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RESIDUAL	7. BEST	USPNF Online	Online	31-Jan-2025	1-May-2025	NA	NA	In paragraph 1

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HOST CELL PRACTICES PROTEIN MEASUREMENT IN REPORTING BIOPHARMACEUTICALS BY ELISA VERSUS LIQUID CHROMATOGRAPHY –MASS SPECTROMETRY							in 7.3 <i>Comparison of ELISA and LC-MS/MS HCP Results:</i> Change the comparing to: comparing
RESIDUAL HOST CELL PROTEIN MEASUREMENT IN BIOPHARMACEUTICALS BY LIQUID CHROMATOGRAPHY –MASS SPECTROMETRY	5. QUANTITATION OF HCPS	USPNF Online Online	31-Jan-2025	1-May-2025	NA	NA	In three instances in 5.1 <i>Methods for HCP Quantitation:</i> Change product to: product protein
RESIDUAL HOST CELL PROTEIN MEASUREMENT IN BIOPHARMACEUTICALS BY LIQUID CHROMATOGRAPHY –MASS SPECTROMETRY	4. SAMPLE PREPARATION, CHROMATOGRAPHIC SEPARATION, AND MASS SPECTROMETRY ANALYSIS	USPNF Online Online	31-Jan-2025	1-May-2025	NA	NA	In paragraph 4 in 4.1 <i>Sample Preparation:</i> Change product (or polysorbate) to: product protein (or polysorbate)
RESIDUAL HOST CELL	1. INTRODUCTION AND	USPNF Online Online	31-Jan-2025	1-May-2025	NA	NA	In paragraph 3: Change

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PROTEIN MEASUREMENT IN BIOPHARMACEUTICALS BY LIQUID CHROMATOGRAPHY–MASS SPECTROMETRY								Residual HCP ELISA to: HCP ELISA
HYDROXYPROPYL BETADEX		USPNF Online	Online	31-Jan-2025	1-Feb-2025	NA	NA	In Limit of Betadex, Propylene Glycol, and Other Related Substances/Chromatographic system: Change Column temperature: 40° to: Temperatures Detector: 40° Columns: 40°
DIBUCAINE	CHROMATOGRAPHIC PURITY	USPNF Online	Online	27-Dec-2024	1-Jan-2025	NA	NA	Change Proceed as directed for Chromatographic purity under

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ACESULFAME POTASSIUM	SPECIFIC TESTS	USPNF Online	Online	27-Dec-2024	1-Jan-2025	NA	NA	<i>Dibucaine Hydrochloride</i> , to: Proceed as directed for <i>Organic Impurities</i> under <i>Dibucaine Hydrochloride</i> , In <i>Acidity or Alkalinity/Analysis</i> : Change If the solution is blue, titrate with 0.01 N hydrochloride acid to: If the solution is blue, titrate with 0.01 N hydrochloric acid
OXALIPLATIN	IMPURITIES	USPNF Online	Online	27-Dec-2024	1-Jan-2025	NA	NA	In <i>Organic Impurities, Procedure 1/Analysis</i> : Change Result = $(r_U/r_S) \times (C$

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INDOMETHACIN SODIUM ADDITIONAL REQUIREMENTS	USPNF Online	Online	22-Nov-2024	1-Dec-2024	NA	NA	$\frac{s}{(C_U)} \times (M_{r1}/M_{r2}) \times 100$ to: Result = $(r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$ In <i>USP Reference Standards</i> ?11?/USP Indomethacin Related Compound A RS: Change (C ₁₂ H ₁₃ NO ₃) to: C ₁₂ H ₁₃ NO ₃ AND In <i>USP Reference Standards</i> ?11?/USP Indomethacin Related Compound B RS: Change (C ₇ H ₅ ClO ₂) to: C ₇ H ₅ ClO ₂ In <i>Dissolution</i> ?711?/Test
TAMSULOSIN HYDROCHLORIDE PERFORMANCE TESTS	USPNF Online	Online	22-Nov-2024	1-Dec-2024	NA	NA	

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IDE CAPSULES							1/Analysis: Change $\text{Result}_3 = \{[(C_3 \times V_2) + (C_2 + V_S)] \times (1/L) \times 100\} + \text{Result}_1$ to: $\text{Result}_3 = \{[(C_3 \times V_2) + (C_2 \times V_S)] \times (1/L) \times 100\} + \text{Result}_1$
TAMSULOSIN ASSAY HYDROCHLORIDE CAPSULES	USPNF Online Online		22-Nov-2024	1-Dec-2024	NA	NA	In <i>Procedure</i> 1/Analysis: Change $C_S =$ concentration of USP Tamsulosin Hydrochloride RS in the <i>Standard stock solution</i> (mg/mL) to: $C_S =$ concentration of USP Tamsulosin Hydrochloride RS in the <i>Standard</i>

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ALUMINUM SULFATE	CHEMICAL INFORMATION	USPNF Online	Online	25-Oct-2024	1-Nov-2024	NA	NA	solution (mg/mL) Change $\text{Al}_2(\text{SO}_4)_3 \cdot x\text{H}_2\text{O}$ (anhydrous) 342.15 to: $\text{Al}_2(\text{SO}_4)_3 \cdot x\text{H}_2\text{O}$ AND Change Anhydrous 342.16 to: Anhydrous 342.13
FLUCONAZOLE	IMPURITIES	USPNF Online	Online	25-Oct-2024	1-Nov-2024	NA	NA	In <i>Organic Impurities/Analysis</i> : Change Calculate the percentage of any individual unspecified impurity in the portion of Fluconazole taken: to: Calculate the percentage of

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								any other specified and unspecified impurity in the portion of Fluconazole taken: AND Change r_U = peak response of any individual impurity from the <i>Sample solution</i> to: r_U = peak response of any other specified and unspecified impurity from the <i>Sample solution</i> In Limit of High Molecular Weight Proteins: Change Acceptance criteria Individual
RALBUMIN HUMAN	IMPURITIES	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	

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RALBUMIN HUMAN	ASSAY	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	impurities: NMT 1.0% to: Acceptance criteria: NMT 1.0% In <i>Albumin Content/Native stock running buffer</i> : Change glycerol to: glycine In <i>Procedure/Solution A</i> : Change sodium phosphate monobasic to: sodium phosphate, monobasic, anhydrous In <i>Organic Impurities/Table 4</i> : Change ^a (2a <i>R</i> ,4 <i>S</i> ,4a <i>S</i> ,6 <i>R</i> ,9 <i>S</i> ,11 <i>S</i>
PHENOXYBEN ZAMINE HYDROCHLORIDE	ASSAY	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	
PACLITAXEL	IMPURITIES	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	

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							,12S,12aR ,12bS)-12b-(Acetyloxy)-12-(benzyloxy)-1,2a,3,4,4a,6,9,10,11,12,12a,12b-dodecahydro-4,6,9,11-tetrahydroxy-4a,8,13,13-tetramethyl-
							<i>H</i> -cyclodeca[3,4]benz[1,2- <i>b</i>]oxet-5-one. to: ^a (2a <i>R</i> ,4 <i>S</i> ,4a <i>S</i> ,6 <i>R</i> ,9 <i>S</i> ,11 <i>S</i> ,12 <i>S</i> ,12a <i>R</i> ,12b <i>S</i>)-12b-(Acetyloxy)-12-(benzoyloxy)-1,2a,3,4,4a,6,9,10,11,12,12a,12b-dodecahydro-4,6,9,11-tetrahydroxy-4a,8,13,13-tetramethyl-7,11-methano-

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MOXIFLOXACIN TABLETS	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	5H -cyclodeca[3,4] benz[1 ,2- <i>b</i>]oxet-5-one. In <i>Organic Impurities/Buffer</i> : Change tetrabutyl ammonium to: tetrabutylammo nium AND In <i>Organic Impurities/Solution C</i> : Change tetrabutyl ammonium to: tetrabutylammo nium
METHOTREXATE ASSAY	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	In <i>Procedure/Buffer</i> : Correct the reagent cross reference <u>1 N sodium hydroxide</u>

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KETOCONAZOLE ASSAY	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	to: 1 N <u>sodium hydroxide</u> In <i>Procedure/Buffer:</i> Change tetrabutyl ammonium to: tetrabutylammonium
FLUCONAZOLE TABLETS ADDITIONAL REQUIREMENTS	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	In <i>USP Reference Standards</i> <11>/USP Fluconazole Related Compound B RS: Change C ₁₃ H ₁₃ FN ₉ O to: C ₁₃ H ₁₃ FN ₆ O
CETIRIZINE HYDROCHLORIDE TABLETS HYMPURITIES	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	In <i>Organic Impurities/Buffer:</i> Change tetrabutyl ammonium to: tetrabutylammonium

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CETIRIZINE HYDROCHLORIDE		USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	nium In <i>Organic Impurities, Procedure 2/Solution A</i> : Change tetrabutyl ammonium to: tetrabutylammonium
CALCITONIN SALMON	SPECIFIC TESTS	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	In <i>Bioidentity/Medium B</i> : Change 2 mM RPMI 1640 to: RPMI 1640
CALCITONIN SALMON	IMPURITIES	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	In <i>Procedure: Related Peptides and Other Related Substances/Test 2</i> : Change Resolution solution : to: System suitability

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AMLODIPINE ASSAY AND BENAZEPRIL HYDROCHLORIDE CAPSULES	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	solution: AND In <i>Procedure: Related Peptides and Other Related Substances/Test 2</i> /Sample solution: Change 100 mL of Buffer C. to: 100 ?L of Buffer C. In <i>Procedure/Buffer 1</i> : Change tetrabutyl ammonium to: tetrabutylammonium In <i>Procedure/Buffer</i> : Change tetrabutyl ammonium
ADENOSINE ASSAY	USPNF Online	Online	27-Sep-2024	1-Oct-2024	NA	NA	In <i>Procedure/Buffer</i> : Change tetrabutyl ammonium

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POTASSIUM PHOSPHATES COMPOUNDED INJECTION	ASSAY	USPNF Online	Online	30-Aug-2024		1-Sep-2024	NA	NA	to: tetrabutylammonium In <i>Procedure for Potassium/Chromatographic system/Column:</i> Change 4.6-mm × 25-cm; packing L97 to: 4-mm × 25-cm; packing L97 AND In <i>Procedure for Phosphate/Chromatographic system/Column:</i> Change 4.6-mm × 25-cm; packing L103 to: 4-mm × 25-cm; packing L103
CRANBERRY	IDENTIFICATION	USPNF Online	Online	26-Jul-2024		1-Aug-2024	NA	NA	In A. HPTLC for

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FRUIT JUICE N DRY EXTRACT							<i>Articles of Botanical Origin</i> <203>/Sample solution: Change Mix 50 mg of Cranberry Fruit Juice Dry Extract with 7 mL of water. Sonicate for 10 min at room temperature, centrifuge, and save the supernatant. Precondition an SPE cartridge (L2; 500 mg/6 mL) with 3 mL of methanol, and drain it with suction. Load 3 mL of water onto the cartridge and apply suction until the solvent reaches 1–2 mm above the top of the

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							cartridge's stationary phase. Then load the cartridge with 1.5 mL of the supernatant, apply suction, and discard the eluate. Add 1 mL of a mixture of water and methanol (80:20). Load 1 mL of methanol and collect the eluate as the <i>Sample solution</i>. to: Mix 50 mg of Cranberry Fruit Juice Dry Extract with 7 mL of water. Sonicate for 10 min at room temperature, centrifuge, and save the supernatant.

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							Precondition an SPE cartridge (L2; 500 mg/6 mL) with 3 mL of methanol, and drain it with suction. Load 3 mL of water onto the cartridge and apply suction until the solvent reaches 1–2 mm above the top of the cartridge's stationary phase. Then load the cartridge with 1.5 mL of the supernatant, apply suction, and discard the eluate. Add 1 mL of a mixture of water and methanol (80:20), apply suction, and discard the

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EXENATIDE INJECTION	PRODUCT-RELATED SUBSTANCES AND IMPURITIES	USPNF Online	Online	26-Jul-2024		1-Aug-2024	NA	NA	eluate. Load 1 mL of methanol and collect the eluate as the <i>Sample solution</i> . In <i>Procedure/Chromatographic system/Column</i> : Change 4.6-mm × 10-cm; 3-μm packing L52 to: 4.6-mm × 10-cm; 3-μm packing L52; two columns in series
NICARDIPINE HYDROCHLORIDE	ADDITIONAL REQUIREMENTS	USPNF Online	Online	26-Jul-2024		1-Aug-2024	NA	NA	In <i>USP Reference Standards <11>/USP Nicardipine Related Compound B RS</i> : Change 3-{2-[Benzyl(me

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							thyl)amino]ethyl }5-methyl 2,6-di methyl-4-(3-nitr ophenyl)pyridin e-3,5-dicarboxyl ate oxalate. to: 3-{2-[Benzyl(me thyl)amino]ethyl } 5-methyl 2,6-di methyl-4-(3-nitr ophenyl)pyridin e-3,5-dicarboxyl ate oxalate. AND In <i>USP</i> <i>Reference</i> <i>Standards</i> <11>/USP Nicardipine Related Compound D RS: Change Bis{2-[benzyl(m ethyl)amino]eth yl}2,6-dimethyl- 4-(3-nitrophenyl)-1,4-dihydropyr idine-3,5-dicarb oxylate dihydrochloride.

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EDETATE DISODIUM COMPOUNDED OPHTHALMIC SOLUTION	DEFINITION	USPNF Online	Online	28-Jun-2024		1-Jul-2024	NA	NA	to: Bis{2-[benzyl(methyl)amino]ethyl} 2,6-dimethyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate dihydrochloride. In two instances: Change to a pH between 6.5 and 7.5. to: to a pH between 6.1 and 7.1.
NEOMYCIN AND POLYMYXIN B SULFATES AND LIDOCAINE CREAM	ASSAY	USPNF Online	Online	28-Jun-2024		1-Jul-2024	NA	NA	Change Assay for neomycin in —Proceed with Cream as directed in the <i>Assay for neomycin</i> under <i>Neomycin and Polymyxin B Sulfates Cream</i> .

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							Assay for polymyxin B—Proceed with Cream as directed in the <i>Assay for polymyxin B</i> under <i>Neomycin and Polymyxin B Sulfates Cream</i>. to: Assay for neomycin in—Proceed as directed under <i>Antibiotics—Microbial Assays</i> ?81?, using an accurately weighed portion of Cream, equivalent to about 1.75 mg of neomycin, shaken in a separator with about 50 mL of ether, and

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							extracted with four 20-mL portions of <i>Buffer B.3</i>. Combine the aqueous extracts, and dilute with <i>Buffer B.3</i> to an appropriate volume to obtain a stock solution of convenient concentration. Dilute this stock solution quantitatively and stepwise with <i>Buffer B.3</i> to obtain a <i>Test Dilution</i> having a concentration assumed to be equal to the median dose level of the Standard. Assay for polymyxin B—Proceed as

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							directed under <i>Antibiotics—Microbial Assays</i> ?81?, using an accurately weighed portion of Cream shaken with about 50 mL of ether in a separator, and extracted with four 25-mL portions of <i>Buffer B.6</i> . Combine the aqueous extracts, and dilute with <i>Buffer B.6</i> to an appropriate volume to obtain a stock solution. Dilute this stock solution quantitatively and stepwise with <i>Buffer B.6</i> to obtain a <i>Test Dilution</i> having

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									a concentration assumed to be equal to the median dose level of the Standard (10 Polymyxin B Units per mL). Add to each test dilution of the Standard a quantity of USP Neomycin Sulfate RS, dissolved in <i>Buffer B.6</i> , to obtain the same concentration of neomycin present in the <i>Test Dilution</i> .
NAPROXEN SODIUM	SPECIFIC TESTS	USPNF Online	Online	28-Jun-2024		1-Aug-2024	NA	NA	In <i>Loss on Drying</i> <731>/Analysis: Change Dry at 105° for 3 h. to: Dry in vacuum at 105° for 3 h.
DESCRIPTION	Hydrogenated	USPNF Online	Online	28-Jun-2024		1-Aug-2026	NA	NA	Change

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AND SOLUBILITY	Castor Oil								White, crystalline wax. Freely soluble in water, in saline TS, and in dextrose solutions; very slightly soluble in alcohol; practically insoluble in chloroform and in ether. Insoluble in water and in most common organic solvents. <i>NF category:</i> Stiffening agent; lubricant; film-forming agent; release-modifying agent. to: White, crystalline wax. Insoluble in water and in most common

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METRONIDAZ OLE CAPSULES	IMPURITIES	USPNF Online Online	31-May-2024	1-Jun-2024	NA	NA	organic solvents. <i>NF category:</i> Stiffening agent; lubricant; film-forming agent; r release-modifying agent. In <i>Organic Impurities:</i> Change Mobile phase, Sample solution, and Chromatographic system: Proceed as directed in the Assay. to: Mobile phase and Chromatographic system: Proceed as directed in the Assay. AND Change

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							Standard solution: 1 µg/mL of metronidazole from USP Metronidazole RS and 2 µg/mL of tinidazole related compound A from USP Tinidazole Related Compound A RS in <i>Mobile phase</i> to: Standard solution: 1 µg/mL of metronidazole from USP Metronidazole RS and 2 µg/mL of tinidazole related compound A from USP Tinidazole Related

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							Compound A RS in <i>Mobile phase</i> Sample solution: Nominally 1 mg/mL of metronidazole prepared as follows. Mix the contents of Capsules (NLT 20). Transfer an amount equivalent to 100 mg of metronidazole to a 100-mL volumetric flask, add 80 mL of <i>Mobile phase</i>, and sonicate with intermittent shaking for 10 min. Shake for 30 min, and dilute with <i>Mobile phase</i> to volume. Centrifuge a portion of the

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DOCETAXEL	IMPURITIES	USPNF Online	Online	31-May-2024	1-Jun-2024	NA	NA	solution. In <i>Organic Impurities, Procedure 1</i>: Change System suitability solution, Standard solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay. to: Mobile phase, Diluent, System suitability solution, Standard solution, Sample solution, and Chromatographic system: Proceed as

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CEFUROXIME ASSAY AXETIL FOR ORAL SUSPENSION	USPNF Online	Online	31-May-2024	1-Jun-2024	NA	NA	directed in the Assay. In Proce dure/System suitability: Change [Note—The relative retention times for acetanilide, cefuroxime axetil diastereoisomer B, cefuroxime axetil diastereoisomer A, and cefuroxime axetil delta-3 isomers are 0.4, 0.8, 0.9, and 1.0, respectively.] to: [Note—The relative retention times for cefuroxime axetil diastereoisomer

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PROCAINAMIDE HYDROCHLORIDE ASSAY		USPNF Online	Online	31-May-2024	1-Jun-2024	NA	NA	B, cefuroxime axetil diastereoisomer A, and cefuroxime axetil delta-3 isomers are 0.8, 0.9, and 1.0, respectively.] In Resolution solution: Change <i>p</i> -aminobenzoic acid to: <i>p</i> -aminobenzoic acid
TYLOSIN INJECTION	SPECIFIC TESTS	USPNF Online	Online	31-May-2024	1-Jun-2024	NA	NA	Change <i>pH</i> ?921? to: <i>pH</i> ?791?
ISOSORBIDE MONONITRATE TABLETS	IMPURITIES	USPNF Online	Online	26-Apr-2024	1-May-2024	NA	NA	In Organic Impurities/Standard solution: Change isosorbide related compound A to: isosorbide mon

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							onitrate related compound A AND In System <i>suitabil</i> <i>ity/Suitability</i> <i>re</i> <i>quire</i> <i>ments/Relative</i> <i>standard</i> <i>deviation:</i> Change isosorbide related compound A, to: isosorbide mon onitrate related compound A, AND In four instances in <i>Analysis:</i> Change isosorbide related compound A, to: isosorbide mon onitrate related compound A,

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DOXORUBICIN ASSAY HYDROCHLORIDE	USPNF Online	Online	26-Apr-2024	1-May-2024	NA	NA	AND In <i>Table 1</i> : Change Isosorbide related compound A to: Isosorbide mononitrate related compound A In <i>Procedure/System suitability solution</i> : Add link to USP Store for USP Epirubicin Hydrochloride RS
RIVASTIGMINE IMPURITIES TARTRATE	USPNF Online	Online	26-Apr-2024	1-May-2024	NA	NA	In <i>Organic Impurities/Procedure 1/Impurity Table 1/footnote d</i> : Change 3-Nitrophenyl ethyl(methyl)carbamate. to: 4-Nitrophenyl et

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RIVASTIGMINE ADDITIONAL REQUIREMENTS	USPNF Online	Online	26-Apr-2024	1-May-2024	NA	NA	hyl(methyl)carbamate. In USP Reference Standards ?11?: Change USP Rivastigmine Tartrate R-Isomer RS to: USP Rivastigmine Tartrate R-Isomer RS (<i>R</i>)-3-[1-(Dimethylamino)ethyl]phenyl ethylmethylcarbamate, hydrogen tartrate. $C_{14}H_{22}N_2O_2 \cdot C_4H_6O_6$ 400.42
BROMPHENIRAMINE MALEATE SPECIFIC TESTS	USPNF Online	Online	26-Apr-2024	1-May-2024	NA	NA	Change Optical Rotation ?781? to: Optical Rotation ,

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DILUTED ISOSORBIDE MONONITRATE	IMPURITIES	USPNF Online	Online	26-Apr-2024	1-May-2024	NA	NA	<i>Angular Rotation ?781A?</i> <i>In Organic Impurities/Standard solution:</i> Change isosorbide related compound A to: isosorbide mononitrate related compound A AND <i>In System suitability/Suitability require ments/Relative standard deviation:</i> Change isosorbide related compound A, to: isosorbide mononitrate related

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DAPSONE TABLETS	PERFORMANCE TESTS	USPNF Online	Online	26-Apr-2024		1-May-2024	NA	NA	compound A, AND In four instances in <i>Analysis</i> : Change isosorbide related compound A, to: isosorbide mononitrate related compound A, AND In <i>Table 1</i> : Change Isosorbide related compound A to: Isosorbide mononitrate related compound A In <i>Dissolution</i> ?711?/ <i>Standard solution</i> : Change USP Dapsone RS of a known concentration in <i>Medium</i>

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LIDOCAINE	ASSAY	USPNF Online	Online	29-Mar-2024		1-Apr-2024	NA	NA	to: (<i>L</i>/1000) mg/mL of USP Dapsone RS in <i>Medium</i>, where <i>L</i> is the label claim in mg/Tablet. Transfer a portion of this solution containing 0.2 mg of dapsone to a 25-mL volumetric flask, add 5 mL of 1 N sodium hydroxide, and dilute with water to volume. In <i>Procedure</i>: Change Column: 3.9-mm × 30-cm; 4-μm packing L1 to: Column: 3.9-mm × 30-cm; 10-μm

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IPRATROPIUM BROMIDE INHALATION SOLUTION	IMPURITIES	USPNF Online	Online	29-Mar-2024		1-Apr-2024	NA	NA	packing L1 In <i>Organic Impurities</i> : Change Column: 4.6-mm × 25-μm; 5-μm packing L1 to: Column: 4.6-mm × 25-cm; 5-μm packing L1
ENSULIZOLE	IDENTIFICATION	USPNF Online	Online	29-Mar-2024		1-Apr-2024	NA	NA	In <i>B.</i> : Change The retention time of the major peak of the <i>Sample solution</i> exhibits maxima and minima at the same wavelengths as those of the <i>Standard solution</i> , as obtained in the Assay. to: The retention

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							time of the major peak of the <i>Sample solution</i> corresponds to that of the <i>Standard solution</i> , as obtained in the Assay.

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