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		Publication		Date	Date	Print Publication	Fix Publication		
DILUTED		<i>USP Reference</i>	<i>USP38–NF33</i>	3973	20-Nov-2015	1-Dec-2015	<i>USP40–NF35</i>	<i>Second</i>	Line 2 of USP

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ISOSORBIDE MONONITRAT E	<i>standards <11></i>							<i>Supplement to USP39–NF34</i>	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 SUSPENSION TESTS/ Dissolution <711>	E	<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 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

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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>	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>).
MANNITOL INJECTION	<i>Specific rotation <781></i> <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

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							<p>requirements of the test for <i>Specific rotation under Mannitol</i>. to:</p> <p>+137° to +145°. 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. 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.</p>

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ATOMIC ABSORPTION SPECTROSCOPY	VALIDATION AND VERIFICATION/ <i>Precision/Intermediate Precision</i>	USP38–NF33	649	20-Nov-2015		1-Dec-2015	USP40–NF35	<i>Second Supplement to USP39–NF34</i>	Line 3: Change As a minimum, the analytical procedure should be 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		USP38–NF33	4625	20-Nov-2015		1-Dec-2015	USP40–NF35	<i>Second</i>	Add

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HYDROCHLORIDE OPHTHALMIC SOLUTION	PURITIES/ <i>Limit of Late Eluting Impurities</i>							<i>Supplement to USP39–NF34</i>	[Note–Protect solutions from light.]
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>	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 round-bottom flask from the extraction apparatus, and discard the hexane. Dry the extraction

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							<p>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 discard the solvent hexane. Dry the extraction thimble to remove residual solvent hexane,</p>

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LOPINAVIR AND RITONAVIR ORAL SOLUTION	IM PURITIES/ <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>	Row 17 of Column 3 of Table 2: Change 0.2 to: 0.2 ^P AND Add footnote ^P Disregard any peak less than 0.01%.
ISOSORBIDE MONONITRATE 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>	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	PERFORMANCE TESTS/ <i>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</i>

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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><i>suitability:</i> Change Proceed as directed in the Assay. 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 <111>, <i>Confidence Intervals for Individual Assays</i>). to:</p>

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PACKAGING AND STORAGE REQUIREMENTS	GENERAL DEFINITIONS	USP38–NF33	447	20-Nov-2015		1-Dec-2015	USP40–NF35	Second Supplement to USP39–NF34	(see <111>, <i>The Confidence Interval and Limits of Potency</i>). Line 1 of <i>Single-Dose</i> (see also <i>Injections <1></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

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CYCLOBENZA IM PRINE HYDRO PUR CHLORIDE TABLETS	ITIES/ <i>Organic Impuri ties/Analysis</i>	USP38–NF33 2972	20-Nov-2015	1-Dec-2015	USP40–NF35	<i>Second Supplement to USP39–NF34</i>	<p>article intended for parenteral administration. A single-dose container is 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</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>	<p>AND</p> <p>Line 6: Change $r_U = \text{peak response of any individual unspecified degradation product from the Sample solution}$ to:</p> <p>$r_U = \text{peak response of any individual degradation product from the Sample solution}$</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</p>

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POWDERED MILK THISTLE	COMPOSITION /Content of Silymarin	Second Supplement to USP38–NF33	7880	20-Nov-2015		1-Dec-2015	USP40–NF35	Second Supplement to USP39–NF34	<p><i>Standard solution.</i></p> <p>to:</p> <p>The oil portion of the <i>Sample</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></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</p>

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							<p>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-extraction apparatus fitted with a 250-mL round-bottom flask containing 150 mL of solvent hexane, and heat the flask on a heating mantle</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>	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 6 of Column 2 of <i>Table 5: Change 0.62 to: 0.82</i>
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 <i>C.3 Apparatus 2 for Inhalation Powders—Marple Miller Impactor/C.3.1 Design—Apparatus 2: Change Adjust the timer</i>

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							<p>controlling the operation of the two-way solenoid valve so that it opens this valve for a duration of T 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 P</i></p>

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							<p><i>owders—Anders en Impactor (with pre-separator)/C.4.1 Design—Apparatus 3: Change</i></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 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</p>

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							<p>apparatus by activating the timer and opening the two-way solenoid 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</p>

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							<p>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 the valve for the duration such that the total volume sampled is at least 4 L. AND 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>: Change</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>	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> . 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. Footnote d of <i>Impurity Table: Change (5-Methyl-2-oxo-1,3-dioxol-4-yl)</i>

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BROMPHENIRAMINE MALEATE	SPECIFIC TESTS/ <i>Optical Rotation, Specific Rotation</i> <781>	USP38–NF33	2475	25-Sep-2015		1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	<p>methyl 4-(2-hydroxypropan-2-yl)-2-propyl-1-((2?-(2-trityl-2H-tetrazol-5-yl)biphenyl-4-yl)methyl)-1H-imidazole-5-carboxylate.</p> <p>to:</p> <p>(5-Methyl-2-oxo-1,3-dioxol-4-yl)methyl 4-(2-hydroxypropan-2-yl)-2-propyl-1-((2?-(2-trityl-2H-tetrazol-5-yl)biphenyl-4-yl)methyl)-1H-imidazole-5-carboxylate.</p> <p>Line 1: Delete <i>Specific Rotation</i> AND Line 1 of <i>Sample: Change</i> 100 mg/mL in</p>

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IPRATROPIUM BROMIDE	DEFINITION	USP38–NF33	3932	25-Sep-2015		1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	water to: 100 mg/mL in water at 20° Line 2: Change (C ₂₀ H ₃₀ BrNO ₃ · H ₂ O) to: (C ₂₀ H ₃₀ BrNO ₃)
OXAZEPAM	SPECIFIC TESTS/pH <791>	USP38–NF33	4683	25-Sep-2015		1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	Line 1: Change Sample solution: 20 mg/mL to: Sample: A suspension of 1 g of Oxazepam in 50 mL water
RIVASTIGMINE IM TARTRATE	PURITIES/Organic Impurities/Procedure 1	USP38–NF33	5213	25-Sep-2015		1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	Footnote c of Impurity Table 1: Change (S)-3-[1-(Dimethylamino)ethyl]phenyl dimethylcarbamate (rivastigmine related compound B). to: (S

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SODIUM STEARYL FUMARATE	SPECIFIC TESTS/ <i>Fats and Oils, Saponification Value <401></i>	USP38–NF33	6877	25-Sep-2015		1-Oct-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>)?3?[1?(Dimethylamino)ethyl]phenyl dimethylcarbamate (racemic mixture is rivastigmine related compound B). Line 6 of <i>Analysis</i> : Change Rinse the condenser with two 10-mL portions of 70% alcohol, add phenolphthalein TS, to: Rinse the condenser with 10 mL of 70% alcohol, followed by three 10-mL portions of water, collecting the rinsings in the flask. Cool, rinse the sides

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ANTIBIOTICS—APPENDIX 1. MICROBIAL ASSAYS FORMULAS FOR MANUAL CALCULATION S OF REGRESSION AND SAMPLE CONCENTRATI ON	USP38–NF33	133	25-Sep-2015	1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	of the flask with two 10-mL portions of 70% alcohol, add phenolphthalein TS, Line 19: Change $b = [(4 \times 17.222) + (2 \times 16.511) ? (2 \times 14.989) ? (4 \times 14.020)] / \{5[\ln(7.81) ? \ln(3.2)]\} = 3.551$ to: $b = [(4 \times 17.222) + (2 \times 16.511) ? (2 \times 14.989) ? (4 \times 14.020)] / \{5[\ln(7.81) ? \ln(3.2)]\} = 3.551$
ETHOTOIN <i>Related com pounds/ Procedure</i>	USP38–NF33	3415	25-Sep-2015	1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	Line 11:Change weight, in mg, on the anhydrous basis, of the portion of Ethotoin taken; to:

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NALOXONE HYIM DROCHLORID PUR E ITIES/ <i>Noroxymorphon e Hydrochloride [(?)-4,5?-Epoxy- 3,14-Dihydroxy morphinan-6-on e-hydrochloride] and Other Impuri ties/ Chromatographi c system</i>	USP38–NF33	4486	25-Sep-2015	1-Oct-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	weight, in mg, of the portion of Ethotoin taken; Add <i>Application volume: 5 µL</i>
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>	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

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ROPIVACAINE USP Reference HYDROCHLOR standards <11> IDE INJECTION	USP38–NF33	5227	25-Sep-2015	1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	lamino)ethyl]phenyl dimethylcarbamate (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-dimethylphenyl)-amide hydrochloride monohydrate.

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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>	eridine-2-carboxylic acid (2,6-dimethylphenyl)-amide hydrochloride monohydrate. Line 3 of <i>Analysis</i> : Change While stirring, add 30 mL of <i>Titrant</i> from a 50-mL buret. to: While stirring, add 15 mL of <i>Titrant</i> from a 50-mL buret.
IPRATROPIUM BROMIDE	ASSAY/ <i>Procedure</i>	USP38–NF33 3932	25-Sep-2015	1-Oct-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	Line 4 of <i>Analysis</i> : Change (C ₂₀ H ₃₀ BrNO ₃ · H ₂ O) to: (C ₂₀ H ₃₀ BrNO ₃)
RIBAVIRIN TABLETS	IMPURITIES/ <i>Organic Impurities, Procedure 1</i>	USP38–NF33 5162	25-Sep-2015	1-Oct-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	Footnote e of <i>Table 2</i> : Change 1-β-D-Ribofuranosyl-1H-1,2,4-triazole-3

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RIVASTIGMINE ADDITIONAL R TARTRATE EQUIREMENT CAPSULES S/USP Reference Standards <11>	USP38–NF33	5215	25-Sep-2015	1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	-carboxamide. to: 1-?-D-Ribofura nosyl-1H -1,2,4-triazole-5 -carboxamide. Line 2 of USP Rivastigmine Related Compound B RS: Change N,N -Dimethylcarba mic acid-3-[1-(di methylamino)et hyl]phenyl ester. to: (RS)?3?[1?(Dimethy lamino)ethyl]ph enyl dimethylcar bamate.	
CHLORPHENI RAMINE MALEATE	SPECIFIC TESTS/Optical Rotation, Specific Rotation <781>	Second Supplement to USP38–NF33	Online	25-Sep-2015	1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	Line 1: Delete Specific Rotation
BOVINE SERUM	APPENDIX 1	USP38–NF33	719	25-Sep-2015	1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	Line 2 of bullet 1 of International

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							<p>Regulations and Guidance Documents in second paragraph: Change http://www.emea.europa.eu/pdfs/human/bwp/026895en.pdf to:</p> <p>http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003684.pdf AND Line 2 of bullet 2 of International Regulations and Guidance Documents in second paragraph: Change http://www.emea.europa.eu/pdfs/human/bwp/026895en.pdf</p>

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									<p>s/human/bwp/179302en.pdf</p> <p>to:</p> <p>http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/WC500003675.pdf</p> <p>AND</p> <p>Line 3 of bullet 3 of International Regulations and Guidance Documents in second paragraph: Change</p> <p>http://www.ema.europa.eu/docs/vet/iwp/074300en.pdf</p> <p>to:</p> <p>http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC50000</p>

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							<p>4575.pdf AND Delete bullet 4 of International Regulations and Guidance Documents in second paragraph AND Line 2 of bullet 5 of International Regulations and Guidance Documents in second paragraph: Change http://www.ema.europa.eu/pdfs/human/bwp/TSSE%20NFG%20410-rev2.pdf to: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC50000</p>

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							3712.pdf AND Line 1 of bullet 6 of International Regulations and Guidance Documents in second paragraph: Change Terrestrial animal health code 2007. Available at http://www.oie.int/eng/normes/mcode/code2007/anc-en_summary.htm . to: Terrestrial animal health code. Available at http://www.oie.int/doc/ged/D10905.pdf .
HYDROXYZINE PAMOATE ORAL	ADDITIONAL R EQUIREMENT S/USP	USP38–NF33 3817	25-Sep-2015	1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	Delete USP Hydroxyzine

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SUSPENSION	<i>Reference Standards <11></i>								Hydrochloride RS
NOREPINEPHRINE BITARTRATE	CHEMICAL INFORMATION	USP38–NF33	4582	25-Sep-2015		1-Oct-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	Line 6: Change [69815-49-2]. to: [108341-18-0].
RIVASTIGMINE TARTRATE	ADDITIONAL REQUIREMENT S/USP <i>Reference Standards <11></i>	USP38–NF33	5213	25-Sep-2015		1-Oct-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	Line 2 of USP Rivastigmine Related Compound B RS: Change <i>N,N</i> -Dimethylcarbamate acid-3-[1-(dimethylamino)ethyl]phenyl ester. to: (<i>RS</i>)?3?[1?(Dimethylamino)ethyl]phenyl dimethylcarbamate.
VALGANCICLOVIR HYDROCHLORIDE	Assay	USP38–NF33	5729	25-Sep-2015		1-Oct-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	Line 4 of <i>Procedure</i> : Change Calculate the percentage, on the anhydrous and solvent-free basis, of

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							<p>$C_{14}H_{22}N_6O_5 \cdot HCl$ to: Calculate the percentage of valganciclovir hydrochloride ($C_{14}H_{22}N_6O_5 \cdot HCl$) AND Line 8 of <i>Procedure:</i> Change $100[(r_U / W_U)(C_F) / (100) / (100 ? S_U)]$ to: $100[(r_U / W_U)(C_F) / (100)]$ AND Line 12 of <i>Procedure:</i> Change C_F is the correction factor; and S_U is the total percent of solvent and water in the test sample. to:</p>

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							<p>and C_F is the correction factor.</p> <p>AND</p> <p>Line 16 of <i>Procedure:</i> Change $(W_S / R_S)[(100 - S_S) / 100]$ to: $(W_S / R_S) / 100$</p> <p>AND</p> <p>Line 18 of <i>Procedure:</i> Change R_S is the area response (sum of two peaks for valganciclovir diastereomers) obtained from the <i>Standard preparation</i>; and S_S is the total percent of solvent and water in USP Valganciclovir Hydrochloride RS. to:</p>

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MUCOSAL DRUG PRODUCTS—PRODUCT QUALITY TESTS FOR MUCOSAL DRUG PRODUCTS /General Necessary Tests/Impurities	PRODUCT QUALITY TESTS FOR MUCOSAL DRUG PRODUCTS /General Necessary Tests/Impurities	USP38–NF33	76	25-Sep-2015		1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	and R_S is the area response (sum of two peaks for valganciclovir diastereomers) obtained from the <i>Standard preparation</i> . Line 1 of footnote 2: Change http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q3B_R2/Step4/Q3B_R2_Guideline.pdf . to: http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html .
CHLOROXYLE NOL	IM PURITIES/Limit of Tetrachloroethylene	USP38–NF33	2774	25-Sep-2015		1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	Row 3 of Column 1 of Table 2: Change

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							210 to: 70 Row 3 of Column 2 of <i>Table 2</i> : Change 0 to: 35
METHOHEXITACHEMICAL L INFORMATION	USP38–NF33	4316	25-Sep-2015	1-Oct-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	Line 5: Change [18652-93-2] to: [151-83-7]
RIVASTIGMINE ADDITIONAL R EQUIREMENT S/USP Reference Standards <11>	USP38–NF33	5212	25-Sep-2015	1-Oct-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	Line 2 of USP Rivastigmine Related Compound B RS: Change Nor impurity; (S)-3-[1-(Dimethyl amino)ethyl]phenyl dimethylcarbamate. to: Nor impurity (racemic mixture); (RS)-3-[1-(Dimethyl

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ROPIVACAINE ADDITIONAL REQUIREMENT	R	USP38–NF33	5225	25-Sep-2015		1-Oct-2015	USP40–NF35	First Supplement to USP39–NF34	lamino)ethyl]phenyl dimethylcarbamate. 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-dimethylphenyl)-amide hydrochloride

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OXAPROZIN TABLETS	IM PURITIES/ <i>Organic Impurities/System suitability/Suitability requirements</i>	USP38–NF33	4681	31-Jul-2015		1-Aug-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	monohydrate. Delete the subsection <i>Signal-to-noise ratio</i> : NLT 3000
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER	DEFINITION	USP38–NF33	6753	31-Jul-2015		1-Aug-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	Line 4: Change Methacrylic acid units in Methacrylic Acid and Ethyl Acrylate Copolymer are NLT 46.0% and NMT 50.6%, calculated on the dried basis. to: Methacrylic acid units in Methacrylic Acid and Ethyl Acrylate Copolymer, previously dried, are NLT 46.0% and NMT 50.6%.

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ALMOTRIPTAN IM MALATE	PURITIES/ <i>Limit Supplement to of Almotriptan Related Compound D and Almotriptan N-Dimer</i>	<i>First</i> USP38–NF33	7325	31-Jul-2015		1-Aug-2015	USP40–NF35	<i>First</i> <i>Supplement to</i> USP39–NF34	Line 1 of <i>Internal standard solution</i> : Change 4-hydroxy-phenylpiperidine to: 4-hydroxy-4-phenylpiperidine
METHOTREXATE IM TE	PURITIES/ <i>Organic Impurities/Procedure 1: Related Compounds</i>	USP38–NF33	4318	31-Jul-2015		1-Aug-2015	USP40–NF35	<i>First</i> <i>Supplement to</i> USP39–NF34	Line 15 of <i>Analysis</i> : Change methotrexate related compound E free acid to: methotrexate related compound E free base AND Line 8 of the second variable definition list for <i>Analysis</i> : Change methotrexate related compound E free acid

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TETRACAINE HYDROCHLORIDE FOR INJECTION	<i>Chromatography USP38–NF33</i>	5508	31-Jul-2015	1-Aug-2015	<i>USP40–NF35</i>	<i>First Supplement to USP39–NF34</i>	<p>to: methotrexate related compound E free base AND Row 5 of Column 1 of <i>Impurity Table 1</i>: Change Methotrexate related compound E free acid^c to: Methotrexate related compound E free base^c</p> <p>Line 1: Change Dissolve an accurately weighed quantity of <i>Tetracaine Hydrochloride for Injection</i> in water to obtain a test solution containing 50 mg per mL, and</p>

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							<p>proceed as directed in the test for <i>Chromatographi c purity</i> under <i>Tetracaine</i>, beginning with "Prepare a Standard solution." to:</p> <p>Dissolve an accurately weighed quantity of Tetracaine Hydrochloride for Injection in water to obtain a test solution containing 50 mg per mL.</p> <p>Prepare a Standard solution of 4-(butylamino) benzoic acid in methanol containing 0.2 mg per mL.</p> <p>Apply separate</p>

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							<p>5-μL portions of the test solution and the Standard solution to a suitable thin-layer chromatographic plate (see <i>Chromatography</i> <621>) coated with a 0.25-mm layer of chromatographic silica gel mixture. Develop the plate in a suitable chromatographic chamber containing a solvent system consisting of a mixture of chloroform, methanol, and isopropylamine (98:7:2) until the solvent front has moved about three-</p>

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METHACRYLIC ASSAY/ ACID AND <i>Procedure</i> METHYL METH ACRYLATE	USP38–NF33	6755	31-Jul-2015	1-Aug-2015	USP40–NF35	<i>First Supplement to USP39–NF34</i>	fourths of the length of the plate. Remove the plate from the chamber, and dry in a current of warm air. Examine the plate under short-wavelength UV light: any spot obtained from the test solution, other than the principal spot, is not more intense than the principal spot obtained from the Standard solution (0.4%), and the sum of the intensities of any such spots is not greater than 0.8%. Line 3 of <i>Acceptance criteria</i> : Delete on the dried

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COPOLYMER							basis AND Line 5 of <i>Acceptance criteria</i> : Delete on the dried basis
BIOTECHNOL INTRODUCTION -- POLYACRYLAMIDE GEL ELECTROPHORESIS	<i>Harmonization Online (Official December 01, 2015)</i>		31-Jul-2015	1-Aug-2015	<i>USP40–NF35</i>	<i>First Supplement to USP39–NF34</i>	A paragraph before the <i>Introduction</i> was deleted: This chapter provides guidance and procedures used for characterization of biotechnology-derived articles by polyacrylamide gel electrophoresis. Portions of the chapter that are not harmonized with the other two pharmacopeias are marked by the symbol ?.

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							<p>This chapter is harmonized with the corresponding chapter in <i>JP</i> and <i>EP</i>. Other characterization tests, also harmonized, are shown in <i>Biotechnology-Derived Articles—Amino Acid Analysis <1052></i>, <i>Biotechnology-Derived Articles—Capillary Electrophoresis <1053></i>, <i>Biotechnology-Derived Articles—Isoelectric Focusing <1054></i>, <i>Biotechnology-Derived Articles—Peptide Mapping <1055></i>, and <i>Biotechnology-</i></p>

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							<i>Derived Articles—Total Protein Assay <1057>.</i>

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