noramco and Buyer for testing (or in the event of a dispute related to cGMP, then to a mutually agreed upon third party expert for resolution). Such laboratory will use the test methods contained in the applicable Specifications. The determination of conformance by such laboratory (or third party expert) with respect to all or part of such API will be final and binding on all parties absent manifest error. The fees and expenses of the laboratory (or third party expert) incurred in making such determination will be paid by Noramco, if the determination is made against Noramco or by Buyer, if the determination is made against Buyer.

7. PRODUCT COMPLAINTS, ADVERSE EXPERIENCES AND RECALLS

7.1 During the term of this Agreement, Noramco shall assist Buyer with any necessary investigation arising from customer complaints relating to Product in accordance with the Quality Agreement. Without in any manner limiting the foregoing, each of Buyer and Noramco shall comply with FDA requirements for complaint handling. Buyer shall maintain a system for monitoring, investigating, and following up on adverse event reports received by it involving Product(s), and shall provide prompt notice to Noramco of any Product complaints, including, but not limited to, information concerning adverse drug events that are required to be reported to FDA, side effects, injury, toxicity, or sensitivity reaction.

7.2 Each Party shall notify the other Party of any regulatory action or other action concerning the safety of the API or the Product in accordance with the Quality Agreement, including but not limited to FDA inspection reports, warning letters or import alerts.

7.3 In the event of a recall that does not result from the breach of Noramco's obligations under Section 2.4 hereof to manufacture API in accordance with cGMP and the Specifications, as between Noramco and Buyer, Buyer shall (a) be responsible for the expenses of the recall, and (b) reimburse Noramco for any costs reasonably expended by Noramco to assist Buyer to effect the recall; provided, however, that Noramco shall, subject to Sections 10.4 and 10.5 , bear the direct expenses of a recall to the extent such recall is caused by the breach of Noramco's obligations under Section 2.4 hereof to manufacture API in accordance with cGMP, the Quality Agreement and the Specifications. For the purposes of this Section 7.3, the direct expenses of recall shall mean the expenses of notification and destruction or return of the recalled Product, the cost of the Product and expenditures made by Buyer or

its Affiliates in connection with the distribution of such Product, and any penalties or damages owed by Buyer or its Affiliates in connection with the recall.

8. MANUFACTURING INTERRUPTIONS, QUOTA RESTRICTIONS AND SHORTAGES

8.1 Manufacturing Interruptions. Buyer acknowledges that the day to day manufacturing operation of the facilities used by Noramco to produce API may be subject to interruptions, fluctuations, slow-downs, suspensions and reductions, due to a variety of reasons in the ordinary course of business (*"Manufacturing Interruptions"*). If Noramco believes that a Manufacturing Interruption is reasonably likely to result in a material reduction of API available to be delivered to Buyer, Noramco shall provide notice to Buyer and consult with Buyer about such Manufacturing Interruption prior to or as soon as reasonably possible after the commencement of such Manufacturing Interruption. After any Manufacturing Interruption resulting in a material reduction of API terminates, Noramco shall promptly communicate to Buyer regarding such Manufacturing Interruption, the reason therefore, and provide notice of the resumption of full supply.

8.2 Manufacturing Quota Restrictions. It is the sole responsibility of Noramco, and Noramco shall use commercially reasonable efforts, to obtain Manufacturing Quota for API(s) provided that Buyer shall reasonably cooperate with Noramco to assist in obtaining Manufacturing Quota. Buyer further acknowledges that the production and supply of API is contingent upon DEA rules, orders, or directives, related to manufacturing quota for API(s), that may limit or restrict the manufacture or supply of any API by Noramco to Noramco's customers (*"Manufacturing Quota Restrictions"*). If Noramco believes that a Manufacturing Quota Restriction is reasonably likely to result in a material reduction or suspension of the delivery of an API to Buyer, Noramco shall promptly consult with Buyer to coordinate with respect to their respective obligations in accordance with Sections 8.4 and 8.5.

8.3 Procurement Quota Restrictions. It is the sole responsibility of Buyer, and Buyer shall use commercially reasonable efforts, to obtain Procurement Quota for API(s) provided that Noramco shall reasonably cooperate with Buyer to assist Buyer in obtaining Procurement Quota. Noramco acknowledges that Buyer's receipt of API manufactured by Noramco is contingent upon DEA rules, orders, or directives related to the procurement quota for API(s) that may limit or restrict Noramco's customers from receiving API manufactured by Noramco (*"Procurement Quota Restrictions"*). If Buyer believes that a Procurement Quota Restriction is reasonably likely to result in Buyer's inability to take delivery of an API from Noramco in accordance with the delivery date set forth in a Purchase Order, Buyer shall promptly consult with Noramco to coordinate with respect to their respective obligations in accordance with Section 8.4.

8.4 Failure to Obtain Quota. Each Party shall use reasonable commercial efforts to prepare and plan for the supply and purchase of API(s) against Purchase Orders to be given in accordance with the Quarterly Forecasts in anticipation of each Party receiving applicable quota from the DEA. However, in the event that a Party has not obtained the necessary Manufacturing Quota or Procurement Quota, as the case may be, to allow it to perform its obligations under this Agreement, such Party shall promptly inform the other Party in writing. In the event that there is not sufficient Manufacturing Quota or Procurement Quota with respect to an outstanding Purchase Order for an API, such Purchase Order shall nonetheless remain valid and binding upon the Parties provided that the Purchase Order delivery date will be adjusted by the Parties for a period not to exceed one month so as to permit receipt of the necessary Manufacturing Quota or Procurement Quota as the case may be. In the event that Manufacturing Quota is not received within one month of the original delivery date, then such Purchase Order may be, but is not required to be, revoked by Buyer by written notice to Noramco. Cancellation of such Purchase Order shall be Buyer's sole and exclusive remedy due to a Manufacturing Quota Restriction. In the event that Buyer has not obtained Procurement Quota within one month of the original delivery date, then such Purchase Order may be, but is not required to be, revoked by Noramco by written notice to Buyer in which event cancellation of such Purchase Order shall be Noramco's sole and exclusive remedy due to a

Procurement Quota Restriction provided however that Buyer shall not be relieved of its minimum purchase requirement. Alternatively, Noramco may elect in lieu of cancellation, to store such API subject to such Procurement Quota Restriction for a period not to exceed three months after the scheduled delivery date at Buyer's reasonable expense. If Buyer still has not obtained Procurement Quota by the end of such three month period Noramco may, in its sole discretion, determine to dispose of such API at Buyer's reasonable expense and invoice Buyer for full payment for such API under the applicable Purchase Order.

8.5 Allocation Among Customers and Cooperation. Buyer recognizes that, due to Manufacturing Interruptions beyond the reasonable control of Noramco or Manufacturing Quota Restrictions, Noramco may produce less API in any given time period than anticipated, and that Noramco may, in its reasonable discretion, allocate its available supply of API among its customers, itself, and its Affiliates on such basis as Noramco deems fair and reasonable. Notwithstanding the above, Noramco shall (i) use commercially reasonable efforts to minimize interruptions in the supply of API, and (ii) use commercially reasonable efforts to coordinate with Buyer to mitigate against the consequences of any shortages related to Manufacturing Interruptions or Manufacturing Quota Restrictions.

8.6 No Liability for Manufacturing Interruptions or Manufacturing Quota Restrictions. Noramco shall not be held liable to Buyer for any damage, inconvenience or any other consequences that may arise from any Manufacturing Interruptions or Manufacturing Quota Restrictions beyond its reasonable control. In the event that Manufacturing Quota is not received within one month of the original delivery date, then such Purchase Order may be, but is not required to be, revoked by Buyer by written notice to Noramco. Cancellation of such Purchase Order shall be Buyer's sole and exclusive *remedy due to a Manufacturing Quota Restriction; provided, however,* that Buyer shall also be relieved of its minimum volume commitment (as set forth in Appendix B) for such affected API(s) in the calendar year during which a Manufacturing Interruption and/or Manufacturing Quota Restriction occurs.

9. WARRANTIES; DISCLAIMER; INSURANCE

9.1 Noramco hereby represents, warrants and covenants to Buyer that:

9.1.1 it has the corporate authority to enter into this Agreement and to perform its obligations hereunder; and

9.1.2 it is not subject to any legal, contractual or regulatory restriction, limitation or conditions that may affect adversely its ability to perform hereunder.

9.2 Buyer hereby represents, warrants and covenants to Noramco that:

9.2.1 it has the corporate authority to enter into this Agreement and to perform its obligations hereunder; and

9.2.2 it is not subject to any legal, contractual or regulatory restriction, limitation or conditions that may affect adversely its ability to perform hereunder.

9.3 Noramco further warrants that

(a) API manufactured hereunder shall conform with the Specifications and is not contaminated or adulterated;

(b) API shall be manufactured hereunder in accordance with all applicable laws and regulations, the Quality Agreement, GMP and the Drug Master File; and

(c) Neither Noramco nor any of its employees have been "debarred" by the FDA or other governmental authority, nor have debarment proceedings against Noramco or any of its employees been commenced. Noramco will promptly notify Buyer in writing if any such proceedings have commenced or if Noramco, or any of its employees are debarred by the FDA or other Regulatory Authority.

9.4 THE PARTIES AGREE THAT, EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 9, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND AND THE LIMITED REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS ARTICLE 9 ARE THE SOLE REPRESENTATIONS AND WARRANTIES WITH RESPECT TO THE API(s) AND THE PRODUCT(s) AND ARE MADE EXPRESSLY IN LIEU OF AND EXCLUDE ANY IMPLIED WARRANTIES OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, OR NON INFRINGEMENT OF THIRD PARTY PATENT RIGHTS AND ALL OTHER EXPRESS OR IMPLIED WARRANTIES PROVIDED BY APPLICABLE LAW, INCLUDING BUT NOT LIMITED TO THE UCC AND THE UN CONVENTION ON CONTRACTS FOR THE INTERNATIONAL SALE OF GOODS.

9.5 Noramco and Buyer shall maintain comprehensive general liability insurance, including product liability insurance against claims regarding the manufacture of API under this Agreement, at a minimum of five million dollars ($5,000,000) per occurrence and ten million dollars ($10,000,000) in the aggregate. Each party shall maintain such insurance during the term of this Agreement and, thereafter, for so long as it customarily maintains insurance for itself for similar products and activities. Each party shall cause the other party to be named as an additional insured under such insurance and shall provide the other party proof of such insurance upon request. In lieu of the insurance policies required hereby, the Parties shall have the right to provide the above coverage through a program of self-insurance upon written notice to the other Party.

10. INDEMNIFICATION; CONSEQUENTIAL DAMAGES AND LIMITATION OF LIABILITY

10.1 Buyer shall indemnify, defend, save and hold Noramco and each of its Affiliates and their respective officers, directors, employees and agents (each a "Noramco Indemnitee") harmless from and against any liability, loss, costs, damage and/or expense, including without limitation, reasonable attorneys, experts and consultants fees and disbursements ("Loss or Losses") in connection with any and all suits, investigations (governmental or otherwise), claims, proceedings or demands (each an "Action") initiated or filed against a Noramco Indemnitee by a third party to the extent resulting from, or arising out of (i) any breach of any representation, warranty or covenant hereunder by any Buyer Indemnitee (ii) a Buyer Indemnitee's negligence or willful misconduct in connection with performance under this agreement or (iii) Buyer's, manufacture, use or sale of Product, in each case except to the extent of Noramco's indemnity obligations described below.

10.2 Noramco shall indemnify, defend, save and hold Buyer and each of its Affiliates and their respective officers, directors, employees and agents (each a "Buyer Indemnitee") harmless from and against Loss or Losses in connection with any Action by a third party to the extent resulting from, or arising out of (i) any breach of any representation, warranty or covenant hereunder by a Noramco Indemnitee or (ii) a Noramco Indemnitee's negligence or willful misconduct in connection with performance under this agreement, in each case except to the extent of Buyer's indemnity obligations described above.

10.3 Upon the occurrence of an event that requires indemnification as set forth above, the indemnified Party shall give prompt written notice to the indemnifying Party providing reasonable details of the nature of the event and basis of the indemnity claim and further expressly stating therein that it is seeking indemnity pursuant to this Agreement. For the avoidance of doubt, and without prejudice to the

indemnified Party's obligation to give prompt written notice, an indemnifying Party's knowledge of events or circumstances pursuant to which an indemnified Party might seek indemnification, including but not limited to correspondence between the Parties regarding a matter for which indemnity is not expressly sought, shall not constitute the notice required by this provision, and any attorneys, experts or consultant fees or expenses incurred by an indemnified Party prior to proper notice shall be the sole responsibility of such Party; provided however that the failure of such timely notice shall not bar any indemnification claim unless the indemnifying Party shall be or has been materially prejudiced by failure to receive such timely notice The indemnifying Party will have the right, at its expense and with counsel of its choice, to defend, contest, or otherwise protect against any Action. The indemnified Party will also have the right, but not the obligation, to participate, at its own expense, in the defense thereof with counsel of its choice. The indemnified Party shall cooperate to the extent reasonably necessary to assist the indemnifying Party in defending, contesting or otherwise protesting against any Action, provided that the reasonable cost in doing so is paid for by the indemnifying Party. If the indemnifying Party fails within thirty (30) days after receipt of notice (i) to notify the indemnified Party of its intent to defend, or (ii) to defend, contest or otherwise protect against any Action or fails to diligently continue to provide the defense after undertaking to do so, the indemnified Party will have the right upon ten (10) days prior written notice to the indemnifying Party to defend, settle and satisfy any Action and recover the costs of the same from the indemnifying Party. No Action may 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, however, that the indemnifying Party shall have no obligation to obtain the consent to any settlement of any Action that does not impose on the indemnified Party any liability or obligation.

10.4 Unless included in Losses under Section 10.1 or 10.2 above, and excluding liabilities associated with breach Article 11 (Confidentiality) below, neither Party shall be liable to the other Party for special, indirect, incidental, punitive or consequential damages (including, but not limited to loss of profits or loss of opportunity), or lost profits even if designated direct damages, whether in contract, warranty, negligence, tort, strict liability or otherwise even if such Party has been advised of the possibility thereof.

10.5 In addition, Noramco's maximum liability to Buyer and Buyer's Affiliates set forth in Appendix D under this Agreement, including its indemnity obligations and obligations under Section 7.3, shall not exceed five million dollars ($5,000,000).

11 CONFIDENTIALITY

11.1 Each Party agrees that (i) it will not disclose any Confidential Information to any third party at any time during the term of this Agreement without the prior written consent of the disclosing Party (ii) it will not make use of any Confidential Information of the other Party for any purpose other than for the purposes set forth in, or in furtherance of the transactions contemplated by, this Agreement and (iii) it will use all reasonable efforts to prevent unauthorized publication or disclosure by any Person of Confidential Information. Notwithstanding the foregoing, a Party may disclose Confidential Information of the disclosing Party to its Affiliates, and to its and their directors, employees, consultants, and agents in each case who have a specific need to know such Confidential Information and who are bound by a like obligation of confidentiality and restriction on use.

11.2 Notwithstanding the foregoing, either Party may upon reasonable prior written notice to the other Party disclose Confidential Information as required by law, regulation or court order provided, however, that the receiving Party provides prior written notice of such disclosure to the disclosing Party and takes reasonable and lawful actions to avoid or minimize the degree of such disclosure.

11.3 All Confidential Information in any form must be returned to the Party who disclosed the Confidential Information within thirty (30) days of the termination or expiration of this Agreement, save

for the retention of one copy of the Confidential Information by the receiving Party as a record of the receiving Party's ongoing confidentiality obligations under this Agreement which copy shall either be returned to the Party who disclosed the Confidential Information within thirty (30) days after the ten-year period referred to in Section 10.4 or, if not returned, shall continue to be subject to the confidentiality provisions of this Agreement indefinitely.

11.4 The confidentiality and non-use obligations of this Agreement shall remain in effect during the term of this Agreement and for a period of five (5) years thereafter.

11.5 **"Confidential Information"** - means all information, data and/or know-how (i) disclosed by either Party electronically or in writing to the other Party concerning the API or the Product or concerning the technology, marketing strategies or business of the disclosing Party (whether disclosed prior to or subsequent to the Effective Date) and (ii) any other information pertaining to the Product or the API which is disclosed by the Parties orally or visually and which is subsequently memorialized in writing by the disclosing Party and/or Affiliate within thirty (30) days of such disclosure. Confidential Information does not include information, data or know-how that the receiving Party can show:

(a) was in the public domain at the time of the disclosure to the receiving Party, or thereafter became part of the public domain without any fault of the receiving Party;

(b) rightfully was in its possession prior to the disclosure by the disclosing Party;

(c) was lawfully obtained from a third party, who had the right to make such disclosures as evidenced by written records; or

(d) was developed by the receiving Party independently of that disclosure as evidenced by written records by individuals who did not have access to Confidential Information.

12 INTELLECTUAL PROPERTY INFRINGEMENT; RESERVATION OF RIGHTS

12.1 If Noramco's process of manufacture of an API becomes or is likely to become the subject of an infringement claim or action, Noramco may at its sole option: (i) procure, at a cost to be reasonably allocated between the Parties, the right to use the applicable intellectual property in the process for manufacture of such API; (ii) modify the process of manufacture to render it non-infringing; or (iii) if, in Noramco's sole discretion, neither (i) nor (ii) above are commercially reasonable, terminate Noramco's obligations (and Buyer's rights) hereunder with respect to further supply of API.

12.2 All rights to and interests in Noramco's and its Affiliates' intellectual property including any improvements thereto will remain solely with Noramco and its Affiliates and no right or interest therein is transferred or granted to Buyer except as expressly provided for herein. Buyer agrees that it does not acquire a license or any other right to Noramco's or its Affiliate's intellectual property or improvements thereto. Noramco and its Affiliates expressly reserve all patent rights related to the API, including but not limited to therapeutic uses in end products, drug delivery technology, or otherwise. Notwithstanding the foregoing or any other language in this Agreement, Noramco hereby grants to Buyer a fully paid-up and royalty-free, worldwide right and license under Noramco's (and, as applicable, its Affiliates') intellectual property to use and sell, test, study and/or otherwise exploit the API supplied hereunder..

13 TERM, RENEWAL AND TERMINATION

13.1 The initial term of this Agreement commences as of the Effective Date and shall expire on December 31, 2016 unless sooner terminated as expressly provided for in this Agreement. Thereafter, the Agreement automatically renews for additional terms of one (1) year each, unless written notice of

termination is given by a Party to the other at least twelve (12) months before the expiration of the initial term or completion of the renewal year as the case may be.

13.2 This Agreement may be terminated by either Party by giving written notice to the other if the other Party (the "**Breaching Party**") is in material breach or default of any of its obligations hereunder (including, without limitation, any payment obligations) as follows: (i) the terminating Party must send written notice of the material breach or material default to the Breaching Party, and (ii) the termination becomes effective forty-five (45) days after written notice thereof was provided to the Breaching Party, unless the Breaching Party has cured that material breach or default prior to the expiration of the forty-five (45) day period or if that material breach or material default is not capable of being cured within that forty-five (45) day period, then the Breaching Party has commenced activities reasonably expected to cure that material breach or material default within that forty-five (45) day period and thereafter uses diligent efforts to complete the cure as soon as practicable, but in no event may that such period exceed sixty (60) days.

13.3 Either Party may terminate this Agreement without prior notice to the other upon the occurrence of any of the following involving the other Party:

(i) that other Party files a petition seeking an order for relief under the Federal Bankruptcy Code (Title 11 of the United States Code), as now or hereafter in effect, or under similar law (including non-United States law), or files a petition in bankruptcy or for reorganization or for an arrangement pursuant to any state bankruptcy law or any similar state law(including non-United States law); or

(ii) an involuntary case against that Party as debtor is commenced by a petition under the Federal Bankruptcy Code (Title 11 of the United States Code), as now or hereafter in effect, or under similar law (including non-United States law), or a petition or answer proposing the adjudication of that Party as a bankrupt or its reorganization pursuant to any state bankruptcy law or any similar state law (including non-United States law) is filed in any court and not dismissed, discharged or denied within sixty (60) days after the filing thereof; or

(iii) a custodian, receiver, United States Trustee, trustee or liquidator of that Party or of all or substantially all of that other Party's property is appointed in any proceedings brought by that Party; or if any custodian, receiver, United States Trustee, trustee or liquidator is appointed in any proceedings brought against that Party and is not be discharged within sixty (60) days after that appointment, or if that Party consents to or acquiesce in that appointment; or

(iv) if that other Party generally does not pay its debts as those debts become due, or makes an assignment for the benefit of creditors, or admits in writing its inability to pay its debts generally as they become due.

13.4 Any expiration or termination of this Agreement does not release the parties from liabilities or obligations accrued as of the date thereof. The obligations undertaken by each Party under Articles 10 (Indemnification; Consequential Damages; Limitations of Liability), 11 (Confidentiality), 12 (Intellectual Property; Reservation of Rights), 15 (Notices) and 19 (Dispute Resolution) shall survive termination and/or expiration of this Agreement indefinitely or for such shorter period as is provided in such Articles.

14 INDEPENDENT CONTRACTORS

The status of the Parties under this Agreement is that of independent contractors. Nothing is this Agreement may be construed as establishing a partnership or joint venture relationship between the Parties hereto. No Party has

the right to enter into any agreements on behalf of the other Party, nor may it represent to any person that it has that right or authority.

15 NOTICES

All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if delivered, addressed or telecopied to the address or telecopier number set forth below and shall be deemed to have been made: (i) on the date of service if served personally on the Party; (ii) on the second business day after delivery to an overnight courier service if first available delivery is indicated and paid for; (iii) on the third business day after mailing if mailed to the Party to whom notice is to be given, by first class mail, registered or certified, postage prepaid; or (iv) on the date of transmission, if sent by telecopier and confirmation of transmittal is received by the transmitting Party. Any Party may change its address for purposes of this Article by giving the other Party's written notice of the new address in the manner set forth above.

If to Buyer:

Buyer
Actavis LLC
Morris Corporate Center III
400 Interpace Parkway
Parsippany, New Jersey 07054

Attention: President

With a copy to:
Actavis Inc.
Morris Corporate Center III
400 Interpace Parkway
Parsippany, New Jersey 07054
Attn: Legal Department
Email: USLegal@actavis.com

If to Noramco:

Noramco, Inc.
500 Swedes Landing Road
Wilmington, Delaware 19801
Attention: Vice President Marketing & Business Development
Facsimile No.: 302-761-2913

16 FORCE MAJEURE

16.1 Neither Party will be liable for non-performance or delay in the fulfillment of its obligations when that non-performance or delay is occasioned by any cause beyond the reasonable control of Buyer or Noramco, as the case may be, including without limitation, acts of God, fire, flood, earthquakes, explosions, sabotage, strikes, or labor disturbances (regardless of the reasonableness of the demands of the labor force), civil commotion, riots, military invasions, wars, failure of utilities, failure of carriers, inability to obtain any required raw material, energy source, equipment, labor or transportation, at prices and on terms Noramco deems reasonable from its usual sources of supply or any acts, restraints, requisitions, regulations, or directives issued by a competent government authority, including changes in law or regulation ("Force Majeure Events"); provided, however, that a Force Majeure Event shall never excuse a Party from paying any sum of money owed under the terms of this Agreement..

16.2 In the event that either Party is prevented from discharging its obligations under this Agreement on account of a Force Majeure Event, that Party shall promptly notify the other, and shall nevertheless make every reasonable endeavor, in the utmost good faith, to discharge its obligations, even if in a partial or compromised manner. In the event that a Force Majeure Event continues for a period of ninety (90) consecutive days, or for periods which aggregate ninety (90) days during any three hundred sixty five (365) day cycle, the Party not claiming the Force Majeure Event will be entitled to terminate this Agreement forthwith, but without penalty or liability to the Party affected by the Force Majeure Event, on written notice to the Party claiming the Force Majeure Event, provided that such termination shall not affect any Party's entitlement to amounts which have accrued or became due prior to the termination.

17 ENTIRE AGREEMENT; MODIFICATION

This Agreement, including the appendices hereto which are incorporated by reference, constitutes the entire agreement of the Parties with respect to its subject matter and supersedes all prior agreements, arrangements, dealings and writings between the Parties that relate to the matters covered herein. Any terms and conditions of an invoice, acknowledgement or similar document provided by Noramco for API, or any terms and conditions of purchase orders provided by Buyer for API which are inconsistent with or in addition to the terms of this Agreement shall be null and void. This Agreement may not be amended or modified except in writing executed by the duly authorized representatives of both Parties.

18 WAIVER

No waiver of a breach or default hereunder will be considered valid unless in writing and signed by the Party giving that waiver, and no waiver will be deemed a waiver of any subsequent breach or default of the same or similar nature.

19 DISPUTE RESOLUTION

19.1 Any controversy or claim arising out of or relating to this Agreement, including any such controversy or claim involving any Affiliate of any Party (a "Dispute"), shall be resolved by arbitration in accordance with the *Commercial Arbitration Rules* of the AAA ("AAA Rules"; *see* www.adr.org) and the Federal Arbitration Act, 9 U.S.C. §1 et seq.. The arbitration shall be conducted in New Jersey, by one arbitrator appointed in accordance with the AAA Rules.

19.2 The arbitrator shall follow the *ICDR Guidelines for Arbitrators Concerning Exchanges of Information* in managing and ruling on requests for discovery. The arbitrator, by accepting appointment, undertakes to exert her or his best efforts to conduct the process so as to issue an award within eight months of her or his appointment, but failure to meet that timetable shall not affect the validity of the award.

19.3 The arbitrator shall decide the Dispute in accordance with the substantive law of New Jersey. The arbitrator may not award special, indirect, incidental, punitive or consequential damages (including, but not limited to loss of profits or loss of opportunity), or lost profits even if designated direct damages, nor may the arbitrator apply any multiplier to any award of actual damages, except as may be required by statute. The award of the arbitrator may be entered in any court of competent jurisdiction.

20 SEVERABILITY

Should any part or provision of this Agreement be held unenforceable or in conflict with applicable law, the invalid or unenforceable part or provision will, provided that it does not go to the essence of this Agreement, be replaced with a revision that accomplishes, to the extent possible, the original commercial purpose of that part or

provision in a valid and enforceable manner, and the balance of this Agreement remains in full force and effect and binding upon the Parties hereto.

21 SUCCESSORS AND ASSIGNS

This Agreement may not be assigned or otherwise transferred by a Party without the prior written consent of the other Parties; provided, however, that either Party may, without such consent, but with notice to the other Parties, assign this Agreement, in whole or in part, (a) in connection with the transfer or sale of all or substantially all of its assets or the line of business for the API or Product to which this Agreement relates, (b) to a successor entity or acquirer in the event of a merger, consolidation or change of control, or (c) to any Affiliate. Any purported assignment in violation of the preceding sentence will be void. Any permitted assignee will assume the rights and obligations of its assignor under this Agreement.

22 COUNTERPARTS

This Agreement may be executed in counterparts, each of which will be an original as against either Party whose signature appears thereon, but all of which together constitutes one and the same instrument.

23 NO BENEFIT TO THIRD PARTIES

The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other persons.

24 PUBLICITY

Neither Party may make any press release or public statement regarding the subject matter of this Agreement or the existence thereof or use the other Party's or its Affiliates' names, trademarks, logos, symbols or other image in any form of advertising, promotion or publicity without the prior written consent of the other Party, except to the extent that the press release or public statement may be required by applicable law.

[Remainder of Page is Intentionally Blank]

IN WITNESS WHEREOF, each of the parties has executed this Agreement effective as of the date set forth above.

Actavis, Inc.		Noramco, Inc.	
Signature:		Signature:	
Print Name:	Helge Cudlaugsdottir	Print Name:	JOHN GIANNONE
Title:	SVP Global Procurement	Title:	DIR US SALES

APPENDIX B

Pricing

Pricing is herewith set as follows:

	Price for Calendar Year in $/kg:		
API	**2014**	**2015**	**2016**
Oxycodone Hydrochloride	1700	1650	See Below
minimum volume commitment	80%	80%	80%
Oxymorphone Hydrochloride	4200	4200	4200
minimum volume commitment	80%	80%	80%
Codeine Phosphate	900	See Below	See Below
minimum volume commitment	80%	80%	80%
Morphine Sulfate	850	See Below	See Below
minimum volume commitment	80%	80%	80%
Hydromorphone Hydrochloride	8600	8600	8600
minimum volume commitment	80%	80%	80%
Methylphenidate Hydrochloride	1300	1300	1300
minimum volume commitment	80%	80%	80%

For Oxycodone Hydrochloride, Noramco agrees to a price of $1600 per KG beginning January 1, 2016, provided Buyer has submitted a valid and appropriate request for change to the FDA prior to January 1, 2016, for authorization to use the product currently known as Oxy3, whose specifications are included herein for reference, regardless of whether FDA has provided such approval prior to January 1, 2016. Otherwise, price shall be $1700/kg until such time as Buyer complies with the aforementioned

For Codeine Phosphate, Noramco agrees to a price of $800 per KG beginning January 1, 2015, provided Buyer has submitted a valid and appropriate request for change to the FDA prior to January 1, 2015, for authorization to use the product currently known as "Tasman" whose specifications are included herein for reference, regardless of whether FDA has provided such approval prior to January 1, 2015. Otherwise, price shall be $900/kg until such time as Buyer complies with the condition and Buyer agrees to pay an additional $100 per KG for any Codeine Phosphate purchased at $800 per KG beginning from the Effective Date of the Agreement.

For Morphine Sulfate, Noramco shall sell to Buyer at a price per KG based on the following formula:

Price for Calendar Year = 2014 Price + 85% (prior year price/kg of Turkish Morphine - $520),

except that at no time during the term of this contract or the renewal thereof, shall prices exceed $950 per KG without mutual agreement of the Buyer. The 2014 Price shall be $850/kg.

For example: If the price of Turkish Morphine in 2015 is $530, the price to Buyer of Morphine Sulfate would be $850/kg + $8.50/kg (85% of $530/kg-$520/kg) = $858.50/kg. Likewise, if the price of Turkish Morphine in 2015 is $510, the price to Buyer of Morphine Sulfate would be $850/kg + (- $8.50/kg) (85% of $510/kg-$520/kg) = $841.50/kg.

If after (twenty four) 24 months following the Effective Date, Buyer receives a "qualified" written offer from a reputable United States producer not controlled by or controlling Buyer, to supply in place of Noramco, all, or a minimum of one (1) year supply of API remaining to be supplied hereunder which is of like quality, for a like use and deliverable in like quantities, at the price defined below, and Buyer determines that it is willing to accept such offer, then upon Buyer's written notice stating all of the terms and conditions, including the quantity that Buyer intends to purchase of the competitive offer, Noramco may by written notice within thirty (30) days of receipt of Buyer's notice: (a) meet the competitive offer for the quantity that Buyer intends to purchase from the competitive source and amend this Agreement accordingly; or (b) choose not to meet such offer but instead deduct from the quantity provided for in this Agreement the quantity that Buyer intends to purchase from the competitive source, and amend this Agreement accordingly.

A reputable United States producer must meet the following criteria in order to qualify:

1. offer the subject API at a price that is 10% or more lower than the average price per kilogram paid by Buyer in the last twelve (12) months under the terms of this Agreement; and,
2. offer an API that Buyer has received approval from the Federal Drug Administration to use in the Buyer's formulation at the time of offer

Actavis, Inc. shall manage any request for a meet or release price adjustment on behalf of itself and any Buyer Affiliate set forth in Appendix D. Any adjustment agreed in accordance with such process shall apply to all Buyers under this Agreement.

APPENDIX A

Specifications:
Each API attached as A-1, A-2, etc.

A-1

NORAMCO INC.

Noramco, Inc., 500 Swedes Landing Road, Wilmington, DE 19801
Telephone: 1-302-761-2909 Fax: 1-302-761-2913

TO: Eddy Cruz
FROM: M. Eclar, QA Specialist 3/27/14
DATE: 3/27/14

CUSTOMER SPECIFICATION REVIEW

Morphine Sulfate, USP (Fine Grade)

Active Pharmaceutical Ingredient

NORAMCO EDMS Specification No.: DS-SPE-18424

SAP No.: 51634001701

Customer Name:	Actavis	Customer Product Number:	RM120000-14
		Customer Specification Number:	N/A

The following NORAMCO Inc. test specifications **MATCH** the customer's test specifications.

TEST	LIMIT
Description	White to off-white crystalline solid
Identification – IR Absorption (Current USP <197A>)	Matches IR of USP Morphine Sulfate Reference Standard (dried @145°C for 1 hour)
Identification – Spot Test (Current USP)	Purple, then blue-violet
Identification – Color Test (Current USP)	Blue then dark red-brown
Identification – Sulfate Test (Current USP <191>)	Barium Chloride TS: A white precipitate should form that is insoluble in either Hydrochloric Acid or Nitric Acid Hydrochloric Acid: No precipitate should form Lead Acetate TS: A white precipitate should form with a neutralized solution of sulfate that is soluble in Ammonium Acetate TS
Specific Rotation (Current USP <781S>)	-107° to -109.5° (Anhydrous Basis)
Acidity (Current USP)	NMT 0.50 ml is required to produce a yellow color
Water (Current USP Method I <921>)	Between 10.4% and 13.4%
Residue on Ignition (Current USP <281>)	Not more than 0.1%, from 500 mg
Chloride (Current USP)	No precipitate or turbidity is produced immediately
Ammonium Salts (Current USP)	No odor of ammonia is perceptible
Residual Ethanol by GC (SOP-NOR-1443) *See Note on page 3	Not more than 5000 ppm
Assay by HPLC (SOP-NOR-1443)	98.0 – 102.0%

A-1

NORAMCO INC.

Noramco, Inc., 500 Swedes Landing Road, Wilmington, DE 19801
Telephone: 1-302-761-2909 Fax: 1-302-761-2913

The following tests have customer specifications, which DO NOT MATCH Noramco's specifications

TEST	LIMIT
Impurities by HPLC (SOP-NOR-1443)- Alternative to USP Limit of Foreign Alkaloids. Noramco certifies that morphine sulfate material, if tested for USP Limit of Foreign Alkaloids, will comply with the established Limit of Foreign Alkaloids specifications.	Morphine N-Oxide: NMT 0.15% w/w Morphinone Sulfate: NMT 0.15% w/w Pseudomorphine Sulfate: NMT 0.15% w/w Codeine Sulfate: NMT 0.20% w/w Individual Unspecified Impurities: NMT 0.10% w/w Total Impurities: NMT 1.0% w/w Noramco specification is listed above while Actavis' specification is listed below: 10-Hydroxymorphine: NMT 0.5% Normorphine: NMT 0.5% Codeine Base: NMT 0.4% Codeine Sulfate: NMT 0.5% Apomorphine: NMT 0.5% Morphine-N-oxide: NMT 0.5% Morphinone: NMT 0.2% Pseudomorphine: NMT 0.5% Single Largest Unknown: NMT 0.1% Total Related Compounds: NMT 2.0% Noramco specification for Total Impurities is tighter than Actavis' specification of NMT 2.0%. Noramco will meet Actavis' specification. Noramco specification for Individual Unspecified Impurities is tighter at NMT 0.10% w/w while Actavis' specification is NMT 0.1%. Noramco will report Individual Unspecified Impurities result in two decimal places. Noramco specification for Morphine N-Oxide is tighter than Actavis' specification of NMT 0.5%. Noramco will meet Actavis' specification. Noramco specification for Morphinone Sulfate (salt form) is tighter than Actavis' specification of NMT 0.2% for Morphinone (base form). Noramco will meet Actavis' specification. Noramco specification for Pseudomorphine Sulfate (salt form) is tighter than Actavis' specification of NMT 0.5% for Pseudomorphine (base form). Noramco will meet Actavis' specification. Noramco specification for Codeine Sulfate is tighter than Actavis' specification of NMT 0.5%. Noramco will meet Actavis' specification. Noramco does not report Codeine (base form) while Actavis does. Noramco cannot meet Actavis specification. 10-Hydroxymorphine Sulfate (salt form), Normorphine Sulfate (salt form) and Apomorphine Sulfate (salt form) are non-filed specifications for Noramco while Actavis specification for 10-Hydroxymorphine (base form) is NMT 0.5%, Normorphine (base form) is NMT 0.5% and Apomorphine (base form) is NMT 0.5%. Noramco will report 10-Hydroxymorphine Sulfate: NMT 0.10% w/w, Normorphine Sulfate: NMT 0.10% w/w and Apomorphine Sulfate: NMT 0.10% w/w on the Certificate of Analysis. This is a customer request for Actavis. Noramco will meet Actavis' specification.

A-1

NORAMCO INC.

Noramco, Inc., 500 Swedes Landing Road, Wilmington, DE 19801
Telephone: 1-302-761-2909 Fax: 1-302-761-2913

The following tests have customer specifications, which **DO NOT MATCH** Noramco's specifications

TEST	LIMIT
Loss on Drying	Noramco does not perform Loss on Drying testing while Actavis does. Noramco cannot meet Actavis' specification.
Solubility	Noramco does not perform Solubility testing while Actavis does. Noramco cannot meet Actavis' specification.
Limit of Foreign Alkaloids (Current USP)	Noramco no longer performs Limit of Foreign Alkaloids testing. Noramco's current validated HPLC method provides superior detection and quantitation of these foreign alkaloid impurities allowing for a lower specification (1.0% Total Impurities) than the current USP limit of 1.5% for foreign alkaloids. Noramco will utilize our current validated HPLC method for impurities as a superior alternative to the USP specified Limit of Foreign Alkaloids test.
Particle Size	Particle Size by Image Analysis is a non-filed test for Noramco: D(v, 0.1): For Information Only D(v, 0.3): NLT 15.3 µm D(v, 0.5): 18 – 33 µm D(v, 0.9): NMT 58 µm Actavis specification is listed below: D(v, 0.3): NLT 8.5 µm D(v, 0.5): 12 - 25 µm D(v, 0.9): NMT 50 µm Noramco specification for Particle Size is based on image analysis while Actavis' specification is based on a laser-diffraction methodology. Noramco will include Particle Size by Image Analysis (Noramco specification) on the Certificate of Analysis for Actavis.
Retest Date	Five years from date of manufacture Noramco retest date is 5 years from date of manufacture while Actavis' retest date is 1 year. The Noramco retest date of 5 years from the date of manufacture for Morphine Sulfate is supported by product stability data.

Noramco's compliance with the current USP <467> residual solvent requirements has been demonstrated through the use of a validated test method to measure solvents likely to be present in the Morphine Sulfate drug substance. Only the Class 3 solvent ethanol is likely to be present. Residual Class 2 solvents are not more than the Option 1 limit and residual Class 3 solvents are not more than 0.5% (5000 ppm). Therefore, Noramco certifies that this material, if tested, will comply with the established residual organic solvent specifications of USP *<467>*.

Please direct questions regarding this review to: Mary Ann Sellers, Customer Service Manager at 302-761-2909.

A-1

Actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM120800-14	**Receiving #:**	**Page 1 of 8**

Manufacturer:	**Manufacturer's Lot #**
Qualified Manufacturer(s): Mallinckrodt, Noramco	

Tests/Methods	Specifications	Results	References
† Description Visual	White to off white, crystalline solid.		Test Date: Ref: Chem: Ck'd:
Identification In-house Method NIR/G145/ID or Tests A, B, C and D as listed below	The Sample is positively identified as Morphine Sulfate, USP		Test Date: Ref: Chem: Ck'd:
A) Current USP † as amended <197K>	A) The IR spectrum of the preparation of test specimen exhibits maxima at the same wavelengths as that of a similar preparation of standard.		

A-1

Actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM120800-14	Receiving #:	Page 2 of 8

Tests/Methods	Specifications	Results	References
Identification			
B) Current USP as amended	B) An intense purple color is produced at once, and quickly changes to a deep blue-violet		Test Date: Ref: Chem: Ck'd:
C) Current USP as amended	C) A blue color is produced which changes to dark red-brown with the addition of 1 drop Nitric acid		Test Date: Ref: Chem: Ck'd:
D) Current USP as amended	D) A solution (1 in 50) responds to the tests for Sulfate <191>		Test Date: Ref: Chem: Ck'd:

A-1

actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM120000-14	**Receiving #:**	**Page 3 of 8**

Tests/Methods	Specifications	Results	References
*** Specific Rotation** Current USP as amended <781S>	Between -107° and -109.5° calculated on the anhydrous basis		Test Date: Ref: Chem: Ck'd:
*** Acidity** Current USP as amended	NMT 0.50 mL of 0.020 N sodium hydroxide is required to produce a yellow color.		Test Date: Ref: Chem: Ck'd:
† Water Current USP as amended <921> Method I	Between 10.4% and 13.4%		Test Date: Ref: Chem: Ck'd:

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actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM120800-14	**Receiving #:**	**Page 4 of 8**

Tests/Methods	Specifications	Results	References
*** Residue on Ignition** Current USP as amended <281>	NMT 0.1%		Test Date: Ref: Chem: Ck'd:
*** Chloride** Current USP as amended	No precipitate or turbidity is produced immediately.		Test Date: Ref: Chem: Ck'd:
*** Ammonium Salts** Current USP as amended	No odor of ammonia is perceptible		Test Date: Ref: Chem: Ck'd:

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Actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM120800-14	Receiving #:	Page 5 of 8

Tests/Methods	Specifications	Results	References
* Limit of Foreign Alkaloids Current USP as amended	NLT 7.5 mL of 0.020N sodium hydroxide is required.		Test Date: Ref: Chem: Ck'd:
Loss on Drying Current USP as amended <731> Dry 1g at 145°C for 1 hour. (In-house requirement)	9.0% to 12.0% w/w		Test Date: Ref: Chem: Ck'd:

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Actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM120800-14	**Receiving #:**	**Page 6 of 8**

Tests/Methods	Specifications	Results	References
† Related Compounds In-house Method LC/3065/RC1	**Process Impurities**		Test Date: Ref: Chem: Ck'd:
	NMT 0.5% 10-Hydroxymorphine		
	NMT 0.5% Normorphine		
	NMT 0.4% Codeine Base		
	NMT 0.5% Codeine Sulfate (%Codeine Base x 696.82/598.74)		
	NMT 0.5% Apomorphine		
	Known Degradants		
	NMT 0.5% Morphine-N-oxide		
	NMT 0.2% Morphinone		
	NMT 0.5% Pseudomorphine		
	NMT 0.1% Single Largest Unknown		
(In-house requirement)	NMT 2.0% Total Related Compounds		

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Actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM120809-14	Receiving #:	Page 7 of 8

Tests/Methods	Specifications	Results	References
Solubility (in-house requirement)	Soluble in 21 parts water Very slightly soluble in alcohol Practically insoluble in chloroform Practically insoluble in ether		Test Date: Ref: Chem: Ck'd:
† **Assay** In-house Method LC/3065/AS1(USP)	98.0% to 102.0% of morphine sulfate calculated on the anhydrous basis		Test Date: Ref: Chem: Ck'd:

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RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM120800-14	Receiving #:	Page 8 of 8

Tests/Methods	Specifications	Results	References
Particle Size In-house Method LD/2054/PS or In-house Method LD/2054/PS1 (in-house requirement)	NLT 8.5 µm D(v,0.3)		Test Date: Ref: Chem: Ck'd:
	12 µm to 25 µm D(v,0.5)		
	NMT 50 µm D(v,0.9)		
Residual Solvent In-house Method GC/1437/RS2	NMT 5000ppm Ethanol		Test Date: Ref: Chem: Ck'd:
COA	Supplier's COA conforms to this specification and to USP requirements for this lot.		
Retest Date	One (1) year		

* Accept supplier's results for Noramco and Mallinckrodt material.

† Tests required for reassay

_____ APPROVED _____ NOT APPROVED _____ FOR INFORMATION

BY: _____ DATE: _____

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RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP	
No.: RM120800-14	**Page 1 of 2**

SUMMARY OF SPECIFICATION UPDATES

Revision No.	Effective Date	Reason for Update	CR Ref No.
DRAFT	07/08/93	New item. DRAFT only. Effective Date 7/8/93	NA
RM120800-01	06/22/94	Addition of the following tests: Related Substances, Loss on Drying, Solubility and Particle Size.	NA
RM120800-02	09/12/94	Addition of Faulding Review signature areas to specification format. Remove draft status. Change for Particle Size Test.	NA
RM120800-03	02/03/95	Update to USP 23/ NF 18.	NA
RM120800-04	12/20/95	Update description. Remove the statement that Morphine darkens upon prolonged exposure to light.	NA
RM120800-05	01/01/00	Update references from USP 23/NF 18 to USP 24/NF 19. Update format. Addition of History page.	CR9-0238
RM120800-06	01/01/02	Update USP references to 'Current USP as amended'.	CR01-543
RM120800-P	12/12/04	For Related Compounds: • Replace 'In-house Method LC/2054/RC' with 'In-house Method LC/3065/RC1'. • List the following as 'Process Impurities'; NMT 0.5% 10-Hydroxymorphine, NMT 0.5% Normorphine, NMT 0.4% Codeine Base, NMT 0.5% Codeine Sulfate, and NMT 0.5% Apomorphine. • List the following as 'Known Degradants'; NMT 0.5 Morphine-N-oxide and NMT 0.5% Pseudomorphine. • Replace 'NMT 0.5% Any Individual Related Substance' with 'NMT 0.2% Single Larges Unknown'. For Assay, replace 'Current USP as amended' with 'In-house Method LC/3065/AS1(USP)'. For Particle Size, update the reporting format to current standards.	CR04-1344
RM120800-P2	04/15/05	Update specification in response to FDA deficiency letter: • For Related Compounds, change Single Larget Unknown limit from 'NMT 0.2%' to 'NMT 0.1%'	CR05-372

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Actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP	
No.: RM120800-14	Page 2 of 2

Revision No.	Effective Date	Reason for Update	CR Ref No.
RM120800-07	11/10/05	FDA approval received. Proposed specifications will be implemented.	CR05-824
RM120800-08	05/25/07	For Related Compounds: • Integrate 'Codeine Sulfate' into 'Codeine Base' and include a calculation for conversion. • Add 'Morphinone' as a known degradant with limits of 'NMT 0.2%'.	CR07-084
RM120800-09	03/07/08	• Place an asterisk next to the following tests: Specific Rotation, Acidity, ROI, Chloride, Ammonium Salts and Limit of Foreign Alkaloids. • Add vendors to the Accept Supplier's Results statement on page 9.	CR07-291
RM120800-10	05/28/08	Tightened Related Compounds specification limits.	587
RM120800-11	07/31/08	• Increase Related Compounds specification limits. • Removed OVI per USP 467 update. • Add Residual Solvents test method GC/7437/RS2.	692
RM120800-12	02/05/09	Identification Test A: Add In-house Method NIR/G145/ID as an alternate identification testing method.	822
RM120800-13	12/08/09	Changed font from Times New Roman to Trebuchet MS size 11. Add after NIR test: or Tests A, B, C, and D as listed below Move the following after the NIR test and comment above: A) Current USP as amended <197K>	951
RM120800-14	Current	Added test method LD/2054/PS1 as an alternate method to the Particle size test.	1892

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NORAMCO INC

Noramco, Inc., 500 Swedes Landing Road, Wilmington, DE 19801
Telephone: 1-302-761-2909 Fax: 1-302-761-2913

TO: Eddy Cruz
FROM: M. Eclar, QA Auditor
DATE: 5/7/14

CUSTOMER SPECIFICATION REVIEW

Morphine Sulfate, USP (Fine Grade)

Active Pharmaceutical Ingredient

NORAMCO Specification No.: DS-SPE-18424

SAP No.: 51634001701

Customer Name:	Pfizer (Actavis)	Customer Product Number:	RM121601(ALO)-04
		Customer Specification Number:	N/A

The following NORAMCO Inc. test specifications **MATCH** the customer's test specifications.

TEST	LIMIT
Description	White to off-white crystalline solid
Identification – IR Absorption (Current USP <197A>)	Matches IR of USP Morphine Sulfate Reference Standard (dried @145°C for 1 hour)
Identification – Spot Test (Current USP)	Purple, then blue-violet
Identification – Color Test (Current USP)	Blue then dark red-brown
Identification – Sulfate Test (Current USP <191>)	Barium Chloride TS: A white precipitate should form that is insoluble in either Hydrochloric Acid or Nitric Acid Hydrochloric Acid: No precipitate should form Lead Acetate TS: A white precipitate should form with a neutralized solution of sulfate that is soluble in Ammonium Acetate TS
Specific Rotation (Current USP <781S>)	-107° to -109.5° (Anhydrous Basis)
Acidity (Current USP)	NMT 0.50 ml is required to produce a yellow color
Water (Current USP Method 1 <921>)	Between 10.4% and 13.4%
Residue on Ignition (Current USP <281>)	Not more than 0.1%, from 500 mg
Chloride (Current USP)	No precipitate or turbidity is produced immediately
Ammonium Salts (Current USP)	No odor of ammonia is perceptible
Residual Ethanol by GC (SOP-NOR-1443) *See Note on page 2	Not more than 5000 ppm
Assay (HPLC) (SOP-NOR-1443)	98.0 – 102.0% (Calculated on the anhydrous basis)

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RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM121601(ALO)-04	Receiving #:	Page 1 of 7

Manufacturer:	Manufacturer's Lot #
Qualified Manufacturer(s): Mallinckrodt, Noramco	

Tests/Methods	Specifications	Results	References
† Description Visual	White to off white crystalline solid.		Test Date: Ref: Chem: Ck'd:
Identification A) Current USP † as amended <197K>	A) The IR spectrum of the preparation of test specimen exhibits maxima at the same wavelengths as that of a similar preparation of standard.		Test Date: Ref: Chem: Ck'd:

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actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM121601(ALO)-04	Receiving #:	Page 2 of 7

Tests/Methods	Specifications	Results	References
Identification			
B) Current USP as amended	B) An intense purple color is produced at once, and quickly changes to a deep blue-violet.		Test Date: Ref: Chem: Ck'd:
C) Current USP as amended	C) A blue color is produced which changes to dark red-brown with the addition of 1 drop Nitric acid.		Test Date: Ref: Chem: Ck'd:
D) Current USP as amended	D) A solution (1 in 50) responds to the tests for Sulfate <191>.		Test Date: Ref: Chem: Ck'd:

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RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM121601(ALO)-04	**Receiving #:**	**Page 3 of 7**

Tests/Methods	Specifications	Results	References
Specific Rotation Current USP as amended <781S>	Between -107° and -109.5°.		Test Date: Ref: Chem: Ck'd:
Acidity Current USP as amended	NMT 0.50 mL of 0.020N sodium hydroxide is required to produce a yellow color.		Test Date: Ref: Chem: Ck'd:
† **Water** Current USP as amended <921> Method I	Between 10.4% and 13.4%.		Test Date: Ref: Chem: Ck'd:

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Actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM121601(ALO)-04	Receiving #:	Page 4 of 7

Tests/Methods	Specifications	Results	References
Residue on Ignition Current USP as amended <281>	NMT 0.1%.		Test Date: Ref: Chem: Ck'd:
Chloride Current USP as amended	No precipitate or turbidity is produced immediately.		Test Date: Ref: Chem: Ck'd:
Ammonium Salts Current USP as amended	No odor of ammonia is perceptible.		Test Date: Ref: Chem: Ck'd:

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RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM121601(ALO)-04	Receiving #:	Page 5 of 7

Tests/Methods	Specifications	Results	References
Limit of Foreign Alkaloids Current USP as amended	NLT 7.5 mL of 0.020N sodium hydroxide is required.		Test Date: Ref: Chem: Ck'd:
† **Related Compounds** In-house Method LC/7437/RC1	**Process Impurities**		Test Date: Ref: Chem: Ck'd:
	NMT 0.15% 10-Hydroxymorphine		
	NMT 0.15% Normorphine		
	NMT 0.20% Codeine Sulfate		
	NMT 0.15% Apomorphine		
	Known Degradants		
	NMT 0.15% Morphine-N-oxide		
	NMT 0.10% Morphinone		
	NMT 0.15% Pseudomorphine		
	NMT 0.10% Single Largest Unknown		
	NMT 1.0% Total Related Compounds		

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actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM121601(ALO)-04	Receiving #:	Page 6 of 7

Tests/Methods	Specifications	Results	References
† Assay In-house Method LC/7437/AS1(USP)	98.0% to 102.0% of morphine sulfate calculated on the anhydrous basis.		Test Date: Ref: Chem: Ck'd:
Particle Size In-house Method LD/7437/PS1	NLT 8.5 µm D(v,0.3)		Test Date: Ref: Chem: Ck'd:
	12 µm to 25 µm D(v,0.5)		
(In-house requirement)	NMT 50 µm D(v,0.9)		

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actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP		
No.: RM121601(ALO)-04	Receiving #:	Page 7 of 7

Tests/Methods	Specifications	Results	References
Residual Ethanol In-house Method GC/7437/RS2	NMT 5000 ppm Ethanol		Test Date: Ref: Chem: Ck'd:
COA	Supplier's COA conforms to this specification and to USP requirements for this lot.		
Retest Date	One (1) year		

† Tests required for reassay

_____ APPROVED _____ NOT APPROVED _____ FOR INFORMATION

BY: _____ DATE:_____

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Actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP	
No.: RM121601(ALO)-04	**Page 1 of 1**

SUMMARY OF SPECIFICATION UPDATES

Revision No.	Effective Date	Reason for Update	CR REF No.
RM121601-01	8/1/08	New issue. Translation of Alpharma specification PIS-QA-SPC-0217-03.	683
RM121601(ALO)-02	11/20/08	Update document number to include (ALO). Related compounds specification limits were tightened for impurities: a. 10-hydroxymorphine from 0.15% to 0.05% b. morphine n-oxide from 0.10% to 0.05% c. morphinone from 0.15% to 0.05% d. pseudomorphine from 0.15% to 0.05% e. Single Largest Unknown from 0.10% to 0.05% Change Residual Solvents to Residual Ethanol.	782
RM121601(ALO)-03	04/09/09	Related Compounds: Change method reference to LC/7437/RC1. Assay: Change method reference to LC/7437/AS1(USP). Particle Size: Change method reference to LD/7437/PS1	891
RM121601(ALO)-04	Current	Update to current format: change font from Trebuchet MS size 11 to Time New Roman size 12. Change the related compound specifications as follows: 10-Hydroxymorphine from: NMT 0.05% to NMT 0.15% Morphine-N-oxide from: NMT 0.05% to NMT 0.15% Morphinone from: NMT 0.05% to NMT 0.10% Pseudomorphine from: NMT 0.05% to NMT 0.15% Single Largest Unknown from: NMT 0.05% to NMT 0.10%	1683

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NORAMCO, INC.
500 SWEDES LANDING ROAD • WILMINGTON, DELAWARE 19801-4417
302-652-3640 • FAX 302-652-4417

TO: Mr. Eddy Cruz, Buyer
FROM: M. Eclar, QA Auditor 2/23/10 A.C. Bartkowski, QA Manager 2-23-2010
DATE: 2/17/10

CUSTOMER SPECIFICATION REVIEW

Morphine Sulfate, USP (Micronized)

Active Pharmaceutical Ingredient

NORAMCO EDMS Specification No.: PR-NOR-214

SAP No.: 51634001706

Customer Name:	Actavis Elizabeth, NJ	Customer Product Number:	RM120801-05
		Customer Specification Number:	ELZ-RM120801

The following NORAMCO Inc. test specifications **MATCH** the customer's test specifications.

TEST	LIMIT
Description	White to off-white crystalline solid
Identification – IR Absorption (Current USP <197A>)	Matches IR of USP Morphine Sulfate Reference Standard (dried @145°C for 1 hour)
Identification – Spot Test (Current USP)	Purple, then blue-violet
Identification – Color Test (Current USP)	Blue then dark red-brown
Identification – Sulfate Test (Current USP<191>)	Barium Chloride TS: A white precipitate should form that is insoluble in either Hydrochloric Acid or Nitric Acid Hydrochloric Acid: No precipitate should form Lead Acetate TS: A white precipitate should form with a neutralized solution of sulfate that is soluble in Ammonium Acetate TS
Specific Rotation (Current USP <781S>)	-107° to -109.5° (Anhydrous Basis)
Acidity (Current USP)	NMT 0.50 ml is required to produce a yellow color
Water (Current USP Method I <921>)	Between 10.4% and 13.4%
Residue on Ignition (Current USP <281>)	Not more than 0.1%, from 500 mg
Chloride (Current USP)	No precipitate or turbidity is produced immediately
Ammonium Salts (Current USP)	No odor of ammonia is perceptible

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The following NORAMCO Inc. test specifications **MATCH** the customer's test specifications

TEST	LIMIT
Limit of Foreign Alkaloids (Current USP)	Not less than 7.5 ml is required (1.5%)
Residual Ethanol by GC (SOP-NOR-1443) *See Note below	Not more than 5000 ppm
Assay (HPLC) (SOP-NOR-1443)	98.0 – 102.0% (Calculated on the anhydrous basis)

The following tests have customer specifications, which **DO NOT MATCH** Noramco's specifications

TEST	LIMIT
Impurities by HPLC (SOP-NOR-1443)	Morphine N-Oxide: NMT 0.15% w/w Morphinone Sulfate NMT 0.15% w/w Pseudomorphine Sulfate: NMT 0.15% w/w Codeine Sulfate: NMT 0.20% w/w Individual Unspecified Impurities: NMT 0.10% w/w Total Impurities: NMT 1.0% w/w Noramco does not report 10-Hydroxymorphine, Normorphine, and Codeine base and while Actavis does. NORAMCO CANNOT MEET ACTAVIS' SPECIFICATION. Noramco specification for Morphinone Sulfate is NMT 0.15% while Actavis specification for Morphinone (base form) is NMT 0.2%. Noramco specification for Pseudomorphine Sulfate is NMT 0.15% while Actavis specification for Pseudomorphine (base form) is NMT 0.5%. NORAMCO WILL MEET ACTAVIS' SPECIFICATION Noramco specification for Morphine N-Oxide: NMT 0.15% is tighter than Actavis specification which is NMT 0.5%. Noramco specification for Codeine Sulfate: NMT 0.20% is tighter than Actavis specification which is NMT 0.5%. Noramco specification for Total Impurities: NMT 1.0% is tighter than Actavis specification which is NMT 2.0%. NORAMCO WILL MEET ACTAVIS' SPECIFICATION Noramco specification (non-filed) for Apomorphine Sulfate is NMT 0.10% and is not reported on the Certificate of Analysis while Actavis specification for Apomorphine (base form) is NMT 0.5%. Noramco will report Apomorphine Sulfate (NMT 0.10%) impurity result on the Certificate of Analysis for Actavis. This is an Actavis customer request and will be added to the Noramco Customer Specification SOP. NORAMCO WILL MEET ACTAVIS' SPECIFICATION The Individual Unspecified Impurities match for Noramco and Actavis.
Laser Diffraction Particle Size	D(v, 0.1): < 1.4 µm D(v, 0.5): < 6 µm D(v, 0.95): < 20 µm D(v, 0.99): < 40 µm Noramco specification (non-filed) for Laser Diffraction Particle Size is listed above while Actavis specification is only "Record Results" and require reporting of this test on the CofA . This is an Actavis customer request and will be added to the Noramco Customer Specification SOP. NORAMCO WILL MEET ACTAVIS' SPECIFICATION

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The following tests have customer specifications, which **DO NOT MATCH** Noramco's specifications

TEST	LIMIT
LOD	Noramco does not perform LOD testing while Actavis does. This is an in-house requirement for Actavis. NORAMCO CANNOT MEET ACTAVIS' SPECIFICATION
Solubility	Noramco does not perform Solubility testing while Actavis does. This is an in-house requirement for Actavis. NORAMCO CANNOT MEET ACTAVIS' SPECIFICATION
Retest Date	9 months from date of micronization The Noramco retest date from date of micronization is supported by product stability data.

*Note: Noramco's compliance with the current USP <467> residual solvent requirements has been demonstrated through the use of a validated test method to measure solvents likely to be present in the Morphine Sulfate drug substance. Only the Class 3 solvent ethanol is likely to be present. Residual Class 2 solvents are below the Option 1 limit and residual Class 3 solvents are below 0.5% (5000 ppm). Therefore, Noramco certifies that this material, if tested, will comply with the established USP <467> residual solvent requirements.

Customer Comments:

_____

_____

_____

Customer Specification Review received and acknowledged by:
(please print, sign and fax to Mary Ann Darby, 302-761-2913)

Name _____ Title _____ Date_____

Please direct questions regarding this review to: Ann C. Bartkowski Quality Assurance Manager 302-888-6464

A-3

Printed On: 11/Feb/2010 13:36:46

Printed By: Cris Eddy

Version No: 5

Doc No: RLZ-RM120801

Actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP (Fine Grade)		
No.: RM120801-05	Receiving #:	Page 1 of 8
Manufacturer:	Manufacturer's Lot #	
Qualified Manufacturer(s): Noramco, Mallinckrodt		

Tests/Methods	Specifications	Results	References
† Description Visual	White to off-white crystalline solid.		Test Date: Ref: Chem: Ck'd:
Identification A) Current USP † as amended <197K>	A) The IR spectrum of the preparation of test specimen exhibits maxima at the same wavelengths as that of a similar preparation of standard.		Test Date: Ref: Chem: Ck'd:

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Printed On: 11/Feb/2010 13:34:46

Printed By: Cruz Eddy

Version No: 5

Doc No: EL2-RM120801

actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP (Fine Grade)		
No.: RM120801-05	Receiving #:	Page 2 of 8

Tests/Methods	Specifications	Results	References
Identification			
B) Current USP as amended	B) An intense purple color is produced at once, and quickly changes to a deep blue-violet.		Test Date: Ref: Chem: Ck'd:
C) Current USP as amended	C) A blue color is produced which changes to dark red-brown with the addition of 1 drop Nitric acid.		Test Date: Ref: Chem: Ck'd:
D) Current USP as amended	D) A solution (1 in 50) responds to the tests for Sulfate <191>.		Test Date: Ref: Chem: Ck'd:

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Actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP (Fine Grade)		
No.: RM120801-05	Receiving #:	Page 3 of 8

Tests/Methods	Specifications	Results	References
Specific Rotation Current USP as amended <781S>	Between -107° and -109.5° calculated on the anhydrous basis.		Test Date: Ref: Chem: Ck'd:
Acidity Current USP as amended	NMT 0.50 mL of 0.020 N sodium hydroxide is required to produce a yellow color.		Test Date: Ref: Chem: Ck'd:
† Water Current USP as amended <921> Method IA	Between 10.4% and 13.4%.		Test Date: Ref: Chem: Ck'd:

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Printed By: Cass Bixby
Version No: 5
Doc No: ELZ-RM120801

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actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP (Fine Grade)		
No.: RM120801-05	Receiving #:	Page 4 of 8

Tests/Methods	Specifications	Results	References
Residue on Ignition Current USP as amended <281>	NMT 0.1%		Test Date: Ref: Chem: Ck'd:
Chloride Current USP as amended	No precipitate or turbidity is produced immediately.		Test Date: Ref: Chem: Ck'd:
Ammonium Salts Current USP as amended	No odor of ammonia is perceptible.		Test Date: Ref: Chem:
			Ck'd:

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Printed By: Cara Eddy

Version No: 5

Doc No: ELZ-RM120801

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Printed By: Cruz Eddy

Version No: 5

Doc No: ELZ-RM120801

Actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP (Fine Grade)		
No.: RM120801-05	Receiving #:	Page 5 of 8

Tests/Methods	Specifications	Results	References
Limit of Foreign Alkaloids Current USP as amended	NLT 7.5 mL of 0.020 N sodium hydroxide is required.		Test Date: Ref: Chem: Ck'd:
Loss on Drying Current USP as amended <731> Dry 1g at 145 °C for 1 hour. (In-house requirement)	9.0% to 12.0% w/w		Test Date: Ref: Chem: Ck'd:
† Assay In-house Method LC/3065/AS1(USP)	98.0% to 102.0% of morphine sulfate calculated on the anhydrous basis.		Test Date: Ref: Chem: Ck'd:

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Printed By: Cora Eddy

Version No: 5

Doc No: EUZ-RM120801

actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP (Fine Grade)		
No.: RM120801-05	Receiving #:	Page 6 of 8

Tests/Methods	Specifications	Results	References
† Related Compounds In-house Method LC/3065/RC1	Process Impurities		Test Date:
	NMT 0.5% 10-Hydroxymorphine		Ref:
	NMT 0.5% Normorphine		Chem:
	NMT 0.4% Codeine Base		Ck'd:
	NMT 0.5% Codeine Sulfate (% Codeine Base x 696.82/598.74)		
	NMT 0.5% Apomorphine		
	Known Degradants		
	NMT 0.5% Morphine-N-oxide		
	NMT 0.2% Morphinone		
	NMT 0.5% Pseudomorphine		
	NMT 0.1% Single Largest Unknown		
(In-house requirement)	NMT 2.0% Total Related Compounds		

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RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP (Fine Grade)		
No.: RM120801-05	Receiving #:	Page: 7 of 8

Tests/Methods	Specifications	Results	References
Solubility (In-house requirement)	Soluble in 21 parts water Very slightly soluble in alcohol Practically insoluble in chloroform Practically insoluble in ether		Test Date: Ref: Chem: Ck'd:
Particle Size In-house Method LD/3065/PS Alternate Testing Facility: Catalent 160 North Cardinal Health Way Morrisville, NC 27560	D(v,0.1) Record results		Test Date: Ref:
	D(v,0.5) Record results		
	D(v,0.95) Record results		Chem:
	D(v,0.99) Record results		Ck'd:
(In-house requirement)			

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Printed On: 11/Feb/2010 13:36:46

Printed By: Cass Eddy

Version No: 5

Doc No: ELZ-RM120801

actavis

RAW MATERIAL SPECIFICATION

PRODUCT: Morphine Sulfate USP (Fine Grade)		
No.: RM120801-05	Receiving #:	Page 5 of 5

Tests/Methods	Specifications	Results	References
Residual Solvents In-house Method GC/7437/RS2	NMT 5000 ppm Ethanol		Test Date: Ref: Chem: Ck'd:
COA	Supplier's COA conforms to USP requirements for this lot.		
Retest Date	One (1) year		

† Tests required for re-assay

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_____ APPROVED _____ NOT APPROVED _____ FOR INFORMATION

BY: _____ DATE: _____

CONFIDENTIAL

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NORAMCO INC.

Noramco, Inc., 500 Swedes Landing Road, Wilmington, DE 19801
Telephone: 1-302-761-2909 Fax: 1-302-761-2913

TO:
FROM: A. Falasca, QA Auditor A.C. Bartkowski, QA Manager
DATE: 11/19/2014 1-22-15

CUSTOMER SPECIFICATION REVIEW
Oxymorphone Hydrochloride, USP

Active Pharmaceutical Ingredient

NORAMCO EDMS Specification No.: DS-SPE-17249

SAP No: 51634009300

Customer Name:	Actavis	Customer Product Number:	RM121300(ASA)-07
		Customer Specification Number:	N/A

The following NORAMCO Inc. test specifications MATCH the customer's test specifications.

TEST	LIMIT
Appearance (Visual)	White to off-white powder
Identification	
(a) Chloride, (Current USP)	Positive for Chloride
(b) Infrared Absorption, (Current USP)	Matches USP Oxymorphone Reference Standard
(c) Ultraviolet Absorption, (Current USP)	Maxima and minima match USP Oxymorphone Reference Standard Absorbance Ratio A_{287nm}/A_{304nm}: 1.75 ± 0.2
(d) Ferric Chloride, (Current USP)	A blue color is produced immediately
Loss on Drying (LOD), (Current USP <731>)	NMT 8.0 %
Specific Rotation, (Current USP <781S>)	Between -145 ° and -155° (on dry basis)
Residue on Ignition, (Current USP <281>)	NMT 0.3 %
Acidity, (Current USP)	NMT 0.30 mL is required to produce a yellow color
Limit of Nonphenolic Substances, (Current USP)	Residue does not exceed 15 mg
Chloride Content (Current USP)	10.2% – 10.8% (on dry basis)
Residual Solvents, (Current USP <467>, See Note on page 3	Ethanol NMT 5000 ppm Isopropanol NMT 5000 ppm Acetonitrile NMT 410 ppm 1-Butanol NMT 5000 ppm
Assay (UPLC)	98.0% – 102.0% (on dry basis)
Impurities by HPLC-MS	≤ 0.0006% w/w 14-Hydroxymorphinone Hydrochloride

NORAMCO INC.

A-4

Noramco, Inc., 500 Swedes Landing Road, Wilmington, DE 19801
Telephone: 1-302-761-2909 Fax: 1-302-761-2913

The following tests have customer specifications, which **DO NOT MATCH** Noramco's specifications

TEST	LIMIT
Impurities by HPLC-MS	≤ 0.0006% w/w 14-Hydroxycodeinone Hydrochloride Noramco no longer reports 14-Hydroxycodeinone Hydrochloride as a specified impurity while Actavis does. 14-Hydroxycodeinone Hydrochloride is considered a non-genotoxic impurity and is controlled as an unspecified impurity at a level of NMT 0.10% w/w.
Assay (Current USP)	97.0% – 102.0% (on dry basis) Noramco calculates Assay (Current USP) on the dry basis while Actavis records assay on the "as-is basis".
Impurities by UPLC	Oxymorphone N-oxide NMT 0.15% w/w Hydromorphone Hydrochloride NMT 0.15% w/w Oxycodone Hydrochloride NMT 0.15% w/w Pyran Bridged Oxymorphone Dimer Hydrochloride NMT 0.15% w/w 2,2'- Bisoxymorphone Hydrochloride NMT 0.15% w/w Individual unspecified impurity NMT 0.10% relative Total Impurities (sum of individual reportable impurities ≥ 0.05%) NMT 1.0% w/w Noramco and Actavis have the same specification for Oxymorphone N-oxide, Hydromorphone Hydrochloride, Oxycodone HCl, Individual unspecified impurities and Total impurities. Noramco reports Pyran Bridged Oxymorphone Dimer HCl and 2,2'-Bisoxymorphone HCl (salt form) while Actavis reports these impurities in the base form. Noramco will continue to report these impurities in the salt form but will meet Actavis' specification of NMT 0.15%. Noramco does not have a specification for 10-Hydroxyoxymorphone and 10-Ketooxymorphone while Actavis does. These impurities will be treated and reported, if present above the reporting threshold, as individual unspecified impurities which have a specification of NMT 0.10%. Noramco will meet Actavis' specification.
Ordinary Impurities	NMT 2.0 % Noramco does not perform Ordinary Impurities testing while Actavis does. Noramco cannot meet Actavis' specification.
Water	6.0 – 8.0 % Noramco does not perform Water testing while Actavis does. Noramco cannot meet Actavis' specification.

NORAMCO INC

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Noramco, Inc., 500 Swedes Landing Road, Wilmington, DE 19801
Telephone: 1-302-761-2909 Fax: 1-302-761-2913

The following tests have customer specifications, which **DO NOT MATCH** Noramco's specifications

TEST	LIMIT
Particle Size by Malvern	D10: Average NMT 30 µm, RSD NMT 15% D50: Average NMT 80 µm, RSD NMT 10% D90: Average NMT 180 µm, RSD NMT 15% This is a non-filed test for Noramco and a customer specific request for Actavis. Noramco will continue to meet Actavis' specification.
Residual Solvents	Methanol: NMT 500 ppm This is a non-filed test for Noramco and a customer specific request for Actavis. Noramco will meet Actavis' specification.
Volatile Impurities	Isopropyl Chloride: NMT 11 ppm Ethyl Chloride: NMT 11 ppm Di-isopropyl Ether: NMT 11 ppm 2-ethoxy Propane: NMT 11 ppm Noramco report volatile impurities as listed above while Actavis report volatile impurities using the chemical synonyms listed below: 2-Chloropropane: NMT 11 ppm Chloroethane: NMT 11 ppm Diisopropyl ether: NMT 11 ppm Ethyl Isopropyl Ether: NMT 11 ppm Noramco will report volatile impurities on the Certificate of Analysis as it is listed for Noramco. This is a non-filed test for Noramco and a customer specific request for Actavis. Noramco will continue to meet Actavis' specification.
Retest Date	24 months from date of manufacture Noramco's retest date is 24 months from date of manufacture while Actavis' retest date is one year.

Note: Noramco's compliance with the current USP <467> residual solvents requirement has been demonstrated through the measurement of residual solvents in Oxymorphone Hydrochloride drug substance. Only the Class 3 solvents Ethanol and Isopropanol are likely to be present and are specified at the Option 1 limit. The Class 2 solvent, Acetonitrile and the Class 3 solvent, 1-Butanol are used in the synthesis route and are specified at the Option 1 limit, but are not likely to be present. Therefore, Noramco certifies that this material, if tested, will comply with the established residual solvent specifications of USP <467>.

Please direct questions regarding this review to: Mary Ann Sellers, Customer Service Manager at 302-761-2909.

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Actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP		
No.: RM120066(T)-07	Receiving:	Page 1 of 6

Manufacturer:	Manufacturer Lot #:
Qualified Manufacturer(s): Noramco, Inc.	

Tests/Methods	Specifications	Results	References
† Description Visual	White to off-white crystalline powder.		Test Date: Ref: Chem: Ck'd:
Identification A) Current USP, as amended USP <741>	Melting range 218°C - 223°C, range not to exceed 2°C.		Test Date: Ref: Chem: Ck'd:
† B) Current USP as amended, USP <197K>	The IR spectrum of the sample exhibits maxima only at the same wavelength as that of a similar preparation of the standard.		Test Date: Ref: Chem: Ck'd:

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actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP		
No.: RM120066(T)-07	**Receiving:**	**Page 2 of 6**

Tests/Methods	Specifications	Results	References
† Assay USP (Method # LC/0066/AS(USP)(T)	97.5% to 102.5% of Oxycodone Hydrochloride, calculated on anhydrous, solvent free basis. Record the assay on the as-is basis.		Test Date: Ref: Chem: Ck'd:
Inorganic Impurities: Residue on Ignition Current USP as amended <281> (See USP monograph for instructions)	NMT 0.05%		Test Date: Ref: Chem: Ck'd:
Organic Impurities Procedure 1: Limit of Alcohol Current USP as amended	Accept supplier certification that ethanol is not used		

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actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP		
No.: RM120066(T)-07	**Receiving:**	**Page 3 of 6**

Tests/Methods	Specifications	Results	References
Organic Impurities **Procedure 2: Impurities** In-house Method LC/0066/AS(USP)(T)	NMT 0.15% Oxymorphone		Test Date: Ref: Chem: Ck'd:
	NMT 0.15% Noroxymorphone		
	NMT 0.15% 10-hydroxyoxycodone		
	NMT 0.15% Hydrocodone		
	*NMT 0.25% 6-α Oxycodol (7, 8-Dihydro-14-hydroxycodeine)		
	*NMT 0.10% 7,8-Dihydro-8β, 14-dihydroxycodeinone		
	NMT 0.10% Individual Unspecified Impurity		
	NMT 1.0% Total Impurities		
Chloride Content Current USP as amended	9.8% - 10.4%, (on anhydrous, solvent-free basis)		Test Date: Ref: Chem: Ck'd:

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actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP		
No.: RM120066(T)-07	**Receiving:**	**Page 4 of 6**

Tests/Methods	Specifications	Results	References
Specific Rotation Current USP as amended <781S> (See USP monograph for instructions)	Between -137° and -149° (Anhydrous, solvent-free basis)		Test Date: Ref: Chem: Ck'd:
† Water Determination Current USP as amended <921>, Method I	3.0% to 7.0%. (Manufacturer's specification)		Test Date: Ref: Chem: Ck'd:
Residual Solvents: In-House (Method # GC/0066/RS(T))	NMT 3000 ppm Methanol NMT 5000 ppm 2-Propranol NMT 5000 ppm 1-Butanol		Test Date: Ref: Chem: Ck'd:

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP		
No.: RM120066(T)-07	**Receiving:**	**Page 5 of 6**

Tests/Methods	Specifications	Results	References
Chromatographic Purity 1 In-house Method LC/2985/RC3 (In-house requirement)	NMT 0.001% 14-Hydroxycodeinone Hydrochloride		Test Date: Ref: Chem: Ck'd:
Chromatographic Purity 2 In-house Method LC/0197/RC2(T) ♦ Regulatory method is Current USP as amended for 7,8-Dihydro-14-hydroxycodeine (6-α oxycodol) and 7,8-Dihydro-8,14-dihydroxycodeinone (Other impurities are in-house requirements)	NMT 0.10% Oxycodone N-oxide		Test Date: Ref: Chem: Ck'd:
	NMT 0.10% 7-Methyl-Oxycodone Hydrochloride		
	NMT 0.10% 1-Hydroxyoxycodone		
	NMT 0.25% 7,8-Dihydro-14-hydroxycodeine (6-α Oxycodol)		
	NMT 0.10% 7,8-Dihydro-8β,14-dihydroxycodeinone		
	NMT 0.10% Oxycodone Ethylenolate		
	NMT 0.10% Individual Unspecified Impurity		
	NMT 1.0% Total Impurities		

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actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP		
No.: RM120066(T)-07	**Receiving:**	**Page 6 of 6**

Tests/Methods	Specifications	Results	References
Particle Size Distribution In-house Method LD/2985/PS (In-house requirement)	D_{10}: NMT 7µm		Test Date: Ref: Chem: Ck'd:
	D_{50}: NMT 30 µm		
	D_{90}: NMT 110 µm		
X-Ray Powder Diffraction: In-house Method XRD/4029/ID (In-house requirement) Testing Facility: ICON Development Solutions LLC One Halsey Road Whitesboro, NY 13492	Conforms to Form B Pattern		Test Date: Ref: Chem: Ck'd
COA The Supplier's CoA has been reviewed.	Meets Specifications		
Retest Date	One (1) year.		

† Tests required for reassay.

*** 6-α Oxycodol and 7, 8-Dihydro – 8, 14- Dihydroxycodeinone are reported as per chromatographic purity 2 method**

_____ APPROVED _____ NOT APPROVED _____ FOR INFORMATION

BY: _____ DATE: _____

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actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP	
No.: RM120066(T)-07	**Page 1 of 3**

SUMMARY OF UPDATES

Revision No.	Effective Date	Updates	CR Ref No
RM120066(T)-01	11/7/08	Translation of Actavis Totowa LLC specification # RM-0197-00.	796
RM120066(T)-02	11/13/08	For X-Ray Powder Diffraction testing change the In-house Totowa method to the In-house Method XRD/4029/ID.	801
RM120066(T)-03	12/23/08	Chromatographic Purity: changed referenced methods to LC/0197/RC1(USP)(T), LC/0197/RC(USP)(T) and LC/2985/RC3. Particle Size Distribution: changed referenced method to LD/2985/PS.	818
RM120066(T)-04	06/24/09	Revised to harmonize with Totowa spec RM0197-02: 1. Identification A – remove Class I from USP <741>. 2. Assay – remove ($C_{18}H_{21}NO_4$.HCl) from specifications. 3. Chromatographic Purity – Two methods LC/0197/RC (USP)(T) and LC/0197/RC1(USP)(T) have been merged into a new method, LC/0197/RC2(T). Add tests for 1-Hydroxyoxycodone, 7-Methyl-Oxycodone Hydrochloride, 7,8-Dihydro-14-hydroxycodeine, 7,8-Dihydro-8,14-dihydroxycodeinone and Oxycodone Ethylenolate. Change Total Impurities limits to NMT 2.00%. 4. Delete tests for Bulk Density and Tapped Density. 5. Add Limit of Alcohol test.	934
RM120066(T)-05	12/16/09	Changed font from Trebuchet MS to Times New Roman size 12 Assay Test under Specifications adding "Record the assay on the as-is basis"	1147

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actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP	
No.: RM120066(T)-07	Page 2 of 3

Revision No.	Effective Date	Updates	CR Ref No
		Layout and order of tests changed to reflect USP 33-NF 28 Oxycodone Hydrochloride USP Monograph Minor editorial changes. USP monograph nomenclature of Inorganic and Organic impurities introduced. Organic Impurities, Procedure 2 Impurities added to *specification. Six USP Monograph known* impurities added with specifications, individual unspecified and total impurities. Footnote for 6-a Oxycodol and 7,8-Dihydro-8,14-dihydroxycodeinone added in Organic Impurities, Procedure 2 section that results for the two impurities will be determined as per filed in house method LC/0197/RC2(T)	
RM120066(T)-06	11/03/10	Previous Chromatographic Purity section divided into Chromatographic Purity 1 and Chromatographic Purity 2. Specifications for Chromatographic Purity known impurities are changed as follows NMT 0.15% Oxycodone N-oxide to NMT 0.10% NMT 0.15% 7-Methyl-Oxycodone Hydrochloride to NMT 0.10% NMT 0.50% 7,8-Dihydro-14-hydroxycodeine to NMT 0.25% NMT 0.25% 1-Hydroxyoxycodone to NMT 0.10% NMT 0.25% Oxycodone Ethylenolate to NMT 0.10% Added the β symbol to NMT 0.10% 7,8-Dihydro-8,14-dihydroxycodeinone Added (USP) to method LC/0066/AS(T)	1377

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actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP	
No.: RM120066(T)-07	**Page 3 of 3**

Revision No.	Effective Date	Updates	CR Ref No
RM120066(T)-07	Current	Assay Testing: change specification limit from "97.0% to 103.0%" to "97.5% to 102.5%". Organic Impurities Procedure 2: change the Total Impurities specification from "NMT 2.0%" to "NMT 1.0%" Chromatographic Purity 2: change the Total Impurities specification from "NMT 2.00%" to "NMT 1.0%" X-Ray Powder Diffraction: change testing facility name from "Prevalere Life Sciences" to "ICON Development Solutions LLC"	1482

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NORAMCO INC.

Noramco, Inc., 500 Swedes Landing Road, Wilmington, DE 19801
Telephone: 1-302-761-2909 Fax: 1-302-761-2913

TO: Mr. Eddy Cruz, Purchasing
FROM: M. Eclar, QA Auditor
DATE: 5/20/14

CUSTOMER SPECIFICATION REVIEW

Oxycodone Hydrochloride, USP (Fine Grade)

Next Generation Formula

NORAMCO EDMS Specification No.: DS-SPE-10074

SAP No.: 51634010201

Customer Name:	**Actavis**	**Customer Product Number:**	**RM121173-09**
		Customer Specification Number:	**N/A**

The following NORAMCO Inc. test specifications MATCH the customer's test specifications.

TEST	LIMIT
Appearance	White to off-white, fine crystalline powder
Identity – Melting Range (Current USP)	218 - 223°C; range not to exceed 2°C
Identity – IR (Current USP<197A>)	Matches IR of USP Oxycodone Standard
Specific Rotation (Current USP <781S>)	-137° to -149° (calculated on the anhydrous, solvent-free basis)
Water (Current USP <921> Method I)	3.0% to 7.0%
Residue on Ignition (Current USP <281>)	0.05% maximum
Chromatographic Purity (HPLC)	14-Hydroxycodeinone Hydrochloride NMT 0.001% w/w
Assay by HPLC/ UPLC	97.5 – 102.5% w/w (Calculated on the anhydrous, solvent-free basis
Chloride Content (Current USP)	9.8 – 10.4% (Calculated on the anhydrous, solvent-free basis)
X-Ray Powder Diffraction	Conforms to Form B Pattern

NORAMCO INC.

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Noramco, Inc., 500 Swedes Landing Road, Wilmington, DE 19801
Telephone: 1-302-761-2909 Fax: 1-302-761-2913

The following tests have customer specifications, which DO NOT MATCH Noramco's specifications

TEST	LIMIT
Chromatographic Purity (Calculated on the anhydrous, solvent-free basis)	Total Impurities (sum of individual reportable impurities ≥ 0.05 %) NMT 1.0 % w/w Individual impurities: Oxycodone N-Oxide NMT 0.10% w/w 7-Methyloxycodone Hydrochloride NMT 0.10% w/w Individual unspecified impurity NMT 0.10% w/w Noramco specification for Chromatographic Purity is listed above while Actavis specification for Chromatographic Purity 2 (In-house Method LC/2985/RC3) is listed below: Oxycodone N-oxide NMT 0.10% 1-Hydroxyoxycodone NMT 0.10% 7,8- Dihydro-14-hydroxycodeine (6-α Oxycodol) NMT 0.25% 7,8-Dihydro-8β,14-dihydroxycodeinone NMT 0.10% Oxycodone Ethylenolate NMT 0.10% Individual unspecified impurity NMT 0.10% 7-Methyl-Oxycodone Hydrochloride NMT 0.10% Total Impurities NMT 1.5% Noramco and Actavis have the same specification for Oxycodone N-Oxide, 7-Methyloxycodone Hydrochloride and Individual Unspecified Impurities. Noramco specification for Total Impurities NMT 1.0% is tighter than Actavis specification of 1.5%. Noramco will meet Actavis' specification. Noramco does not have a specification for 1-Hydroxyoxycodone, 7,8-Dihydro-14-hydroxycodeine, 7,8-Dihydro-8β,14-dihydroxycodeinone and Oxycodone Ethylenolate while Actavis does. Noramco's validated method has been proven to separate these impurities and these impurities are captured in the Individual Unspecified Impurities with a specification of NMT 0.10%. Noramco will meet Actavis' specification.
Organic Impurities Procedure 2 (Actavis test)	Oxymorphone NMT 0.15% Noroxymorphone NMT 0.15% 10-Hydroxyoxycodone NMT 0.15% Hydrocodone NMT 0.15% 6-α Oxycodol NMT 0.25% 7,8-Dihydro-8β-14-dihydroxycodeinone NMT 0.10% Individual Unspecified Impurity NMT 0.10% Total Impurities NMT 2.0% Noramco does not perform any other chromatographic purity testing aside from "Chromatographic Purity" listed above. However, USP 37 impurities-oxymorphone, noroxymorphone, 10-hydroxyoxycodone, hydrocodone, 7,8-dihydro-14-hydroxycodeine (6-α oxycodol), and 7,8-dihydro-8β,14-dihydroxycodeinone are not observed in the Noramco process. Thus, the USP 37 impurities are not specified, but are controlled as individual unspecified impurities at NMT 0.10%.

NORAMCO INC.

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Noramco, Inc., 500 Swedes Landing Road, Wilmington, DE 19801
Telephone: 1-302-761-2909 Fax: 1-302-761-2913

The following tests have customer specifications, which DO NOT MATCH Noramco's specifications

TEST	LIMIT
Residual Solvents. See note below	Methanol NMT 3000 ppm 2-Propanol NMT 5000 ppm 1-Butanol NMT 5000 ppm Noramco and Actavis have the same specification for 2-Propanol and 1-Butanol. Noramco cannot meet Actavis' specification of NMT 1000 ppm for Methanol at this time. A process capability evaluation was performed on recent data for Oxycodone Hydrochloride (nOXY) lots and it was determined that Noramco's current process for Oxycodone Hydrochloride (nOXY) is capable of consistently meeting a specification of NMT 2250 ppm for Methanol.
Particle Size by Malvern	D (v, 0.1): ≥1.0 µm D (v, 0.9): ≤ 300.0 µm Noramco specification for particle size is listed above while Actavis' specification is listed below: D (v, 0.1): NMT 7µm D (v, 0.5): NMT 30 µm D (v, 0.9): NMT 110 µm This is a customer request for Actavis. Noramco will continue to meet Actavis' specification.
Tapped Density	As of September 20, 2012, Actavis no longer require Tapped Density to be reported on the Certificate of Analysis.
Limit of Alcohol (C_2H_5OH) (Current USP)	Ethanol is not used in the manufacturing process, and therefore the Limit of Alcohol USP testing for this solvent is not performed. Noramco does not test for Ethanol while Actavis does.
Retest Date	Three years from date of manufacture Noramco retest date is 3 years from date of manufacture while Actavis' retest date is 1 year. The Noramco retest date of 3 years from the date of manufacture for next generation Oxycodone Hydrochloride is supported by product stability data.

Note: Noramco's compliance with the current USP <467> residual solvent requirements has been demonstrated through the use of a validated test method to measure solvents likely to be present in the Oxycodone Hydrochloride drug substance. Only the Class 2 solvent methanol and Class 3 solvents 2-propanol and 1-butanol are likely to be present. Residual Class 2 solvents are not more than the Option 1 limit and residual Class 3 solvents are not more than 0.5% (5000 ppm). Therefore, Noramco certifies that this material, if tested, will comply with the established residual organic solvent specifications of USP <467>.

Please direct questions regarding this review to: Mary Ann Sellers, Customer Service Manager at 302-761-2909.

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actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: *Oxycodone Hydrochloride USP (Fine Grade) (Next Generation)*		
No.: RM121173-09	**Receiving:**	**Page 1 of 8**

Manufacturer:	**Manufacturer Lot #:**
Qualified Manufacturer(s): Noramco, Inc.	

Tests/Methods	Specifications	Results	References
† Description Visual	White to off-white, fine crystalline powder.		Test Date: Ref: Chem: Ck'd:
Identification A) Current USP as amended <741>	A) Between 218°C and 223°C but the range between beginning and end of melting does not exceed 2°C.		Test Date: Ref: Chem: Ck'd:
† B) Current USP as amended <197K> Use a portion of the dried precipitate from Identification A.	B) The IR spectrum of the preparation of test specimen exhibits maxima at the same wavelengths as that of a similar preparation of standard.		Test Date: Ref: Chem: Ck'd:

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actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride USP (Fine Grade) (Next Generation)		
No.: RM121173-09	Receiving:	Page 2 of 8

Tests/Methods	Specifications	Results	References
† Assay In-house Method LC/4029/AS4(USP) or LC/0066/AS(USP) (T)	97.5% to 102.5% of oxycodone hydrochloride, calculated on anhydrous, solvent-free basis. Record the assay on the *as-is* basis.		Test Date: Ref: Chem: Ck'd:
Inorganic Impurities: **Residue on Ignition** Current USP as amended <281> (See USP monograph for instructions)	NMT 0.05%		Test Date: Ref: Chem: Ck'd:
Organic Impurities Procedure 1: **Limit of Alcohol** In-house Method GC/4029/RS2 ♦ ♦ Regulatory method is Current USP as amended	NMT 1.0% (w/w) Ethanol		Test Date: Ref: Chem: Ck'd:

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Actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride USP (Fine Grade) (Next Generation)		
No.: RM121173-09	Receiving:	Page 3 of 8

Tests/Methods	Specifications	Results	References
Organic Impurities Procedure 2: **Impurities** LC/4029/AS4(USP) ♦ or In-house Method LC/0066/AS(USP)(T) ♦ ♦ Regulatory method is current USP as amended	NMT 0.15% Oxymorphone		Test Date: Ref: Chem: Ck'd:
	NMT 0.15% Noroxymorphone		
	NMT 0.15% 10-hydroxyoxycodone		
	NMT 0.15% Hydrocodone		
	NMT 0.25% 6-α Oxycodol (7, 8-Dihydro-14-hydroxycodeine)	Do not report these individual impurity results. Refer to Chromatographic Purity 2 method for reportable results. Area percent values from this method are to be included in the Total Impurities	
	NMT 0.10% 7,8-Dihydro-8β, 14-dihydroxycodeinone		
	NMT 0.10% Individual Unspecified Impurity		
	NMT 2.0% Total Impurities		
Chloride Content Current USP as amended	Between 9.8% and 10.4%, calculated on the anhydrous, solvent-free basis.		Test Date: Ref: Chem: Ck'd:

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actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride USP (Fine Grade) (Next Generation)		
No.: RM121173-09	Receiving:	Page 4 of 8

Tests/Methods	Specifications	Results	References
Specific Rotation Current USP as amended <781S>	Between -137° and -149° (Anhydrous, Solvent-Free basis)		Test Date: Ref: Chem: Ck'd:
† Water Current USP as amended <921> Method I	3.0 to 7.0%.		Test Date: Ref: Chem: Ck'd:
Residual Solvents 1 In-house Method GC/4029/RS2 or GC/2985/RS2	NMT 1000 ppm Methanol*		Test Date: Ref: Chem: Ck'd:

*Report higher value of Methanol results obtained by either method GC/4029/RS2 or GC/2985/RS2

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Actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride USP (Fine Grade) (Next Generation)		
No.: RM121173-09	Receiving:	Page 5 of 8

Tests/Methods	Specifications	Results	References
Residual Solvents 2 GC/2985/RS2	NMT 5000 ppm 2-Propanol NMT 5000 ppm 1-Butanol		Test Date: Ref: Chem: Ck'd:
Chromatographic Purity 1 LC/2985/RC3 (In-house requirement)	NMT 0.001% 14-Hydroxycodeinone Hydrochloride		Test Date: Ref: Chem: Ck'd:

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actavis

RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride USP (Fine Grade) (Next Generation)		
No.: RM121173-09	Receiving:	Page 6 of 8

Tests/Methods	Specifications	Results	References
Chromatographic Purity 2 In-house Method LC/4029/RC6 ♦ Or LC/0197/RC2 (T) ♦ (In-house requirement) ♦ Regulatory method is current USP as amended for 7,8-Dihydro-14-hydroxycodeine (6-α Oxycodol) and 7,8-Dihydro-8β,14-dihydroxycodeinone	NMT 0.10% Oxycodone N-oxide		Test Date: Ref: Chem: Ck'd:
	NMT 0.10% 1-Hydroxyoxycodone		
	NMT 0.25% 7,8-Dihydro-14-hydroxycodeine (6-α Oxycodol)		
	NMT 0.10% 7,8-Dihydro-8β,14-dihydroxycodeinone		
	NMT 0.10% Oxycodone Ethylenolate		
	NMT 0.10% Individual Unspecified Impurity		
LC/2985/RC1 or LC/0197/RC2 (T)	NMT 0.10% 7-Methyl-Oxycodone Hydrochloride		Test Date: Ref: Chem: Ck'd:
Total of all Related Compound Impurities	NMT 1.5%		

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride USP (Fine Grade) (Next Generation)		
No.: RM121173-09	Receiving:	Page 7 of 8

Tests/Methods	Specifications	Results	References
Particle Size Distribution In-house Method LD/4029/PS or LD/2985/PS (In-house requirement)	NMT 7 µm D(v,0.1) 10% NMT 30 µm D(v,0.5) 50% NMT 110 µm D(v,0.9) 90%		Test Date: Ref: Chem: Ck'd:
▲Polymorph Identification In-House Method XRD/4029/ID (In-house requirement) Testing Facility: ICON Development Solution LLC One Halsey Road Whitesboro, NY 13492	The x-ray powder diffraction pattern of the test preparation exhibits all of the distinct peaks identified in the method.		Test Date: Ref: Chem: Ck'd:

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride USP (Fine Grade) (Next Generation)		
No.: RM121173-09	**Receiving:**	**Page 8 of 8**

Tests/Methods	Specifications	Results	References
Tapped Density In-house Method QA/021/TD (In-house requirement)	0.60 g/mL to 0.80 g/mL		Test Date: Ref: Chem: Ck'd:
COA	Supplier's COA conforms to the USP requirements for this lot.		
Retest Date	One (1) year.		

† Tests required for reassay.

_____ APPROVED _____ NOT APPROVED _____ FOR INFORMATION

BY: _____ DATE: _____

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride USP (Fine Grade) (Next Generation)	
No.: RM121173-09	**Page 1 of 4**

SUMMARY OF UPDATES

Revision No.	Effective Date	Updates	CR Ref No
RM121173-01	07/12/2006	New item.	N/A
RM121173-02	12/20/2006	1. Indicate only identification B is required for reassay and add reassay symbol to Limit of Alcohol. 2. Add Polymorph Identification, Residual Solvent, Particle Size Distribution and Tapped Density tests. 3. Add in-house methods to Limit of Alcohol and Assay tests. 4. Add Ethanol and regulatory note to Limit of Alcohol. 5. Remove Chromatographic Purity test and add Related Compound test.	N/A
RM121173-03	12/22/2006	To correct Related Compounds Method from LC/4026/RC6 and Assay Method from LC/4026/AS4(USP).	N/A
RM121173-04	08/29/2007	Update 1H-Oxycodone and Ethylenolate from NMT 0.25% to NMT 0.15% and Total Impurities from NMT 2.0% to NMT 1.5% per FDA request.	N/A
RM121173-05	1/31/08	Update format for commercial use.	CR08-035
RM121173-06	07/01/08	Rgmove 'In-house requirement' from Residual Solvents Testing as per USP 31/NF 26.	639
RM121173-P	N/A	1. Water: change specifications to 3.0 to 7.0% 2. Residual Solvents: Add method GC/2985/RS2 3. Add new Residual Solvents 2 test. 4. Related Compounds: Add methods LC/2985/RC3 and LC/2985/RC1. Change limit on 14H-Codeinone to 0.001%. Add test for 7-Methyloxycodone HCl. 5. Assay: change limits to 97.5 % to 102.5% 6. Particle Size: add method LD/2985/PS. Change test limits to NMT 7 µm D(v,0.1) 10%; NMT 30 µm D(v,0.5) 50%; NMT 110 µm D(v,0.9) 90%	874

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride USP (Fine Grade) (Next Generation)	
No.: RM121173-09	Page 2 of 4

Revision No.	Effective Date	Updates	CR Ref No
RM121173-07	06/19/09	1. Water: change specifications to 3.0 to 7.0% 2. Residual Solvents: Add method GC/2985/RS2 3. Add new Residual Solvents 2 test. 4. Related Compounds: Add methods LC/2985/RC3 and LC/2985/RC1. Change limit on 14H-Codeinone to 0.001%. Add test for 7-Methyloxycodone HCl. 5. Assay: change limits to 97.5 % to 102.5% 6. Particle Size: add method LD/2985/PS. Change test limits to NMT 7 µm D(v,0.1) 10%; NMT 30 µm D(v,0.5) 50%; NMT 110 µm D(v,0.9) 90%	979
RM121173-08	06/19/09	Incorrect document scanned into Qumas. Document revision only to correct scan. No content changes were made.	981

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride USP (Fine Grade) (Next Generation)	
No.: RM121173-09	Page 3 of 4

Revision No.	Effective Date	Updates	CR Ref No
RM121173-09	Current	Sequence of Tests/Methods was changed to mimic raw material specifications RM120066(T)-06 (Oxycodone Hydrochloride, USP). The following test methods were renamed to reflect current USP33-NF28 monograph nomenclature and specification RM120066(T)-06 From: Residue on Ignition changed to "*Inorganic Impurities: Residue on Ignition*". From: Limit of Alcohol changed to "*Organic Impurities Procedure 1: Limit of Alcohol*" and removed the reassay test requirement. From: Related Compounds changed to "*Chromatographic Purity 1 and Chromatographic Purity 2*". New Tests/Method and respective specification requirements added to comply with current USP33-NF28 monograph: "*Organic Impurities Procedure 2 Impurities*"; LC/4029/AS4(USP) or LC/0066/AS(USP)(T) with note "*Regulatory method is current USP as amended*". Specification limits added: Oxymorphone NMT0.15%, Noroxymorphone NMT0.15%, 10-Hydroxycodone NMT 0.15%, Hydrocodone NMT 0.15%, 7,8-Dihydro-14-hydroxycodeine (6-alpha Oxycodol NMT 0.25%, 7,8-Dihydro-8 Beta, 14-dihydroxycodeinone NMT 0.10%, Individual unspecified impurities NMT 0.10%, Total Impurities NMT 2.0%. Tests/Method: Assay – added alternate method to read; "*LC/4029/AS4(USP) or LC/0066/AS(USP)(T)*". Tests/Method: Residual Solvents – Deleted statement "*Regulatory method is current USP as amended*". Added footnote: Report higher value of Methanol results by either method GC/4029/RS2 or GC/2985/RS2. Tests/Method: Specific Rotation – Added "*(Anhydrous, solvent free basis)*"to be consistent with USP monograph. Tests/Method: Polymorph Identification – Added testing facility information.	1442

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride USP (Fine Grade) (Next Generation)	
No.: RM121173-09	Page 4 of 4

Revision No.	Effective Date	Updates	CR Ref No
RM121173-09 cont'd	Current	Tests/Methods: Related Compounds- changed name to "Chromatographic Purity 1 (LC/2985/RC3) and Chromatographic purity 2 LC/4029RC6; added alternate method to chromatographic purity 2 to read "*LC/4029/RC6 or LC/0197/RC2(T)*" and "*LC/2985/RC1 or LC/0197/RC2(T)*". Changed name of specified related compounds and specification limits to be consistent with raw material specifications RM120066(T)-06 and API suppliers specifications: from 14H-Codeinone NMT 0.001% to "*14-Hydroxycodeinone Hydrochloride NMT 0.001%*"; from N-oxide NMT 0.15% to "*Oxycodone N-oxide NMT 0.10%*"; from 1H-Oxycodone NMT 0.15% to "*1-Hydroxyoxycodone NMT 0.10%*"; from H-codeine NMT 0.50% to "*7,8-Dihydro-14-hydroxycodeine (6-alpha Oxycodol) NMT 0.25%*"; from DH-codeinone NMT 0.50% to "*7,8-Dihydro-8 beta, 14-dihydroxycodeinone NMT 0.10%*"; from Ethylenolate NMT 0.15% to "*Oxycodone ethylenolate NMT 0.10%*"; from 7-Methyloxycodone HCl NMT 0.15% to "*7-Methyl-Oxycodone Hydrochloride NMT 0.10%*";from single largest unknown impurity NMT 0.10% to "*Individual Unspecified Impurity NMT 0.10%*";from Total Impurities to "*Total of all Related Compound Impurities*". Replaced note: "*Regulatory method is the Chromatographic Purity test in current USP as amended*" with "*Regulatory method is current USP as amended for 7,8-Dihydro-14-hydroxycodeine (6-alpha Oxycodol) and 7,8-Dihydro-8 beta, 14-dihydroxycodeinone*". Deleted Testing Facility Prevalere Life Sciences from the last page of the specification.	1442

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP (Next Generation)		
No.: RM120066(T)-10	**Receiving:**	**Page 1 of 8**

Manufacturer:	**Manufacturer Lot #:**
Qualified Manufacturer(s): Noramco, Inc. / Johnson Matthey	

Tests/Methods	Specifications	Results	References
† Description Visual	White to off-white crystalline powder.		Test Date: Ref: Chem: Ck'd:
Identification A) * Current USP, as amended USP <741>	Melting range 218°C - 223°C, range not to exceed 2°C.		Test Date: Ref: Chem: Ck'd:
† B) Current USP as amended, USP <197K>	The IR spectrum of the sample exhibits maxima only at the same wavelength as that of a similar preparation of the standard.		Test Date: Ref: Chem: Ck'd:

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP (Next Generation)		
No.: RM120066(T)-10	Receiving:	Page 2 of 8

Tests/Methods	Specifications	Results	References
† Assay USP (Method # LC/0066/AS(USP)(T)	97.5% to 102.5% of Oxycodone Hydrochloride, calculated on anhydrous, solvent free basis. Record the assay on the as-is basis.		Test Date: Ref: Chem: Ck'd:
* Inorganic Impurities: Residue on Ignition Current USP as amended <281> (See USP monograph for instructions)	NMT 0.05%		Test Date: Ref: Chem: Ck'd:
Organic Impurities Procedure 1: Limit of Alcohol Current USP as amended [For Noramco]	Accept supplier certification that ethanol is not used		Test Date: Ref:
In-house Method GC/2879/RS [For Johnson Matthey]	Ethanol - NMT 0.5% (5000 ppm) Methanol - NMT 0.1% (1000 ppm)		Chem: Ck'd:

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP (Next Generation)		
No.: RM120066(T)-10	Receiving:	Page 3 of 8

Tests/Methods	Specifications	Results	References
Volatile Process Impurities In-house method GC/2879/RS **[For Johnson Matthey]**	Ethyl ether – NMT 0.05% (500 ppm) Chloroethane – NMT 0.07% (700 ppm)		Test Date: Ref: Chem: Ck'd:
† Organic Impurities Procedure 2: Impurities In-house Method LC/0066/AS(USP)(T)	NMT 0.15% Oxymorphone		Test Date: Ref: Chem: Ck'd:
	NMT 0.15% Noroxymorphone		
	NMT 0.15% 10-hydroxyoxycodone		
	NMT 0.15% Hydrocodone		
	NMT 0.25% 6-α Oxycodol (7, 8-Dihydro-14-hydroxycodeine)	Do not report these individual impurity results. Refer to Chromatographic Purity 1B and 2B methods for reportable results. Percent values from these methods are to be included in the Total Impurities.	
	NMT 0.10% 7,8-Dihydro-8β, 14-dihydroxycodeinone		
	NMT 0.10% Individual Unspecified Impurity		
	NMT 1.0% Total Impurities		

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP (Next Generation)		
No.: RM120066(T)-10	Receiving:	Page 4 of 8

Tests/Methods	Specifications	Results	References
* Chloride Content Current USP as amended	9.8% - 10.4%, (on anhydrous, solvent-free basis)		Test Date: Ref: Chem: Ck'd:
* Specific Rotation Current USP as amended <781S> (See USP monograph for instructions)	Between -137° and -149° (Anhydrous, solvent-free basis)		Test Date: Ref: Chem: Ck'd:
† Water Determination Current USP as amended <921>, Method I	3.0% to 7.0%. (Noramco specification)		Test Date: Ref:
	NMT 7.0 % (Johnson Matthey specification)		Chem: Ck'd:

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP (Next Generation)		
No.: RM120066(T)-10	Receiving:	Page 5 of 8

Tests/Methods	Specifications	Results	References
* Residual Solvents: In-House (Method # GC/0066/RS(T) [For Noramco Only]	NMT 3000 ppm Methanol NMT 5000 ppm 2-Propranol NMT 5000 ppm 1-Butanol		Test Date: Ref: Chem: Ck'd:
Chromatographic Purity 1A In-house Method LC/2985/RC3 [In-house requirement for Noramco]	NMT 0.001% 14-Hydroxycodeinone Hydrochloride		Test Date: Ref: Chem: Ck'd:

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP (Next Generation)		
No.: RM120066(T)-10	Receiving:	Page 6 of 8

Tests/Methods	Specifications	Results	References
† Chromatographic Purity 1B In-house Method LC/0197/RC2(T) ♦ Regulatory method is Current USP as amended for 7,8-Dihydro-14-hydroxycodeine (6-α oxycodol) and 7,8-Dihydro-8β,14-dihydroxycodeinone (Other impurities are in-house requirements) [For Noramco Only]	NMT 0.10% Oxycodone N-oxide		Test Date: Ref: Chem: Ck'd:
	NMT 0.10% 7-Methyl-Oxycodone Hydrochloride		
	NMT 0.25% 7,8-Dihydro-14-hydroxycodeine (6-α Oxycodol)		
	NMT 0.10% 7,8-Dihydro-8β,14-dihydroxycodeinone		
	NMT 0.10% Individual Unspecified Impurity		
	NMT 1.0% Total Impurities		
Chromatographic Purity 2A In-house Method LC/2879/RC [In-house requirement for Johnson Matthey]	NMT 0.001% 14-Hydroxycodeinone		Test Date: Ref: Chem: Ck'd:
	NMT 0.001% Codeinone		

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP (Next Generation)		
No.: RM120066(T)-10	Receiving:	Page 7 of 8

Tests/Methods	Specifications	Results	References
† Chromatographic Purity 2B In-house Method LC/0197/RC2(T) ♦ Regulatory method is Current USP as amended for 7,8-Dihydro-14-hydroxycodeine (6-α oxycodol) and 7,8-Dihydro-8β,14-dihydroxycodeinone (Other impurities are in-house requirements) [For Johnson Matthey Only]	NMT 0.10% Oxycodone N-oxide		Test Date: Ref: Chem: Ck'd:
	NMT 0.15% 7,8-Dihydro-14-hydroxycodeine (6-α Oxycodol)		
	NMT 0.10% 7,8-Dihydro-8β,14-dihydroxycodeinone		
	NMT 0.10% Codeine		
	NMT 0.10% Thebaine		
	NMT 0.10% Individual Unspecified Impurity		
	NMT 0.50% Total Impurities		
* Particle Size Distribution In-house Method LD/2985/PS	D_{10}: NMT 7µm		Test Date: Ref: Chem: Ck'd:
	D_{50}: NMT 30 µm		
	D_{90}: NMT 110 µm		
* X-Ray Powder Diffraction: In-house Method XRD/4029/ID (In-house requirement) Testing Facility: ICON Development Solutions LLC One Halsey Road Whitesboro, NY 13492	Conforms to Form B Pattern, exhibiting the following distinct peaks (± 0.2° 2θ): 8.3° 2θ 10.7° 2θ 12.0° 2θ 16.2° 2θ 19.1° 2θ		Test Date: Ref: Chem: Ck'd

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP (Next Generation)		
No.: RM120066(T)-10	**Receiving:**	**Page 8 of 8**

Tests/Methods	Specifications	Results	References
Palladium Content In-house method ICP/2879/PAL [For Johnson Matthey Only] **Testing Facility:** Metrics Inc. 1240 Sugg Parkway Greenville, NC 27834	NMT 0.005% W/W		Test Date: Ref: Chem: Ck'd
COA The Supplier's CoA has been reviewed.	Meets Specifications		
Retest Date	One (1) year.		

† Tests required for reassay.

*** Accept supplier's results from Noramco Inc, Wilmington site only.**

_____ APPROVED _____ NOT APPROVED _____ FOR INFORMATION

BY: _____ DATE: _____

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP (Next Generation)	
No.: RM120066(T)-10	Page 1 of 4

SUMMARY OF UPDATES

Revision No.	Effective Date	Updates	CR Ref No
RM120066(T)-01	11/07/08	Translation of Actavis Totowa LLC specification # RM-0197-00.	796
RM120066(T)-02	11/13/08	For X-Ray Powder Diffraction testing change the In-house Totowa method to the In-house Method XRD/4029/ID.	801
RM120066(T)-03	12/23/08	Chromatographic Purity: changed referenced methods to LC/0197/RC1(USP)(T), LC/0197/RC(USP)(T) and LC/2985/RC3. Particle Size Distribution: changed referenced method to LD/2985/PS.	818
RM120066(T)-04	06/24/09	Revised to harmonize with Totowa spec RM0197-02: 1. Identification A – remove Class I from USP <741>. 2. Assay – remove ($C_{18}H_{21}NO_4$.HCl) from specifications. 3. Chromatographic Purity – Two methods LC/0197/RC (USP)(T) and LC/0197/RC1(USP)(T) have been merged into a new method, LC/0197/RC2(T). Add tests for 1-Hydroxyoxycodone, 7-Methyl-Oxycodone Hydrochloride, 7,8-Dihydro-14-hydroxycodeine, 7,8-Dihydro-8,14-dihydroxycodeinone and Oxycodone Ethylenolate. Change Total Impurities limits to NMT 2.00%. 4. Delete tests for Bulk Density and Tapped Density. 5. Add Limit of Alcohol test.	934
RM120066(T)-05	12/16/09	Changed font from Trebuchet MS to Times New Roman size 12 Assay Test under Specifications adding "Record the assay on the as-is basis"	1147

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP (Next Generation)	
No.: RM120066(T)-10	Page 2 of 4

Revision No.	Effective Date	Updates	CR Ref No
		Layout and order of tests changed to reflect USP 33-NF 28 Oxycodone Hydrochloride USP Monograph Minor editorial changes. USP monograph nomenclature of Inorganic and Organic impurities introduced. Organic Impurities, Procedure 2 Impurities added to specification. Six USP Monograph known *impurities added with specifications*, individual unspecified and total impurities. Footnote for 6-a Oxycodol and 7,8-Dihydro-8,14-dihydroxycodeinone added in Organic Impurities, Procedure 2 section that results for the two impurities will be determined as per filed in house method LC/0197/RC2(T)	
RM120066(T)-06	11/03/10	Previous Chromatographic Purity section divided into Chromatographic Purity 1 and Chromatographic Purity 2. Specifications for Chromatographic Purity known impurities are changed as follows NMT 0.15% Oxycodone N-oxide to NMT 0.10% NMT 0.15% 7-Methyl-Oxycodone Hydrochloride to NMT 0.10% NMT 0.50% 7,8-Dihydro-14-hydroxycodeine to NMT 0.25% NMT 0.25% 1-Hydroxyoxycodone to NMT 0.10% NMT 0.25% Oxycodone Ethylenolate to NMT 0.10% Added the β symbol to NMT 0.10% 7,8-Dihydro-8,14-dihydroxycodeinone Added (USP) to method LC/0066/AS(T)	1377

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP (Next Generation)	
No.: RM120066(T)-10	Page 3 of 4

Revision No.	Effective Date	Updates	CR Ref No
RM120066(T)-07	04/01/11	Assay Testing: change specification limit from "97.0% to 103.0%" to "97.5% to 102.5%". Organic Impurities Procedure 2: change the Total Impurities specification from "NMT 2.0%" to "NMT 1.0%" Chromatographic Purity 2: change the Total Impurities specification from "NMT 2.00%" to "NMT 1.0%" X-Ray Powder Diffraction: change testing facility name from "Prevalere Life Sciences" to "ICON Development Solutions LLC"	1482
RM120066(T)-P	N/A	Johnson Matthey included into Qualified Manufacturer. Organic Impurities Procedure 1, Limit of Alcohol: [Current USP as amended], specified for Noramco. An in-house method GC/4029/RS2 and manufacturer's limit of NMT 0.5% included for Johnson Matthey. Organic Impurities Procedure 2, Impurities: A note included to refer to Chromatographic Purity 1B and 2B methods for reportable results of 6-α Oxycodol (7, 8-Dihydro-14-hydroxycodeine) and 7,8-Dihydro-8β, 14-dihydroxycodeinone. Water Determination: Johnson Matthey specification of NMT 7.0% included. Residual Solvents: Test requirement specified for Noramco material only. Chromatographic Purity 1 and 2 renumbered as 1A and 1B and these tests requirement is specified for Noramco material. New tests of chromatographic purity 2A and 2B included with their method number and these tests requirement is specified for Johnson Matthey material. Organic Impurities Procedure 2, Impurities, Chromatographic Purity 1B and Chromatographic Purity 2B tests are identified as requirement for reassay. XRD specification format changed to include XRD peaks.	1530
RM120066(T)-P1	N/A	Change the particle size method from LD/2985/PS-P to LD/2985/PS.	1634

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RAW MATERIAL SPECIFICATION

RAW MATERIAL: Oxycodone Hydrochloride, USP (Next Generation)	
No.: RM120066(T)-10	Page 4 of 4

Revision No.	Effective Date	Updates	CR Ref No
RM120066(T)-P2	N/A	Palladium Content test added for Johnson Matthey material. Limit of Alcohol test included from Johnson Matthey Method number updated from GC/4029/RS2 to GC/2879/RS Volatile Process Impurities test included for Johnson Matthey.	1641
RM120066(T)-P3	N/A	Updated Actavis logo. Removed Noramco's old generation impurities (1-hydroxyoxycodone and Oxycodone Ethylenolate), from Chromatographic Purity 1B, as per FDA's request.	1900
RM120066(T)-08	08/01/11	Add the following tests to reduced testing: Identification A - Melting Range, Residue on Ignition, Chloride Content, Specific Rotation, Residual Solvents, Particle Size Distribution, X-Ray Powder Diffraction for materials received from Wilmington Delaware site. Change the note for Organic Impurities Procedure 2: Impurities. Formatting.	1570
RM120066(T)-09	02/08/13	Incorporate changes from "P" specifications. Add (Next Generation) to title of RM. Indicate the suppliers results can be accepted from Noramco, Inc. Wilmington site only. Remove "P" designation from Chromatographic Purity 1B and 2B method LC/0197/RC2 (T)	1964
RM120066(T)-10	Current	Organic Impurities section: Change note in Results column to "...Percent values from these methods are to be included in the Total Impurities".	2093

Appendix C
21 PAGES

DS-XFRM-3083

NORAMCO INC.

Quality Agreement

Supplier ☐	Customer ☒	Contract Laboratory ☐
Name: Watson Laboratories, Inc. (Actavis)		
Material / Product: Hydrocodone Bitartrate Oxycodone HCL, USP Morphine Sulfate Oxymorphone Hydromorphone Hydrochloride		
SAP No.: N/A		
Mat'l. Specification Document No.: N/A		
Doc. Ver. N/A		
*Service Provided: N/A		

*Required for Contract Laboratory

The attached signed documents serve as a Quality Agreement between both companies.

NORAMCO INC.

Quality Agreement

Between

Watson Laboratories, Inc.

And

Noramco, Inc.

March 2014

Version:1.0

QUALITY AGREEMENT

FOR ACTIVE PHARMACEUTICAL INGREDIENT

This Quality Agreement ("Agreement") is entered into effective as of the last date of signature ("Effective Date"), by and between Watson Laboratories, Inc. ("Watson"), with corporate headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, USA and Noramco, Inc. ("Noramco"), with offices at 500 Swedes Landing Road, Wilmington, DE 19803 and 1440 Olympic Drive, Athens, GA 30601 with regard to all product(s) purchased by Watson from Noramco (individually and collectively referred to herein as "API").

NOW, THEREFORE, the parties hereby agree as follows:

1. **MANUFACTURING**

1.1. Noramco shall manufacture the API at its plant as detailed in the Drug Master File (DMF) or Certificate of Suitability (CEP) as applicable for each and every applicable API.

1.2. Noramco shall not use or transfer at a later date any of the manufacturing or testing operations for the API to third parties or other sites without prior notification to Watson of any such proposed change so that Watson may make any required regulatory filings and to prevent any material adverse effect on Watson's business.

1.3. Noramco shall take all actions to qualify (and thereafter maintain qualification of) the facilities at which such manufacturing takes place, and shall ensure that equipment for manufacturing and instruments for testing are in compliance with the current applicable regulations and guidance documents.

1.4. Noramco shall take all actions to comply with the most current version of the ICH Guidelines pertaining to Active Pharmaceutical Ingredient (API) manufacturing, specifically ICH Q7A, Good Manufacturing Practice Guidelines for Active Pharmaceutical Ingredients.

1.5. Noramco shall also comply with market specific requirements and local legislations provided Watson has notified Noramco of such requirements and regulations.

1.6. Noramco is responsible for approving all suppliers of starting materials and all suppliers of intermediates.

1.7. Noramco shall have a system for evaluating the suppliers of critical materials and intermediates used in the manufacture of the API. It is recommended that Noramco audit their suppliers of critical starting materials and suppliers of critical intermediates.

1.8. Each API shall be manufactured in accordance with the specifications as agreed upon by the Parties in writing.

1.9. Changes to these specifications must be mutually agreed upon and communicated in writing between the Parties, except for compendial changes, or specification tightening. In this case Noramco shall notify Watson after Noramco becomes aware of the need for such change.

1.10. Noramco shall use approved validated test methods for testing of raw materials, in-process materials and APIs in accordance with the applicable DMF or Certificate of

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Sul72057tability (CEP) as applicable and any other test requirement(s) which has been mutually agreed between Noramco and Watson Quality Department.

1.11. Noramco shall use its established cGMP systems for evaluation, approval and maintenance of all sub-contracted services with a cGMP impact on API manufactured.

2. CERTIFICATE OF ANALYSIS

2.1. Noramco shall provide a signed Certificate of Analysis (and Certificate of Compliance as applicable) with each shipment of API listing the actual batch analytical test results obtained with confirmation that the results have been reviewed and approved by Noramco Quality Assurance.

2.2. The Certificate shall include;

2.2.1. Name of API

2.2.2. Batch number

2.2.3. Reference to the agreed specification (DMF, Ph.Eur., USP, etc)

2.2.4. Date of manufacture

2.2.5. Retest date or Expiration Date

2.2.6. Name of each test performed

2.2.7. Acceptance limits

2.2.8. Numerical or text results of each test.

2.3. The name, address and telephone number of the manufacturing location shall appear on each Certificate and it shall be signed by authorized personnel.

2.4. Noramco certifies by signing the Certificate of Analysis that the API has been manufactured in accordance with cGMPs.

3. API ACCEPTANCE/REJECTION

3.1. Watson shall test each delivery of API according to mutually agreed upon specification or follow internal approved procedure for abbreviated testing.

3.2. API that fails to meet acceptance criteria will be rejected. Watson will notify Noramco, in writing, the reason for the rejection.

3.3. Noramco guarantees compliance of the API with the agreed specifications throughout the shelf life.

3.4. In the case of any dispute over results, an arbitrary lab chosen by Watson will test the API and results obtained will be considered final.

4. STABILITY

4.1. Noramco shall have a documented on-going testing program designed to monitor the stability characteristics of the API in containers that simulate the commercial packaging.

4.2. The results of the stability testing should be used to confirm the API storage conditions and expiry and/or retest date.

4.3. Noramco will notify Watson within three business days of any confirmed stability failure relating to the batches of API sent to Watson that occur before the assigned expiry or retest date. Written notification shall be provided to Watson immediately if the API fails to meet its expiration or retest date.

4.4. The stability analytical test method shall be validated and stability indicating.

5. EXPIRATION/RETEST DATE

5.1. The expiry and/or retest date shall be based on data derived from stability studies in containers that simulate the commercial packaging or small-scale packaging of similar or identical material composition.

5.2. The expiry and/or retest date shall appear on the Certificate of Analysis.

5.3. Noramco shall notify Watson immediately of any changes to the assigned expiration/ retest date during the life of the API.

6. DOCUMENTATION

6.1. Noramco shall be responsible for keeping records and documentation of manufacturing and testing of the API, intermediates and starting materials in accordance with the law, including:

6.1.1. Batch records

6.1.2. In process results

6.1.3. Laboratory testing records

6.1.4. Equipment usages

6.1.5. Raw material inventory records

6.2. Noramco shall document all deviations from the manufacturing process and/or testing of the API in the batch records or testing records.

6.3. Noramco shall maintain original documentation for each batch according to its standard record retention procedures but in any event no less than one year after the expiration date of the batch.

6.4. For APIs with retest dates, documents should be retained for at least three years after the batch is completely distributed.

6.5. These documents shall be available for on-site review by Watson, for batches delivered to Watson, upon request.

7. REGULATORY INSPECTION

7.1. Noramco shall inform Watson in advance of any upcoming Regulatory Inspection, when it is foreseen that the inspection will or could cover any batches of API supplied to Watson.

7.2. Noramco shall inform Watson, within three (3) business days, of any Regulatory Inspection that relates to the manufacture of any batches of API supplied to Watson. Noramco shall provide Watson with a report on the inspection outcome, upon request.

7.3. Noramco shall advise Watson in writing of any regulatory compliance issues, including, but not limited to, the receipt of a deficiency letter, any responses or notices such as a FDA Form 483 or a Warning letter received from any applicable regulatory authorities, with respect to Noramco's manufacturing, packaging, testing or storage of the API, which relate to or may adversely impact production of the API. All documents may be redacted as needed.

8. AUDITS

8.1. Noramco shall allow Watson to conduct a facility site compliance audit, upon prior written notification, for the purpose of reviewing Noramco manufacturing and control systems used to produce the API.

8.2. Watson may conduct an audit once every 3 (three) years, or more frequently if an event occurs that is reasonably likely to affect the ability of Noramco to supply the API to Watson (e.g., Warning Letters, product recalls, etc.).

8.3. During any such audit, Watson may inspect any documents that Noramco is obliged to maintain under this Agreement, and any of the facilities of Noramco used in the manufacture, testing, packaging or storage of the API.

8.4. Watson audits will be maintained in confidence, and will be made available only to competent regulatory authorities (upon request e.g., EMEA, MRA, and QP) or where otherwise legally obligated.

9. RESERVED/RETAINED SAMPLES

9.1. Noramco shall reserve and retain a sufficient quantity of the API batch to conduct at least two full specification testing procedures.

9.2. Appropriately identified reserve samples should be retained for one year after the expiry date of the batch assigned by Noramco or for three years after the distribution of the batch, whichever is the longer. For APIs with retest dates retain samples should be retained for three years after the complete distribution of the batch.

9.3. Reserved samples shall be stored in the same packaging system or equivalent scale to the packaging system used to ship to Watson.

10. INVESTIGATIONS

10.1. Noramco shall be responsible for and use commercially reasonable efforts in investigating any test result or in-process testing that fails to meet applicable specifications. Noramco will conduct a laboratory investigation, which must be approved by Noramco's Quality Unit.

11. VALIDATIONS

11.1. Noramco shall ensure that the manufacturing process is validated before any routine production can start. The validation should ensure that the process is capable of consistently achieving the applicable API acceptance specifications.

11.2. Noramco shall ensure that the analytical test methods used to test the manufacturing process are validated.

11.3. Noramco shall ensure that equipment-cleaning procedures and laboratory test methods are validated.

11.4. A validation protocol should describe;

11.4.1. The equipment to be cleaned

11.4.2. Procedures

11.4.3. Materials

11.4.4. Acceptable cleaning levels

11.4.5. Parameters to be monitored and controlled

11.4.6. Analytical methods

11.5. Noramco shall ensure that any related GMP computer system used for the manufacturing and control of the API is validated.

11.6. Computer systems and electronic records must comply with applicable regulatory requirements (e.g., Section 5.4 of ICH Q7 21CFR Part 11, EudraLex Vol. 4 Annex 11).

12. REPROCESSED / REWORKED API

12.1. Noramco shall ensure that any reprocessing of API is documented. Reprocessing approved procedures shall be in agreement with the current applicable DMF.

12.1.1. "Reprocessing" is defined for purposes hereof as subjecting material to a repeat of the original manufacturing procedure that is included in the manufacturing process in the applicable DMF.

12.2. The first batch manufactured under a new reprocess should be included in the ongoing stability program required hereunder.

12.3. Noramco shall not supply reworked API to Watson.

12.3.1. "Reworking" is defined for purposes hereof as subjecting material to non-original process manufacturing step(s).

13. PACKAGING/SHIPPING

13.1. Noramco shall ensure the API is packaged in accordance with the packing material that complies with the specification contained within the applicable filing.

13.2. Noramco shall make commercially reasonably efforts to ensure that, during packaging, storage, and shipping of the API, there is no possibility of deterioration, contamination, or mix up with any other material.

13.3. If products manufactured under this agreement are shipped to Watson on wooden pallets, these must not be chemically treated or contain wood treated with preservatives. Noramco will use only heat-treated pallets that are in compliance with ISPM No. 15.

13.4. Noramco shall, upon Watson's request provide information pertaining to the supply chain of the API from manufacturer warehouse to receipt by Watson facility where the responsibility is transferred to Watson.

14. CHANGE CONTROL

14.1. Noramco shall have a documented and effective change control system in place. Noramco shall notify Watson on a common email address: apivariations@tevapi.com of any significant changes from established production and process control procedures that can impact the quality of the supplied API and/or any regulatory applications related to the API.

14.2. Noramco shall not make any modifications or changes to the DMF or API, which could affect Watson's manufacture of its finished drug product that incorporates the API, without first advising Watson in writing of the proposed change. The proposed change notification should, include but not be limited to;

14.2.1. The manufacturing process

14.2.2. Analytical methods and specifications

14.2.3. API starting material vendors

14.2.4. Site of manufacture

14.3. Watson and Noramco shall mutually agree upon a change schedule and, if necessary, any amendment to the DMF prior to the initiation of such change.

14.4. Noramco shall only supply Watson with API manufactured in compliance with the applicable DMF and Watson' existing regulatory filings until such time as the API manufactured following such change is permitted under the regulatory filings therefore. Noramco is responsible for supplying Watson with an up to date copy of the applicable sections of the Drug Master File (or EDQM Certificate of Suitability, etc.) for any of the APIs.

15. RECALL

15.1. In the event Watson or Noramco believes it may be necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar action with respect to Watson's finished drug product containing Noramco's API, Noramco and Watson shall consult with each other as to how best to proceed.

15.2. The final decision as to any recall of any Watson's finished drug product shall be made by Watson.

16. COMPLAINTS

16.1. Noramco shall have a written procedure for the investigation of quality-related complaints.

16.2. Noramco shall respond to Watson within 30 calendar days from the date of submittal of the complaint by Watson. The response shall include the conclusions driven by the investigation performed and the corrective/preventive actions defined.

16.3. In case the investigation could not be finalized within 30 calendar days, Noramco will provide an interim report to Watson.

16.4. Watson will make relevant information and samples of the affected batch(es) of the API available to assist in the investigation of Noramco (as appropriate).

16.5. Noramco will inform Watson if any received complaint could also have a serious impact on batches supplied to Watson (i.e., the complaint constitutes a potential risk to patients' health or safety).

16.6. The statutory and/or contractual obligations of Watson to inspect the goods upon delivery and to promptly notify any defect or shortage remain unaffected.

17. **PRODUCT QUALITY REVIEW**

17.1. Noramco shall conduct and document a quality review of the API annually. The product quality review for the API shall be available for on-site review by Watson.

17.2. On an annual basis, when requested by Watson, Noramco shall provide Watson with a statement regarding the BSE/TSE status of the API.

18. **REGULATORY DOCUMENTS**

18.1. Noramco is responsible for preparation, submission and maintenance of the appropriate registration documents for the API (i.e. dossier for CEP, DMF, or equivalent).

18.2. Noramco is responsible for all contact with relevant regulatory authorities with jurisdiction over the API.

18.3. Upon written request, Noramco shall allow Watson to refer to Noramco's registration documents for the API, in order to support Watson' Marketing Authorization Applications for finished drug product made from API.

18.4. Noramco shall provide current information on the API to Watson, as reasonably requested, for submission of any regulatory dossier for finished drug product made from API by Watson. Such information will include either access to CEP (including the appropriate stability data for the API, if no retest date is defined in the CEP), or applicants part to DMF, or equivalent.

18.5. Watson is responsible for submitting the regulatory dossier for Marketing Authorization Applications associated with any finished drug products made from the API. Such regulatory dossier will refer to Noramco's CEP, DMF or equivalent, where applicable.

19. **TRAINING**

19.1. GMP training shall be conducted for those individuals who are involved in the manufacturing, testing, packaging, and distribution of the API. The training shall be documented and available for review by Watson.

20. **TERMINATION**

20.1. Quality Agreement shall become effective and binding upon the date of the final signature and shall remain in effect until 2 years after the last delivery of the Product by Noramco to Watson.

20.2. The Agreement can be cancelled by either Party by giving 6 (six) months written notice to the other Party.

21. KEY RESPONSIBILITIES

Regulatory Compliance		
Responsibilities	Watson	Noramco
1. Adhere to approved registration documentation (Marketing Authorization, NDA, IND, DMF, CEP, etc, as applicable)	X	X
2. Maintaining valid manufacturing license(s), as applicable		X
3. Maintaining site master file, as applicable		X
4. Inform on significant changes		X
5. Prepare, submit and maintain registration documents for the API (i.e. CEP, DMF, or equivalent)	X	
6. Submitting change notifications/applications to authorities for updating of existing regulatory filings	X	

API Starting Materials, Raw Materials, Process Aids, Intermediates, and API		
Responsibilities	Watson	Noramco
7. Setting specifications for API, materials and intermediates		X
8. Purchasing materials according to specifications		X
9. Qualifying and monitoring material suppliers		X
10. Sampling and testing of incoming material, as appropriate		X
11. Generating and approving Master Batch Procedure/Record		X
12. Manufacturing API according to Master Batch Procedure (incl. reprocessing, packaging, labelling)		X
13. Performing batch record review		X
14. Assigning batch numbers		X
15. Sampling, testing, and releasing of intermediates and API		X
16. Performing In Process Controls		X
17. Storing retention samples		X
18. Documenting all deviations, investigating OOS and critical deviations		X
19. Maintaining (certified) reference standards		X
20. Purchasing and Testing of Packaging Material		X
21. Labelling, Label Printing and Label Reconciliation		X

Storage and Shipment		
Responsibilities	Watson	Noramco
22. Storing API under labelled conditions	X	X

23. Maintaining storage conditions during transportation until agreed transition point		X
24. Provide Material Safety Data Sheets or equivalent		X

Documentation		
Responsibilities	**Watson**	**Noramco**
25. Establishing synthesis scheme (including definition of API SMs)		X
26. Archiving the original manufacturing and control documents		X
27. Issuing Certificate of Analysis		X
28. Preparing reports on OOS, critical deviations		X
29. Providing test procedures, quality statements, stability reports, and other documents as mutually agreed between the parties		X

Equipment Cleaning		
Responsibilities	**Watson**	**Noramco**
		X

Qualification / Validation		
Responsibilities	**Watson**	**Noramco**
30. Qualifying of equipment, utilities and facilities		X
31. Validating the manufacturing process, cleaning procedures, analytical methods, and computerized systems		X

Stability		
Responsibilities	**Watson**	**Noramco**
32. Performing stability studies, incl. on-going stability studies, under ICH conditions (incl. testing)		X
33. Assigning retest period (or shelf-life) 34. Notify Watson immediately of any changes to the assigned retest period (or shelf-life) during the life of the API		X
35. Notify Watson within three business days of any confirmed stability failures relating to the API that occur before the assigned expiry or retest date		X

Product Quality Review		
Responsibilities	**Watson**	**Noramco**
36. Conduct and document a quality review of the API annually; The product quality review for the API shall be available for on-site review by Watson		X
37. On an annual basis, when requested by Watson, provide Watson with a statement regarding the BSE/TSE status of the		X

API		

Complaints and Recall		
Responsibilities	**Watson**	**Noramco**
38. Have written procedures in place to document, investigate, and respond to all quality related complaints within 30 calendar days from the date of submittal of the complaint by Watson		X
39. Implementing corrective actions, if necessary		X
40. Deciding to initiate recall	X[1]	X[2]
41. Have procedures in place to facilitate the recall of an API as necessary and notify authorities, external customers, or consumers	X[1]	X[2]
42. Clarifying root cause	X[1]	X[2]
43. Storing or disposing returned product	X[1]	X[2]

[1] Responsibility regarding finished drug product made from API
[2] Responsibility regarding API

Sub-Contracting		
Responsibilities	**Watson**	**Noramco**
44. Qualifying and monitoring sub-contractors		X
45. Maintain a Quality agreement for the subcontracted activity, which shall be available for on-site review by Watson		X
Regulatory Inspections		
Responsibilities	**Watson**	**Noramco**
46. *Advise Watson in writing of any regulatory compliance issues* including receipt of any regulatory reports or notices (e.g., Form FDA 483, Health Canada Inspection Exit Notice) or warning letters with respect to the manufacturing, packaging, testing, or storage of the batches of API sent to Watson.		X

Audits		
Responsibilities	**Watson**	**Noramco**
47. Watson shall provide prior audit written notification to Noramco	X	
48. Allow Watson or Designee to conduct a facility site compliance audit		X
49. Watson shall issue Noramco an audit report summarizing audit observations within 30 days from audit date or as agreed between the parties	X	
50. Noramco shall issue responses to all observations documented in the issued audit report in writing to Watson Quality Assurance within 30 days of receipt of the report or as agreed between the parties		X

Reprocessed / Reworked API

Responsibilities	Watson	Noramco
51. Inform Watson in writing if a reprocessed batch is to be supplied		X
52. Noramco shall not supply reworked API to Watson		X

Change Control		
Responsibilities	**Watson**	**Noramco**
53. Notify Watson of changes from established production and process control procedures that can impact the quality of the API		X
54. Advise Watson in writing before Modifications or changes to the DMF, CEP or API, including but not limited to the manufacturing process, analytical methods and specifications, API starting material vendors, or site of manufacture.		X
55. Watson and Noramco shall mutually agree upon a change schedule and, if necessary, any amendment to the DMF prior to the initiation of such change	X	X

22. MISCELLANEOUS

22.1. Amendment.

22.1.1. This Agreement may only be amended or modified by a written instrument executed by both parties hereto.

22.2. Assignment

22.2.1. This Agreement shall inure to the benefit of, and shall be binding upon each of, the parties hereto and their respective successors and permitted assigns.

22.3. Severability

22.3.1. In the event that any one or more of this Agreement, provisions or terms contained herein shall be declared invalid, illegal or unenforceable in any respect, the validity of the remaining agreements, provisions of terms contained herein shall in no way be affected, prejudiced or invalidated thereby.

22.4. Section Headings

22.4.1. The section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

22.5. Counterparts

22.5.1. This Agreement may be executed in any number of separate counterparts, each of which shall be deemed to be an original, but which together shall constitute one and the same instrument.

22.6. Confidentiality of this Agreement

22.6.1. Confidentiality of this Agreement is covered by any Mutual Confidential Disclosure Agreement executed between Watson and Supplier that is in effect on the date of signing of this agreement or executed during the term of this Quality Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as set forth below.

WATSON LABORATORIES, INC.		NORAMCO INC.	
By:	Sigríður Jónsd	By:	
Name:	Sigríður Elín Jónsdóttir	Name:	James Guro
Title:	Department Manager Global Quality Agreements	Title:	Director of Quality
Date:	20. des. 2013	Date:	1/20/14

List of Appendices

Appendix 1	Change History
Appendix 2	List of APIs
Appendix 3	Contact Persons

APPENDIX 1

CHANGE HISTORY

Rev.	Change	Date
0.0	New edition	18 Aug 2008
1.0	Completely updated Quality Agreement	29 Nov 2013

APPENDIX 2

LIST OF APIs

APIs covered by this Agreement:

API Name	Manufacturer Name	Manufacturing Address
Hydrocodone Bitartrate	Noramco Inc.	500 Swedes Landing Wilmington, DE 19803 1440 Olympic Drive Athens, GA 30601
Oxycodone HCl, USP		
Morphine Sulfate		
Oxymorphone		
Hydromorphone Hydrochloride	Noramco Inc.	1440 Olympic Drive Athens, GA 30601

The above list of APIs may not be exhaustive. The listed APIs may be purchased by different Watson sites or APIs may be further added to the above list by mutual agreement. The changes will be presented in the form of a newly stated Appendix 2. The general terms and conditions of this Agreement shall apply to the newly added APIs as well.

The specifications for the above APIs are to be agreed on separately by Noramco and the respective Watson site using the API. Watson will provide valid substance specification with each purchase order.

Subcontractors, which may be used by Noramco:

API Name	Name and Address of Contractor	Activity
	Not Applicable	

Note: Updates to this appendix can be executed via addendums, and do not require an update to or revision of the agreement.

APPENDIX 3

CONTACT PERSONS

Area	Watson	Noramco
Procurement	Primary Contact Diane Beldeman Executive Director, Global Procurement Watson Laboratories, Inc. 400 Interpace Parkway Parsippany, N.J. 07054 USA Tel: 862-261-7312 Email: diane.beldeman@watson.com Emergency Contact Sebastian S Bova Associated Dir. Global Sourcing Tel: 551-261-7085 Email: sebastian.bova@watson.com	
Quality Operations Florida	Primary Contact Patricia A Denver Quality Assurance Engineer, Sr. Watson Laboratories, Florida 13900 NW 2nd Street, Bldg A, Sunrise Fl 33325 Tel: 954-382-7982 Email: pat.denver@watson.com Backup Contact Linda Savage Associate Director, QA Compliance Watson Laboratories Florida 13900 NW 2nd Street, Bldg A, Sunrise, FL 33325 Phone (954) 382-7632 Email: linda.savage@watson.com	

Area	Watson	Noramco
Quality Operations Corona-US	Mo Agharahimi Exec Dir, Quality Operations Corona, CA (Bldg 1) – CA E Mail: mo.agharahimi@watson.com T: 951-493-4366	
Quality Agreement	Snezhana Petkova Actavis Operations EOOD Quality Agreements Specialist 29, Atanas Dukov 1407 Sofia, Bulgaria T: +359 2 9321 796 E Mail: spetkova@actavis.bg Sigridur Elín Jónasdóttir Department Manager Global Quality Agreements ACTAVIS GROUP PTC ehf Dalshraun 1 IS-220 Hafnarfjordur Iceland Tel: +354 550 3307 Fax: +354 550 3301 E-mail: sjonasdottir@actavis.com	JIM GURO DIRECTOR OF QUALITY NORAMCO 302-888-6486 JGURO@ITS.JNJ.COM

Note: Updates to this appendix will be executed via addendums, and do not require an update to or revision of the agreement.

Appendix D
Buyer's Affiliates

IN WITNESS WHEREOF, each of the parties set forth below has executed this Agreement, acknowledges its terms and shall be entitled to the rights and obligations of Buyer hereunder.

Watson Laboratories, Inc.

Signature: Helge Gudlaugsd

Print Name: Helga Gudlaugsd

Title: SVP Global Procurement

Warner Chilcott, Inc.

Signature: Helge Gudlaugsd

Print Name: Helge Gudlaugsd

Title: SVP Global Procurement

Watson Laboratories, Inc. (Florida)

Signature: Helge Gudlaugsd

Print Name: Helge Gudlaugsdothe

Title: SVP Global Procuremen

Actavis Totowa LLC

Signature: Helge Gudlaugsdo

Print Name: Helge Gudlaugsdothe

Title: SVP Global Procuremen

Actavis Elizabeth, LLC (DE)

Signature: Helge Gudlaugsdo

Print Name: Helge Gudlaugsdothe

Title: SVP Global Procuremen

APPROVAL PAGE

Approver Name	Justification	Date
James Guro	Quality Approval	25-Mar-2014 13:45:34 EDT
Susan Daniel	Quality Approval	27-Mar-2014 10:08:01 EDT