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## How to Use

- **Searching:** Type keyword in search field at top of page. Search by all or part of a monograph title. For searches using multiple criteria, you will find items that match each of the specified criteria unless quotation marks are used.
  - For example, a search on Aminosalicic Acid Tablets will result in anything that contains “Aminosalicic” OR “Acid” OR “Tablets”
  - A search for “Aminosalicic Acid Tablets” will result in anything that specifically contains “Aminosalicic Acid Tablets”
- **Sorting:** Click on any column header title to sort alphabetically or chronologically in ascending or descending order. Note: the page load column is sorted alphabetically so that a number is ordered by first digit vs. by the actual number; thus, numbers will not always be in order.
  - For example, page 2178 will come before page 74 on a page sort.
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OXANDROLON <i>Dissolution</i>	USP39–NF34	5193	27-May-2016	1-Jun-2016	USP40–NF35	USP40–NF35	Line 3 of

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E TABLETS	<711>/Test 3								Chromatographic system: Change 30-cm column to: 3-cm column
RANITIDINE TABLETS	USP Reference standards <11>	USP39–NF34	5672	27-May-2016		1-Jun-2016	USP40–NF35	USP40–NF35	Line 2 of USP Ranitidine Related Compound C RS: Change <i>N</i> -[2-[[[5-[(Dimethylamino)methyl]-2-furanyl]methyl]sulfinyl]ethyl]- <i>N</i> -methyl-2-nitro-1,1-ethenediamine. to: <i>N</i> -{2-[[[5-[(Dimethylamino)methyl]-2-furanyl]methyl]sulfinyl]ethyl}- <i>N</i> -methyl-2-nitro-1,1-ethenediamine.

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CHONDROITIN IM SULFATE SODIUM, SHARK	PURITIES/ <i>Limit of Protein</i>	USP39–NF34 6570	27-May-2016	1-Jun-2016	USP40–NF35	USP40–NF35	?-methyl-2-nitro-1,1-ethenediamine. Line 2 of <i>Instrumental conditions</i> : Change (See <i>Spectrophotometry and Light-Scattering &lt;851&gt;</i> .) to: (See <i>Ultraviolet-Visible Spectroscopy &lt;857&gt;</i> .)
MYRISTYL ALCOHOL	ASSAY/ <i>Procedure</i>	USP39–NF34 7413	27-May-2016	1-Jun-2016	USP40–NF35	USP40–NF35	Line 1 of <i>Standard solution</i> : Change Prepare 1.0 mg/mL of USP Myristyl Alcohol RS in <i>Internal standard solution</i> , and heat the solution in a sealed container in a

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							<p>50° water bath until myristyl alcohol is dissolved. Allow the solution to cool to room temperature, and mix well.</p> <p>to:</p> <p>1.0 mg/mL of USP Myristyl Alcohol RS in <i>Internal standard solution</i></p> <p>AND</p> <p>Line 1 of <i>Sample solution</i>: Change Prepare 1.0 mg/mL of Myristyl Alcohol in <i>Internal standard solution</i>, and heat the solution in a sealed container in a 50° water bath</p>

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SELENOMETHICHEMICAL ONINE INFORMATION	USP38–NF33	6226	25-Mar-2016	1-Apr-2016	USP40–NF35	USP40–NF35	until myristyl alcohol is dissolved. Allow the solution to cool to room temperature, and mix well. to: 1.0 mg/mL of Myristyl Alcohol in <i>Internal standard solution</i> Line 3: Change [1464-42-2] to: [3211-76-5]
PLASTIC MATERIALS OF CONSTRUCTION	TEST METHOD S/ <i>Extractions/ Table 3</i>	USP39–NF34 493	25-Mar-2016	1-Apr-2016	USP40–NF35	USP40–NF35	Line 1 of footnote b: Change For nonplasticized polyethylene only. to: For polyethylene only.
FLUTICASONE ASSAY/ PROPIONATE AND	<i>Procedure</i>	USP39–NF34 4020	25-Mar-2016	1-Apr-2016	USP40–NF35	USP40–NF35	Line 3 of <i>System suitability</i> .

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SALMETEROL INHALATION POWDER									Change for salmeterol and fluticasone propionate are to: for fluticasone propionate and salmeterol are
CONTAINERS-MOISTURE -PERFORMAN CE TESTING	VAPOR TRANS MISSI ON/ <i>Packaging System Classification for Multiple-Unit Containers and Unit-Dose Containers for Liquid Oral Dosage Forms/ Procedure</i>	USP38–NF33	465	25-Mar-2016		1-Apr-2016	USP40–NF35	USP40–NF35	Line 1 of the Equation: Change $\left[ \frac{W_{1i}}{W_T} \right] \left[ \frac{W_{14i}}{W_T} \right] \left[ \frac{W_{C1}}{W_{C14}} \right] \times 365 \times \left\{ \left[ \frac{100}{W_{1i}} \right] \times 14 \right\}$ to: $\left[ \frac{W_{1i}}{W_T} \right] \left[ \frac{W_{14i}}{W_T} \right] \left[ \frac{W_{C1}}{W_{C14}} \right] \times 365 \times \frac{100}{W_{1i}} \times 14$
PLASTIC MATERIALS OF CONSTRU CTION	SPECIFICATIO NS/ <i>Polyethylene Terephthalate and Polyethylene Terephthalate G/Extractable Metals</i>	USP39–NF34	493	25-Mar-2016		1-Apr-2016	USP40–NF35	USP40–NF35	Line 1 of <i>Titanium</i> : Change 0.1 µg/g. to: 1 µg/g.

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CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS IM PURITIES/ <i>Organic Impurities</i>	<i>USP39–NF34</i>	2895	25-Mar-2016	1-Apr-2016	<i>USP40–NF35</i>	<i>USP40–NF35</i>	Row 3 of Column 1 of <i>Table 6</i> : Change Candesartan related compound A <sup>b,c</sup> to: Candesartan cilexetil related compound A <sup>b,c</sup>
MEMANTINE HYDROCHLORIDE TABLETS IM PURITIES/ <i>Organic Impurities</i>	<i>Revision Bulletin (Official October 01, 2015)</i>	Online	25-Mar-2016	1-Apr-2016	<i>USP40–NF35</i>	<i>USP40–NF35</i>	Line 3 of <i>Analysis</i> : Change of USP Memantine Related Compound E RS or to: of memantine related compound E or AND In the variable definition list: Change $r_U$ = peak response of USP Memantine Related

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RESIDUAL HOST CELL PROTEIN MEASUREMENT IN V BIOPHARMACEUTICALS	4. HCP IMMUNOASSAY METHOD VALIDATION/4.3	<i>Second Supplement to USP38–NF33</i>	7647	25-Mar-2016		1-Apr-2016	USP40–NF35	USP40–NF35	Compound E RS or any individual degradation product from the <i>Sample solution</i> to: $r_U$ = peak response of memantine related compound E or any individual degradation product from the <i>Sample solution</i>  Product column: Change 10.00 (neat), 5.00, 2.50, 1.25, 0.63, 0.31, 0.16 to: 10.00 (neat), 5.00, 2.50, 1.25, 0.625, 0.3125, 0.15625 AND <i>Sample 1/HCP ratio</i> column:



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							Change 4.9, 5.7, 4.8, 5.9, 5.0, 5.1, <6 to: 4.90, 5.70, 4.80, 5.92, 4.96, 5.12, <6 AND <i>Sample 2/HCP</i> <i>ratio</i> column: Change 2.0, 3.3, 4.0, 5.9, 5.3, 6.1, <6 to: 2.00, 3.30, 4.00, 5.92, 5.28, 6.08, <6 AND <i>Sample 3/HCP</i> <i>ratio</i> column: Change 0.3, 0.5, 0.6, 0.9, 1.4, <6, <6 to: 0.32, 0.50, 0.60, 0.88, 1.44, <6, <6 AND <i>Sample 3/%</i> <i>max ratio value</i> column:

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PLASTIC MATERIALS OF CONSTRUCTION	TEST METHOD S/ <i>Physicochemical Tests/Absorbance</i>	<i>USP39–NF34</i>	493	25-Mar-2016		1-Apr-2016	<i>USP40–NF35</i>	<i>USP40–NF35</i>	Change 83% to: 61% Line 3 of <i>Plasticized polyvinyl chloride</i> : Delete Additionally, for nonplasticized polyvinyl chloride materials only, determine the spectrum between 250 and 330 nm in the alcohol sample associated with <i>Solution S6</i> .
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER	IM PURITIES/ <i>Limit of Methacrylic Acid and Ethyl Acrylate</i>	<i>First Supplement to USP39–NF34</i>	Online	25-Mar-2016		1-Apr-2016	<i>USP40–NF35</i>	<i>USP40–NF35</i>	Line 5 of <i>Standard solution</i> : Change Mix 10.0 mL of this solution to: Mix 5.0 mL of this solution AND

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							<p>Line 7 of <i>Standard solution</i>: Change about 0.67 µg/mL to: about 0.5 µg/mL</p> <p>Line 4 of <i>Sample solution</i>: Change 10.0 mL of this solution to: 5.0 mL of this solution</p> <p>AND</p> <p>In the variable definition list in <i>Analysis</i>: Change <math>V_F</math> = final volume of the <i>Sample solution</i>, 15 mL <math>D</math> = dilution factor for preparation of the <i>Sample solution</i>, 5</p>

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ARGININE HYDROLYSIS SPECIFIC ROCHLORIDE TESTS/ <i>Chloride</i> <i>Content</i>	USP38–NF33	2279	25-Mar-2016	1-Apr-2016	USP40–NF35	USP40–NF35	<p>to:  <math>V_F</math> = final volume of the <i>Sample solution</i>, 10 mL  <math>D</math> = dilution factor for preparation of the <i>Sample solution</i>, 10 mL</p> <p>Delete the subsection <i>Blank</i>: 140 mL of water and 1 mL of dichlorofluorescein TS AND  The equation in the <i>Analysis</i>:  Change  <math>\text{Result} = [(V ? B) \times N \times F \times 100] / W</math>  to:  <math>\text{Result} = (V \times N \times F \times 100) / W</math>  AND  Line 10 of <i>Analysis</i>: Delete <math>B = \text{Blank}</math> titrant volume (mL)</p>

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PLASTIC MATERIALS OF CONSTRUCTION	TEST METHOD S/ <i>Extractions/</i> <i>Table 3</i>	USP39–NF34	493	25-Mar-2016		1-Apr-2016	USP40–NF35	USP40–NF35	Column 4 of S3 row: Change Extractable metals: Al, Sb, As, Ba, Cd, Co, Ge, Hg, Mn, Ni, Pb, Ti, V, and Zn to: Extractable metals: Al, As, Ba, Cd, Co, Hg, Mn, Ni, Pb, Ti, V, and Zn
DIPHENHYDRAMINE HYDROCHLORIDE INJECTION	ASSAY/ <i>Procedure</i>	USP39–NF34	3529	25-Mar-2016		1-Apr-2016	USP40–NF35	USP40–NF35	Line 1 of <i>System suitability solution</i> : Change USP Diphenhydramine Hydrochloride Related Compound A RS to: USP Diphenhydramine Related Compound A RS AND Line 4 of

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									<p><i>System suitability:</i> Change for diphenhydramine hydrochloride related compound A and diphenhydramine hydrochloride are to: for diphenhydramine related compound A and diphenhydramine are</p>
PLASTIC MATERIALS OF CONSTRUCTION	SPECIFICATION	USP39–NF34	493	25-Mar-2016		1-Apr-2016	USP40–NF35	USP40–NF35	Line 1 of <i>Zirconium</i> : Change 1 µg/g. to:
	<i>Polymethylacrylate/Extractable Metals</i>								0.1 µg/g.
DISSOLUTION	INTERPRETATION/Immediate-Release Dosage Forms/Immediate-Release	USP39–NF34	540	25-Mar-2016		1-Apr-2016	USP40–NF35	USP40–NF35	Row 3 of Column 1 of <i>Acceptance Table for a Pooled Sample</i> : Change

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								<i>S<sub>1</sub></i> to: <i>S<sub>2</sub></i> AND Row 4 of Column 1 of <i>Acceptance Table for a Pooled Sample:</i> Change <i>S<sub>1</sub></i> to: <i>S<sub>3</sub></i>
DIGOXIN	IM PUR ITIES/Related Glyc osides/System suitability	<i>Interim Revision Announcement (Official November 01, 2015)</i>	Online	25-Mar-2016	1-Apr-2016	USP40–NF35	USP40–NF35	Line 2: Change <i>Sample: System suitability solution</i> to: <i>Samp les: System suitability solution and Standard solution</i> AND Line 2 of <i>Suitability requirements:</i> Change <i>Resolution: NLT</i>

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							<p>1.5 between the digoxin and lanatoside C peaks</p> <p><i>Relative standard deviation: NMT 2.0%, determined from the digoxin peak in replicated injections to:</i></p> <p><i>Resolution: NLT 1.5 between the digoxin and lanatoside C peaks, System suitability solution</i></p> <p><i>Relative standard deviation: NMT 2.0%, determined from the digoxin peak in replicated injections, Standard</i></p>



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HYDROCHLORIC ACID INJECTION <i>Procedure</i>	USP38–NF33	3770	29-Jan-2016	1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	<i>solution</i> Line 8 of Analysis: Change $F$ = equivalency factor, 18.23 mg/mEq to: $F$ = equivalency factor, 36.46 mg/mEq
DONEPEZIL HYDROCHLORIDE IM PURITIES/Organic Impurities/Procedure 2	First Supplement to USP38–NF33	7384	29-Jan-2016	1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	Footnote h of Table 3: Change 1-Benzyl-4-[(5,6-dimethoxyindan-2-yl)methyl]piperidine. to: 1-Benzyl-4-[(5,6-dimethoxyindan-2-yl)methyl]piperidine.
DEXAMETHASONE SODIUM PHOSPHATE INJECTION <i>Procedure</i>	Interim Revision Announcement (Official May 01, 2015)	Online	29-Jan-2016	1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	Line 9 of Analysis: Change $C_S$ = concentration of USP Dexamethasone Sodium

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GALANTAMINE IM HYDROBROMI PUR DE ITIES/ <i>Organic Impurities</i>	USP38–NF33	3646	29-Jan-2016	1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	Phosphate RS in the <i>Standard solution</i> (µg/mL) to: C <sub>S</sub> = concentration of USP Dexamethasone Sodium Phosphate RS in the <i>Standard solution</i> (mg/mL) Line 8 of <i>Analysis</i> : Change Result = (r <sub>U</sub> /r <sub>S</sub> ) × (C <sub>S</sub> /C <sub>U</sub> ) × (1/F) × (100/100 ? L) to: Result = (r <sub>U</sub> /r <sub>S</sub> ) × (C <sub>S</sub> /C <sub>U</sub> ) × (1/F) × (100/[100 ? L])
GLUCOSAMINE SULFATE POTASSIUM CHLORIDE CHEMICAL INFORMATION	USP38–NF33	6074	29-Jan-2016	1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	Line 5: Change [38899-05-7]. to: [1296149-08-0]
ALTEPLASE FOR ASSAY/ <i>Biological</i>	USP39–NF34	2401	29-Jan-2016	1-Feb-2016	USP40–NF35	Second Supplement to	Line 1 of <i>Human</i>

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INJECTION	<i>Potency</i>							<i>USP39–NF34</i>	<i>thrombin solution: Change 33 Units in terms of the U.S. Standard Thrombin/mL in Buffer to: 33 U.S. Units in terms of the U.S. Standard Thrombin/mL in Buffer AND Line 5 of Analysis: Change Standard solution and Sample solution, to: Standard solution or Sample solution, Line 4 of Procedure: Change Calculate the</i>
RISPERIDONE TABLETS	Assay	<i>USP38–NF33</i>	5195	29-Jan-2016		1-Feb-2016	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	<i>Line 4 of Procedure: Change Calculate the</i>

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IMIQUIMOD CREAM	SPECIFIC TESTS/pH <791>	<i>First Supplement to USP38–NF33</i>	7409	29-Jan-2016		1-Feb-2016	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	quantity, in mg, of risperidone to: Calculate the percentage of the labeled amount of risperidone Line 1 of <i>Sample</i> : Change Nominally 50 mg/mL of imiquimod from Cream in water. to: Nominally 2.5 mg/mL of imiquimod from Cream in water.
DEXAMETHASONE SODIUM PHOSPHATE OPHTHALMIC SOLUTION	ASSAY/ <i>Procedure</i>	<i>Interim Revision Announcement (Official May 01, 2015)</i>	Online	29-Jan-2016		1-Feb-2016	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	Line 9 of <i>Analysis</i> : Change $C_S$ = concentration of USP Dexamethasone Sodium Phosphate RS in the <i>Standard solution</i> ( $\mu\text{g/mL}$ ) to:

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GALANTAMINE PERFORMANC TABLETS E TESTS/ <i>Dissolution</i>	USP38–NF33	3649	29-Jan-2016	1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	<p><math>C_S =</math> concentration of USP Dexameth asone Sodium Phosphate RS in the <i>Standard solution</i> (mg/mL)</p> <p>Line 6 of <i>Analysis in Test 1</i>: Change Result = <math>(A_U/A_S)</math> <math>\times (C_S/L) \times</math> <math>(M_{r1}/M_{r2}) \times 100</math> to: Result = <math>(A_U/A_S)</math> <math>\times (C_S/L) \times</math> <math>(M_{r1}/M_{r2}) \times V \times</math> 100 AND Add to the variable definition list in <i>Test 1</i> <math>V =</math> volume of <i>Medium</i>, 500 mL AND Equation in <i>Test 3</i>: Change Result = <math>(r</math></p>

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									$\frac{u}{r_s} \times (C_s/L) \times (M_{r1}/M_{r2}) \times 100$ to: $\text{Result} = (r_u/r_s) \times (C_s/L) \times (M_{r1}/M_{r2}) \times V \times 100$ AND Add to the variable definition list in <i>Test 3</i> V = volume of <i>Medium</i> , 500 mL
GLUCOSAMINE SULFATE SODIUM CHLORIDE	CHEMICAL INFORMATION	USP38–NF33	6075	29-Jan-2016		1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	Line 5: Change [38899-05-7]. to: [1296149-13-7]
ROPINIROLE TABLETS	IMPURITIES/ <i>Organic Impurities</i>	USP39–NF34	5756	29-Jan-2016		1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	Footnote b of <i>Table 2</i> : Change 4-[2-(Dipropylnitro)ethyl]-1,3-dihydro-2H-indol-2-one. to: <i>N</i>

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DEXTROAMPH ASSAY/ ETAMINE SULFATE	<i>USP38–NF33</i>	3060	29-Jan-2016	1-Feb-2016	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	<p>-[2-(2-Oxoindolin-4-yl)eth yl]-N-propylpropan-1-amine oxide.</p> <p>Line 1 of <i>System suitability solution</i>: Change 0.02 µg/mL each of USP Dextroamphetamine Related Compound A RS and USP Dextroamphetamine Related Compound B RS in <i>Standard solution</i> to: Transfer about 40 mL of the <i>Standard solution</i> to a 50-mL volumetric flask. Using a microliter</p>

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TAMSULOSIN ASSAY/ HYDROCHLORIDE CAPSULES	USP38–NF33	5442	29-Jan-2016	1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	syringe, add 1 µL each of USP Dextroamphetamine Related Compound A RS and USP Dextroamphetamine Related Compound B RS. Dilute with <i>Standard solution</i> to volume. Line 1 of <i>Standard solution</i> : Change Prepare a solution containing 1.0 mg/mL of USP Tamsulosin Hydrochloride RS in methanol. to: Prepare a solution containing 0.1 mg/mL of USP Tamsulosin Hydrochloride



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ALTEPLASE	ASSAY/ <i>Biological Potency</i>	USP39–NF34	2398	29-Jan-2016		1-Feb-2016	USP40–NF35	<i>Second Supplement to USP39–NF34</i>	<p>RS in methanol. AND Line 6 of <i>Sample solution:</i> Change Add 30 mL of <i>Mobile phase</i>, and shake by mechanical means for 30 min. to: Add 30 mL of <i>Mobile phase</i>, shake by mechanical means for 30 min, and dilute with <i>Mobile phase</i> to volume.</p> <p>Line 1 of <i>Human thrombin solution:</i> Change 33 Units in terms of the U.S. Standard Thrombin/mL in</p>

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							<i>Buffer</i> to: 33 U.S. Units in terms of the U.S. Standard Thrombin/mL in <i>Buffer</i> AND Line 5 of <i>Analysis:</i> Change <i>Standard solution</i> and <i>Sample solution</i> , to: <i>Standard solution</i> or <i>Sample solution</i> , Line 4 of <i>Medium:</i> Change 6 g/L to: 10 g/L
NIFEDIPINE EXPERFORMANC TENDED- RELEASE TABLETS	Revision <i>Bulletin (Official</i> <i>December 01,</i> <i>2015)</i> <i>Dissolution</i> <711>/ <i>Test 9</i>	Online	29-Jan-2016	1-Feb-2016	USP40–NF35	Second <i>Supplement to</i> USP39–NF34	Line 4 of <i>Medium:</i> Change 6 g/L to: 10 g/L
ATOMIC ABSORPTION SPECTROSCO PY	VALIDATION AND VERIFICA TION/ <i>Precisi</i> <i>on/Intermediate</i>	USP38–NF33 649	20-Nov-2015	1-Dec-2015	USP40–NF35	Second <i>Supplement to</i> USP39–NF34	Line 3: Change As a minimum, the analytical procedure should be

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<i>Precision</i>							assessed by performing the repeatability test in any of the conditions previously mentioned (totaling 12 measurements). to: As a minimum, the analytical procedure should be assessed by performing the repeatability test in any combination of at least two of the conditions previously mentioned (totaling 12 measurements).
OLOPATADINE IM HYDROCHLOR PURITIES/ <i>Limit</i> IDE <i>of Late Eluting</i> OPHTHALMIC <i>Impurities</i> SOLUTION	USP38–NF33	4625	20-Nov-2015	1-Dec-2015	USP40–NF35	<i>Second Supplement to USP39–NF34</i>	Add [Note–Protect solutions from light.]
MILK THISTLE COMPOSITION	<i>Second</i>	7878	20-Nov-2015	1-Dec-2015	USP40–NF35	<i>Second</i>	Line 3 of

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<i>/Content of Silymarin</i>	<i>Supplement to USP38–NF33</i>					<i>Supplement to USP39–NF34</i>	<p><i>Sample stock solution:</i>  Change  Transfer the thimble to a continuous-extraction apparatus fitted with a 250-mL round-bottom flask containing 150 mL of hexane, and heat the flask on a heating mantle for 4 h. After the extraction, detach the round-bottom flask from the extraction apparatus, and discard the hexane. Dry the extraction thimble to remove residual hexane,  to:  Transfer the</p>

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LOPINAVIR AND RITONAVIR ORAL SOLUTION	IM PUR ITIES/ <i>Organic Impurities</i>	<i>Second Supplement to USP38–NF33</i>	8139	20-Nov-2015		1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	thimble to a continuous-extraction apparatus fitted with a 250-mL round-bottom flask containing 150 mL of solvent hexane, and heat the flask on a heating mantle for 4 h. After the extraction, detach the round-bottom flask from the extraction apparatus, and discard the solvent hexane. Dry the extraction thimble to remove residual solvent hexane, Row 17 of Column 3 of Table 2: Change 0.2

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ISOSORBIDE MONONITRAT E TABLETS	<i>USP Reference standards &lt;11&gt;</i>	<i>USP38–NF33</i>	3974	20-Nov-2015		1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	to: 0.2 <sup>p</sup> AND Add footnote <sup>p</sup> Disregard any peak less than 0.01%. Line 2 of USP Diluted Isosorbide Mononitrate Related Compound A RS: Change 1,4:3,5-Dianhydro-D-glucitol 2-nitrate. to: 1,4:3,6-Dianhydro-D-glucitol 2-nitrate.
METAXALONE TABLETS	PERFORMANC E TESTS/ <i>Dissolution</i> <711>	<i>First Supplement to USP38–NF33</i>	7432	20-Nov-2015		1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	Line 2 of <i>Buffer, Mobile phase, Chromatographic system, and System suitability</i> . Change Proceed as directed in the Assay.

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CORTICOTRO ASSAY/ PIN FOR Procedure INJECTION	<i>Second Supplement to USP38–NF33</i>	8061	20-Nov-2015	1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	<p>to: Proceed as directed in the Assay, except use 270 nm for analysis. AND Line 10 of <i>Analysis</i>: Change V = volume of the <i>Medium</i>, 750 mL to: V = volume of the <i>Medium</i>, 900 mL Line 7 of <i>Replication</i>: Change (see &lt;111&gt;, <i>Confidence Intervals for Individual Assays</i>). to: (see &lt;111&gt;, <i>The Confidence Interval and Limits of Potency</i>).</p>

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PACKAGING AND STORAGE REQUIREMENTS	GENERAL DEFINITIONS	USP38–NF33	447	20-Nov-2015		1-Dec-2015	USP40–NF35	<i>Second Supplement to USP39–NF34</i>	Line 1 of <i>Single-Dose</i> (see also <i>Injections &lt;1&gt;</i> , <i>Containers for Injections</i> ): Change A single-unit package for an article intended for parenteral administration. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled. to: A single-unit package for an article intended for parenteral administration. A single-dose container is



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CYCLOBENZA IM PRINE HYDRO PUR CHLORIDE TABLETS	<i>ITIES/Organic Impurities/Analysis</i>	USP38–NF33 2972	20-Nov-2015	1-Dec-2015	USP40–NF35	<i>Second Supplement to USP39–NF34</i>	<p>labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.</p> <p>Line 3: Change Calculate the percentage of any individual unspecified degradation product to: Calculate the percentage of any individual degradation product AND Line 6: Change <math>r_U</math> = peak response of any individual</p>

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LIGHT MINERAL OIL	SPECIFIC TESTS/ <i>Readily Carbonizable Substances Test &lt;271&gt;</i>	USP38–NF33	6763	20-Nov-2015		1-Dec-2015	USP40–NF35	<i>Second Supplement to USP39–NF34</i>	<p>unspecified degradation product from the <i>Sample solution</i> to:  <math>r_U</math> = peak response of any individual degradation product from the <i>Sample solution</i></p> <p>Line 1 of <i>Acceptance criteria</i>: Change The <i>Sample</i> may turn hazy, but it remains colorless, or shows a slight pink or yellow color, and the <i>Sample</i> does not become darker than the <i>Standard solution</i>.  to:  The oil portion of the <i>Sample</i></p>

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POWDERED MILK THISTLE	COMPOSITION	<i>Second Supplement to USP38–NF33</i>	7880	20-Nov-2015		1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	may turn hazy, but it remains colorless or shows a slight pink or yellow color, and the acid portion of the <i>Sample</i> does not become darker than the <i>Standard solution</i> . Line 3 of <i>Sample stock solution</i> : Change Transfer the thimble to a continuous-extraction apparatus fitted with a 250-mL round-bottom flask containing 150 mL of hexane, and heat the flask on a heating mantle for 4 h. After the

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							<p>extraction, detach the round-bottom flask from the extraction apparatus, and discard the hexane. Dry the extraction thimble to remove residual hexane, to:</p> <p>Transfer the thimble to a continuous-extraction apparatus fitted with a 250-mL round-bottom flask containing 150 mL of solvent hexane, and heat the flask on a heating mantle for 4 h. After the extraction, detach the round-bottom flask from the</p>

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MOEXIPRIL HYIM DROCHLORID PUR E AND HYDRO ITIES/ <i>Organic Chlorothiaz Impurities</i> IDE TABLETS	<i>Second Supplement to USP38–NF33</i>	8158	20-Nov-2015	1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	extraction apparatus, and discard the solvent hexane. Dry the extraction thimble to remove residual solvent hexane, Row 6 of Column 2 of Table 5: Change 0.62 to: 0.82
INHALATION C. AERODYNA AND NASAL MIC SIZE DIST DRUG PRODU RIBUTION—INH CTS—AEROSOALATION LS, SPRAYS, AEROSOLS, AND POWDER SPRAYS, AND S—PERFORMAPOWDERS NCE QUALITY TESTS	<i>USP38–NF33</i>	388	20-Nov-2015	1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	Line 13 of paragraph 2 of C.3 Apparatus 2 for Inhalation Powders—Marple Miller Impactor/C.3.1 Design—Apparatus 2: Change Adjust the timer controlling the operation of the two-way solenoid valve so that it opens

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							<p>this valve for a duration of <math>T</math> seconds as determined during testing for <i>Delivered-Dose Uniformity</i>.</p> <p>to:</p> <p>Adjust the timer controlling the operation of the two-way solenoid valve so that it opens this valve for a duration such that the total volume sampled is at least 4 L.</p> <p>AND</p> <p>Line 3 of paragraph 2 of <i>C.4 Apparatus 3 for Inhalation Powders—Andersen Impactor (with pre-separator)</i>/C.4.1 Design—Apparat</p>

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							<p><i>us 3: Change</i>  Once the product is positioned, discharge the powder into the apparatus by activating the timer and opening the two-way solenoid valve for the required duration, <math>T \pm 5\%</math>, as determined during testing for <i>Delivered-Dose Uniformity</i>.  to:  Once the product is positioned, discharge the powder into the apparatus by activating the timer and opening the two-way solenoid</p>

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							<p>valve for the required duration such that the total volume sampled is at least 4 L.</p> <p>AND</p> <p>Line 19 of paragraph 2 of <i>C.5 Apparatus 4 for Inhalation Powders—Multistage Liquid Impinger/C.5.1 Design—Apparatus 4</i>: Change Adjust the timer controlling the operation of the two-way solenoid valve so that it opens the valve for the same duration, <i>T</i>, as used during testing for <i>Delivered-Dose Uniformity</i>.</p> <p>to:</p>



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							<p>Adjust the timer controlling the operation of the two-way solenoid valve so that it opens the valve for the duration such that the total volume sampled is at least 4 L.</p> <p>AND</p> <p>Line 9 of paragraph 4 of <i>C.6 Apparatus 5 for Inhalation Powders—Next Generation Impactor (with pre-separator)/C.6.2 Procedure—Apparatus 5:</i></p> <p>Change</p> <p>Adjust the timer controlling the operation of the two-way solenoid valve</p>

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OLMESARTAN IM MEDOXOMIL PUR ITIES/ <i>Organic Impurities</i>	<i>USP38–NF33</i>	4622	20-Nov-2015	1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	<p>so that it opens the valve for the same duration, <i>T</i>, as used during testing for <i>Delivered-Dose Uniformity</i>.</p> <p>to: Adjust the timer controlling the operation of the two-way solenoid valve so that it opens this valve for a duration such that the total volume sampled is at least 4 L.</p> <p>Footnote d of <i>Impurity Table: Change</i> (5-Methyl-2-oxo-1,3-dioxol-4-yl) methyl 4-(2-hydroxypropan-2-yl)-2-propyl-1-((2?)-(2-trityl-1H</p>

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							-tetrazol-5-yl)biphenyl-4-yl)methyl)-1 <i>H</i> -imidazole-5-carboxylate. to: (5-Methyl-2-oxo-1,3-dioxol-4-yl)methyl 4-(2-hydroxypropan-2-yl)-2-propyl-1-((2?-(2-trityl-2 <i>H</i> -tetrazol-5-yl)biphenyl-4-yl)methyl)-1 <i>H</i> -imidazole-5-carboxylate.

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