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		Publication		Date	Date	Print Publication	Fix Publication	
ALMOTRIPTAN	ADDITIONAL R	<i>Second</i>	8708	17-Nov-2017	1-Dec-2017	<i>USP42–NF37</i>	<i>Second</i>	Line 4 of USP

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TABLETS	EQUIREMENT S/USP Reference Standards <11>	<i>Supplement to USP40–NF35</i>					<i>Supplement to USP41–NF36</i>	Almotriptan Related Compound B RS: Change C ₁₅ H ₂₂ N ₃ O ₂ S to: C ₁₅ H ₂₁ N ₃ O ₂ S AND Line 2 of USP Almotriptan Related Compound D RS: Change 1-[(3-[2-(Dimethylamino)ethyl]indol-5-yl)methyl]sulfonylpyrrolidine N-oxide. C ₁₇ H ₂₅ N ₃ O ₃ S 351.46 to: 1-[(3-[2-(Dimethylamino)ethyl]indol-5-yl)methyl]sulfonylpyrrolidine N-oxide hydrochloride. C ₁₇ H ₂₅ N ₃ O ₃ S · HCl 387.92
HAZARDOUS DRUGS—HANDPROTECTIVE	7. PERSONAL PROTECTIVE	<i>First Supplement to</i>	Online	17-Nov-2017	1-Dec-2017	<i>USP42–NF37</i>	<i>Second Supplement to</i>	Line 2 of paragraph 2:

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LING IN HEALTHCARE SETTINGS	EQUIPMENT	USP40–NF35						USP41–NF36	Change antineoplastic HDs. to: injectable antineoplastic HDs.
CHLOROQUIN E PHOSPHATE PURITIES/Organic Impurities	IM	USP40–NF35	3377	17-Nov-2017		1-Dec-2017	USP42–NF37	Second Supplement to USP41–NF36	Line 3 of Analysis: Change Calculate the percentage of each specified impurity to: Calculate the percentage of each specified impurity, other than chloroquine related compound G, AND In Analysis/second equation/variable definition list: Change r_U =peak response of

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GLUTARAL CO ASSAY/ NCENTRATE <i>Procedure</i>	USP40–NF35	4414	17-Nov-2017	1-Dec-2017	USP42–NF37	Second Supplement to USP41–NF36	chloroquine <i>N</i> -oxide or any other impurity from the <i>Sample solution</i> r_U =peak response of chloroquine related compound G or any other impurity from the <i>Sample solution</i> Line 7 of <i>Analysis</i> : Change Add a weighed quantity of Concentrate containing 1.2 g of glutaral by means of a suitable weighing pipet. to: Add 1.2 g of Glutaral Concentrate.
MYCOPHENOL IM IC ACID DELAYPUR	USP40–NF35	5257	17-Nov-2017	1-Dec-2017	USP42–NF37	Second Supplement to	Change <i>Mobile phase</i> ,

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ED-RELEASE TABLETS	ITIES/ <i>Organic Impurities</i>							USP41–NF36	Standard solution, Sample solution, and Chromatographic system: to: Mobile phase, Diluent, Standard solution, Sample solution, and Chromatographic system:
VISUAL INSPECTION OF INJECTIONS	4. INSPECTION LI FE-CYCLE/4.2 <i>Prevention of Particulates</i>	<i>First Supplement to USP40–NF35</i>	8099	17-Nov-2017		1-Dec-2017	USP42–NF37	<i>Second Supplement to USP41–NF36</i>	Line 5 of paragraph 1 of <i>Robust Design During Development</i> . Change lamellae (46,47) to: lamellae as discussed in <i>Evaluation of the Inner Surface Durability of Glass Containers</i>

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SODIUM LAURYL SULFATE	IDENTIFICATION	<i>Second Supplement to USP40–NF35</i>	8946	17-Nov-2017		1-Dec-2017	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	<1660> and by the FDA (45) AND Line 2 of paragraph 4 of <i>Robust Design During Development</i> . Change (ICH)-relevant trials. to: (ICH)-relevant trials (46). Line 1 of A.: Change Infrared Absorption <197K> or <197A> to: ?A. Infrared Absorption <197K> or <197A>?
DEXCHLORPHENIRAMINE MALEATE	ADDITIONAL REQUIREMENT S/USP Reference Standards <11>	<i>USP40–NF35</i>	3685	17-Nov-2017		1-Dec-2017	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	Line 2 of USP C chlorpheniramine Related Compound C RS: Change 3-(4-Chlorophe

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IRINOTECAN HADDITIONAL R YDROCHLORI EQUIREMENT DE	<i>USP40–NF35</i> <i>S/USP</i> <i>Reference</i> <i>Standards <11></i>	4676	17-Nov-2017	1-Dec-2017	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	nyl- <i>N</i> -methyl-3-(pyridi n-2-yl)propan-1- amine. $C_{15}H_{17}ClN_2$ 260.76 to: 3-(4-Chlorophe nyl)- <i>N</i> -methyl-3-(pyridi n-2-yl)propan-1- amine maleate. $C_{15}H_{17}ClN_2 \cdot$ $C_4H_4O_4$ 376.83 Line 2 of USP Irinotecan Related Compound C RS: Change (S)-9-[(1,4?-Bipipe ridine)-1?-carbo nyloxy]-4-methy l-11-ethyl-3,4,12 ,14-tetrahydro-4 -hydroxy-3,14-di oxo-1 <i>H</i> -pyrano[3?,4?:6,

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									<p><i>b</i>]quinoline hydrochloride. to: 11-Ethyl-4-hydroxy-4-methyl-3,14-dioxo-3,4,12,</p> <p><i>H</i> -pyrano[3,4:6,</p> <p><i>b</i>]quinolin-9-yl (1,4-bipiperidine)-1-carboxylate hydrochloride. Line 3 of <i>B</i>.: Change obtained in the Assay. to: obtained in the Assay for <i>Content of Stearic Acid and Palmitic Acid</i>.</p>
CALCIUM STEARATE	IDENTIFICATION	USP40–NF35	7557	17-Nov-2017		1-Dec-2017	USP42–NF37	Second Supplement to USP41–NF36	Line 3 of <i>B</i> .: Change obtained in the Assay. to: obtained in the Assay for <i>Content of Stearic Acid and Palmitic Acid</i> .
DIVALPROEX SODIUM EXTENDED RELEASE TABLETS	ASSAY/ Procedure	Second Supplement to	8752	17-Nov-2017		1-Dec-2017	USP42–NF37	Second Supplement to	Line 2 of <i>Mobile phase</i> : Change

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NDED- RELEASE TABLETS		<i>USP40–NF35</i>						<i>USP41–NF36</i>	Adjust with phosphoric acid to a pH of 5.0. to: Adjust with diluted sodium hydroxide or phosphoric acid to a pH of 5.0.
IDENTIFICATI ON TESTS— GENERAL	CHEMICAL IDE GENTIFICATION TESTS/ <i>Thiosulfate</i>	<i>Second Supplement to USP40–NF35</i>	Online	17-Nov-2017		1-Dec-2017	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	Line 1 of A.: Change yellow; with the addition of sulfur dioxide, filter paper moistened with mercurous nitrate TS blackens. to: yellow, and evolve sulfur dioxide, which blackens filter paper moistened with mercurous nitrate TS.
CHLORPHENI RAMINE MALEATE	ADDITIONAL R EQUIREMENT S/ <i>USP</i>	<i>USP40–NF35</i>	3385	17-Nov-2017		1-Dec-2017	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	Line 2 of USP C hlorpheniramine Related

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<i>Reference Standards <11></i>							Compound C RS: Change 3-(4-Chlorophenyl)- <i>N</i> -methyl-3-(pyridin-2-yl)propan-1-amine. C ₁₅ H ₁₇ ClN ₂ 260.76 to: 3-(4-Chlorophenyl)- <i>N</i> -methyl-3-(pyridin-2-yl)propan-1-amine maleate. C ₁₅ H ₁₇ ClN ₂ · C ₄ H ₄ O ₄ 376.83
HYDROXYZINE ASSAY/ HYDROCHLORIDE IDE	USP40–NF35	4539	17-Nov-2017	1-Dec-2017	USP42–NF37	Second Supplement to USP41–NF36	Line 2 of Solution B: Change (0.5: 99.5) to: (0.05: 99.95)
PILOCARPINE ASSAY/ HYDROCHLORIDE OPHTHALMIC SOLUTION	USP40–NF35	5706	17-Nov-2017	1-Dec-2017	USP42–NF37	Second Supplement to USP41–NF36	Line 2 of Standard solution: Change water to: methanol
HYDROXYZINE ASSAY/	First	8299	17-Nov-2017	1-Dec-2017	USP42–NF37	Second	Line 2 of

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HYDROCHLORIDE ORAL SOLUTION	<i>Procedure</i>	<i>Supplement to USP40–NF35</i>						<i>Supplement to USP41–NF36</i>	<i>Solution B: Change (0.5: 99.5) to: (0.05: 99.95)</i>
HAZARDOUS DRUGS—HANDLING IN HEALTHCARE SETTINGS	5. FACILITIES ENGINEERING CONTROLS/5.4 <i>Containment Supplemental Engineering Controls</i>	<i>First Supplement to USP40–NF35</i>	Online	17-Nov-2017		1-Dec-2017	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	Line 5 of paragraph 1: Change containment reduction. to: contamination reduction.
DONEPEZIL HYDROCHLORIDE	IMPURITIES/ <i>Organic Impurities, Procedure 2</i>	<i>USP40–NF35</i>	3859	17-Nov-2017		1-Dec-2017	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	Footnote b of Table 3: Change (E)-4-[(5,6-Dimethoxy-1-oxo-1 <i>H</i> -inden-2-yl)methyl]pyridine 1-oxide. to: (E)-4-[(5,6-Dimethoxy-1-oxo-1,3-dihydro-2 <i>H</i> -inden-2-ylidene)methyl]pyridine 1-oxide.

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MYCOPHENOL PERFORMANC IC ACID DELAYE ED-RELEASE TESTS/ TABLETS		USP40–NF35	5257	17-Nov-2017		1-Dec-2017	USP42–NF37	Second Supplement to USP41–NF36	In Acid stage/ Analysis s/variable definition list: Change V = volume of Medium, 750 mL to: V = volume of Acid stage medium, 750 mL AND In Buffer stage/ Analysis s/variable definition list: Change V = volume of Medium, 1000 mL to: V = volume of Buffer stage medium, 1000 mL
VISUAL INSPECTION	2. BACKGROU ND/2.2 Patient	First Supplement to	8099	17-Nov-2017		1-Dec-2017	USP42–NF37	Second Supplement to	Line 6 of paragraph 3:

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OF INJECTIONS	Risk	USP40–NF35						USP41–NF36	Change 109 particles/kg to: 10 ⁹ particles/kg
FLUVOXAMINE ASSAY/MALEATE	Procedure	Second Supplement to USP40–NF35	8797	17-Nov-2017		1-Dec-2017	USP42–NF37	Second Supplement to USP41–NF36	Line 2 of Solution A: Change 1 g/L to: 1.1 g/L
ALMOTRIPTAN ADDITIONAL MALATE	EQUIREMENT S/USP Reference Standards <11>2017)	Interim Revision Announcement (Official May 01, 2017)	Online	17-Nov-2017		1-Dec-2017	USP42–NF37	Second Supplement to USP41–NF36	Line 2 of USP Almotriptan Related Compound D RS: Change 1-[(3-[2-(Dimethylamino)ethyl]indol-5-yl)methyl]sulfonylpyrrolidine N-oxide. C ₁₇ H ₂₅ N ₃ O ₃ S 351.46 to: 1-[(3-[2-(Dimethylamino)ethyl]indol-5-yl)methyl]sulfonylpyrrolidine N-oxide hydrochloride. C ₁₇ H ₂₅ N ₃ O ₃ S · HCl 387.92

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REAGENTS	REAGENT SPE	USP40–NF35	2339	29-Sep-2017		1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	Line 1 of Buffer solution: Change Add 150 mg of sodium chloride to: Add 150 g of sodium chloride
	<i>Bromelain/Activity Determination</i>								
FENOLDOPAM MESYLATE	USP Reference standards <11>	USP40–NF35	4159	29-Sep-2017		1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	Line 2 of USP Fenoldopam Related Compound A RS: Change 1-Methyl-3-benzazepine-7,8-diol, 6-chloro-2,3,4,5-tetrahydro-1-(4-hydroxyphenyl)-, methanesulfonate (salt). $C_{17}H_{18}ClNO_3 \cdot CH_4SO_3$ 415.89 to: 6-Chloro-1-(4-hydroxyphenyl)-3-methyl-2,3,4,5-tetrahydro-1H-benzo[d]azepine-7,8-dio

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MEBENDAZOL E	IM PUR ITIES/ <i>Organic Impurities/ Table 2</i>	USP40–NF35 4968	29-Sep-2017	1-Oct-2017	USP42–NF37	<i>First Supplement to USP41–NF36</i>	I hydrochloride (<i>N</i> -Methyl-6-chloro-2,3,4,5-tetrahydro-1-(4-hydroxyphenyl)-1 <i>H</i> -3-benzazepine-7,8-diol hydrochloride). C ₁₇ H ₁₉ ClNO ₃ · HCl 356.24 Change footnotes ^d Ethyl 5-benzoyl-1-methylbenzimidazol-2-ylcarbamate. ^e Methyl 5-(4-toluooyl)-1-methylbenzimidazol-2-yl carbamate. to: ^d Ethyl (5-benzoyl-1 <i>H</i> -benzimidazol-2-yl)carbamate. ^e Methyl 5-

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MYCOPHENOLIM ATE SODIUM PUR ITIES/ <i>Organic Impurities</i>	<i>USP40–NF35</i>	5256	29-Sep-2017	1-Oct-2017	<i>USP42–NF37</i>	<i>First Supplement to USP41–NF36</i>	(4-t oluoyl)- 1 <i>H</i> -benzimidazol-2 -ylcarbamate. Footnote a of <i>Table 2:</i> Change (<i>RS</i>)-7-Hydroxy-5- methoxy-4-meth yl-6-[2-(5-methy l-2-oxo-tetrahyd rofur-5-yl)eth yl]-3 <i>H</i> -isobenzofurany l-1-one. to: (<i>RS</i>)-7-Hydroxy-5- methoxy-4-meth yl-6-[2-(5-methy l-2-oxo-tetrahyd rofur-5-yl)eth yl]-3 <i>H</i> -isobenzofuran- 1-one.
CANDESARTA N CILEXETIL TABLETS	ADDITIONAL R EQUIREMENT S/ <i>USP Reference</i>	<i>Second</i> 8730	29-Sep-2017	1-Oct-2017	<i>USP42–NF37</i>	<i>First Supplement to USP41–NF36</i>	Line 2 of <i>USP</i> Candesartan Cilexetil Related Compound D

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							<p>RS: Change 1-[[Cyclohexylo xycarbonyloxy)c arbonyl]oxy}eth yl</p> <p><i>H</i> -tetrazol-5-yl)bip henyl-4-yl]meth yl}-2-oxo-2,3-di hydro-1<i>H</i> -benzimidazole- 4-carboxylate. to: 1-[[Cyclohexyl oxy)carbonyl]ox y)ethyl</p> <p><i>H</i> -tetrazol-5-yl)-[1 ,1'-biphenyl]-4-y l]methyl)-2-oxo- 2, 3-di hydro-1<i>H</i> -benzimidazole- 4-carboxylate.</p>

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ENALAPRIL MALEATE TABLETS	PERFORMANC E TESTS/ <i>Dissolution</i> <711>/Table 1	USP40–NF35	3971	29-Sep-2017		1-Oct-2017	USP42–NF37	<i>First Supplement to USP41–NF36</i>	Row 3 of Column 3: Change 100 to: 200
ISOSORBIDE DINITRATE EX TENDED- RELEASE TABLETS	Assay	USP40–NF35	4710	29-Sep-2017		1-Oct-2017	USP42–NF37	<i>First Supplement to USP41–NF36</i>	Change <i>Buffer solution, Mobile phase, Internal standard solution, Standard preparation, and Chromatographic system</i> —Prepare as directed in the Assay under <i>Diluted Isosorbide Dinitrate</i> . to: <i>Buffer solution</i> —Dissolve 15.4 g of ammonium acetate in water, add 11.5 mL of glacial

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							<p>acetic acid, dilute with water to 1000 mL, and mix to obtain a solution having a pH of about 4.7.</p> <p><i>Mobile phase</i>—Mix 350 mL of water, 100 mL of <i>Buffer solution</i>, and 550 mL of methanol. Cool to room temperature, dilute with water to 1000 mL, mix, degas, and filter. Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> <621>).</p> <p><i>Internal standard solution</i> —Transfer a quantity of</p>

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							<p>diluted nitroglycerin to a suitable volumetric flask, add about 60% of the flask volume of methanol, sonicate for 5 minutes, and shake for 30 minutes. Dilute with methanol to volume to obtain a solution having a concentration of about 3 mg of nitroglycerin per mL, and mix. Allow any undissolved material to settle, filter, and store the filtrate in an airtight container.</p> <p><i>Standard preparation</i></p> <p>—Transfer about</p>

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							125 mg of recently mixed USP Diluted Isosorbide Dinitrate RS, accurately weighed, to a 50-mL volumetric flask, add about 30 mL of <i>Mobile phase</i> , shake for 30 minutes, dilute with <i>Mobile phase</i> to volume, and mix. Pipet 10 mL of the resulting solution into a 25-mL volumetric flask, and add 4.0 mL of <i>Internal standard solution</i> and 4 mL of dilute <i>Buffer solution</i> (1 in 10). Cool to room temperature,

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							<p>dilute with <i>Mobile phase</i> to volume, and mix to obtain a solution having a known concentration of about 0.25 mg of isosorbide dinitrate per mL, based on the quantity of USP Diluted Isosorbide Dinitrate RS weighed and the labeled content of isosorbide dinitrate. Pass a portion of this solution through a 0.45-μm filter. AND Change <i>Procedure</i>—Proceed as directed for <i>Procedure</i> in the Assay under <i>Diluted</i></p>

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							<p><i>Isosorbide Dinitrate.</i></p> <p>to:</p> <p><i>Chromatographic system (see Chromatography <621>)</i>—The liquid chromatograph is equipped with a 220-nm detector and a 4-mm × 25-cm column that contains packing L1. The flow rate is about 1 mL per minute.</p> <p>Chromatograph the <i>Standard preparation</i>, and record the peak responses as directed for <i>Procedure</i>: the resolution, <i>R</i>, between isosorbide dinitrate and nitroglycerin is</p>

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							<p>not less than 2.0; and the relative standard deviation for replicate injections determined from the peak response ratios is not more than 2%.</p> <p>[NOTE—The relative retention times are about 0.75 for isosorbide dinitrate and 1.0 for nitroglycerin. The relative retention times for isosorbide mononitrates, if present, are about 0.38.]</p> <p><i>Procedure</i></p> <p>—Separately inject equal volumes (about 20 µL) of the</p>

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MYCOPHENOL ADDITIONAL REQUIREMENT FOR ORAL SUSPENSION	USP40–NF35 S/USP Reference Standards <11>	5251	29-Sep-2017	1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Line 2 of USP Mycophenolate Mofetil Related Compound B RS: Change (RS)-7-Hydroxy-5-methoxy-4-methyl-6-[2-(5-methyl-2-oxo-tetrahydrofuran-5-yl)ethyl]-3H-isobenzofuranyl-1-one. to: (RS)-7-Hydroxy-5-methoxy-4-methyl-6-[2-(5-methy

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POWDERED A SHWAGANDH A ROOT EXTRACT	COMPOSITION /Content of Withanolides	USP40–NF35	6804	29-Sep-2017		1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	l-2-oxo-tetrahydrofuran-5-yl)ethyl]-3H-isobenzofuran-1-one. Add Solution B: Acetonitrile, filtered and degassed
EFAVIRENZ	SPECIFIC TESTS/ Enantiomeric Purity	Second Supplement to USP40–NF35	Online	29-Sep-2017		1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	Line 1 of Mobile phase: Change Hexane and ethanol (97:3) to: Hexane and absolute alcohol (97:3)
REAGENTS, INDICATORS AND SOLUTIONS	S OLUTION S/Volumetric Solutions/1 N Sulfuric Acid VS	USP40–NF35	2434	29-Sep-2017		1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	Line 3 of Standardization: Change dried at 150° to: dried at 105°
GADOTERIDOL	Chromatographic purity/ Test 2 (Nongadolinium-Containing Impurities)	USP40–NF35	4360	29-Sep-2017		1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	Line 1 of pH 5.0 Buffer. Change 50 mM Ammonium to: 50 mM Ammonium

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MEMANTINE H PERFORMANC YDROCHLORI E DE TABLETS TESTS/ <i>Dissolution</i> <711>/ <i>Analysis</i>	USP40–NF35	5000	29-Sep-2017	1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	<p><i>phosphate buffer</i> AND Line 1 of <i>pH 7.0 Buffer</i>: Change <i>50 mM Ammonium</i> to: <i>50 mM Ammonium phosphate buffer</i></p> <p>In the variable definition list: Change C_S = concentration of USP Memantine Hydrochloride RS in the <i>Standard solution</i> ($\mu\text{g/mL}$) to: C_S = concentration of USP Memantine Hydrochloride RS in the <i>Standard stock</i></p>

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PEMETREXED IM DISODIUM PUR ITIES/ <i>Organic Impurities/ Table 2</i>	<i>USP40–NF35</i>	5588	29-Sep-2017	1-Oct-2017	<i>USP42–NF37</i>	<i>First Supplement to USP41–NF36</i>	<i>solution (mg/mL)</i> Footnote b: Change {4-[2-(2-Amino-1-methyl-4-oxo-4,7-dihydro-1H-pyrimidin-5-yl)ethyl]benzoyl}-4-L-glutamyl-L-glutamic acid. to: {4-[2-(2-Amino-4-oxo-4,7-dihydro-1H-pyrimidin-5-yl)ethyl]benzoyl}-4-L-glutamyl-L-glutamic acid. Line 4:Change 5-Methoxy-4'-(trifluoromethyl)valerophenone
FLUVOXAMINE CHEMICAL MALEATE INFORMATION	<i>Second Supplement to USP40–NF35</i>	8797	29-Sep-2017	1-Oct-2017	<i>USP42–NF37</i>	<i>First Supplement to USP41–NF36</i>	

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ENOXAPARIN SODIUM INJECTION	SPECIFIC TESTS/ <i>Anti-Factor IIa Activity</i>	USP40–NF35	3982	29-Sep-2017		1-Oct-2017	USP42–NF37	<i>First Supplement to USP41–NF36</i>	(E)-O -(2-aminoethyl) oxime, maleate (1:1) to: (E)-5-Methoxy-4'- (trifluoromethyl) valerophenone O -(2-aminoethyl) oxime, maleate (1:1) Delete <i>Standard solutions:</i> Dilute USP Enoxaparin Sodium Solution for Bioassays RS with <i>pH 7.4</i> <i>buffer</i> to obtain four dilutions having concentrations in the range between 0.015 and 0.075 IU of Anti-Factor IIa activity/mL.

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ISOSORBIDE <i>Dissolution</i> DINITRATE EX <711>/Test 2 TENDED- RELEASE TABLETS	USP40–NF35	4710	29-Sep-2017	1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	Line 1: Change <i>Buffer solution</i> and <i>Mobile</i> <i>phase</i> —Prepare as directed in the Assay under <i>Diluted</i> <i>Isosorbide</i> <i>Dinitrate</i> . to: <i>Buffer solution</i> and <i>Mobile</i> <i>phase</i> —Prepare as directed in the Assay. AND Line 1 of <i>Chromatographi</i> <i>c system</i> : Change (see <i>Chromatograph</i> <i>y</i> <621>)—Proceed as directed in the Assay under <i>Diluted</i> <i>Isosorbide</i> <i>Dinitrate</i> . to:

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MYCOPHENOL ADDITIONAL R ATE SODIUM EQUIREMENT S/USP Reference Standards <11>	USP40–NF35	5256	29-Sep-2017	1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	(see Chromatograph y <621>)—Proceed as directed in the Assay. Line 2 of USP Mycophenolate Mofetil Related Compound B RS: Change (RS)-7-Hydroxy-5- methoxy-4-meth yl-6-[2-(5-methy l-2-oxo-tetrahyd rofur-5-yl)eth yl]-3H -isobenzofurany l-1-one. to: (RS)-7-Hydroxy-5- methoxy-4-meth yl-6-[2-(5-methy l-2-oxo-tetrahyd rofur-5-yl)eth yl]-3H -isobenzofuran- 1-one.

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MONOBASIC POTASSIUM PHOSPHATE	IM PUR ITIES/Arsenic, Method I <211>	USP40–NF35	7847	29-Sep-2017		1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	Line 1: Change 3 µg/g to: NMT 3 µg/g
POTASSIUM CITRATE EXTENDED-RELEASE TABLETS	ASSAY/ Procedure	Revision Bulletin (Official April 01, 2017)	Online	29-Sep-2017		1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	Line 1 of Chromatographic system/Column: Change 10-µm to: 5-µm AND In the variable definition list in Analysis: Change r_U = citrate peak area from the Sample solution r_S = citrate peak area from the Standard solution to: r_U = citric acid peak area from the Sample solution r_S = citric acid peak area from

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CALCIPOTRIE IM NE OINTMENT PUR ITIES/ <i>Organic Impurities</i>	USP40–NF35	3114	29-Sep-2017	1-Oct-2017	USP42–NF37	<i>First Supplement to USP41–NF36</i>	the <i>Standard solution</i> AND Change M_{r2} = molecular weight of citrate ($C_6H_5O_7$), 189.10 to: M_{r2} = molecular weight of citric acid ($C_6H_8O_7$), 192.13 Footnote a of <i>Table 1</i> : Change (5Z,7Z,22E,24R)-24-Cyclopropyl-9,10-secochol- α -5,7,10(19),22-tetraene-1?,3?,24-triol. to: (5Z,7Z,22E,24S)-24-Cyclopropyl-9,10-secochol- α -5,7,10(19),22-tetraene-1?,3?,24-triol.

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ISOSORBIDE Assay DINITRATE EX TENDED- RELEASE CAPSULES	USP40–NF35	4708	29-Sep-2017	1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	Change Buffer solution, Mobile phase, Internal standard solution, Standard preparation, and Chromatographic system—Prepare as directed in the Assay under Diluted Isosorbide Dinitrate. to: Buffer solution —Dissolve 15.4 g of ammonium acetate in water, add 11.5 mL of glacial acetic acid, dilute with water to 1000 mL, and mix to obtain a solution having a pH of about

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							<p>4.7. <i>Mobile phase</i>—Mix 350 mL of water, 100 mL of <i>Buffer solution</i>, and 550 mL of methanol. Cool to room temperature, dilute with water to 1000 mL, mix, degas, and filter. Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> <621>). <i>Internal standard solution</i> —Transfer a quantity of diluted nitroglycerin to a suitable volumetric flask, add about 60%</p>

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							<p>of the flask volume of methanol, sonicate for 5 minutes, and shake for 30 minutes. Dilute with methanol to volume to obtain a solution having a concentration of about 3 mg of nitroglycerin per mL, and mix. Allow any undissolved material to settle, filter, and store the filtrate in an airtight container.</p> <p><i>Standard preparation</i></p> <p>—Transfer about 125 mg of recently mixed USP Diluted Isosorbide Dinitrate RS,</p>

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							accurately weighed, to a 50-mL volumetric flask, add about 30 mL of <i>Mobile phase</i> , shake for 30 minutes, dilute with <i>Mobile phase</i> to volume, and mix. Pipet 10 mL of the resulting solution into a 25-mL volumetric flask, and add 4.0 mL of <i>Internal standard solution</i> and 4 mL of dilute <i>Buffer solution</i> (1 in 10). Cool to room temperature, dilute with <i>Mobile phase</i> to volume, and mix to obtain a solution having

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							<p>a known concentration of about 0.25 mg of isosorbide dinitrate per mL, based on the quantity of USP Diluted Isosorbide Dinitrate RS weighed and the labeled content of isosorbide dinitrate. Pass a portion of this solution through a 0.45-μm filter.</p> <p>AND</p> <p>Change <i>Procedure</i>—Proceed as directed for <i>Procedure</i> in the <i>Assay</i> under <i>Diluted Isosorbide Dinitrate</i>.</p> <p>to:</p> <p><i>Chromatographic system</i> (see</p>

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							<p><i>Chromatograph y <621>—The liquid chromatograph is equipped with a 220-nm detector and a 4-mm x 25-cm column that contains packing L1. The flow rate is about 1 mL per minute.</i></p> <p><i>Chromatograph the <i>Standard preparation</i>, and record the peak responses as directed for <i>Procedure</i>: the resolution, <i>R</i>, between isosorbide dinitrate and nitroglycerin is not less than 2.0; and the relative standard deviation for</i></p>

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							<p>replicate injections determined from the peak response ratios is not more than 2%.</p> <p>[NOTE—The relative retention times are about 0.75 for isosorbide dinitrate and 1.0 for nitroglycerin. The relative retention times for isosorbide mononitrates, if present, are about 0.38.]</p> <p><i>Procedure</i></p> <p>—Separately inject equal volumes (about 20 µL) of the <i>Standard preparation</i> and the <i>Assay preparation</i> into the</p>

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MYCOPHENOL ADDITIONAL REQUIREMENT FOR INJECTION	USP40–NF35 S/USP Reference Standards <11>	5250	29-Sep-2017	1-Oct-2017	USP42–NF37	First Supplement to USP41–NF36	chromatograph, record the chromatograms, and measure the responses for the major peaks. Line 2 of USP Mycophenolate Mofetil Related Compound B RS: Change (RS)-7-Hydroxy-5-methoxy-4-methyl-6-[2-(5-methyl-2-oxo-tetrahydrofuran-5-yl)ethyl]-3H-isobenzofuran-1-one. to: (RS)-7-Hydroxy-5-methoxy-4-methyl-6-[2-(5-methyl-2-oxo-tetrahydrofuran-5-yl)ethyl]-3H-isobenzofuran-1-one.

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PEMETREXED FOR INJECTION	ASSAY/ <i>Proce dure/Analysis</i>	<i>USP40–NF35</i>	5590	29-Sep-2017		1-Oct-2017	<i>USP42–NF37</i>	<i>First Supplement to USP41–NF36</i>	In the variable definition list: Change M_{r2} = molecular weight of pemetrexed disodium, 597.49 to: M_{r2} = molecular weight of pemetrexed disodium (anhydrous), 473.37
FLUVOXAMINE IM MALEATE	PUR ITIES/ <i>Organic Impurities/ Table 1</i>	<i>Second Supplement to USP40–NF35</i>	8797	29-Sep-2017		1-Oct-2017	<i>USP42–NF37</i>	<i>First Supplement to USP41–NF36</i>	Footnote b:Change 5-Methoxy-1-[4-(trifluoromethyl)phenyl]-1-pentanone (<i>E</i>)-O-[2-[(2-succinyl)amino]ethyl]oxide. to: (<i>E</i>)-5-Methoxy-1-[4-(trifluoromethyl)phenyl]-1-pentanone O

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ERYTHROMYCIN ASSAY/ OPHTHALMIC OINTMENT	<i>First Supplement to USP40–NF35</i>	8276	28-Jul-2017	1-Aug-2017	<i>USP42–NF37</i>	<i>First Supplement to USP41–NF36</i>	-[2-[(2-succinyl)amino]ethyl]oxime. AND Footnotes c– g: Delete the space before oxime Line 9 of the third variable definition list: Change <i>P</i> = potency of erythromycin C in USP Erythromycin B RS (mg/mg) to: <i>P</i> = potency of erythromycin C in USP Erythromycin C RS (mg/mg)
VITAMIN D ASSAY	<i>ASSAY/ Chromatographic Method s/Procedure 8</i>	<i>USP40–NF35</i> 462	28-Jul-2017	1-Aug-2017	<i>USP42–NF37</i>	<i>First Supplement to USP41–NF36</i>	<i>Clean-up chromatographic system: Add Flow rate: 1.1 mL/min</i> AND <i>Analytical chromatographic</i>

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ONDANSETRO ADDITIONAL REQUIREMENT S/USP Reference Standards <11>	USP40–NF35	5445	28-Jul-2017	1-Aug-2017	USP42–NF37	First Supplement to USP41–NF36	<p>system: Add Flow rate: 1.0 mL/min</p> <p>Line 2 of USP Ondansetron Related Compound A RS: Change 3[(Dimethylamino)methyl]-1,2,3,9-tetrahydro-9-methyl-4H-carbazol-4-one .</p> <p>to: 3-[(Dimethylamino)methyl]-1,2,3,9-tetrahydro-9-methyl-4H-carbazol-4-one hydrochloride.</p>

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