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| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| ANALYTICAL | 4. FACTORS | *Second* | Online | 26-Feb-2021 | 1-May-2021 | *NA* | *NA* | In paragraph 1: |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| METHODOLOGIES BASED ON SCATTERING PHENOMENA—PARTICLE COUNTING VIA LIGHT SCATTERING | THAT AFFECT THE TESTING | *Supplement to USP43–NF38* | | | | | | Change an airborne liquid counter. to: an airborne counter. |
| FEXOFENADINE HYDROCHLORIDE | ADDITIONAL REQUIREMENTS/*USP Reference Standards <11>* | *USP43–NF38* | 1869 | 29-Jan-2021 | 1-Feb-2021 | *NA* | *NA* | In USP Fexofenadine Related Compound B RS: Change 3-[1-Hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]butyl]-?,?-dimethyl benzeneacetic acid hydrochloride. $C_{32}H_{39}NO_4$ · HCl 538.12 to: 3-[1-Hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]butyl]-?,?-dimethyl benzeneacetic acid |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | hydrochloride monohydrate; Also known as 2-(3-{1-Hydroxy-4-[4-(hydroxydiphenylmethyl)piperidin-1-yl]butyl}phenyl)-2-methylpropanoic acid hydrochloride monohydrate. $C_{32}H_{39}NO_4 \cdot HCl \cdot H_2O$ 556.14 |
| HYDROMORPHONE HYDROCHLORIDE ORAL SOLUTION | IMPURITIES/*Organic Impurities* | *USP43–NF38* | 2252 | 29-Jan-2021 | 1-Feb-2021 | *NA* | *NA* | In footnote g of *Table 3*: Change 2,2?-Bihydromorphone. to: (5?)-3-Hydroxy-2-[(5?)-3-hydroxy-17-methyl-6-oxo-4,5-epoxymorphinan-2-yl]-17-methyl-4,5-epoxymorphinan-6-one dihydrochloride. |
| RISKS AND | 4. RISK | *Second* | Online | 29-Jan-2021 | 1-Feb-2021 | *NA* | *NA* | In *4.1* |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| MITIGATION STRATEGIES FOR THE STORAGE AND TRANSPORTATION OF FINISHED DRUG PRODUCTS | MITIGATION CATEGORIES AS QMS ELEMENTS | *Supplement to USP43–NF38* | | | | | | *Documentation and Procedures/4.1.3 Labels*: Change The use of symbols that are recognized by international organizations is strongly recommended. to: The use of symbols that are recognized by international organizations is strongly recommended. See *General Notices, 10.20. Labeling*. |
| DOPAMINE HYDROCHLORIDE AND DEXTROSE INJECTION | *Limit of 5-hydroxymethylfurfural and related substances* | *USP43–NF38* | 1495 | 18-Dec-2020 | 1-Jan-2021 | *NA* | *NA* | In *Cation-exchange column*: Change Proceed as directed under *Column Partition Chrom* |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | *atography* (see *Chromatography* ?621?), to: Proceed as directed under *Chromatography* ?621?, *General Procedures*, *Column Chromatography*, |
| CARVEDILOL | IM PURITIES/*Organic Impurities, Procedure 2* | *USP43–NF38* | Online | 18-Dec-2020 | 1-Jan-2021 | *NA* | *NA* | In *Table 3*/footnote b: Change 1-(2-(2-Methoxyphenoxy)ethylamino)-3-(6,7,8,9-tetrahydro-5*H*-carbazol-4-yloxy)propan-2-ol. to: 1-(2-(2-Methoxyphenoxy)ethylamino)-3-(2,3,4,9-tetrahydro-1*H*-carbazol-5-ylox |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | y)propan-2-ol. |
| NOREPINEPHRINE BITARTRATE | IDENTIFICATION/*C. Procedure* | *USP43–NF38* | Online | 18-Dec-2020 | 1-Jan-2021 | *NA* | *NA* | In *Sample solution*: Change 0.01 µg/mL to: 0.1 mg/mL |
| ELASTOMERIC COMPONENT FUNCTIONAL SUITABILITY IN PARENTERAL PRODUCT PACKAGING/DELIVERY SYSTEMS | 5. NEEDLE AND SPIKE ACCESS FUNCTIONAL SUITABILITY TESTS | *Second Supplement to USP43–NF38* | Online | 18-Dec-2020 | 1-Jan-2021 | *NA* | *NA* | In paragraph 4 of *5.1 Fragmentation/Cartridge systems/Procedure A*: Change graticlule to: graticule |
| PINDOLOL TABLETS | ASSAY/*Procedure* | *Second Supplement to USP43–NF38* | Online | 18-Dec-2020 | 1-Jan-2021 | *NA* | *NA* | In *Chromatographic system*/*Run time*: Change NLT 2 times the retention time of the nortriptytine peak to: NLT 2 times the retention time of |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
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| | | | | | | | | the nortriptyline peak |
| FENTANYL | CHEMICAL INFORMATION | *USP43–NF38* | Online | 18-Dec-2020 | 1-Jan-2021 | *NA* | *NA* | Change 336.47 to: 336.48 |
| DOBUTAMINE IN DEXTROSE INJECTION | ASSAY/ *Procedure 1: Dextrose* | *USP43–NF38* | 1470 | 18-Dec-2020 | 1-Jan-2021 | *NA* | *NA* | In *Analysis*: Change Result = [(100 × *a*) × (*I*/?)] × (1/$C_U$) × ($M_{r1}$/$M_{r2}$) × 100 to: Result = [(100 × *a*)/(*I* × ?)] × (1/$C_U$) × ($M_{r1}$/$M_{r2}$) × 100 |
| CARVEDILOL | ADDITIONAL REQUIREMENTS/*USP Reference Standards* | *USP43–NF38* | Online | 18-Dec-2020 | 1-Jan-2021 | *NA* | *NA* | In USP Carvedilol Related Compound A RS: Change 629.74 to: 629.75 AND In USP Carvedilol Related Compound B RS: Change |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | 645.74<br>to:<br>645.76<br>AND<br>In USP Carvedilol Related Compound C RS: Change<br>496.60<br>to:<br>496.61<br>AND<br>In USP Carvedilol Related Compound E RS: Change<br>2-(2-Methoxyphenoxy)ethylamine.<br>$C_9H_{13}NO_2$<br>167.21<br>to:<br>[Note—This material may be available in the free base or salt form.]<br>2-(2-Methoxyphenoxy)ethyl |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
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| | | | | | | | | amine. $C_9H_{13}NO_2$ 167.21 2-(2-Methoxyphenoxy)ethyl amine hydrochloride monohydrate. $C_9H_{13}NO_2$ ? HCl ? $H_2O$ 221.68 AND In USP Carvedilol System Suitability Mixture RS: Change Mixture of approximately 0.1% carvedilol related compound F (1-(2-(2-Methoxyphenoxy)ethylamino)-3-(2,3,4,9-tetra hydro-1*H*-carbazol-5-yloxy)propan-2-ol) in a matrix of carvedilol drug |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | substance. to: Contains a mixture of carvedilol related compound F in a matrix of carvedilol drug substance: Carvedilol. Carvedilol related compound F. [Note—This material may be available in the free base or salt form.] 1-(2-(2-Methoxyphenoxy)ethylamino)-3-(2,3,4,9-tetrahydro-1*H*-carbazol-5-yloxy)propan-2-ol. $C_{24}H_{30}N_2O_4$ 410.51 1-(2-(2-Methoxyphenoxy)ethyla |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | mino)-3-(2,3,4,9-tetrahydro-1*H*-carbazol-5-yloxy)propan-2-ol acetate. $C_{24}H_{30}N_2O_4$ ? $C_2H_4O_2$ 470.57 |
| NALOXONE HYDROCHLORIDE INJECTION | IMPURITIES/*Limit of 2,2?-Bisnaloxone* | *Revision Bulletin (Official September 01, 2020)* | Online | 18-Dec-2020 | 1-Jan-2021 | *NA* | *NA* | In *Analysis*: Change [Note—The relative retention times for naloxone and 2,2?-bisnaloxone (4,5?:4?,5?-diepoxy-3,3?,14,14?-tetrahydroxy-17,17?-bis(prop-2-enyl)-2,2?-bimorphinanyl-6,6?-dione) are 1.0 and 2.8, respectively.] to: [Note—The relative retention times for naloxone and 2,2?-bisnal |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | oxone (4,5?:4?,5??-diepoxy-3,3?,14,14?-tetrahydroxy-17,17?-bis(prop-2-enyl)-2,2?-bimorphinanyl-6,6?-dione) are 1.0 and 2.8, respectively.] |
| FENTANYL CITRATE INJECTION | *Assay* | *USP43–NF38* | 1849 | 18-Dec-2020 | 1-Jan-2021 | *NA* | *NA* | In *Procedure*: Change<br>$CD(r_U/r_S)$<br>in which 336.48 and 528.59 are the molecular weights<br>to:<br>$CD(r_U/r_S)$<br>in which 336.48 and 528.60 are the molecular weights |
| TRYPSIN | CHEMICAL INFORMATION | *Second Supplement to USP43–NF38* | Online | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | Change<br>$C_{1012}H_{1555}N_{279}O_{324}S_{14}$ |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | 23,293 (for bovine ?-Trypsin)<br>to:<br>$C_{1012}H_{1585}N_{279}O_{324}S_{14}$<br>23,293 (for bovine ?-Trypsin) |
| TIAGABINE HY DROCHLORID E | ASSAY/ *Procedure* | *USP43–NF38* | 4365 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In the *Standard solution*: Change Transfer suitable volumes of the *Standard stock solution* and *Internal standard solution* into a suitable volumetric flask and dilute with *Diluent* to volume.<br>to:<br>0.1 mg/mL of USP Tiagabine Hydrochloride RS and 0.04 mg/mL of |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | butylparaben in *Diluent* prepared as follows. Transfer suitable volumes of the *Standard stock solution* and *Internal standard solution* into a suitable volumetric flask and dilute with *Diluent* to volume. AND In the *Sample solution*: Change Transfer suitable volumes of the *Sample stock solution* and *Internal standard solution* into a suitable volumetric flask |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | and dilute with *Diluent* to volume.<br>to:<br>0.1 mg/mL of Tiagabine Hydrochloride and 0.04 mg/mL of butylparaben in *Diluent* prepared as follows.<br>Transfer suitable volumes of the *Sample stock solution* and *Internal standard solution* into a suitable volumetric flask and dilute with *Diluent* to volume. |
| AMIODARONE HYDROCHLORIDE | ADDITIONAL REQUIREMENTS/*USP Reference Standards <11>* | *USP43–NF38* | Online | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In USP Amiodarone Related Compound H RS: Change 2-Chlo |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | ro-*N*,*N*-diethylethanamine. $C_6H_{14}ClN$ 135.64 to: 2-Chloro-*N*,*N*-diethylethanamine hydrochloride. $C_6H_{14}ClN \cdot HCl$ 172.09 |
| THE DISSOLUTION PROCEDURE: DEVELOPMENT AND VALIDATION | 1. PRELIMINARY ASSESSMENT | *Second Supplement to USP43–NF38* | Online | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In paragraph 4 of *1.4 Choosing an apparatus*: Change peak vessels to: apex vessels |
| PLASTIC MATERIALS OF CONSTRUCTION | POLYAMIDE 6 | *First Supplement to USP43–NF38* | Online | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In *Related Substances*/*Chromatographic system*/*Column*: Change 0.25-mm × 0.25-µm; phase G25 to: |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| ORBIFLOXACIN | *Related compounds* | *USP43–NF38* | 3275 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | 30-m × 0.25-mm; 0.25-µm phase G25<br>In *Procedure*: Change $20{,}000(C_S)(r_i/r_S)(1/F)$ in which $C_S$ is the concentration, in mg per mL, of orbifloxacin in the *Standard solution*; $r_i$ is the peak area response for each impurity obtained from the *Test solution*; $r_S$ is the peak area response for the orbifloxacin peak obtained from the *Standard solution*; and $F$ is the relative response factor for each |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | impurity, as presented in *Table 1*.<br>to:<br>$20{,}000(C_S)(r_i/r_S)(1/F)(1/W)$<br>in which $C_S$ is the concentration, in mg per mL, of orbifloxacin in the *Standard solution*; $r_i$ is the peak area response for each impurity obtained from the *Test solution*; $r_S$ is the peak area response for the orbifloxacin peak obtained from the *Standard solution*; $F$ is the relative response factor for each impurity, as presented in |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | *Table 1*; and *W* is the sample weight taken to prepare the *Test solution* (mg). |
| GOSERELIN ACETATE | IM PURITIES/*Organic Impurities: Related Compounds* | *Interim Revision Announcement (Official May 01, 2020)* | Online | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In *Table 1*: Change Goserelinare to: Goserelin |
| AMLODIPINE AND ATORVASTATIN TABLETS | ADDITIONAL REQUIREMENTS/*USP Reference Standards <11>* | *USP43–NF38* | 265 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In USP Atorvastatin Related Compound H RS: Change 540.62 to: 540.64 |
| RESIDUAL SOLVENTS | *Appendix 3* | *Interim Revision Announcement (Official December 01, 2020)* | Online | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In the denominator in the equation in the final paragraph: Change at mK$^{?1}$ to: atm K$^{?1}$ |
| RESIDUAL SOLVENTS—VERIOF | VERIFICATION | *USP43–NF38* | 8404 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In *Limit Procedures:* |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| FICATION OF COMPENDIAL PROCEDURES AND VALIDATION OF ALTERNATIVE PROCEDURES | COMPENDIAL PROCEDURES | | | | | | | *Procedure A and Procedure B/Verification when solvents likely to be present (LTBP) are not known/Specificity*: Change or acetonitrile and *cis* -dichloroethene to: or methylisobutylketone and *cis* -dichloroethene |
| MIRTAZAPINE TABLETS | ADDITIONAL REQUIREMENTS | *USP43–NF38* | 2978 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In *USP Reference Standards <11>*/USP Mirtazapine Resolution Mixture RS: Change This resolution mixture contains approximately 0.1% w/w each of the following: |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Impurity A: 1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-*a*]pyrido[2,3-*c*][2]benzazepine 2-oxide.<br>to:<br>Mirtazapine.<br>Impurity A: 1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-*a*]pyrido[2,3-*c*][2]benzazepine 2-oxide. |
| EFAVIRENZ TABLETS | IMPURITIES/*Organic Impurities* | *USP43–NF38* | 1591 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In the footnotes in *Table 2*:<br>Change<br>[d](*S,E*)-6-Chloro-4-(pent-3-en-1-ynyl)-4-(trifluoromethyl)-2*H*-3,1-benzoxazin |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | -2-one. [e](*S,Z*)-6-Chloro-4-(pent-3-en-1-ynyl)-4-(trifluoromethyl)-2*H*-3,1-benzoxazin-2-one. to: [d](*S,Z*)-6-Chloro-4-(pent-3-en-1-ynyl)-4-(trifluoromethyl)-2*H*-3,1-benzoxazin-2-one. [e](*S,E*)-6-Chloro-4-(pent-3-en-1-ynyl)-4-(trifluoromethyl)-2*H*-3,1-benzoxazin-2-one. |
| ATORVASTATIN CALCIUM | ADDITIONAL REQUIREMENTS/*USP Reference Standards <11>* | *USP43–NF38* | 414 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In USP Atorvastatin Related Compound C RS: Change Difluoro impurity, or (3*R*,5*R* |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | )-7-[3-(phenylcarbamoyl)-4,5-bis(4-fluorophenyl)-2-iso propyl-1*H*-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid, calcium salt. to: Calcium (3*R*,5*R*)-7-[2,3-Bis(4-fluorophenyl)-5-isopropyl-4-(phenylcar bamoyl)-1*H*-pyrrol-1-yl]-3,5-dihydroxyheptanoate (1:2); Also known as Difluoro impurity, or (3*R*,5*R*)-7-[3-(phenylcarbamoyl)-4,5-bis(4-fluorophenyl)-2-iso |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | propyl-1*H*-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid, calcium salt. AND In USP Atorvastatin Related Compound D RS: Change Epoxide impurity, or 3-(4-fluorobenzoyl)-2-isobutyryl-3-phenyl-oxirane-2-carboxylic acid phenylamide. to: 3-(4-Fluorobenzoyl)-2-isobutyryl-*N*,3-diphenyloxirane-2-carboxamide; Also known as Epoxide impurity, or 3-(4-fluorobenzoyl)-2-isobutyryl-3-phenyl-oxirane-2-carboxylic acid |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | phenylamide. AND In USP Atorvastatin Related Compound E RS: Change 3*S*,5*S* Enantiomer, or (3*S*,5*S*)-7-[3-(phenylcarbamoyl)-5-(4-fluorophenyl)-2-isopropyl-4-phenyl-1*H*-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid, calcium salt. $C_{66}H_{68}CaF_2N_4O_{10}$ 1155.34 to: Calcium (3*S*,5*S*)-7-[2-(4-Fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)-1*H*-pyrrol-1-yl]-3,5-dihydroxyhepta |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | noate (1:2); Also known as 3*S*,5*S* Enantiomer, or (3*S*,5*S* )-7-[3-(phenylcarbamoyl)-5-(4-fluorophenyl)-2-isopropyl-4-phenyl-1*H* -pyrrol-1-yl]-3,5-dihydroxyheptanoic acid, calcium salt. $C_{66}H_{68}CaF_2N_4O_{10}$ 1155.38 AND In USP Atorvastatin Related Compound H RS: Change 540.62 to: 540.64 AND In Atorvastatin Related Compound I RS: Change 654.81 |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | to:<br>654.82 |
| PLASTIC PACKAGING SYSTEMS FOR PHARMACEUTICAL USE | SCOPE/*Table 1* | *First Supplement to USP43–NF38* | Online | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | Change<br>If light protection is necessary[c]<br>to:<br>If light protection is necessary<br>AND<br>Change Row 11 Chemical Suitability for Use Assessment Risk-based testing Risk-based testing<br>to:<br>Chemical Suitability for Use Assessment Risk-based testing Risk-based testing |
| FENOPROFEN CALCIUM | CHEMICAL INFORMATION | *USP43–NF38* | 1843 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | Functionality Change<br>[53746-45-5];<br>to: |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| MEBENDAZOLE ORAL SUSPENSION | *Identification* | *USP43–NF38* | 2744 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | [71720-56-4]; Change Mix a quantity of Oral Suspension, equivalent to about 200 mg of mebendazole, with 20 mL of a mixture of chloroform and 96 percent formic acid (19:1). Proceed as directed for *Identification* under *Mebendazole Tablets*, beginning with “Warm the suspension on a water bath for a few minutes.” The specified result is obtained. to: Mix a quantity of Oral Suspension, |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | equivalent to about 200 mg of mebendazole, with 20 mL of a mixture of chloroform and 96 percent formic acid (19:1). Warm the suspension on a water bath for a few minutes, cool, and filter through a mediu m-porosity, sintered-glass filter. Apply 10 ?L of this solution and 10 ?L of a *Standard solution* of USP Mebendazole RS in a mixture of chloroform and 96 percent formic acid (19:1) containing 10 mg per mL to a |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | suitable thin-layer chromatographic plate (see *Chromatography* <621>) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of chloroform, methanol, and 96 percent formic acid (90:5:5) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | chamber, mark the solvent front, allow the solvent to evaporate, and examine the plate under shor t-wavelength UV light: the $R_F$ value of the principal spot obtained from the *Test solution* corresponds to that obtained from the *Standard solution*. |
| THE DISSOLUTION PROCEDURE: DEVELOPMEN T AND VALIDATION | 6. ACCEPTANCE CRITERIA | *Second Supplement to USP43–NF38* | Online | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In Row 1 of *Table 5* and *Table 6*: Align Times with Acceptance Criteria |
| ATORVASTATI N CALCIUM TABLETS | ADDITIONAL R EQUIREMENT S/*USP Reference Standards <11>* | *USP43–NF38* | 418 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In USP Atorvastatin Related Compound H RS: Change |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| PLASTIC MATERIALS OF CONSTRUCTION | INTRODUCTION | *First Supplement to USP43–NF38* | Online | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | 540.62<br>to:<br>540.64<br>Delete<br>An example of an extractable elements testing strategy is provided in *Evaluation of Plastic Packaging Systems and Their Materials of Construction with Respect to Their User Safety Impact* ?1661?. |
| TIAMULIN | IMPURITIES/*Organic Impurities* | *USP43–NF38* | 4368 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In the equation in *Analysis*:<br>Change<br>Result = $(r_U/r_T)$ x 100<br>to:<br>Result = $(r_U/r_T)$ x *D* x 100<br>AND<br>Add<br>*D* = dilution factor for the |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| MIRTAZAPINE | ADDITIONAL REQUIREMENTS | *USP43–NF38* | 2976 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | *Sample solution*, 0.01 In *USP Reference Standards* <*11*>/USP Mirtazapine Resolution Mixture RS: Change This resolution mixture contains approximately 0.1% w/w each of the following: Impurity A: 1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-*a*]pyrido[2,3-*c*][2]benzazepine 2-oxide. to: Mirtazapine. Impurity A: 1,2,3,4,10,14b-Hexahydro-2-methyl |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | pyr azino[ 2,1-*a* ]pyri do[2,3-*c* ][2]benzazepine 2-oxide. |
| GUIDELINES ON THE ENDOTOXINS TEST | METHOD SUITABILITY | *USP43–NF38* | 7665 | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In Row 2 of Column 3 of *Table 3*: Change hydrochloride to: hydrochloric acid AND In paragraph 2 of *Method Suitability Testing/ Common Test Interferences*: Change hydrochloride to: hydrochloric acid |
| THE APPLICATION OF MOISTURE VAPOR TRANS | EQUIVALENCY AND APPLICATION OF MVTR DET | *Second Supplement to USP43–NF38* | Online | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In *Appli cation* /paragraph 3: |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| MISSION RATES FOR SOLID ORAL DOSAGE FORMS IN PLASTIC PACKAGING SYSTEMS | ERMINATION METHOD | | | | | | | Change ?0.8/day/tablet to: ?0.8 mg/day/tablet |
| THE DISSOLUTION PROCEDURE: DEVELOPMENT AND VALIDATION | 2. METHOD DEVELOPMENT | *Second Supplement to USP43–NF38* | Online | 20-Nov-2020 | 1-Dec-2020 | *NA* | *NA* | In paragraph 2 of *2.4 Study Design*/*2.4.1 Time Points*: Change *Assessment of Drug Product Performance—Bioavailability, Bioequivalence, and Dissolution* ?1090?. to: *Assessment of Solid Oral Drug Product Performance and Interchangeability, Bioavailability, Bioequivalence, and Dissolution* ?1090?. |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| OIL-SOLUBLE VITAMINS WITH MINERALS TABLETS | ADDITIONAL REQUIREMENTS/*Labeling* | *USP43–NF38* | 5378 | 30-Oct-2020 | 1-Nov-2020 | *NA* | *NA* | In footnote 1:<br>Change<br>1 mg of -alpha tocopheryl acetate<br>to:<br>1 mg of *all-rac*-alpha tocopheryl acetate |
| ANISE OIL | IDENTIFICATION/*A. Chromatographic Identity* | *First Supplement to USP43–NF38* | Online | 30-Oct-2020 | 1-Nov-2020 | *NA* | *NA* | In *Acceptance criteria/ Chromatographic similarity*:<br>Change<br>[Note—The chromatogram of the *Standard* is similar to the reference chromatogram provided with the lot of being used.]<br>to:<br>[Note—The chromatogram of the *Standard* is similar to the reference chromatogram |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | provided with the lot of USP Anise Oil RS being used.] |
| VERAPAMIL HYDROCHLORIDE | IMPURITIES/*Organic Impurities* | *USP43–NF38* | 4604 | 30-Oct-2020 | 1-Nov-2020 | *NA* | *NA* | Change *Buffer*, *Mobile phase*, and *Chromatographic system*: Proceed as directed in the *Assay*. to: *Buffer* and *Mobile phase*: Prepare as directed in the *Assay*. |
| METHYLENE BLUE | CHEMICAL INFORMATION | *First Supplement to USP43–NF38* | Online | 30-Oct-2020 | 1-Nov-2020 | *NA* | *NA* | Change Phenothiazin-5-ium, 3,7-bis(dimethylamino)-, chloride; 3,7-Bis(dimethylamino)phenothiazin-5-ium chloride; to: Phenothiazin?5?ium, 3,7?bis(dimethylamino)?, |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | chloride, hydrate (1:1:x); 3,7?Bis(dimethylamino)phenothiazin?5?ium chloride hydrate; [122965?43?9]. AND Change Monohydrate [122965-43-9]. to: Monohydrate [67183?68?0]. |
| CELL-BASED ADVANCED THERAPIES AND TISSUE-BASED PRODUCTS | REGULATIONS AND STANDARDS | *USP43–NF38* | 7400 | 30-Oct-2020 | 1-Nov-2020 | *NA* | *NA* | In *Table 5*/Row 8 of Column 2: Change 221 CFR 1271 to: 21 CFR 1271 |
| EVALUATION OF PLASTIC PACKAGING SYSTEMS AND THEIR MATERIALS OF CONSTRUCTION WITH RESPECT TO THEIR USER | 6. APPLICABILITY AND APPLICATION OF <661.1> | *First Supplement to USP43–NF38* | Online | 30-Oct-2020 | 1-Nov-2020 | *NA* | *NA* | In *6.2 Application*/*6.2.5 Unaddressed Materials*: Change physiochemical to: physicochemical |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| SAFETY IMPACT MEDICAL AIR | IMPURITIES | *USP43–NF38* | 100 | 30-Oct-2020 | 1-Nov-2020 | *NA* | *NA* | Change *Impurities Testing in Medical Gases Assay* ?413? to: *Impurities Testing in Medical Gases* ?413? |
| HYDROXYPROPYL BETADEX | CHEMICAL INFORMATION | *USP43–NF38* | 5818 | 30-Oct-2020 | 1-Nov-2020 | *NA* | *NA* | Change [94035-02-6]. to: [128446-35-5]. |
| APREPITANT CAPSULES | PERFORMANCE TESTS/ *Dissolution <711>* | *USP43–NF38* | 362 | 30-Oct-2020 | 1-Nov-2020 | *NA* | *NA* | In *Test 3/Apparatus 2*: Change peak vessels. to: apex vessels. |
| PLASTIC PACKAGING SYSTEMS AND THEIR MATERIALS OF CONSTRUCTION | POLYETHYLENE TEREPHTHALATE BOTTLES AND POLYETHYLENE TEREPHTHALATE G CONTAINERS | *First Supplement to USP43–NF38* | Online | 30-Oct-2020 | 1-Nov-2020 | *NA* | *NA* | In *Heavy Metals, Total Terephthaloyl Moieties, and Ethylene Glycol/ Extracting media*: Change *50 percent* |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | *alcohol*: Dilute 125 mL of alcohol with water to 238 mL, and mix. *25 percent alcohol*: Dilute 125 mL of *50 percent alcohol* with water to 250 mL, and mix. *General procedure*: [Note— Use an *Extracting medium* of *50 percent alcohol* for PET bottles and *25 percent alcohol* for PETG bottles.] to: *Purified Water*: See monograph. *50 percent alcohol*: Dilute 125 mL of alcohol with water to 238 |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | mL, and mix. *25 percent alcohol*: Dilute 125 mL of *50 percent alcohol* with water to 250 mL, and mix. *n-Heptane* *General procedure*: [Note— Use an *Extracting medium* of *50 percent alcohol* for PET bottles and *25 percent alcohol* for PETG bottles.] AND In four instances in *Heavy Metals, Total Terephthaloyl Moieties, and Ethylene Glycol/Heavy Metals*: Change *Extracting media* |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | to: *Purified Water Extracting medium* AND In *Heavy Metals, Total Terephthaloyl Moieties, and Ethylene Glycol/Ethylene Glycol/Test solution*: Change *Extracting media* to: *Purified Water Extracting medium* AND In *Heavy Metals, Total Terephthaloyl Moieties, and Ethylene Glycol/Ethylene Glycol/ Proce dure*/paragraph 1: Change |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | *Extracting media* extract *Extracting medium* to: *Purified Water Extracting medium* AND In *Heavy Metals, Total Terephthaloyl Moieties, and Ethylene Glycol/Ethylene Glycol/ Proce dure*/paragraph 2: Change using as the blank the solution from the *Extracting media*: the absorbance of the solution to: using *Purified Water Extracting medium* as the |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | blank: the absorbance of the solution |
| CLOMIPHENE CITRATE TABLETS | ADDITIONAL REQUIREMENTS/*USP Reference Standards <11>* | *First Supplement to USP43–NF38* | Online | 30-Oct-2020 | 1-Nov-2020 | *NA* | *NA* | In USP Clomiphene Related Compound A RS: Change (*E,Z*)-2-[4-(1,2-Diphenylethyl)phenoxy]-*N,N*-diethylethanamine hydrochloride. to: (*E,Z*)-2-[4-(1,2-Diphenylethenyl)phenoxy]-*N,N*-diethylethanamine hydrochloride. |
| GELATIN | SPECIFIC TESTS/*Sulfur Dioxide* | *Harmonization (Official May 01, 2020)* | 5783 | 30-Oct-2020 | 1-Nov-2020 | *NA* | *NA* | In three instances in *Analysis*: Change 0.1 M sodium hydroxide to: *Titrant* |

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date Sort ascending | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | AND<br>In the equation:<br>Change<br>*M*<br>to:<br>*N*<br>AND<br>In the variable definition list:<br>Change<br>*M* = actual molarity of the *Titrant* (mol/L)<br>to:<br>*N* = actual normality of the *Titrant* |

**Pagination**


- First page « First
- Previous page ‹ Previous
- Page 1
- Page 2
- Page 3
- Page 4
- Page 5
- Page 6
- Page 7
- Page 8
- Page 9

- …
- Next page Next ›
- Last page Last »