CSV November 24, 2022 through November 24, 2024 All Errata for USP–NF How to use

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**How to Use**

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| AMLODIPINE | PERFORMANC | *First* | 8270 | 23-Feb-2018 | 1-Mar-2018 | *USP42–NF37* | *Second* | In the variable |

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| AND ATORVASTATIN TABLETS | TESTS/ *Dissolution <711>* | *Supplement to USP41–NF36* | | | | | *Supplement to USP41–NF36* | definition list of the second equation in *Analysis*: Change $M_{r2}$ = molecular weight of atorvastatin calcium, 1209.39 to: $M_{r2}$ = molecular weight of atorvastatin calcium, 1155.34 |
| NOREPINEPHRINE BITARTRATE | ASSAY/ *Procedure* | *USP40–NF35* | 5380 | 23-Feb-2018 | 1-Mar-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 1 of *Sample solution*: Change 25 mg/mL of Norepinephrine Bitartrate in glacial acetic acid. If necessary warm slightly to effect solution. to: Dissolve 500 mg of |

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| | | | | | | | | Norepinephrine Bitartrate in 20 mL of glacial acetic acid, warming slightly if necessary to effect solution. |
| STATISTICAL TOOLS FOR PROCEDURE VALIDATION | 3. ACCURACY AND PRECISION/*3.1 Methods for Estimating Accuracy and Precision* | *USP41–NF36* | 7622 | 23-Feb-2018 | 1-Mar-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Paragraph 4:<br>Change<br>For example, with ? = 0.05 and $n$ = 9, $t_{0.95:8}$ = 1.860 provides a 100(1? 2 × 1.05)%<br>to:<br>For example, with ? = 0.05 and $n$ = 9, $t_{0.95:8}$ = 1.860 provides a 100(1 ? 2 × 0.05)% |
| CHLORHEXIDINE GLUCONATE ORAL RINSE | *Identification* | *USP40–NF35* | 3367 | 23-Feb-2018 | 1-Mar-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 1 of *C*:<br>Change<br>Undiluted Oral Rinse used as the test solution meets the requirements |

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| | | | | | | | | for *Identification* test *B* under *Calcium Gluconate*, except that a Standard solution containing about 0.6 mg of USP Potassium Gluconate RS per mL is used and 15 ?L of the test solution and the Standard solution are applied to the thin-layer chrom atographic plate.<br>to:<br>Use undiluted Oral Rinse as the test solution and prepare a Standard solution of USP Potassium Gluconate RS in water |

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| | | | | | | | | containing 0.6 mg/mL. Apply separate 15-?L portions of the test solution and the Standard solution to a suitable thin-layer chromatographic plate (see *Chromatography* <621>) coated with a 0.25-mm layer of chromatographic silica gel, and allow to dry. Develop the chromatogram in a solvent system consisting of a mixture of alcohol, water, ammonium hydroxide, and ethyl acetate (50:30:10:10) until the solvent |

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| | | | | | | | | front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and dry at 110° for 20 minutes. Allow to cool and spray with a spray reagent prepared as follows. Dissolve 2.5 g of ammonium molybdate in about 50 mL of 2 N sulfuric acid in a 100-mL volumetric flask, add 1.0 g of ceric sulfate, swirl to dissolve, dilute with 2 N sulfuric acid to volume, and mix. Heat the plate at 110° for about 10 minutes: the |

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| | | | | | | | | principal spot obtained from the test solution corresponds in color, size, and $R_F$ value to that obtained from the Standard solution. |
| REAGENTS | REAGENT SPECIFICATIONS | *USP41–NF36* | 5724 | 23-Feb-2018 | 1-Mar-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 2 of *9Z-Retinoic Acid*: Change *Acidalitretinoin)*, to: *Alitretinoin)*, |
| AMLODIPINE AND ATORVASTATIN TABLETS | IMPURITIES/*Organic Impurities Related to Atorvastatin* | *First Supplement to USP41–NF36* | 8270 | 23-Feb-2018 | 1-Mar-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | In the variable definition list in *Analysis*: Change $M_{r2}$ = molecular weight of atorvastatin calcium, 1209.39 to: $M_{r2}$ = molecular weight of atorvastatin calcium, 1155.34 |
| PIPERACILLIN | IM | *USP40–NF35* | 5728 | 23-Feb-2018 | 1-Mar-2018 | *USP42–NF37* | *Second* | Footnote m: |

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| AND TAZOBACTAM FOR INJECTION | PUR ITIES/*Organic Impurities, Procedure 2*/*Table 3* | | | | | | *Supplement to USP41–NF36* | Change (2*S*,5*R*,6*R*)-Ethyl 6-((*R*)-2-{(2*S*,5*R*,6*R*)-6-[(*R*)-2-(4-ethyl-2,3-dioxopiperazine-1-carboxamido)-2-phenylacetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxamido}-2-phenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate. to: 2-(((3-Acetyl-4-(ethoxycarbonyl)-5,5-dimethylthiazolidin-2-yl)methyl)amino)-2-oxo-1-phenylethyl 6-(2-(4-ethyl-2,3-dioxopiperazine-1-carboxamid |

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| | | | | | | | | o)-2-phenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate. |
| AMLODIPINE AND ATORVASTATIN TABLETS | ASSAY/*Procedure* | *First Supplement to USP41–NF36* | 8270 | 23-Feb-2018 | 1-Mar-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | In the variable definition list of the second equation in *Analysis*:<br>Change<br>$M_{r2}$ = molecular weight of atorvastatin calcium, 1209.39<br>to:<br>$M_{r2}$ = molecular weight of atorvastatin calcium, 1155.34 |
| NOREPINEPHRINE BITARTRATE | IDENTIFICATION/*B. Procedure* | *USP40–NF35* | 5380 | 23-Feb-2018 | 1-Mar-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 1 of *Analysis*:<br>Change<br>Add 1 drop of ferric chloride TS.<br>to:<br>Add 1 drop of |

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| | | | | | | | | ferric chloride TS to 2 mL of *Sample solution*. |
| INHALATION AND NASAL DRUG PRODUCTS: AEROSOLS, SPRAYS, AND POWDERS—PERFORMANCE QUALITY TESTS | C. AERODYNAMIC SIZE DISTRIBUTION—INHALATION AEROSOLS, SPRAYS, AND POWDERS | *USP41–NF36* | 6327 | 23-Feb-2018 | 1-Mar-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | *Figure 6*: Change Boquilla del Inhalador to: Inhaler Mouthpiece AND Change Tubo de Admisión to: Induction Port AND Change Cono de Ingreso to: Entrance Cone |
| ANTIBIOTICS—MICROBIAL ASSAYS | CALCULATIONS/*Turbidimetric Assay*/*Sample Data* | *USP40–NF35* | 143 | 23-Feb-2018 | 1-Mar-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Second equation in *Step 1*: Change 0.0125 = to: 0.0062 = AND Third equation |

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| | | | | | | | | in *Step 1*: Change 0.0325 = to: 0.0322 = |
| BRETYLIUM TOSYLATE IN DEXTROSE INJECTION | *Identification* | *USP40–NF35* | 3049 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 1 of *B*: Change It responds to the *Identification test* under *Dextrose*. to: Add a few drops of a solution (1 in 20) to 5 mL of hot alkaline cupric tartrate TS. A copious red precipitate of cuprous oxide is formed. |
| LIDOCAINE HYDROCHLORIDE AND DEXTROSE INJECTION | *Identification* | *USP40–NF35* | 4852 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 1 of *B*: Change It responds to the *Identification* test under *Dextrose*. to: |

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| POWDERED ECHINACEA ANGUSTIFOLIA EXTRACT | IDENTIFICATION | *USP40–NF35* | 6928 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Add a few drops of a solution (1 in 20) to 5 mL of hot alkaline cupric tartrate TS. A copious red precipitate of cuprous oxide is formed. Line 5 of *A. Thin-Layer Chromatography/Presence of echinacoside and dicaffeoylquinic acid*/*System suitability*: Change *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower $R_F$) and chlorogenic acid (higher *R* |

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| | | | | | | | | $_F$) that are clearly separated, to: *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (higher $R_F$) and chlorogenic acid (lower $R_F$) that are clearly separated, AND Line 3 of *C*.: Change *Standard solution B*; to: *Standard solution C*; |
| ECHINACEA PURPUREA ROOT | IDENTIFICATION | *USP40–NF35* | 6940 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 3 of *A. Thin-Layer Chromatography/ Presence of* |

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| | | | | | | | | *chicoric acid and absence of ec hinac oside*/*System suitability*: Change *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower $R_F$) and chlorogenic acid (higher $R_F$) that are clearly separated, to: *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric |

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| | | | | | | | | acid (higher $R_F$) and chlorogenic acid (lower $R_F$) that are clearly separated, |
| ECHINACEA SPECIES DRY EXTRACT TABLETS | IDENTIFICATION | *USP41–NF36* | 4592 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 4 of *A. HPTLC for Articles of Botanical Origin <203>/For Tablets containing Echinacea angustifolia Dry Extract/System suitability*: Change *Standard solution B* shows two major blue bands at about the middle section due to caftaric acid (lower $R_F$) and chlorogenic acid (higher $R_F$) that are clearly separated, to: |

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| | | | | | | | | *Standard solution B* shows two major blue bands at about the middle section due to caftaric acid (higher $R_F$) and chlorogenic acid (lower $R_F$) that are clearly separated, |
| NIACIN EXTEN DED-RELEASE TABLETS | ASSAY/ *Procedure* | *Revision Bulletin (Official January 01, 2018)* | Online | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 3 of *System suitability*: Change *Table 4* to: *Table 13* |
| DOPAMINE HY DROCHLORIDE AND DEXTROSE INJECTION | *Identification* | *USP40–NF35* | 3866 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 1 of *A*: Change It responds to the *Identification* test under *Dextrose*. to: Add a few drops of a solution (1 in 20) to 5 mL of |

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| | | | | | | | | hot alkaline cupric tartrate TS. A copious red precipitate of cuprous oxide is formed. |
| ECHINACEA ANGUSTIFOLIA | IDENTIFICATION | *USP40–NF35* | 6923 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 5 of *A. Thin-Layer Chromatography/Presence of echinacoside and dicaffeoylquinic acid*/*System suitability*: Change *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower $R_F$) and chlorogenic acid (higher $R_F$) that are clearly separated, to: |

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| POWDERED ECHINACEA PALLIDA EXTRACT | IDENTIFICATION | *USP40–NF35* | 6935 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (higher $R_F$) and chlorogenic acid (lower $R_F$) that are clearly separated, AND<br>Line 3 of *C.*: Change *Standard solution B*; to: *Standard solution C*;<br>Line 5 of *A. Thin-Layer Chromatography/Presence of echinacoside and absence of dicaffeoylquinic acid*/*System suitability*: |

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| | | | | | | | | Change *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower $R_F$) and chlorogenic acid (higher $R_F$) that are clearly separated, to: *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (higher $R_F$) and chlorogenic acid (lower $R_F$) that are clearly separated, AND |

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| | | | | | | | | Lines 3 and 6 of *C.*: Change *Standard solution B,* to: *Standard solution C,* AND Change *Standard solution C*) to: *Standard solution D*) |
| PHENYTOIN ORAL SUSPENSION | PERFORMANCE TESTS/ *Dissolution <711>* | *USP41–NF36* | 3286 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | In the *Analysis*: Change $C_S$ = concentration of USP Phenytoin RS in the *Standard solution* to: $C_S$ = concentration of USP Phenytoin RS in the *Standard solution* (mg/mL) |
| ESZOPICLONE | ADDITIONAL R | *Revision* | Online | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second* | Line 2 of USP |

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| TABLETS | EQUIREMENTS/*USP Reference Standards <11>* | *Bulletin (Official August 01, 2017)* | | | | | *Supplement to USP41–NF36* | Eszopiclone Related Compound A RS: Change 6-(5-Chloropyridin-2-yl)-7-oxo-6,7-dihydro-5*H*-pyrrolo[3,4-*b*]pyrazin-5-yl 4-methylpiperazine-1-carboxylate 4-oxide. $C_{17}H_{17}ClN_6O_4$ 404.81 to: [Note—This material may be available in the free base or salt form.] 6-(5-Chloropyridin-2-yl)-7-oxo-6,7-dihydro-5*H*-pyrrolo[3,4-*b*]pyrazin-5-yl 4-methylpiperazine-1-carboxylat |

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| | | | | | | | | e 4-oxide. $C_{17}H_{17}ClN_6O_4$ 404.81 6-(5-Chloropyridin-2-yl)-7-oxo-6,7-dihydro-5*H*-pyrrolo[3,4-*b*]pyrazin-5-yl 4-methylpiperazine-1-carboxylate 4-oxide, 3-chlorobenzoic salt (1:1). $C_{17}H_{17}ClN_6O_4 \cdot C_7H_5ClO$ 561.38 |
| POWDERED DIGITALIS | IDENTIFICATION/*B. Thin-Layer Chromatographic Identification Test* | *USP40–NF35* | 3762 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 3 of *Standard solution A*: Change lead acetate, to: lead acetate TS, AND Line 11 of *Analysis*: Change Locate the two prominent |

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| | | | | | | | | bands from *Standard solution A* corresponding in $R_F$ value to the two bands from *Standard solution B*.<br>to:<br>Locate the prominent bands from *Standard solution A* corresponding in $R_F$ value to the band from *Standard solution B*. |
| NEVIRAPINE TABLETS | IM PUR ITIES/*Organic Impurities* | *USP40–NF35* | 5333 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 1 of *Standard solution*:<br>Change<br>0.125 ?g/mL of USP Nevirapine Anhydrous RS from *Standard stock solution A* in *Diluent*<br>to:<br>0.125 ?g/mL of |

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| ECHINACEA PALLIDA | IDENTIFICATION | *USP40–NF35* | 6931 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | USP Nevirapine Anhydrous RS in *Diluent* Line 5 of *A. Thin-Layer Chromatography/Presence of echinacoside and absence of dicaffeoylquinic acid/System suitability*: Change *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower $R_F$) and chlorogenic acid (higher $R_F$) that are clearly separated, to: *Standard solution B* shows two |

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| | | | | | | | | major blue bands at about the middle of the chromatogram due to caftaric acid (higher $R_F$) and chlorogenic acid (lower $R_F$) that are clearly separated, AND Lines 3 and 6 of *C.*: Change *Standard solution B,* to: *Standard solution C,* AND Change *Standard solution C*) to: *Standard solution D*) |
| POWDERED ECHINACEA PURPUREA | IDENTIFICATION | *USP40–NF35* | 6942 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 3 of *A. Thin-Layer Chromatography/ Presence of* |

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| | | | | | | | | *chicoric acid and absence of ec hinac oside*/*System suitability*: Change *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower $R_F$) and chlorogenic acid (higher $R_F$) that are clearly separated, to: *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric |

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| | | | | | | | | acid (higher $R_F$) and chlorogenic acid (lower $R_F$) that are clearly separated, |
| ECHINACEA SPECIES POWDER CAPSULES | IDENTIFICATION | *USP41–NF36* | 4595 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 4 of *A. HPTLC for Articles of Botanical Origin <203>/For Capsules containing Echinacea angustifolia powder prepared from dried rhizome and roots/System suitability*: Change *Standard solution B* shows two major blue bands at about the middle section due to caftaric acid (lower $R_F$) and chlorogenic acid |

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| | | | | | | | | (higher $R_F$) that are clearly separated, to: *Standard solution B* shows two major blue bands at about the middle section due to caftaric acid (higher $R_F$) and chlorogenic acid (lower $R_F$) that are clearly separated, |
| TIMOLOL MALEATE | ADDITIONAL REQUIREMENTS/*USP Reference Standards <11>* | *First Supplement to USP40–NF35* | 8416 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 2 of USP Timolol Related Compound A RS: Change (*R*)-1-(*tert*-Butylamino)-3-(4-morpholino-1,2,5-thiadiazol-3-yloxy)propan-2-ol. $C_{13}H_{24}N_4O_3S$ 316.42 to: |

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| | | | | | | | | (*R*)-1-(*tert*-Butylamino)-3-(4-morpholino-1,2,5-thiadiazol-3-yloxy)propan-2-ol maleate. $C_{13}H_{24}N_4O_3S \cdot C_4H_4O_4$ 432.49<br>AND<br>Line 2 of USP Timolol Related Compound C RS: Change *N*-(*tert*-Butyl)-2,3-bis(4-morpholino-1,2,5-thiadiazol-3-yloxy)propan-1-amine. $C_{19}H_{31}N_7O_4S_2$ 485.19<br>to:<br>*N*-(*tert*-Butyl)-2,3-bis(4-morpholino-1,2,5-thiadiazol-3-yloxy)propan-1-amine maleate. $C_{19}H_{31}N_7O_4S_2$ ? $C_4H_4O_4$ 601.69<br>AND |

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| | | | | | | | | Line 3 of USP Timolol Related Compound D RS: Change $C_6H_9N_7O_4S$ to: $C_6H_9N_3O_2S$ AND Line 2 of USP Timolol Related Compound E RS: Change (*S*)-3-(*tert*-Butylamino)-1-(4-morpholino-1,2,5-thiadiazol-3-yloxy)propan-2-yl hydrogen maleate. $C_{17}H_{26}N_4O_6S$ 414.48 to: (*S*,*Z*)-4-({1-(*tert*-Butylamino)-3-[(4-morpholino-1,2,5-thiadiazol-3-yl)oxy]propan-2-yl}oxy)-4-oxobut-2-enoic acid |

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| | | | | | | | | maleate salt (1:1) $C_{17}H_{26}N_4O_6S$ ? $C_4H_4O_4$ 530.55 |
| IMMUNOLOGICAL TEST METHODS—ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) | PROCEDURES/*Solid Phase* | *USP40–NF35* | 1344 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 7 of *Coating the Solid Phase—Immobilization of Capture Reagent*: Change 1–10 µg/well to: 1–10 µg/mL |
| ESZOPICLONE | ADDITIONAL REQUIREMENTS/*USP Reference Standards <11>* | *USP40–NF35* | 4090 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 2 of USP Eszopiclone Related Compound A RS: Change 6-(5-Chloropyridin-2-yl)-7-oxo-6,7-dihydro-5*H*-pyrrolo[3,4-*b*]pyrazin-5-yl 4-methylpiperazine-1-carboxylate 4-oxide. $C_{17}H_{17}ClN_6O_4$ 404.81 |

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| | | | | | | | | to: [Note—This material may be available in the free base or salt form.] 6-(5-Chloropyridin-2-yl)-7-oxo-6,7-dihydro-5*H*-pyrrolo[3,4-*b*]pyrazin-5-yl 4-methylpiperazine-1-carboxylate 4-oxide. $C_{17}H_{17}ClN_6O_4$ 404.81 6-(5-Chloropyridin-2-yl)-7-oxo-6,7-dihydro-5*H*-pyrrolo[3,4-*b*]pyrazin-5-yl 4-methylpiperazine-1-carboxylate 4-oxide, 3-chlorobenzoic salt (1:1). C |

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| POWDERED ECHINACEA ANGUSTIFOLIA | IDENTIFICATION | *USP40–NF35* | 6926 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | $^{17}H_{17}ClN_6O_4 \cdot C_7H_5ClO$ 561.38 Line 5 of *A. Thin-Layer Chromatography/Presence of echinacoside and dicaffeoylquinic acid/System suitability*: Change *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower $R_F$) and chlorogenic acid (higher $R_F$) that are clearly separated, to: *Standard solution B* shows two major blue |

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| | | | | | | | | bands at about the middle of the chromatogram due to caftaric acid (higher $R_F$) and chlorogenic acid (lower $R_F$) that are clearly separated, AND Line 3 of *C*.: Change *Standard solution B*, to: *Standard solution C*, |
| ECHINACEA PURPUREA AERIAL PARTS | IDENTIFICATION | *USP40–NF35* | 6937 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 3 of *A. Thin-Layer Chromatography/ Presence of chicoric acid and absence of echinacoside/System suitability*: Change *Standard* |

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| | | | | | | | | *solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower $R_F$) that are clearly separated, to: *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (higher $R_F$) and chlorogenic acid (lower $R_F$) that are clearly separated, |
| ECHINACEA SPECIES DRY EXTRACT CAPSULES | IDENTIFICATION | *USP41–NF36* | 4590 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 4 of *A. HPTLC for Articles of Botanical Origin <203>/For* |

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| | | | | | | | | *Capsules containing Echinacea angustifolia Dry Extract*/*System suitability*: Change *Standard solution B* shows two major blue bands at about the middle section due to caftaric acid (lower $R_F$) and chlorogenic acid (higher $R_F$) that are clearly separated, to: *Standard solution B* shows two major blue bands at about the middle section due to caftaric acid (higher $R_F$) and chlorogenic acid |

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| | | | | | | | | (lower $R_F$) that are clearly separated, |
| QUETIAPINE EXTENDED-RELEASE TABLETS | IMPURITIES/*Organic Impurities* | *Revision Bulletin (Official November 01, 2017)* | Online | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Footnote a of *Table 5*: Change total impurities. to: total degradation products. AND Footnote b: Change total impurities. to: total degradation products. |
| DOBUTAMINE IN DEXTROSE INJECTION | *Identification* | *USP40–NF35* | 3843 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 1 of *B*: Change It meets the requirements for the *Identification* test under *Dextrose*. to: Add a few drops of a solution (1 in 20) to 5 mL of |

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| | | | | | | | | hot alkaline cupric tartrate TS. A copious red precipitate of cuprous oxide is formed. |
| TIMOLOL MALEATE TABLETS | ADDITIONAL REQUIREMENTS/*USP Reference Standards <11>* | *USP40–NF35* | 6481 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 3 of USP Timolol Related Compound D RS: Change $C_6H_9N_7O_4S$ to: $C_6H_9N_3O_2S$ |
| POWDERED ECHINACEA PALLIDA | IDENTIFICATION | *USP40–NF35* | 6933 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 5 of *A. Thin-Layer Chromatography/Presence of echinacoside and absence of dicaffeoylquinic acid/System suitability*: Change *Standard solution B* shows two major blue bands at about the middle of the chromatogram |

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| | | | | | | | | due to caftaric acid (lower $R_F$) and chlorogenic acid (higher $R_F$) that are clearly separated,<br>to:<br>*Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (higher $R_F$) and chlorogenic acid (lower $R_F$) that are clearly separated,<br>AND<br>Lines 3 and 6 of *C.*: Change *Standard solution B,*<br>to:<br>*Standard solution C,*<br>AND<br>Change |

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| | | | | | | | | *Standard solution C*) to: *Standard solution D*) |
| POWDERED ECHINACEA PURPUREA EXTRACT | IDENTIFICATION | *USP40–NF35* | 6944 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 3 of *A. Thin-Layer Chromatography/Presence of chicoric acid and absence of echinacoside/System suitability*: Change *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower $R_F$) and chlorogenic acid (higher $R_F$) that are clearly separated, to: |

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| | | | | | | | | *Standard solution B* shows two major blue bands at about the middle of the chromatogram due to caftaric acid (higher $R_F$) and chlorogenic acid (lower $R_F$) that are clearly separated, |
| L104 | CHROMATOGRAPHIC COLUMNS/*Packings* | *First Supplement to USP41–NF36* | 8503 | 26-Jan-2018 | 1-Feb-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Add L104—Triazol groups chemically bonded to porous silica particles, 1.5–10 ?m in diameter. |
| POWDERED VALERIAN | IDENTIFICATION/*C. Thin-Layer Chromatography* | *USP40–NF35* | 7240 | 29-Dec-2017 | 1-Jan-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 2 of *Chromatographic system/ Developing solvent system*:Change acetic acid |

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| | | | | | | | | to: glacial acetic acid AND Line 2 of *Chromatographic system*/*Derivatization reagent B*: Change aceticacid to: glacial acetic acid |
| OLMESARTAN MEDOXOMIL TABLETS | ASSAY/*Chromatographic system* | *Revision Bulletin (Official August 01, 2017)* | Online | 29-Dec-2017 | 1-Jan-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 1 of *Detector*: Change *Identification B* to: *Identification A* |
| REAGENTS, INDICATORS AND SOLUTIONS | *Solutions*/*Test Solutions*/*3. Solutions Prepared Fresh* | *USP40–NF35* | 2419 | 29-Dec-2017 | 1-Jan-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 2 of *0.06 M Phosphoric Acid TS*: Change volumetric flask to: 1000-mL volumetric flask |
| VALERIAN TABLETS | IDENTIFICATION/*A. Thin-Layer* | *USP40–NF35* | 7244 | 29-Dec-2017 | 1-Jan-2018 | *USP42–NF37* | *Second Supplement to* | Line 2 of *Chromatographi* |

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| | *Chromatography* | | | | | | *USP41–NF36* | *c system/ Developing solvent system*:Change acetic acid to: glacial acetic acid AND Line 2 of *Chromatographic system/ Derivatization reagent B*: Change aceticacid to: glacial acetic acid |
| POWDERED VALERIAN EXTRACT | IDENTIFICATION/*A. Thin-Layer Chromatography* | *USP40–NF35* | 7241 | 29-Dec-2017 | 1-Jan-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 2 of *Chromatographic system/ Developing solvent system*:Change acetic acid to: |

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| | | | | | | | | glacial acetic acid AND Line 2 of *Chromatographic system*/ *Derivatization reagent B*: Change aceticacid to: glacial acetic acid |
| VALERIAN | IDENTIFICATION/*C. Thin-Layer Chromatography* | *USP40–NF35* | 7238 | 29-Dec-2017 | 1-Jan-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 2 of *Chromatographic system*/ *Developing solvent system*:Change acetic acid to: glacial acetic acid AND Line 2 of *Chromatographic* |

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| | | | | | | | | *system*/ *Derivatization reagent B*: Change aceticacid to: glacial acetic acid |
| CLINDAMYCIN PHOSPHATE | IMPURITIES/*Organic Impurities*/*Table 2* | *Revision Bulletin (Official May 01, 2017)* | Online | 29-Dec-2017 | 1-Jan-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Footnote e and f: Change [e] Methyl 7-chloro-6,7,8-trideoxy-6-[(2*S*,4*R*)-1-methyl-4-ethylpyrrolidine-2-carboxamido]-1-thio-L-*threo*-?-D-*galacto*-octopyranoside 3-phosphate. [f] Methyl 7-chloro-6,7,8-trideoxy-6-[(2*S*,4*R*)-1-methyl-4-propylpyrrolidine-2-carboxamido]-1-thio-D-*threo*-?-D-*galacto*-octopyranoside |

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| | | | | | | | | . to: [e] Methyl 7-chloro-6,7,8-trideoxy-6-[(2*S*,4*R*)-1-methyl-4-propylpyrrolidine-2-carboxamido]-1-thio-L-*threo*-?-D-*galacto*-octopyranoside 3-phosphate. [f] Methyl 7-chloro-6,7,8-trideoxy-6-[(2*S*,4*R*)-1-methyl-4-propylpyrrolidine-2-carboxamido]-1-thio-L-*threo*-?-D-*galacto*-octopyranoside . |
| VALERIAN TINCTURE | IDENTIFICATION/*A. Thin-Layer Chromatography* | *USP40–NF35* | 7243 | 29-Dec-2017 | 1-Jan-2018 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 2 of *Chromatographic system/ Developing solvent system*:Change |

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|---|---|---|---|---|---|---|---|---|
| | | | | | | | | acetic acid<br>to:<br>glacial acetic acid<br>AND<br>Line 2 of *Chromatographic system*/ *Derivatization reagent B*: Change aceticacid<br>to:<br>glacial acetic acid |
| CILOSTAZOL | *USP Reference standards <11>* | *USP40–NF35* | 3418 | 17-Nov-2017 | 1-Dec-2017 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 2 of USP Cilostazol Related Compound C RS: Change 1-(4-(5-Cyclohexyl-1*H*-tetrazol-1-yl)butyl)-6-(4-(1-cyclohexyl-1*H*-tetrazol-5-yl)butoxy)-3,4-dihydroq |

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| | | | | | | | | uinoli n-2(1*H*)-one. $C_{31}H_{43}N_9O_3$ 589.73 to: 1-(4-(1-Cyclohe xyl-1*H* -tetrazol-5-yl)bu tyl)-6-(4-(1-cycl ohexyl- 1*H* -tetrazol-5-yl)bu toxy)-3,4-dihydr oq uinoli n-2(1*H*)-one. $C_{31}H_{45}N_9O_2$ 575.75 |
| HYDROXYZINE HYDROCHLOR IDE TABLETS | ASSAY/ *Procedure* | *USP40–NF35* | 4542 | 17-Nov-2017 | 1-Dec-2017 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Line 2of *Solution B*: Change (0.5: 99.5) to: (0.05: 99.95) |
| VERAPAMIL H YDROCHLORI DE EXTENDED-RELEASE TABLETS | PERFORMANC E TESTS/ *Dissolution <711>* | *USP40–NF35* | 6680 | 17-Nov-2017 | 1-Dec-2017 | *USP42–NF37* | *Second Supplement to USP41–NF36* | Row 5 of column 2 of *Table 9*: Change 4 to: 5 |

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