

# ANDA FILING CHECKLIST

**ANDA:**

APPLICANT:  
RELATED APPLICATION(S):

DRUG NAME:  
DOSAGE FORM:

LETTER DATE:  
RECEIVED DATE:

Type II DMF #:  
Therapeutic Code:  
Archival Copy:  
EDR Email:

**BASIS OF SUBMISSION:**

NDA/ANDA:  
FIRM:  
RLD:  
On Cards:  Yes  No

**APPLICATION PROPERTIES**

P-IV

**EXPEDITED REVIEW REQUEST**

MaPP 5240.1 or 5240.3 or GDUFA  Approved  Denied

**FIRST GENERIC Received**

Market Availability  Rx  OTC

PEPFAR

PET

Product Type  Small Molecule Drug

USP Drug Product (at time of filing review)

**\*\*Document Room Note: for New Strength amendments and supplements, if specific reviewer(s) have already been assigned for the original, please assign to those reviewer(s) instead of the default random team(s).**

**Review Team:**

RPM: <input type="checkbox"/> Activity	Div. of Bioequivalence: <input type="checkbox"/> Activity
CHEM Team: <input type="checkbox"/> FYI	Dissolution Review: <input type="checkbox"/> FYI
CHEM PQRPM: <input type="checkbox"/> FYI	Division of Clinical Review: <input type="checkbox"/> Activity
CHEM Team Leader: <input type="checkbox"/> No Assignment Needed in DARRTS	DMF Review Team Leader: <input type="checkbox"/> FYI
Labeling Team: <input type="checkbox"/> Activity	Micro Review: <input type="checkbox"/> Activity
<b>SPECIAL INSTRUCTIONS FOR DOCUMENT ROOM (applicable only for a response to a refuse to receive):</b>	

Regulatory Reviewer:  Date:	Recommendation:  <input type="checkbox"/> FILE <input type="checkbox"/> REFUSE to RECEIVE
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1. Edit Application Property Type in DARRTS
2. Edit Submission Patent Records  
 Yes
3. Edit Contacts Database with Bioequivalence Recordation where applicable  
 Yes
4. EER (internal notation: RSB to submit at time of filing)  
 Yes
5. GDUFA Obligations Met (Filing Fee, Type II DMF Fee, and Facility Fee)  
 Yes
6. DMF Complete Assessment  
 Yes

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**ADDITIONAL COMMENTS REGARDING THE ANDA:**

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# MODULE 1: ADMINISTRATIVE

			COMMENT(S)
1.1	1.1.2	<p><b>Signed and Completed Application Form (356h)</b> (Rx / OTC Status) (original signature) <b>Electronic, Fillable Copy</b> (if a signed, scanned copy is provided) Refer to the links provided for the newly revised form 356h and updated instructions. <a href="http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM321897.pdf">http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM321897.pdf</a> <a href="http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/ucm082348.pdf">http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/ucm082348.pdf</a> <b>**PLACE ESTABLISHMENT CONTACT INFORMATION IN SECTION 29: MANUFACTURING STEPS AND/OR TYPE OF TESTING**</b></p>	
		<b>Form FDA 3794 (PDF)</b> GDUFA	
1.2	*	<b>Cover Letter</b> Is the drug product subject to REMS requirements? <input type="checkbox"/> Yes <input type="checkbox"/> No	
	1.2.1	<b>Form FDA 3674 (PDF)</b> 42 U.S.C. 282(j)(5)(B) <b>Electronic, Fillable Copy</b> (if a signed, scanned copy is provided)	
*	*	<b>Table of Contents</b> (paper submission only)	
1.3	1.3.1	<b>Contact/Sponsor/Applicant Information</b> <b>1.3.1.2 U.S. Agent Appointment Letter</b> 21 CFR §314.50(a)(5) If the applicant identifies a U.S. Agent on the 356h, a U.S. Agent Appointment letter should be provided.	
	1.3.2	<b>Field Copy Certification</b> 21 CFR §314.94(d)(5) (Original Signature)	
	1.3.3	<b>Debarment Certification</b> Generic Drug Enforcement Act (GDEA)/ Other: (no qualifying statement) FD&C Act §306(k), §306(a) and (b) (21 U.S.C. 335a(k), 335(a) and (b)) 1. Debarment Certification (original signature) 2. List of Convictions statement (original signature)	
	1.3.4	<b>Financial Certifications</b> 21 CFR §54   21 CFR §54.2(e)   21 CFR §314.94(a)(13) Bioavailability/Bioequivalence Financial Certification (Form FDA 3454) Disclosure Statement (Form FDA 3455)	
	1.3.5	<b>Patent and exclusivity</b> <b>1.3.5.1 Patent Information</b> 21 CFR §314.94(a)(12)   FD&C Act 505(j)(2)(A)(vii) Patents listed for the RLD in the Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations <b>1.3.5.2 Patent Certification</b> 21 CFR §314.94(a)(12)(i)(A)(1) through (4) or §314.94(a)(12)(iii) 1. Patent number(s) 2. Paragraph: (Check all certifications that apply) No Relevant Patents <input type="checkbox"/> MOU <input type="checkbox"/> PI <input type="checkbox"/> PII <input type="checkbox"/> PIII <input type="checkbox"/> PIV <input type="checkbox"/> Statement of Notification (21 CFR §314.95   505(j)(2)(B)) <input type="checkbox"/> 3. Expiration of Patent(s): a. Pediatric exclusivity submitted? b. Expiration of Pediatric Exclusivity? <b>1.3.5.3 Exclusivity Claim</b> Exclusivity Statement: State marketing intentions?	
1.4	1.4.2	<b>Statement of right of references</b> 21 CFR §314.50(g)(1) DMF Written Statement of authorization for reference (copy of LoA received from DMF holders) 1. Type II DMF authorization letter(s) or synthesis for Active Pharmaceutical Ingredient 2. Type II DMF# 3. Type III DMF authorization letter(s) for container closure 4. Type III or V DMF authorization letter(s) for sterile product sterilization process	
1.12	1.12.4	<b>Request for Comments and Advice</b> - Proprietary name requested If Yes, did the firm provide the request as a separate electronic amendment labeled "Proprietary Name Request" at initial time of filing 1. Yes 2. No - contact the firm to submit the request as a separate electronic amendment	

	1.12.11	<p><b>Basis for Submission</b> 21 CFR §314.94(a)(3)  NDA #  Ref Listed Drug:  Firm:  <b>ANDA suitability petition required?</b> 21 CFR §10.20   21 CFR §10.30   21 CFR §314.93  If Yes, provide petition number and copy of FDA’s correspondence approving the petition (21 CFR §314.94(a)(3)(iii))  <b>ANDA Citizen’s Petition required?</b> 21 CFR §10.25(a)   21 CFR §10.30   21 CFR §314.122  If Yes, provide petition number and copy of petition</p>	
	1.12.12	<p><b>Comparison between Generic Drug and RLD</b> 505(j)(2)(A)   21 CFR §314.94(a)(4) to (6)  1. Conditions of Use  2. Active Ingredients  3. Inactive Ingredients (21 CFR §314.94(a)(9)(ii))  4. Route of Administration  5. Dosage Form  6. Strength</p>	
	1.12.14	<p><b>Environmental Analysis</b> 21 CFR §25.31 and §25.15(d), if applicable  Environmental Assessment (EA) (21 CFR §25.20)  If applicable, Environmental Impact Statement (EIS) (21 CFR 25.22)  Claim of Categorical Exclusion (21 CFR §25.30 or 21 CFR §25.31)</p>	
	1.12.15	<p><b>Request for Waiver</b> 21 CFR 320.22   320.24(b)(6)  Request for Waiver of In-Vivo BA/BE Study(ies)</p>	
1.14	1.14.1	<p><b>Draft Labeling</b> (Multi Copies N/A for E-Submissions) 21 CFR 314.94(a)(8)(ii)  <b>1.14.1.1 Draft carton and container labels</b>  4 copies of draft for paper submission only (each strength and container)  <b>1.14.1.2 Annotated draft labeling text</b> 21 CFR §314.94(a)(8)(iv)  Side by side labeling comparison of container(s) and carton(s) for each strength with all differences visually highlighted and annotated  <b>1.14.1.3 Draft labeling text</b>  1 package insert (content of labeling) in PDF and WORD format, and SPL submitted electronically  <b>1.14.1.4 Labeling Comprehension Studies</b>  Refer to Pharmacy Bulk Package Sterility Assurance Table (for PBP’s only)  See link below for table:  <a href="http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM352612.pdf">http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM352612.pdf</a></p>	
	1.14.3	<p><b>Listed Drug Labeling</b>  <b>1.14.3.1 Annotated comparison with listed drug</b> 21 CFR §314.94(a)(8)(iv)  1 side by side labeling (package and patient insert) comparison with all differences visually highlighted and annotated  <b>1.14.3.3 Labeling text for reference listed drug</b>  RLD package insert, 1 RLD container label, and if applicable, 1 RLD outer container label</p>	

## MODULE 2: CTD SUMMARIES

	COMMENT(S)
<p data-bbox="168 130 591 163">Quality Overall Summary (QOS)</p> <p data-bbox="168 197 407 226">E-Submission: PDF</p> <p data-bbox="168 260 561 289">Word Processed, e.g., MS Word</p> <p data-bbox="168 323 899 352">Additional information regarding QbR may be found at the following link:</p> <p data-bbox="168 352 1349 407"><a href="http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm120971.htm">http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm120971.htm</a></p> <p data-bbox="168 436 539 470">Question based Review (QbR)</p> <p data-bbox="168 499 938 533"><b>2.3.S Drug Substance (Active Pharmaceutical Ingredient)</b></p> <ul data-bbox="217 533 646 764" style="list-style-type: none"><li>2.3.S.1 General Information</li><li>2.3.S.2 Manufacture</li><li>2.3.S.3 Characterization</li><li>2.3.S.4 Control of Drug Substance</li><li>2.3.S.5 Reference Standards</li><li>2.3.S.6 Container Closure System</li><li>2.3.S.7 Stability</li></ul> <p data-bbox="94 743 136 772">2.3</p> <p data-bbox="168 798 435 831"><b>2.3.P Drug Product</b></p> <ul data-bbox="217 831 1247 1390" style="list-style-type: none"><li>2.3.P.1 Description and Composition of the Drug Product</li><li>2.3.P.2 Pharmaceutical Development<ul data-bbox="298 898 1247 1192" style="list-style-type: none"><li>2.3.P.2.1 Components of the Drug Product<ul data-bbox="380 932 724 995" style="list-style-type: none"><li>2.3.P.2.1.1 Drug Substance</li><li>2.3.P.2.1.2 Excipients</li></ul></li><li>2.3.P.2.2 Drug Product <b>Oral Solids</b>: Immediate Release or Modified Release (Matrix Technology or Compressed Film Coated Components) tablet scoring data per Draft <i>Guidance for Industry, Tablet Scoring: Nomenclature, Labeling and Data for Evaluation</i> (if applicable)</li><li>2.3.P.2.3 Manufacturing Process Development</li><li>2.3.P.2.4 Container Closure System</li></ul></li><li>2.3.P.3 Manufacture</li><li>2.3.P.4 Control of Excipients</li><li>2.3.P.5 Control of Drug Product</li><li>2.3.P.6 Reference Standards and Materials</li><li>2.3.P.7 Container Closure System</li><li>2.3.P.8 Stability</li></ul>	

## MODULE 2: CTD SUMMARIES (cont.)

COMMENT(S)

### Clinical Summary (Bioequivalence) Model BE Data Summary Tables

<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM120957.pdf>

**\*\* In addition to the standard tables, see the link below for tables specifically designed for in-vitro binding studies \*\***

<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM364105.pdf>

E-Submission: PDF

Word Processed: e.g., MS Word

### 2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods

#### 2.7.1.1 Background and Overview

Table 1. Submission Summary

Table 4. Bioanalytical Method Validation

Table 6. Formulation Data

Table 10. Study Information

Table 11. Product Information

Table 17. Comparative Physicochemical Data of Ophthalmic Solution Products

#### 2.7.1.2 Summary of Results of Individual Studies

Table 5. Summary of In Vitro Dissolution

(include complete comparative In Vitro Dissolution Data (individual) with Certificate of Analysis [CoA] for Test and Reference products including: potency, assay, content uniformity, date of manufacture and lot number)

Table 9. Reanalysis of Study Samples

Table 12. Dropout Information

Table 13. Protocol Deviation

Table 14. Summary of Standard Curve and QC Data for Bioequivalence Sample Analysis

#### 2.7.1.3 Comparison and Analyses of Results Across Studies

Table 2. Summary of Bioavailability (BA) Studies

Table 3. Statistical Summary of the Comparative BA Data:

1. Unscaled Average – Table A
2. Reference-scaled Average BE Studies – Tables A and B  
BE Studies

Table 16. Composition of Meal Used in Fed Bioequivalence Study

#### 2.7.1.4 Appendix

Table 15. SOPs Dealing with Bioanalytical Repeats of Study Samples

### 2.7.4 Summary of Clinical Safety

#### 2.7.4.1.3 Demographic and Other Characteristics of Study Population

Table 7. Demographic Profile of Subjects Completing the Bioequivalence Study

#### 2.7.4.2.1.1 Common Adverse Events

Table 8. Incidence of Adverse Events in Individual Studies

2.7

# MODULE 3: QUALITY

## 3.2.S DRUG SUBSTANCE (Active Pharmaceutical Ingredient)

COMMENT(S)

3.2.S.1	<b>General Information</b> (Do not refer to DMF) <b>3.2.S.1.1 Nomenclature</b> <b>3.2.S.1.2 Structure</b> <b>3.2.S.1.3 General Properties</b>																	
3.2.S.2	<b>Manufacturer</b> <b>Drug Substance (Active Pharmaceutical Ingredient)</b> Must correlate to the establishment information submitted in annex to Form FDA 356h 1. Name and Full Address(es) of the Facility(ies) 2. Contact name, phone and fax numbers, email address 3. U.S. Agent's Name (if applicable) 4. Specify function or responsibility 5. Type II DMF number(s) for API(s) 6. CFN, FEI, or DUNS number (if available) 7. Additional sources of API and information (1 through 6) as applicable																	
3.2.S.3	<b>Characterization</b> All potential impurities should be listed in tabular format as follows: <table border="1" data-bbox="300 714 1347 829"> <thead> <tr> <th data-bbox="300 714 511 787">IUPAC Chemical Name</th> <th data-bbox="511 714 722 787">Code #</th> <th data-bbox="722 714 933 787">Chemical Structure</th> <th data-bbox="933 714 1144 787">Process/Degradation Impurity</th> <th data-bbox="1144 714 1347 787">Source/Mechanism</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <a href="http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf">http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf</a>	IUPAC Chemical Name	Code #	Chemical Structure	Process/Degradation Impurity	Source/Mechanism												
IUPAC Chemical Name	Code #	Chemical Structure	Process/Degradation Impurity	Source/Mechanism														
<b>Control of Drug Substance (Active Pharmaceutical Ingredient)</b>																		
3.2.S.4	<b>3.2.S.4.1 Specification</b> Testing specifications and data from drug substance manufacturer(s)																	
	<b>3.2.S.4.2 Analytical Procedures</b>																	
	<b>3.2.S.4.3 Validation of Analytical Procedures</b> (API that is USP or reference made to DMF, <b>MUST</b> provide verification of USP or DMF procedures) 1. Spectra and chromatograms for <b>reference standards</b> and <b>test samples</b> 2. Samples-Statement of Availability and Identification (21 CFR §314.50(e)(1)) a. Drug Substance b. API lot numbers																	
	<b>3.2.S.4.4 Batch Analysis</b> 1. COAs specifications and test results from drug substance manufacturer(s) 2. Drug Product manufacturer's Certificates of analysis																	
	<b>3.2.S.4.5 Justification of Specification</b> Provide data in tabular format: <table border="1" data-bbox="300 1449 1347 1596"> <thead> <tr> <th data-bbox="300 1449 430 1522">Chemical Name</th> <th data-bbox="430 1449 511 1522">Code #</th> <th data-bbox="511 1449 592 1522">MDD</th> <th data-bbox="592 1449 641 1522">IT</th> <th data-bbox="641 1449 706 1522">QT</th> <th data-bbox="706 1449 820 1522">TDI of Impurity</th> <th data-bbox="820 1449 1015 1522">Proposed AC for Unspecified Impurities</th> <th data-bbox="1015 1449 1177 1522">Proposed AC for Specified Impurities</th> <th data-bbox="1177 1449 1347 1522">Justification if AC&gt;QT for Specified Impurities</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <a href="http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf">http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf</a>		Chemical Name	Code #	MDD	IT	QT	TDI of Impurity	Proposed AC for Unspecified Impurities	Proposed AC for Specified Impurities	Justification if AC>QT for Specified Impurities							
Chemical Name	Code #	MDD	IT	QT	TDI of Impurity	Proposed AC for Unspecified Impurities	Proposed AC for Specified Impurities	Justification if AC>QT for Specified Impurities										
3.2.S.5	<b>Reference Standards or Materials</b> (Do NOT refer to DMF)																	
3.2.S.6	<b>Container Closure Systems</b>																	
3.2.S.7	<b>Stability</b> 1. Retest date or expiration date of API(s)																	

**MODULE 3: QUALITY (cont.)**

**3.2.P DRUG PRODUCT**

		COMMENT(S)
3.2.P.1	<p><b>Description and Composition of the Drug Product</b></p> <ol style="list-style-type: none"> <li>Unit composition with indication of the function of the inactive ingredient(s)</li> <li>Inactive ingredients and amounts are appropriate per IIG (per/dose justification) (provide justification in a tabular format)</li> <li>Conversion from % to mg/dose values for inactive ingredients (if applicable)</li> <li>Elemental iron: provide daily elemental iron calculation or statement of adherence to 21 CFR 73.1200 (calculation of elemental iron intake based on <b>maximum daily dose (MDD)</b> of the drug product is preferred if this section is applicable)</li> <li>Injections: If the reference listed drug is packaged with a drug specific diluent, then the diluent must be Q1/Q2 and must be provided in the package configuration</li> </ol>	
3.2.P.2	<p><b>Pharmaceutical Development</b></p> <ol style="list-style-type: none"> <li>Pharmaceutical Development Report</li> <li>Microbial Attributes               <ol style="list-style-type: none"> <li>Container/Closure Integrity Testing Report for Sterile Products</li> <li>Antimicrobial Effectiveness Testing for Multi-dose Sterile Products</li> </ol> </li> </ol>	
<b>Manufacture</b>		
3.2.P.3.1	<p><b>Drug Product Manufacturer(s)</b> Must correlate to the establishment information submitted in annex to Form 356h for the finished dosage manufacturer and all outside contract testing laboratories.</p> <ol style="list-style-type: none"> <li>Name and Full Address(es) of the Facility(ies)</li> <li>Contact name, phone and fax numbers, email address</li> <li>U.S. Agent's name (if applicable)</li> <li>Specify function or responsibility</li> <li>cGMP Certification (from both applicant and drug product manufacturer, if different entities)</li> <li>CFN, FEI, or DUNS numbers (if available)</li> </ol>	
3.2.P.3.2	<b>Batch Formula</b>	
3.2.P.3.3	<p><b>Description of Manufacturing Process and Process Controls</b></p> <ol style="list-style-type: none"> <li>Description of the Manufacturing Process and (for aseptic fill products) Facility</li> <li>Master Production Batch Record(s) for largest intended production runs (no more than 10x pilot batch) with equipment specified</li> <li>Master Packaging Records for intended marketing container(s)</li> <li>If sterile product</li> <li>Reprocessing Statement (cite 21 CFR 211.115, submitted by the drug product manufacturer and the applicant, if different entities)</li> </ol>	
3.2.P.3.4	<b>Controls of Critical Steps and Intermediates</b>	
3.2.P.3.5	<p><b>Process Validation and/or Evaluation</b></p> <ol style="list-style-type: none"> <li>Terminally Sterilized Product           <ul style="list-style-type: none"> <li>Validation of production terminal sterilization process</li> <li>Validation of depyrogenation of all product containers and closures</li> <li>Validation of container-closure package integrity</li> <li>Holding Periods</li> </ul> </li> <li>Aseptically Filled Product           <ul style="list-style-type: none"> <li>Validation (bacterial retention studies) of sterilizing grade filter(s)</li> <li>Validation of the sterilization of sterile bulk drug or product contact equipment, components, containers, and closures</li> <li>Validation of depyrogenation of product containers and closures</li> <li>Validation of aseptic filling process/line/room (media fills/process simulations)</li> <li>Validation of container-closure package integrity</li> <li>Holding Periods</li> <li>Action taken after a media fill failure</li> </ul> </li> </ol>	



### Controls of Excipients (Inactive Ingredients)

*	Source of Inactive Ingredients Identified
3.2.P.4	<b>Specifications</b> 1. Testing specifications (including identification and characterization) 2. Supplier's COA (specifications and test results)
	<b>Analytical Procedures</b>
	<b>Validation of Analytical Procedures</b>
	<b>Justification of Specifications</b> (as applicable) 1. Applicant COA 2. Residual solvents statement(s) from manufacturer(s) 3. Bovine spongiform encephalopathy (BSE) statement (as applicable) 4. Transmissible spongiform encephalopathy (TSE) statement (as applicable) 5. Melamine Certifications statement (as applicable)

### Controls of Drug Product

3.2.P.5	<b>3.2.P.5.1 Specification(s)</b> <b>3.2.P.5.2 Analytical Procedures</b> <b>3.2.P.5.3 Validation of Analytical Procedures</b> (if using USP procedure, must provide verification of USP procedure) Samples - Statement of Availability and Identification (21 CFR §314.50(e)(1)) 1. Finished Dosage Form 2. Lot numbers and strength of Drug Products																		
	<b>3.2.P.5.4 Batch Analysis</b> Certificates of Analysis for Finished Dosage Form																		
	<b>3.2.P.5.5 Characterization of Impurities</b> Provide in tabular format as below: <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">IUPAC Chemical Name</th> <th style="width: 15%;">Code #</th> <th style="width: 25%;">Chemical Structure</th> <th style="width: 15%;">Degradation Impurity</th> <th style="width: 20%;">Source/Mechanism</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <a href="http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf">http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf</a>	IUPAC Chemical Name	Code #	Chemical Structure	Degradation Impurity	Source/Mechanism													
IUPAC Chemical Name	Code #	Chemical Structure	Degradation Impurity	Source/Mechanism															
	<b>3.2.P.5.6 Justification of Specifications Select</b> Provide data in tabular format: <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">Chemical Name</th> <th style="width: 5%;">Code#</th> <th style="width: 5%;">MDD</th> <th style="width: 5%;">IT</th> <th style="width: 5%;">QT</th> <th style="width: 15%;">TDI of Degradation Product</th> <th style="width: 15%;">Proposed AC for Unspecified Degradation Product</th> <th style="width: 15%;">Proposed AC for Specified Degradation Product</th> <th style="width: 20%;">Justification if AC&gt;QT for Degradation Product</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <a href="http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf">http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf</a>	Chemical Name	Code#	MDD	IT	QT	TDI of Degradation Product	Proposed AC for Unspecified Degradation Product	Proposed AC for Specified Degradation Product	Justification if AC>QT for Degradation Product									
Chemical Name	Code#	MDD	IT	QT	TDI of Degradation Product	Proposed AC for Unspecified Degradation Product	Proposed AC for Specified Degradation Product	Justification if AC>QT for Degradation Product											

3.2.P.7	<b>Container Closure System</b> 1. Summary of Container/Closure System (if new resin, provide data) 2. Components Specification and Test Data 3. Packaging Configurations and Sizes 4. Container/Closure Testing (recommended additional testing for all plastic) a. Solid Orals: water permeation, light transmission b. Liquids: leachables, extractables, light transmission 5. Source of supply and suppliers address
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**Stability**

3.2.P.8.1	<b>Stability Summary and Conclusion (Finished Dosage Form)</b> 1. Stability Protocol Submitted 2. Expiration Dating Period for Marketed Packaging 3. Expiration Dating Period for Bulk packaging (if applicable)	
3.2.P.8.2	<b>Post-Approval Stability Protocol and Stability Commitment</b> 1. Post-Approval Protocol and Commitment (From Applicant and Drug Product Manufacturer, if different entities)	
3.2.P.8	<b>3.2.P.8.3 Stability Data</b> (Refer to the Final Guidance for Industry ANDAs: <i>Stability Testing Drug Substances and Products</i> , dated June 2013) 1. 3 batches? a. Two API lots used? 2. Additional stability data to support additional API sources, if proposed 3. Data- At minimum, 6 months <b>and</b> 3 time points a. Accelerated 1. Significant change occurred 2. If yes, 6 months intermediate stability data b. Long term storage (Room Temperature) 4. Batch numbers on stability records the same as the test batch 5. Date accelerated stability study initiated 6. Date accelerated stability sample removed from stability chamber for each testing time point 7. For liquid and semi-solid products, upright and inverted/horizontal storage orientation	

**MODULE 3: QUALITY (cont.)**

**3.2.R REGIONAL INFORMATION** 21 CFR §314.50(d)(1)(ii)(b)

COMMENT(S)

REGIONAL INFORMATION (DRUG SUBSTANCE)		
3.2.R.S Drug Substance	3.2.R.1.S	Executed Batch Records for drug substance (if available)
	3.2.R.2.S	Comparability Protocols
	3.2.R.3.S	Methods Validation Package (Required for Non-USP drugs) Methods Validation Package (3 copies for paper and N/A for E-Submissions)

REGIONAL INFORMATION (DRUG PRODUCT)			
3.2.R.P Drug Product	3.2.R.1.P	<p><b>1. Executed Batch Records</b>                      Two (2) Pilot Scales and one (1) Small Scale OR Three (3) Pilot scales (Refer to <b>batch size and packaging information</b> that meet the minimum threshold amount for specified dosage forms (solid oral dosage forms, oral powders/solutions/suspensions, parenteral drug products, ophthalmic/otic drug products, transdermal patches, topicals (e.g. creams/lotions/gels and inhalation solutions/nasal sprays, etc). Refer to FDA’s guidance for industry, ANDAs: <i>Stability Testing of Drug Substances and Products, Questions and Answers.</i> (<a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM366082.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM366082.pdf</a>)                      Copies of Executed Batch Records with Equipment Specified, including Packaging Records (Packaging and Labeling Procedures)                      Batch Reconciliation and Label Reconciliation</p> <ol style="list-style-type: none"> <li>Theoretical Yield</li> <li>Actual Yield</li> <li>Packaged Yield</li> </ol> <p>Bulk Package Reconciliation for all bulk packaging considered a commercial container is recommended if bulk packaging is used to achieve the minimum package requirement.                      Provide the following information in their respective sections:</p> <ol style="list-style-type: none"> <li>Bulk Package Label (1.14.1)</li> <li>Bulk Package Stability (3.2.P.8)                             <ol style="list-style-type: none"> <li>If bulk is to be shipped, provide accelerated stability data at 0,3,6 months</li> <li>If bulk is only warehoused for repackaging, provide RT stability data at 0,3,6 months</li> </ol> </li> <li>Bulk Package Container and Closure information (3.2.P.7)</li> </ol>	
		3.2.R.2.P	Comparability Protocols
		3.2.R.3.P	Methods Validation Package Methods Validation Package (3 copies for paper and N/A for E-Submissions) (Required for Non-USP drugs)

## MODULE 5: CLINICAL STUDY REPORTS

		COMMENT(S)
5.2		<b>Tabular Listing of Clinical Studies</b>
5.3	5.3.1	<b>Bioavailability/Bioequivalence</b> 1. Formulation data same? a. Comparison of all Strengths (proportionality of multiple strengths) b. Parenterals, Ophthalmics, Otics and Topicals (21 CFR 314.94 (a)(9)(iii)-(v)) 2. Lot Numbers and strength of Products used in BE Study(ies) 3. Study Type: IN-VIVO PK STUDY(IES) (Continue with the appropriate study type box below)
	*	<b>See Module 2.7 Clinical Summary for placement of BA/BE Summary for tables 9 – 16.</b>  <b>The study data that support the BA/BE summary tables should be provided in the corresponding sections below:</b> 5.3.1.2 Comparative BA/BE Study Reports 5.3.1.3 In Vitro-In Vivo Correlation Study Reports (exception: all dissolution data should be placed in 2.7) 5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies  <b>Case Report Forms</b> should be placed under the study to which they pertain, and appropriately tagged. Refer to The eCTD Backbone File Specification for Study Tagging <a href="http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163560.pdf">http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163560.pdf</a>
5.4		<b>Literature References</b>
		<b>Possible Study Types:</b>
Study Type		<b>IN-VIVO BE STUDY(IES) with PK ENDPOINTS</b> (i.e., fasting/fed/sprinkle) 1. Study(ies) meets BE criteria (90% CI of 80-125, Cmax , AUC) 2. In-Vitro Dissolution
Study Type		<b>IN-VIVO BE STUDY with CLINICAL ENDPOINTS</b> Division of Clinical Review Consult Complete <input type="checkbox"/> Yes <input type="checkbox"/> No
Study Type		<b>IN-VITRO BE STUDY(IES)</b> (i.e., in vitro binding assays) 1. Study(ies) meets BE criteria (90% CI of 80-125) 2. In-Vitro Dissolution
Study Type		<b>NASALLY ADMINISTERED DRUG PRODUCTS</b> Refer to the attached links for Nasal Product BE Tables: <a href="http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM209446.pdf">http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM209446.pdf</a> <b>AND</b> <a href="http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM271017.pdf">http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM271017.pdf</a> Division of Bioequivalence Consult Complete <input type="checkbox"/> Yes <input type="checkbox"/> No
Study Type		<b>IN-VIVO BE STUDY(IES) with PD ENDPOINTS</b> (e.g., topical corticosteroid vasoconstrictor studies) Division of Bioequivalence Consult Complete <input type="checkbox"/> Yes <input type="checkbox"/> No
Study Type		<b>TRANSDERMAL DELIVERY SYSTEMS</b> Division of Clinical Review Consult Complete <input type="checkbox"/> Yes <input type="checkbox"/> No

Effective as of 06/20/2014 and supersedes any previous checklists.

For More Information on Submission of an ANDA in Electronic Common Technical Document (eCTD) Format please go to:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm>

For a Comprehensive Table of Contents Headings and Hierarchy please go to: <http://www.fda.gov/cder/regulatory/ersr/5640CTOC-v1.2.pdf>

Draft Guidance for Industry ANDA Submissions – Content and Format of Abbreviated New Drug Applications:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400630.pdf>