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How to Use

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ORAL REHYDRASSAY/		*USP38–NF33*	5145	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 10 of

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ATION SALTS	*Dextrose*							*Analysis*: Change *A* = 100 mm divided by the length of the polarimeter tube (mm) to: *A* = 100 divided by the length of the polarimeter tube (dm) AND Line 21 of *Analysis*: Change *A* = 100 mm divided by the length of the polarimeter tube (mm) to: *A* = 100 divided by the length of the polarimeter tube (dm)
SODIUM CHLORIDE	IM PURITIES/*Limit of Phosphates*	*Harmonization (Official December 01, 2015)*	Online	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 2 of *Analysis*: Change add 4 mL of sulfomolybdic

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								acid TS, to: add 4 mL of *Sulfomolybdic acid solution*,
GENE THERAPY PRODUCTS	REGULATIONS AND STANDARDS	*USP38–NF33*	883	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 8: Delete and, in particular, www.fda.gov/cber/publications.htm
CROMOLYN SODIUM OPHTHALMIC SOLUTION	*Assay*	*USP38–NF33*	2962	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 1 of *Procedure*: Change Proceed as directed for *Procedure* in the *Assay* under *Cromolyn Sodium Inhalation Solution*. to: Concomitantly determine the absorbances of the *Standard preparation* and the *Assay preparation* in 1-cm cells at

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								the wavelength of maximum absorbance at about 326 nm, with a suitable s pectrophotomet er, using a 1 in 100 aqueous solution of *pH 7.4 Sodium phosphate buffer* as the blank. Calculate the quantity, in mg, of $C_{23}H_{14}Na_2O_{11}$ in each mL of the Ophthalmic Solution taken by the formula: $(C/V)(A_U/A_S)$ in which C is the concentration, in µg per mL, of USP Cromolyn Sodium RS in the *Standard preparation*; V is the volume, in mL, of

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								Ophthalmic Solution taken; and A_U and A_S are the absorbances of the solutions obtained from the *Assay preparation* and the *Standard preparation*, respectively.
ALUMINUM CHLOROHYDRATE	CHEMICAL INFORMATION	*USP38–NF33*	2130	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 8: Change Dihydrate [12042-91-0].Anhydrous [1327-41-9]. to: Dihydrate [12359-72-7].Anhydrous [12042-91-0].
CEFOTAXIME FOR INJECTION	ASSAY/ *Procedure*	*USP38–NF33*	2678	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 10 of the Calculate statement in the *Analysis*: Change C_U = nominal concentration of cefotaxime sodium in *Sample solution*

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								1, *2*, *3*, or *4* (mg/mL) to: C_U = nominal concentration of cefotaxime in *Sample solution 1*, *2*, *3*, or *4* (mg/mL)
LEVETIRACETAM	IMPURITIES/*Organic Impurities*	*USP38–NF33*	4060	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 2 of *Procedure 2*: Change *Buffer, Solution A, Solution B, Mobile phase, System suitability solution,* and *Chromatographic system*: to: *Buffer, Solution A, Solution B, Mobile phase, System suitability solution, Chromatographic system,* and *System suitability*:

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PROTAMINE SULFATE	SPECIFIC TESTS/*pH <791>*	*USP38–NF33*	5069	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Delete the test for pH
NIACIN	IM PUR ITIES/*Related Compounds*	*First Supplement to USP38–NF33*	7447	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Row 14 of Column 1 of *Table 2*: Change Total impurities to: Total specified impurities
ELEMENTAL I MPURITIES--LI MITS	DRUG SUBSTANCE AND E XCI PIENTS/*Table 2*	*Second Supplement to USP38–NF33*	7594	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 1 of Row 1 of Column 2: Change (g/g) to: (µg/g) AND Line 1 of Row 1 of Column 3: Change (g/g) to: (µg/g) AND Line 1 of Row 1 of Column 4: Change (g/g) to: (µg/g)

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GOOD DISTRIBUTION PRACTICES FOR BULK PHARMACEUTICAL EXCIPIENTS	SECTION 4: RETURNED GOODS, DISPATCH, TRANSPORT, IMPORTATION, ADULTERATION, AND TRACEABILITY/*4.7 Importation*	*USP38–NF33*	1396	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Footnote 11: Delete http://www.fda.gov/ForIndustry/ImportProgram/AdmissibilityDeterminationsforShipmentsofForeign-originOASIS/ucm077691.htm (Accessed June 6, 2011).
CEFAZOLIN FOR INJECTION	ASSAY/ *Procedure*	*USP38–NF33*	2652	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 7 of *Analysis*: Change Result = $(R_U/R_S) \times (C_S/C_U) \times P \times F \times 100$ to: Result = $(R_U/R_S) \times (C_S/C_U) \times P \times 100$ AND Line 17 of *Analysis*: Change *P* = potency of cefadroxil in USP Cefadroxil

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								RS (µg/mg) to: *P* = potency of cefazolin in USP Cefazolin RS (mg/mg) AND Line 19 of *Analysis*: Delete *F* = conversion factor, 0.001 mg/µg
FEXOFENADINE HYDROCHLORIDE TABLETS	PERFORMANCE TESTS/ *Dissolution <711>/Test 1*	*USP38–NF33*	3487	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 4 of *System suitability solution*: Change [Note—A small amount of acetic acid, to: [Note—A small amount of glacial acetic acid,
METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE TABLETS	PERFORMANCE TESTS/ *Dissolution <711>/Test 2*	*USP38–NF33*	4348	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 3 of *Apparatus 7*: Change coil sample holder (*Figure 4d*).

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								to: spring sample holder (*Figure 5d*).
BANABA LEAF POWDER	DEFINITION	*USP38–NF33*	5903	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 1: Change dried leaves of *Lagerstroemia speciosa* (L.) Pers. (Fam. Lythraceae) by extraction with hydroalcoholic mixtures. to: dried leaves of *Lagerstroemia speciosa* (L.) Pers. (Fam. Lythraceae) reduced to powder or very fine powder.
TELMISARTAN TABLETS	ASSAY/ *Procedure*	*Revision Bulletin (Official December 01, 2014)*	Online	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 2 of *Standard solution*: Change of USP Telmisartan Related Compound A RS in *Mobile*

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								phase. to: of USP Telmisartan Related Compound A RS in *Mobile phase* from the *Standard stock solution*.
GENE THERAPY PRODUCTS	APPENDIX	*USP38–NF33*	883	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 8 of *National and International Regulatory Documents*: Delete (http://www4.od.nih.gov/oba/guidelines.html)
ISONIAZID	IMPURITIES/*Organic Impurities*	*First Supplement to USP38–NF33*	7413	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Row 2 of Column 1 of *Table 1*:Change Isoniacin to Isoniacin[a] AND Row 5 of Column 1 of *Table 1*: Change

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								Picolinohydrazide to Picolinohydrazide[b] AND Row 6 of Column 1 of *Table 1*: Change Isonicotinonitrile to: Isonicotinonitrile[c] AND Add footnotes to *Table 1*: [a] Isonicotinic acid. [b] 2-Isoniazid. [c] 4-Cyanopyridine.
AZATHIOPRINE	ASSAY/ *Procedure*	*USP38–NF33*	2334	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 1 of *Standard stock solution*: Change 0.1 mg/mL of USP Azathioprine RS prepared as follows.

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								to: 0.5 mg/mL of USP Azathioprine RS prepared as follows.
CISATRACURIUM BESYLATE	SPECIFIC TESTS/*Water Determination, Method Ia <921>*	*USP38–NF33*	2828	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 1: Change *Method Ia* to: *Method Ic*
LEVODOPA CAPSULES	IMPURITIES/*Organic Impurities*	*USP38–NF33*	4078	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 2 of *Spray reagent*: Change (10 mg/mL) to: (100 mg/mL)
QUININE SULFATE	CHEMICAL INFORMATION	*USP38–NF33*	5122	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 4: Change dihydrate [6119-70-6]. to: dihydrate [207671-44-1].
VERAPAMIL HYDROCHLORIDE EXTENDED-RELEASE TABLETS	PERFORMANCE TESTS/*Dissolution <711>/Test 7*	*First Supplement to USP38–NF33*	7478	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 6 of *Analysis*: Change 37 ± 0.5° at each time point. to: 37 ± 0.5°. AND

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								Line of 40 of *Analysis*:Delete the equation $Result_5 = (\{C_5 \times [V\ ?\ (4 \times V_s)]\} + [(C_4 + C_3 + C_2 + C_1) \times V_s]) \times (1/L) \times 100$ AND Row 5 of Column 2 of *Table 11*: Change 4 to: 5
CROMOLYN SODIUM OPHTHALMIC SOLUTION	*Related compounds*	*USP38–NF33*	2962	29-May-2015	1-Jun-2015	*USP39–NF34*	*USP39–NF34*	Line 1: Change It meets the requirements of the test for *Related compounds* under *Cromolyn Sodium Inhalation Solution*, “Ophthalmic Solution” being read in place of “Inhalation Solution.”

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								to: Apply 10-µL portions of Ophthalmic Solution and Standard solutions of USP Cromolyn Sodium RS in a mixture of water, stabilizer-free tetrahydrofuran, and acetone (6:4:1) containing 10 mg per mL (*Standard solution A*) and 0.1 mg per mL (*Standard solution B*) to a suitable thin-layer chromatographic plate (see *Chromatography <621>*) coated with a 0.25-mm layer of chromatographic silica

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								gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of chloroform, methanol, and glacial acetic acid (9:9:2) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by viewing under short-wavelength UV

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								light: the R_F value of the principal spot obtained from the Ophthalmic Solution corresponds to that obtained from *Standard solution A*. Any spot in the chromatogram obtained from the Ophthalmic Solution moving ahead of the principal spot is not more intense than the spot in the chromatogram obtained from *Standard solution B* (1.0%).
PHENYTOIN SODIUM	*USP Reference standards <11>*	*USP37–NF32*	4289	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 3 of USP Phenytoin Related Compound A RS: Change C

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								$^{14}H_{15}NO_2$ to: $C_{14}H_{13}NO_2$
SORBITOL SORBITAN SOLUTION	SPECIFIC TESTS	*USP37–NF32*	6197	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 1 of *pH <791>*: Change 4.0–7.0, in a 14% solution of Sorbitol Sorbitan Solution in carbon dioxide-free water to: 4.0–7.0, in a 14% (w/w) solution of Sorbitol Sorbitan Solution in carbon dioxide-free water
MINERAL OIL	SPECIFIC TESTS/*Readily Carbonizable Substances Test <271>*	*Second Supplement to USP37–NF32*	Online	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 1 of *Acceptance criteria*: Change The *Sample* may turn hazy, but it remains colorless, or shows a slight pink or yellow color, and the

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								Sample does not become darker than the *Standard solution*. to: The oil portion of the *Sample* may turn hazy, but it remains colorless or shows a slight pink or yellow color, and the acid portion of the *Sample* does not become darker than the *Standard solution*.
COSYNTROPIN	SPECIFIC TESTS/*UV Absorption Spectrophotometry*	*USP38–NF33*	2958	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 1 of *Sample solution*: Change hydrochloride to: hydrochloric acid
AMINOBENZOIC ACID	IMPUR	*USP37–NF32*	1730	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Add the subsection:

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	ITIES/*Organic Impurities*							*Standard stock solution:* 0.25 mg/mL each of USP Benzocaine RS and 4-nitrobenzoic acid in methanol AND Line 2 of *Standard solution*: Change in *Mobile phase* to: in *Mobile phase*, from the *Standard stock solution*
ASPARTAME	ASSAY/ *Procedure*	*USP37–NF32*	5857	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 3 of *Analysis*: Change crystal violet to: crystal violet TS
RIVASTIGMINE TARTRATE	ADDITIONAL REQUIREMENTS/*USP*	*First Supplement to USP37–NF32*	Online	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 2 of USP Rivastigmine Related

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	Reference Standards <11>							Compound A RS: Change Di-*p*-toluoyl-D-(+)-tartaric acid monohydrate. $C_{20}H_{20}O_9$ 404.37 to: (+)-Di-(*p*-toluoyl)-D-tartaric acid. $C_{20}H_{18}O_8$ 386.35
CLARITHROMYCIN TABLETS	IMPURITIES/*Organic Impurities/ Chromatographic system*	*USP38–NF33*	2850	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 1 of *Column*: Change 4.6-mm × 10-cm; 3-µm packing L1 to: 4.6-mm × 10-cm; 3.5-µm packing L1
RIVASTIGMINE TARTRATE CAPSULES	ADDITIONAL REQUIREMENTS/*USP Reference Standards <11>*	*USP37–NF32*	4616	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 2 of USP Rivastigmine Related Compound A RS: Change Di-*p*-toluoyl-D-(+)-tartaric

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								acid monohydrate. $C_{20}H_{20}O_9$ 404.37 to: (+)-Di-(*p*-toluoyl)-D-tartaric acid. $C_{20}H_{18}O_8$ 386.35
TREHALOSE	IM PURITIES/*Heavy Metals, Method I <231>*	*USP37–NF32*	6247	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 1 of *Monitor preparation*: Change Prepare with 2.5 mL of *Standard Lead Solution*. to: Prepare with 2.0 mL of *Standard Lead Solution*.
BISMUTH SUB CARBONATE	IM PURITIES/*Limit of Lead*	*USP38–NF33*	2449	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 1 of *Acceptance criteria*: Change Meets the requirements to: NMT 0.002%
QUETIAPINE	IM	*USP38–NF33*	5102	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 2 of *Peak*

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FUMARATE	PUR ITIES/*Organic Impurities*							*identification solution*: Change USP Quetiapine Fumarate Related Compound B RS to: USP Quetiapine Related Compound B RS AND Line 3 of *Peak identification solution*: Change USP Quetiapine Fumarate Related Compound G RS to: USP Quetiapine Related Compound G RS
BETAMETHASONE DIPROPI	ASSAY/ *Procedure*	*USP37–NF32*	1961	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 2 of *Sample*

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ONATE								*solution*: Change 5.0 mL each of the *Internal standard solution* and the *Standard stock solution* to: 5.0 mL each of the *Internal standard solution* and the *Sample stock solution*
PURIFIED BENTONITE	IDENTIFICATION/*A. X-Ray Diffraction <941>*	*USP37–NF32*	5862	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 4 of *Acceptance criteria*: Change from the pattern of *Sample B* is 1.492 and 1.504 Å. to: from the pattern of *Sample B* is between 1.492 and 1.504 Å.
FERRIC AMMONIUM CITRATE	*Mercury*	*Second Supplement to USP37–NF32*	Online	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 1 of *Procedure*: Change

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								Add 5 mL of stannous chloride solution (1 in 10) to each solution to: Add 5 mL of *Stannous Chloride Solution* to each solution
COSYNTROPIN	IDENTIFICATION/*B. Amino Acid Analysis*	*USP38–NF33*	2958	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 8 of *Sample hydrolysate preparation*: Change hydrochloride to: hydrochloric acid
WITCH HAZEL	*Limit of tannins*	*USP37–NF32*	5177	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 3 of *Chromatographic system*: Change 5.0-mm × 15-cm to: 4.6-mm × 15-cm
BUTORPHANOL TARTRATE	IMPUR	*First Supplement to*	6596	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Row 3 of Column 1 of

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NASAL SOLUTION	ITIES/*Organic Impurities*	*USP37–NF32*						*Table 1*: Change 6-Butorphanol to: ?6-Butorphanol
CISATRACURIUM BESYLATE INJECTION	ASSAY/ *Procedure*	*USP38–NF33*	2830	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 11 of *Analysis*: Change C_S = concentration of USP Cisatracurium Besylate RS in the *Standard solution* to: C_S = concentration of USP Cisatracurium Besylate RS in the *Standard solution* (mg/mL)
QUETIAPINE TABLETS	PERFORMANCE TESTS/ *Dissolution <711>/Test 3*	*USP38–NF33*	5104	27-Mar-2015	1-Apr-2015	*USP39–NF34*	*USP39–NF34*	Line 7 of *Instrumental conditions*: Change 10 0mg, to: 100 mg,

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								AND Line 5 of *Tolerances*: Change *For Tablets labeled to contain 100 mg, 200 mg, 300 mg, or 400 mg*: to: *For Tablets labeled to contain 50 mg, 100 mg, 200 mg, 300 mg, or 400 mg*:
MESALAMINE RECTAL SUSPENSION	OTHER COMPONENTS/*Content of Sodium Benzoate (if present)*	*USP38–NF33*	4270	30-Jan-2015	1-Feb-2015	*USP39–NF34*	*Second Supplement to USP38–NF33*	Line 5 of *Analysis*: Change Result = $(r_U/r_S) \times C_S \times (10/W) \times 100$ to: Result = $(r_U/r_S) \times C_S \times (10/W)$
CHLORAMPHENICOL SODIUM SUCCINATE	*Limit of free chloramphenicol*	*USP37–NF32*	2285	30-Jan-2015	1-Feb-2015	*USP39–NF34*	*Second Supplement to USP38–NF33*	Line 10 of *Chromatographic system*: Change Chromatograph the *Standard*

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								solution, and record the peak areas as directed for *Procedure*: the relative standard deviation for replicate injections is not less than 2.0%. to: Chromatograph the *Standard solution*, and record the peak areas as directed for *Procedure*: the relative standard deviation for replicate injections is not more than 2.0%.
CIPROFLOXACIN EXTENDED-RELEASE TABLETS	PERFORMANCE TESTS/ *Dissolution <711>*	*Revision Bulletin (Official October 01, 2014)*	Online	30-Jan-2015	1-Feb-2015	*USP39–NF34*	*Second Supplement to USP38–NF33*	Line 13 of *Analysis* in *Test 1*: Change M_{r2} = molecular weight of

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								ciprofloxacin hydrochloride, 367.81 to: M_{r2} = molecular weight of anhydrous ciprofloxacin hydrochloride, 367.81 AND Line 12 of *Analysis* in *Test 2*: Change M_{r2} = molecular weight of ciprofloxacin hydrochloride, 367.81 to: M_{r2} = molecular weight of anhydrous ciprofloxacin hydrochloride, 367.81 AND Line 13 of *Analysis* in *Test 3*: Change *M*

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								r_2= molecular weight of ciprofloxacin hydrochloride, 367.81 to: M_{r2} = molecular weight of anhydrous ciprofloxacin hydrochloride, 367.81
METHOTREXATE	IMPURITIES/*Organic Impurities/Procedure 1: Related Compounds*	*USP37–NF32*	3762	30-Jan-2015	1-Feb-2015	*USP39–NF34*	*Second Supplement to USP38–NF33*	Line 1 of *Standard solution A*: Change 0.1 ?g/mL of USP Methotrexate RS in *Solution A*, from the *Standard stock solution* to: 0.1 µg/mL of USP Methotrexate RS in *Solution A*, from *Standard stock*

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								solution A
TERAZOSIN TABLETS	PERFORMANCE TESTS/ *Dissolution <711>*	*USP37–NF32*	4874	30-Jan-2015	1-Feb-2015	*USP39–NF34*	*Second Supplement to USP38–NF33*	Line 10 of *Analysis*: Change M_{r2} = molecular weight of terazosin hydrochloride dihydrate, 459.92 to: M_{r2} = molecular weight of terazosin hydrochloride, 423.89
EXTENDED PHENYTOIN SODIUM CAPSULES	IDENTIFICATION/*A. Infrared Absorption—General <197>*	*First Supplement to USP37–NF32*	6681	30-Jan-2015	1-Feb-2015	*USP39–NF34*	*Second Supplement to USP38–NF33*	Line 1 of *Sample*: Change 6 mg/mL of phenytoin sodium in water from a suitable number of Capsules prepared as follows. Nominally transfer 300 mg of the powder into 50 mL of

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								water in a separator. to: 300 mg of phenytoin sodium from the contents of Capsules in 50 mL of water in a separator.

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