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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 Aminosalicyclic Acid Tablets will result in anything that contains “Aminosalicyclic” OR “Acid” OR “Tablets”
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- **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.
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- **Downloading:** You can download the Errata table in Comma-separated Value (.csv). The download will include the Errata that you have filtered on.
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CANDESARTA IM	USP39–NF34	2895	25-Mar-2016	1-Apr-2016	USP40–NF35	USP40–NF35	Row 3 of

Monograph Title Section	Source Publication	Page Number	Errata Post Date Sort ascending	Errata Official Date	Target Errata Print Publication	Target Online Fix Publication	Description
N CILEXETIL PUR AND HYDROCHLORIDE TABLETS HLOTIAZIDE TABLETS ITIES/ <i>Organic Impurities</i>							Column 1 of <i>Table 6</i> : Change Candesartan related compound A ^{b,c} to: Candesartan cilexetil related compound A ^{b,c}
MEMANTINE HYDROCHLORIDE TABLETS ITIES/ <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 Compound E

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RESIDUAL HOST CELL PROTEIN MEA SUREMENT IN V BIOPHARMAC EUTICALS	4. HCP IMMUN OASSAY METHOD ALIDATION/4.3 <i>Sample</i> <i>Linearity/Table</i> 4	<i>Second</i> <i>Supplement to</i> <i>USP38–NF33</i>	7647	25-Mar-2016		1-Apr-2016	<i>USP40–NF35</i>	<i>USP40–NF35</i>	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> <i>Product column:</i> 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</i> <i>ratio column:</i> Change

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							<p>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 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 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/% max ratio value</i> column: Change</p>

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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>	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	IMPURITIES/ <i>Limit Supplement to of Methacrylic Acid and Ethyl Acrylate</i>	<i>First 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 Line 7 of

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							<p><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 V_F = final volume of the <i>Sample solution</i>, 15 mL D = dilution factor for preparation of the <i>Sample solution</i>, 5 to:</p>

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ARGININE HYDSPECIFIC ROCHLORIDE TESTS/ <i>Chloride Content</i>	USP38–NF33	2279	25-Mar-2016	1-Apr-2016	USP40–NF35	USP40–NF35	<p>V_F = final volume of the <i>Sample solution</i>, 10 mL D = dilution factor for preparation of the <i>Sample solution</i>, 10</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 Result = $[(V ? B) \times N \times F \times 100] / W$ to: Result = $(V \times N \times F \times 100) / W$ AND Line 10 of <i>Analysis</i>: Delete $B = \textit{Blank}$ titrant volume (mL)</p>
PLASTIC TEST	USP39–NF34	493	25-Mar-2016	1-Apr-2016	USP40–NF35	USP40–NF35	Column 4 of S3

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MATERIALS OF CONSTRUCTION	ME THODS/ <i>Extractions/</i> <i>Table 3</i>								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 <i>System</i>

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									<i>suitability:</i> Change for diphenhydramine hydrochloride related compound A and diphenhydramine hydrochloride are to: for diphenhydramine related compound A and diphenhydramine are
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: 0.1 µg/g.
DISSOLUTION	INTERPRETATION/Immediate-Release Dosage Forms/Immediate-Release Dosage Forms	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 S ₁ to:

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									<p><i>Pooled Sample</i></p> <p>S₂ AND Row 4 of Column 1 of <i>Acceptance Table for a Pooled Sample:</i> Change S₁ to: S₃</p>
DIGOXIN	IM PUR ITIES/ <i>Related Glyc osides/System suitability</i>	<i>Interim Revision Announcement (Official November 01, 2015)</i>	Online	25-Mar-2016		1-Apr-2016	USP40–NF35	USP40–NF35	<p>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 1.5 between the digoxin and</i></p>

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HYDROCHLOR ASSAY/	USP38–NF33	3770	29-Jan-2016	1-Feb-2016	USP40–NF35	Second	lanatoside C peaks <i>Relative standard deviation:</i> NMT 2.0%, determined from the digoxin peak in replicated injections to: <i>Resolution:</i> NLT 1.5 between the digoxin and lanatoside C peaks, <i>System suitability solution</i> <i>Relative standard deviation:</i> NMT 2.0%, determined from the digoxin peak in replicated injections, <i>Standard solution</i> Line 8 of

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IC ACID INJECTION	<i>Procedure</i>							<i>Supplement to USP39–NF34</i>	<i>Analysis: Change F = equivalency factor, 18.23 mg/mEq to: F = equivalency factor, 36.46 mg/mEq</i>
DONEPEZIL HYDROCHLORIDE	IM PURITIES/ <i>Organic Impurities/Procedure 2</i>	<i>First Supplement to USP38–NF33</i>	7384	29-Jan-2016		1-Feb-2016	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	<i>Footnote h of Table 3: Change 1-Benzyl-4-[(5,6-dimethoxyindan-2-yl)methyl]piperidine. to: 1-Benzyl-4-[(5,6-dimethoxyinden-2-yl)methyl]piperidine.</i>
DEXAMETHASONE SODIUM PHOSPHATE INJECTION	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>	<i>Line 9 of Analysis: Change C_S = concentration of USP Dexamethasone Sodium Phosphate RS in the Standard</i>

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GALANTAMINE IM HYDROBROMI DE	PUR ITIES/ <i>Organic Impurities</i>	USP38–NF33	3646	29-Jan-2016		1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	<p><i>solution</i> (µg/mL) to: $C_S =$ concentration of USP Dexameth asone Sodium Phosphate RS in the <i>Standard solution</i> (mg/mL) Line 8 of <i>Analysis:</i> Change Result = (r_U/r_S) $\times (C_S/C_U) \times$ $(1/F) \times (100/100$ $? L)$ to: Result = (r_U/r_S) $\times (C_S/C_U) \times$ $(1/F) \times$ $(100/[100 ? L])$</p>
GLUCOSAMIN E SULFATE POTASSIUM CHLORIDE	CHEMICAL INFORMATION	USP38–NF33	6074	29-Jan-2016		1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	<p>Line 5: Change [38899-05-7]. to: [1296149-08-0]</p>
ALTEPLASE FOR INJECTION	ASSAY/ <i>Biological Potency</i>	USP39–NF34	2401	29-Jan-2016		1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	<p>Line 1 of <i>Human thrombin solution:</i></p>

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RISPERIDONE Assay TABLETS	USP38–NF33	5195	29-Jan-2016	1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	<p>Change 33 Units in terms of the U.S. Standard Thrombin/mL in <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>Procedure</i>: Change Calculate the quantity, in mg, of risperidone</p>

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IMIQUIMOD CREAM	SPECIFIC TESTS/pH <791>	<i>First Supplement to USP38–NF33</i>	7409	29-Jan-2016		1-Feb-2016	USP40–NF35	<i>Second Supplement to USP39–NF34</i>	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	USP40–NF35	<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: $C_S =$ concentration of

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

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									$r_1/M_{r2}) \times 100$ 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: N-[2-(2-Oxoindolin-4

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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>	-yl)eth yl]-N -propylpropan-1 -amine oxide. Line 1 of <i>System suitability solution:</i> Change 0.02 µg/mL each of USP De xtroamphetamin e Related Compound A RS and USP De xtroamphetamin e 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 syringe, add 1 µL each of USP

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TAMSULOSIN ASSAY/ HYDROCHLORIDE CAPSULES	USP38–NF33	5442	29-Jan-2016	1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	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 RS in methanol. AND

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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>Line 6 of <i>Sample solution</i>: Change Add 30 mL of <i>Mobile phase</i>, and shake by mechanical means for 30 min.</p> <p>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 <i>Buffer</i></p> <p>to:</p>

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									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,
NIFEDIPINE EXPERFORMANC TENDED- RELEASE TABLETS	E TESTS/ Dissolution <711>/Test 9	Revision Bulletin (Official December 01, 2015)	Online	29-Jan-2016		1-Feb-2016	USP40–NF35	Second Supplement to USP39–NF34	Line 4 of Medium: Change 6 g/L to: 10 g/L
ATOMIC ABSORPTION SPECTROSCOPY	VALIDATION AND VERIFICATION/ Precision/Intermediate Precision	USP38–NF33	649	20-Nov-2015		1-Dec-2015	USP40–NF35	Second Supplement to USP39–NF34	Line 3: Change As a minimum, the analytical procedure should be assessed by performing the

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							<p>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).</p>
OLOPATADINE IM HYDROCHLOR PURITIES/ <i>Limit</i> IDE <i>of Late Eluting</i> OPHTHALMIC <i>Impurities</i> SOLUTION	<i>USP38–NF33</i>	4625	20-Nov-2015	1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	<p>Add [Note–Protect solutions from light.]</p>
MILK THISTLE COMPOSITION <i>/Content of Silymarin</i>	<i>Second Supplement to USP38–NF33</i>	7878	20-Nov-2015	1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	<p>Line 3 of <i>Sample stock solution:</i></p>

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							<p>Change</p> <p>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:</p> <p>Transfer the thimble to a continuous-</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>	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 to: 0.2 ^p

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ISOSORBIDE MONONITRATE E TABLETS	<i>USP Reference standards <11></i>	<i>USP38–NF33</i>	3974	20-Nov-2015		1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	AND Add footnote ^p 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 PERFORMANCE TABLETS	<i>TESTS/ Dissolution <711></i>	<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. to: Proceed as

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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>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</p> <p>Line 7 of <i>Replication</i>: Change (see <111>, <i>Confidence Intervals for Individual Assays</i>). to: (see <111>, <i>The Confidence Interval and Limits of Potency</i>).</p>
PACKAGING AND GENERAL DEFINITIONS	<i>USP38–NF33</i>	447	20-Nov-2015	1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to</i>	Line 1 of <i>Single-Dose</i> (see also

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STORAGE RE QUIREMENTS						USP39–NF34	<p><i>Injections <1>, 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.</p> <p>to: A single-unit package for an article intended for parenteral administration. A single-dose container is labeled as such. Examples of</p>

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CYCLOBENZA IM PRINE HYDRO PUR CHLORIDE ITIES/ <i>Organic</i> TABLETS <i>Impurities/Analysis</i>	USP38–NF33	2972	20-Nov-2015	1-Dec-2015	USP40–NF35	<i>Second Supplement to USP39–NF34</i>	<p>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 r_U = peak response of any individual unspecified degradation</p>

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LIGHT MINERAL OIL	SPECIFIC TESTS/ <i>Readily Carbonizable Substances Test <271></i>	USP38–NF33	6763	20-Nov-2015		1-Dec-2015	USP40–NF35	<i>Second Supplement to USP39–NF34</i>	product from the <i>Sample solution</i> to: r_U = peak response of any individual degradation product from the <i>Sample solution</i> 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> may turn hazy, but it remains

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POWDERED MILK THISTLE	COMPOSITION <i>/Content of Silymarin</i>	<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>	<p>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>.</p> <p>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 extraction, detach the</p>

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							<p>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 extraction apparatus, and</p>

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MOEXIPRIL HYIM DROCHLORID PUR E AND HYDRO ITIES/ <i>Organic</i> CHLOROTHIAZ <i>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>	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 this valve for a duration of <i>T</i>

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							<p>seconds as determined during testing for <i>Delivered-Dose Uniformity</i>. 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. AND Line 3 of paragraph 2 of <i>C.4 Apparatus 3 for Inhalation Powders—Andersen Impactor (with pre-separator)</i>/C.4.1 Design—Apparatus 3: Change Once the</p>

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

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							<p>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: Adjust the timer controlling the</p>

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							<p>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 pr e-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 so that it opens the valve for the</p>

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OLMESARTAN IM MEDOXOMIL PUR ITIES/ <i>Organic Impurities</i>	USP38–NF33	4622	20-Nov-2015	1-Dec-2015	USP40–NF35	<i>Second Supplement to USP39–NF34</i>	<p>same duration, <i>T</i>, as used during testing for <i>Delivered-Dose Uniformity</i>. 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-1<i>H</i>-tetrazol-5-yl)biphenyl-4-yl)meth</p>

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DESCRIPTION SUNFLOWER AND OIL SOLUBILITY		<i>Second Supplement to USP38–NF33</i>	7761	20-Nov-2015		1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	<p>yl)-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. Line 5: Change <i>NF category</i>: Coating agent; emollient; solvent; tablet and/or capsule diluent; vehicle (oleaginous). to: <i>NF category</i>: Coating agent; emollient; solvent; diluent; vehicle (oleaginous).</p>

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REPOSITORY ASSAY/ CORTICOTRO Procedure PIN INJECTION	<i>Second Supplement to USP38–NF33</i>	8063	20-Nov-2015	1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	Line 7 of Replication: Change (see <111>, Confidence Intervals for Individual Assays). to: (see <111>, The Confidence Interval and Limits of Potency).
DILUTED ISOSORBIDE MONONITRATE E	<i>USP Reference standards <11></i>	USP38–NF33 3973	20-Nov-2015	1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	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.
CEFDINIR FOR PERFORMANC ORAL E SUSPENSION TESTS/	<i>First Supplement to USP38–NF33</i>	7357	20-Nov-2015	1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	Line 5 of Analysis: Change

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<i>Dissolution</i> <711>							Result = $(A_U/A_S) \times C_S \times d \times V \times D \times (1/L) \times 100$ to: Result = $(A_U/A_S) \times C_S \times (d/W_U) \times V \times D \times (1/L) \times 100$ AND Add to the variable definition list W_U = weight of reconstituted Cefdinir for Oral Suspension taken (mg) Line 7 of <i>Replication</i> : Change (see <111>, <i>Confidence Intervals for Individual Assays</i>). to: (see <111>, <i>The Confidence Interval and Limits of Potency</i>).
CORTICOTRO ASSAY/ PIN INJECTION <i>Procedure</i>	<i>Second Supplement to USP38–NF33</i>	8059	20-Nov-2015	1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	

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MANNITOL INJECTION	<i>Specific rotation</i> <781>	<i>Second Supplement to USP38–NF33</i>	Online	20-Nov-2015		1-Dec-2015	<i>USP40–NF35</i>	<i>Second Supplement to USP39–NF34</i>	Line 1: Change Transfer an accurately measured volume of Injection, equivalent to about 1 g of mannitol as determined by the Assay, to a 100-mL volumetric flask:it meets the requirements of the test for <i>Specific rotation</i> under <i>Mannitol</i> . to: +137° to +145°.Transfer an accurately measured volume of Injection, equivalent to about 1 g of mannitol as determined by the Assay, to a

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RIVASTIGMINE IM PUR ITIES/ <i>Organic Impurities</i>	USP38–NF33	5212	25-Sep-2015	1-Oct-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	100-mL volumetric flask. Add 40 mL of a 1-in-10 ammonium molybdate solution, previously filtered if necessary. Add 20 mL of 1 N sulfuric acid, and dilute with water to volume. Row 3 of Column 1 of <i>Table 1</i> : Change Nor impurity (rivastigmine related compound B) to: Nor impurity ^a AND Add footnote a: ^a (S)?3?[1?(Dimethy lamino)ethyl]ph enyl dimethylcar

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ROPIVACAINE <i>USP Reference Standards</i> <11> HYDROCHLORIDE INJECTION	USP38–NF33	5227	25-Sep-2015	1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	<p>bamate (racemic mixture is rivastigmine related compound B). Line 2 of USP Ropivacaine Related Compound B RS: Change (R)-ropivacaine hydrochloride monohydrate; (R)-(?)-1-propylpiperidine-2-carboxylic acid (2,6-dimethylphenyl)-amide hydrochloride monohydrate. to: (R)-Ropivacaine hydrochloride monohydrate; (R)-(+)-1-propylpiperidine-2-carboxylic acid (2,6-di</p>

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CALCIUM LACTATE TABLETS	ASSAY/ <i>Procedure</i>	USP38–NF33	2553	25-Sep-2015	1-Oct-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	<p>methylphenyl)-amide hydrochloride monohydrate.</p> <p>Line 3 of <i>Analysis:</i> Change</p> <p>While stirring, add 30 mL of <i>Titrant</i> from a 50-mL buret.</p> <p>to:</p> <p>While stirring, add 15 mL of <i>Titrant</i> from a 50-mL buret.</p>

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