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## How to Use

- **Searching:** Type keyword in search field at top of page. Search by all or part of a monograph title. For searches using multiple criteria, you will find items that match each of the specified criteria unless quotation marks are used.
  - For example, a search on Aminosalicyclic Acid Tablets will result in anything that contains “Aminosalicyclic” OR “Acid” OR “Tablets”
  - A search for “Aminosalicyclic Acid Tablets” will result in anything that specifically contains “Aminosalicyclic Acid Tablets”
- **Sorting:** Click on any column header title to sort alphabetically or chronologically in ascending or descending order. Note: the page load column is sorted alphabetically so that a number is ordered by first digit vs. by the actual number; thus, numbers will not always be in order.
  - For example, page 2178 will come before page 74 on a page sort.
- **Downloading:** You can download the Errata table in Comma-separated Value (.csv). The download will include the Errata that you have filtered on.
- **Importing:** You will need to import the file into Excel or Open Office with UTF-8 encoding, as opposed to simply opening it. To import, open Excel or Open Office and select import from the File drop-down. Depending on the version you are using, you should be presented with import formatting options to include UTF-8 as one of the first steps. Importing via UTF-8 should eliminate odd character conversions.

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| DOXYCYCLINE CAPSULES            | ADDITIONAL REQUIREMENT<br><i>S/USP Reference Standards &lt;11&gt;</i> | <i>USPNF Online</i>                | Online                      | 24-Jun-2022                      | 1-Jul-2022                           | NA                                              | NA                                                                                 | In USP Doxycycline Related Compound A RS: Change 444.43 to: 444.44 AND Change (4S,4aR,5S,5aR,6S,12aS)-4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacene-9-carboxamide monohydrate chloride.<br>C <sub>22</sub> H <sub>24</sub> N <sub>2</sub> O <sub>8</sub> · HCl 480.13 to: (4S,4aR,5S,5aR,6S,12aS)-4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacene-9-carboxamide monohydrate chloride.<br>C <sub>22</sub> H <sub>24</sub> N <sub>2</sub> O <sub>8</sub> · HCl 480.13 |

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| ANETHOLE            | DEFINITION           | USPNF Online       | Online      | 28-Oct-2022      | 1-Nov-2022           | NA                              | NA                                               | ino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphtacenecarboxamide hydrochloride. C <sub>22</sub> H <sub>24</sub> N <sub>2</sub> O <sub>8</sub> · HCl 480.90<br>Change (E)-1-methyl-4-(1-propenyl) benzene to: (E)-1-methoxy-4-(1-propenyl) benzene<br>Change (±)-1-[[?-(2-Isop |
| BISOPROLOL FUMARATE | CHEMICAL INFORMATION | USPNF Online       | Online      | 28-Apr-2023      | 1-May-2023           | NA                              | NA                                               | p-tolyl]oxy]-3-(isopropyl amino)-2-propanol                                                                                                                                                                                                                                                                             |

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|                                 |                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | fumarate (2:1) (salt) to: (±)-1-[[?-(2-Isop                                                                                                                                                     |
|                                 |                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <i>p</i><br>-tolyl]oxy]-3-(iso propylamino)-2-propanol fumarate (2:1) (salt)                                                                                                                    |
| DIGOXIN TABLETS                 | ASSAY                   | USPNF Online                       | Online                      | 29-Sep-2023                      | 1-Oct-2023                           | NA                                              | NA                                                                                 | In <i>Procedure/Analysis</i> : Change $C_U$ = nominal concentration of in the <i>Sample solution</i> (µg/mL) to: $C_U$ = nominal concentration of digoxin in the <i>Sample solution</i> (µg/mL) |
| PROCHLORPE RAZINE MALEATE       | PERFORMANCE TESTS/      | USPNF Online                       | Online                      | 26-Aug-2022                      | 1-Sep-2022                           | NA                                              | NA                                                                                 | In <i>Analysis</i> : Change Results =                                                                                                                                                           |

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| TABLETS                         | <i>Dissolution</i><br><711> |                                    |                             |                                  |                                      |                                                 |                                               |                                   | $(A_U/A_S) \times C_S \times D \times (1/L) \times V \times 100$ $A_U =$ absorbance of the <i>Sample solution</i><br>$A_S =$ absorbance of the <i>Standard solution</i><br>$C_S =$ concentration of USP Prochlorperazine Maleate RS in the <i>Standard solution</i><br>$D =$ dilution factor for <i>Sample solution</i> , if needed<br>$L =$ label claim (mg/Tablet)<br>$V =$ volume of <i>Medium</i> , 500 mL<br>to:<br>Result = (A |

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|                        |                    |             |                  |                      |                                 | <a href="#">_Sort descending_</a> | $\frac{U}{A_S}) \times C_S \times V \times D \times (M_{r1}/M_{r2}) \times (1/L) \times 100$ $A_U =$ absorbance of the <i>Sample solution</i><br>$A_S =$ absorbance of the <i>Standard solution</i><br>$C_S =$ concentration of USP Prochlorperazine Maleate RS in the <i>Standard solution</i><br>V = volume of <i>Medium</i> , 500 mL<br>D = dilution factor for the <i>Sample solution</i> , if needed<br>$M_{r1}$ = molecular weight of prochlorperazine, |

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| Methyl Acetate                  | CHEMICAL INFORMATION    | USPNF Online                       | Online                      | 27-Jan-2023                      | 1-Feb-2023                           | NA                                              | NA                                                                                 | 373.94<br>$M_{r2}$ = molecular weight of prochlorperazine maleate, 606.09<br>$L$ = label claim (mg/Tablet)<br>Change CAS RN®: 74-20-9.<br>to:<br>CAS RN®: 79-20-9.                                                                                |
| PURIFIED SILICEOUS EARTH        | IMPURITIES              | USPNF Online                       | Online                      | 28-Jul-2023                      | 1-Aug-2023                           | NA                                              | NA                                                                                 | In <i>Leachable Arsenic/ Analysis:</i><br>Change A 3.0-mL portion of the <i>Sample solution</i> meets the requirements in <i>Arsenic ?211?</i> , <i>Procedures, Procedure.</i><br>to:<br>A 3.0-mL portion of the <i>Sample solution</i> meets the |

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| GLUCAGON                        | PROCESS-RELATED IMPURITIES AND OTHER COMPONENTS | USPNF Online                       | Online                      | 29-Dec-2023                      | 1-Jan-2024                           | NA                                              | NA                                                                                 | <p>requirements in <i>Arsenic</i> ?211?, <i>Procedures, Procedure 1.</i></p> <p>In <i>Acetic Acid in Peptides/Analysis:</i></p> <p>Change <math>C_{SPA}</math> = concentration of potassium acetate in each of the <i>Standard solutions</i> (mg/mL) to: <math>C_{SPA}</math> = concentration of potassium acetate in each of the <i>Standard solutions</i> (µg/mL)</p> <p>AND</p> <p>In <i>Ammonium/Analysis:</i></p> <p>Change C</p> |

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|                                                  |                         |                                    |                             |                                  |                                      |                                                 |                                               | SAC=<br>concentration of ammonium chloride in each of the <i>Standard solutions</i> (mg/mL)<br>to:<br>$C_{SAC}$ =<br>concentration of ammonium chloride in each of the <i>Standard solutions</i> (µg/mL) |
| METHYLNALT<br>REXONE<br>BROMIDE                  | CHEMICAL<br>INFORMATION | USPNF Online                       | Online                      | 23-Feb-2024                      | 1-Mar-2024                           | NA                                              | NA                                            | Correct the chemical structure                                                                                                                                                                           |
| AMMONIUM G<br>LYCYRRHIZAT<br>E                   | CHEMICAL<br>INFORMATION | USPNF Online                       | Online                      | 24-Jun-2022                      | 1-Jul-2022                           | NA                                              | NA                                            | Change 840.08 to: 839.97                                                                                                                                                                                 |
| PSEUDOEPHE<br>DRINE HYDRO<br>CHLORIDE<br>TABLETS | PERFORMANC<br>E TESTS   | USPNF Online                       | Online                      | 28-Apr-2023                      | 1-May-2023                           | NA                                              | NA                                            | Change<br><b>Uniformity of Dosage Units ?905?</b><br><b>Procedure for content uniformity</b><br>to:                                                                                                      |

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| TELMISARTAN PERFORMANCE TESTS                           | USPNF Online                       | Online                      | 27-Oct-2023                      | 1-Nov-2023                           | NA                                              | NA                                                                                 | <b>Uniformity of Dosage Units ?905?:</b> Meets the requirements<br><b>Procedure for content uniformity, chewable tablets only</b><br>AND<br>In <i>Uniformity of Dosage Units</i> : Delete<br><b>Acceptance criteria:</b> Meet the requirements for chewable tablets<br>In <i>Dissolution ?711?/Test 1/Analysis</i> : Change<br>Determine the percentage of telmisartan (C <sub>33</sub> H <sub>30</sub> N <sub>4</sub> O <sub>2</sub> ) dissolved: |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>Result = <math>(A_U \times C_S \times V \times 100)/(A_S \times D \times L)</math></p> <p>to:</p> <p>Calculate the percentage of the labeled amount of telmisartan (<math>C_{33}H_{30}N_4O_2</math>) dissolved:</p> <p>Result = <math>(A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100</math></p> <p>AND</p> <p>Change</p> <p><math>C_S</math> = concentration of the <i>Standard solution</i> (mg/mL)</p> <p>to:</p> <p><math>C_S</math> = concentration of USP Telmisartan RS in the <i>Standard solution</i> (mg/mL)</p> |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>AND</p> <p>In <i>Dissolution</i> ?711?/Test 2/Analysis: Change <math>r_U</math> = peak response from the <i>Sample solution</i> <math>r_S</math> = peak response from the <i>Standard solution</i> to: <math>r_U</math> = peak response of telmisartan from the <i>Sample solution</i> <math>r_S</math> = peak response of telmisartan from the <i>Standard solution</i></p> <p>AND</p> <p>In <i>Dissolution</i> ?711?/Test 3/Analysis: Change C</p> |

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| MUPIROCIN NASAL OINTMENT        | <i>Related com pounds/Table 1</i> | USPNF Online                       | Online                      | 29-Apr-2022                      | 1-May-2022                           | NA                                              | NA                                                                                 | <p><math>S =</math><br/>concentration of the <i>Standard solution</i> (mg/mL)<br/>to:<br/><math>C_S =</math><br/>concentration of USP<br/>Telmisartan RS in the <i>Standard solution</i> (mg/mL)</p> <p>In footnote 2:<br/>Change<br/>9-<math>\{(E)-4-[(2R,3aS,6S,7S,8aRS)-2-\{(1RS,2S,3S)-1,3-Dihydroxy-2-methylbutyl\}-7-hydroxyhexahydro-2H-furo[3,2-c]</math>pyran-6-yl]-3-methylbut-2-enoyloxy}nonanoic acid.</p> |

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|                                                |                              |                                    |                             |                                  |                                      |                                                 |                                               |                                   | to:                                                                                                                                                                    |
|                                                |                              |                                    |                             |                                  |                                      |                                                 |                                               |                                   | 9- <i>{(E)-4-[(2R,3aS,6S,7S)-2-<i>{(1RS,2S,3S)-1,3-Dihydroxy-2-methylbutyl}-7-hydroxyhexahydro-2H-furo[3,2-c]pyran-6-yl]-3-methylbut-2-enoyloxy}nonanoic acid.</i></i> |
| N-Benzoyl-L-arginine Ethyl Ester Hydrochloride | REAGENT SPECIFICATIONS       | USPNF Online                       | Online                      | 30-Sep-2022                      | 1-Dec-2022                           | NA                                              | NA                                            |                                   | Change Crystallized Trypsin (USP Monograph). to: Trypsin (USP Monograph).                                                                                              |
| GLYCYL-L-TYROSINE                              | IMPURITIES/Related Compounds | USPNF Online                       | Online                      | 24-Feb-2023                      | 1-Jun-2023                           | NA                                              | NA                                            |                                   | In <i>Buffer solution</i> : Change Dissolve 6.84 g of potassium phosphate in                                                                                           |

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| UREA C 13                       | IMPURITIES                                        | USPNF Online                       | Online                      | 25-Aug-2023                      | 1-Sep-2023                           | NA                                              | NA                                                                                 | 1000 mL of water.<br>to:<br>Dissolve 6.84 g of monobasic potassium phosphate in 1000 mL of water.<br>In <i>Isotopic Purity/Chromatographic system</i> :<br>Change<br><b>Flow rate:</b> Flow rate<br>to:<br><b>Flow rate:</b> 1 mL/min<br>Change<br><b>Test 1</b> Dilute 1 mL of phosphoric acid with water to 1 L.<br>to:<br><b>Test 1</b><br>AND<br>Change |
| APREPITANT CAPSULES             | PERFORMANCE TESTS/<br><i>Dissolution</i><br><711> | USPNF Online                       | Online                      | 27-May-2022                      | 1-Jun-2022                           | NA                                              | NA                                                                                 |                                                                                                                                                                                                                                                                                                                                                             |

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| DOXORUBICIN ASSAY/<br>HYDROCHLORIDE FOR<br>INJECTION | <i>Procedure</i>        | USPNF Online                       | Online                      | 28-Oct-2022                      | 1-Nov-2022                           | NA                                              | NA                                                                                 | <p><b>Dilute phosphoric acid:</b><br/>to:<br/><b>Dilute phosphoric acid:</b> Dilute 1 mL of phosphoric acid with water to 1 L.</p> <p>In <i>Analysis</i>:<br/>Change<br/><i>P</i> = potency of doxorubicin in USP Doxorubicin Hydrochloride RS (µg/mg)<br/>to:<br/><i>P</i> = potency of doxorubicin hydrochloride in USP Doxorubicin Hydrochloride RS (µg/mg)<br/>Change<br/>Calcium lactate</p> |
| CALCIUM LACTATE                                      | CHEMICAL INFORMATION    | USPNF Online                       | Online                      | 31-Mar-2023                      | 1-Apr-2023                           | NA                                              | NA                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                   |

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| FOSAMPRENA PERFORMANCE TESTS<br>VIR CALCIUM TABLETS     | USPNF Online                       | Online                      | 25-Aug-2023                      | 1-Sep-2023                           | NA                                              | NA                                                                                 | (1:2) hydrate to:<br>Calcium lactate hydrate<br>AND<br>Change<br>Calcium lactate (1:2) pentahydrate to:<br>Calcium lactate pentahydrate<br>In <i>Dissolution</i> ?711?/ <i>Medium</i> :<br>Change<br>26.7 g/L of sodium acetate trihydrate in water. Add 133 mL of glacial acetic acid to this solution, and then dilute with water to 10 L; 900 mL.<br>to:<br>0.02 M sodium acetate buffer, pH 3.5, prepared as |

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| SUTURES--NE PROCEDURE<br>EDLE<br>ATTACHMENT             | USPNF Online Online                               |                             | 29-Jul-2022                      | 1-Aug-2022                           | NA                                              | NA                                                                                 | follows.<br>Dissolve 2.67 g of sodium acetate in 100 mL of water. Add 13.3 mL of glacial acetic acid and then dilute with water to 1000 mL; 900 mL.<br>In <i>Removable Needle Attachment</i> : Change For USP sizes 5-0 through 2-0, to:<br>For USP sizes 5-0 through 2, In <i>System suitability</i> : Change [Note—The approximate relative retention times for (3S,3'S)-zeaxanthin, |
| MESO-ZEAXANTHIN                                         | COMPOSITION<br><i>/Stereoisomeric Composition</i> | USPNF Online Online         | 27-Jan-2023                      | 1-Jun-2023                           | NA                                              | NA                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                        |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>(3<i>R</i>,3?<i>S</i>-<i>meso</i>)-zeaxanthin, (3<i>R</i>,3?<i>R</i>)-zeaxanthin, and (3<i>R</i>,3?<i>R</i>,6?<i>R</i>)-lutein are 0.94, 1.00, 1.06, and 1.11, respectively.] to: [Note—The approximate relative retention times for (3<i>S</i>,3?<i>S</i>)-zeaxanthin, (3<i>R</i>,3?<i>S</i>)-zeaxanthin, (3<i>R</i>,3?<i>R</i>)-zeaxanthin, and (3<i>R</i>,3?<i>R</i>,6?<i>R</i>)-lutein are 0.94, 1.00, 1.06, and 1.11, respectively.] AND</p> |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>In System suitability/Suitability requirements/Resolution: Change (3R,3?S-meso)-zeaxanthin to: (3R,3?S)-zeaxanthin AND In Analysis: Change (3R,3?S-meso)-zeaxanthin to: (3R,3?S)-zeaxanthin AND In Acceptance criteria: Change (3R,3?S-meso)-Zeaxanthin to:</p> |

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| ATORVASTATIN ASSAY/<br>N CALCIUM <i>Procedure</i><br>TABLETS | USPNF Online Online                |                             | 30-Jun-2023                      | 1-Jul-2023                           | NA                                              | NA                                                                                 | (3R,3'S)-Zeaxanthin<br>In <i>Analysis</i> :<br>Change<br>$M_{r1}$ = molecular<br>weight of<br>atorvastatin,<br>558.64<br>$M_{r2}$ = molecular<br>weight of<br>atorvastatin<br>calcium,<br>1155.34<br>to:<br>$M_{r1}$ = molecular<br>weight of<br>atorvastatin,<br>558.65<br>$M_{r2}$ = molecular<br>weight of<br>atorvastatin<br>calcium,<br>1155.36 |
| OLMESARTAN PERFORMANC<br>MEDOXOMIL    E TESTS<br>TABLETS     | USPNF Online Online                |                             | 17-Nov-2023                      | 1-Dec-2023                           | NA                                              | NA                                                                                 | In <i>Dissolution</i><br>?711?/Test<br>5/Apparatus 2:<br>Change<br>50 rpm. Use<br>peak vessels.<br>to:                                                                                                                                                                                                                                               |

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| DOXYCYCLINE FOR INJECTION       | ADDITIONAL REQUIREMENT S/USP Reference Standards <11> | USP NF Online                      | Online                      | 24-Jun-2022                      | 1-Jul-2022                           | NA                                              | NA                                                                                 | 50 rpm. Use apex vessels. In USP Doxycycline Related Compound A RS: Change 444.43 to: 444.44 AND Change (4S,4aR,5S,5aR,6S,12aS)-4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacene-9-carboxamide, monohydrate chloride. C <sub>22</sub> H <sub>24</sub> N <sub>2</sub> O <sub>8</sub> · HCl 480.13 to: (4S,4aR,5S,5aR,6S |

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| NALOXONE HYIMPURITIES DROCHLORIDE                       | USPNF Online                       | Online                      | 28-Oct-2022                      | 1-Dec-2022                           | NA                                              | NA                                                                                 | ,12aS<br>)-4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenenecarboxamide hydrochloride.<br>C <sub>22</sub> H <sub>24</sub> N <sub>2</sub> O <sub>8</sub> · HCl 480.90<br>In <i>Limit of Naloxone Related Compound D</i> : Delete<br><b>Sensitivity solution:</b> 1.25 µg/mL of USP Naloxone Related Compound D RS in 0.1 N hydrochloric acid<br>AND<br>In <i>System suitability</i> |

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| ISOFLURANE                      | IM<br>PUR<br>ITIES/ <i>Organic Impurities</i> | USPNF Online                       | Online                      | 28-Apr-2023                      | 1-May-2023                           | NA                                              | NA                                                                                 | <i>ity/Samples:</i><br>Delete<br><i>Sensitivity solution,</i><br>AND<br>In System<br><i>suitabil</i><br><i>ity/Suitability requirements:</i><br>Delete<br><b>Signal-to-noise ratio:</b> NLT 10,<br><i>Sensitivity solution</i><br>In Analysis:<br>Change<br>Result = $(r_U/r_S)$<br>$\times C_S \times (1/F)$<br>to:<br>Result = $(r_U/r_S)$<br>$\times C_F \times (1/F)$<br>AND<br>Change<br>$C_S$ = final<br>concentration of<br>USP Isoflurane<br>Related<br>Compound B<br>RS in the<br><i>Standard</i> |

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| DIVALPROEX SODIUM EXTENDED-RELEASE TABLETS<br>PERFORMANCE TESTS | USPNF Online                       | Online                      | 29-Sep-2023                      | 1-Oct-2023                           | NA                                              | NA                                                                                 | <i>solution (%) to:</i><br><i>C<sub>F</sub></i> = final concentration of USP Isoflurane Related Compound B RS in the <i>Standard solution (%) In Dissolution ?711?/Test 8/Tolerances: Change</i><br>The percentage of the labeled amount of valproic acid (C <sub>8</sub> H <sub>16</sub> O <sub>2</sub> ) dissolved at the times specified conform to <i>Dissolution &lt;711&gt;, Acceptance Table 1.</i><br><i>to:</i><br>The percentage of the labeled amount of |

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| PROMETHAZINE HYDROCHLORIDE      | IMPURITIES/Organic Impurities | USPNF Online                       | Online                      | 26-Aug-2022                      | 1-Sep-2022                           | NA                                              | NA                                                                                 | valproic acid (C <sub>8</sub> H <sub>16</sub> O <sub>2</sub> ) dissolved at the times specified conform to <i>Dissolution</i> <711>, <i>Acceptance Table 2</i> .<br>Change <b>System suitability solution</b> : 5 µg/mL each of USP Promethazine Hydrochloride RS and USP Promethazine Related Compound B RS from the <i>Standard stock solution</i> and <i>System suitability stock solution</i> , respectively<br><b>Standard solution</b> |

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|                        |                    |             |                  |                      |                                 | <a href="#">_Sort descending_</a> | : 5<br>µg/mL of USP<br>Promethazine<br>Hydrochloride<br>RS from the<br><i>Standard stock solution</i><br><b>Sensitivity solution:</b> 0.25 µg/mL of USP Promethazine Hydrochloride RS from the <i>Standard solution</i><br>to:<br><b>System suitability solution:</b> 5 µg/mL each of USP Promethazine Hydrochloride RS and USP Promethazine Related Compound B RS from the <i>Standard stock</i> |

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| METARAMINO SPECIFIC<br>L BITARTRATE TESTS/ <i>Content of Tartaric Acid</i> | USPNF Online Online                |                             | 27-Jan-2023                      | 1-Feb-2023                           | NA                                              | NA                                                                                 | <i>solution and System suitability stock solution, respectively, in Diluent</i><br><b>Standard solution:</b> 5 µg/mL of USP Promethazine Hydrochloride RS from the <i>Standard stock solution in Diluent</i><br><b>Sensitivity solution:</b> 0.25 µg/mL of USP Promethazine Hydrochloride RS from the <i>Standard solution in Diluent</i><br><i>In Analysis:</i><br>Change Result = $\frac{\{(V_S \times V_B) \times N \times F\}}{2 \times W} \times 100$ |

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| REAGENTS AND REFERENCE TABLES   | <i>Reagent S pec ification/ Tosylchloramide Sodium</i> | USPNF Online                       | Online                      | 28-Jul-2023                      | 1-Aug-2023                           | NA                                              | NA                                                                                 | to:<br>Result =<br>$\{[(V_S \div V_B) \times N \times F]/(2 \times W)\} \times 100$<br>Change 127-65-1 to:<br>7080-50-4                                                                                                                                      |
| SECOBARBITAL SODIUM             | OTHER REQUIREMENTS                                     | USPNF Online                       | Online                      | 29-Dec-2023                      | 1-Jan-2024                           | NA                                              | NA                                                                                 | Change<br>Where the label states that Secobarbital Sodium is sterile, it meets the requirements for <i>Sterility Tests</i> 71? and for <i>Bacterial endotoxins</i> under <i>Secobarbital Sodium for Injection</i> . Where the label states that Secobarbital |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>Sodium must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for <i>Bacterial endotoxins</i> under <i>Secobarbital Sodium for Injection</i>. to:</p> <p>Where the label states that Secobarbital Sodium is sterile, it meets the requirements for <i>Sterility Tests</i> ?71? and the level of bacterial endotoxins is not more than</p> |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>0.9 USP<br/>Endotoxin Units<br/>per mg of<br/>secobarbital<br/>sodium tested<br/>per <i>Bacterial<br/>Endotoxins Test</i><br/>&lt;85&gt;. Where<br/>the label states<br/>that<br/>Secobarbital<br/>Sodium must be<br/>subjected to<br/>further<br/>processing<br/>during the<br/>preparation of<br/>injectable<br/>dosage forms,<br/>the level of<br/>bacterial<br/>endotoxins is<br/>not more than<br/>0.9 USP<br/>Endotoxin Units<br/>per mg of<br/>secobarbital<br/>sodium tested<br/>per <i>Bacterial<br/>Endotoxins Test</i></p> |

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| DEXTROMETH Assay<br>ORPHAN HYD<br>ROBROMIDE<br>ORAL<br>SOLUTION | USPNF Online                       | Online                      | 25-Aug-2023                      | 1-Sep-2023                           | NA                                              | NA                                                                                 | <85>.<br>In<br><i>Chromatographi<br/>c system and<br/>Procedure:</i><br>Change<br>C is the<br>concentration,<br>in mg per mL, of<br>USP Dextromet<br>horphan<br>Hydrobromide<br>RS, on the<br>anhydrous<br>basis, in the<br><i>Standard<br/>preparation;</i><br>to:<br>C is the<br>concentration,<br>in mg per mL, of<br>USP Dextromet<br>horphan<br>Hydrobromide<br>RS in the<br><i>Standard<br/>preparation;</i> |
| METOLAZONE IMPURITIES                                           | USPNF Online                       | Online                      | 23-Feb-2024                      | 1-Mar-2024                           | NA                                              | NA                                                                                 | In <i>Organic<br/>Impuri<br/>ties/</i>                                                                                                                                                                                                                                                                                                                                                                             |

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| AMMONIUM G<br>LYCYRRHIZAT<br>E  | ASSAY/<br>Content<br>of Ammonium<br>18?- and 18?-<br>Glycyrrhizate | USPNF Online                       | Online                      | 24-Jun-2022                      | 1-Jul-2022                           | NA                                              | NA                                            |                                   | <p><i>Chromatographic system/Column: Change 4.6-mm × 25-cm; 5-μm packing 1 to: 4.6-mm × 25-cm; 5-μm packing L1</i></p> <p><i>In Analysis: Change <math>M_{W(Salt)}</math> = molecular weight of ammonium glycyrrhizate, 840.08 g/mol <math>M_{W(Acid)}</math> = molecular weight of glycyrrhizic acid, 821.59 g/mol to: <math>M_{W(Salt)}</math> = molecular weight of ammonium</i></p> |

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| MAFENIDE ACETATE FOR TOPICAL SOLUTION | IM PURITIES/ <i>Organic Impurities</i> | USPNF Online                       | Online                      | 16-Dec-2022                      | 1-Jan-2023                           | NA                                              | NA                                            |                                   | <p>glycyrrhizate, 839.97 g/mol</p> <p><math>M_{W(Acid)}</math> = molecular weight of glycyrrhizic acid, 822.94 g/mol</p> <p>In System suitability: Change <b>Samples:</b> System suitability solution, Standard solution A, and Standard solution B to:</p> <p><b>Samples:</b> System suitability solution and Standard solution A AND In Analysis: Change</p> |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p><b>Samples:</b><br/><i>Mobile phase, Standard solution A, and Sample solution Chromatograph the Standard solution and adjust the integration parameters so that the response is 5%–15% of full-scale deflection. to:</i></p> <p><b>Samples:</b><br/><i>Mobile phase, Standard solution A, Standard solution B, and Sample solution Chromatograph Standard solution B and adjust the integration parameters so</i></p> |

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| OSELTAMIVIR PHOSPHATE           | IM PURITIES/Organic Impurities/Procedure 3: Limit Of Tributyl Phosphine Oxide | USPNF Online                       | Online                      | 26-May-2023                      | 1-Jun-2023                           | NA                                              | NA                                                                                 | that the response is 5%–15% of full-scale deflection. In <i>System suitability/Suitability requirements/Relative standard deviation</i> : Change NMT 10.0% for the tributyl phosphine oxide and oseltamivir phosphate peaks to: NMT 10.0% for the tributyl phosphine oxide and oseltamivir phosphate peaks |
| COLOR AND ACHROMICITY           | METHOD II: INSTRUMENTAL                                                       | USPNF Online                       | Online                      | 17-Nov-2023                      | 1-Dec-2023                           | NA                                              | NA                                                                                 | In <i>Table 5</i> : Change                                                                                                                                                                                                                                                                                 |

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|                                       | (QUANTITATIVE)<br>ASSESSMENT OF COLOR AND COLOR MATCHES |                                    |                             |                                  |                                      |                                                 | <a href="#">Sort descending</a>               | Sum 98.809<br>100.000<br>107.307<br>White point<br>98.811 100.000<br>107.304<br>to:<br>Sum 94.809<br>100.000<br>107.307<br>White point<br>94.811 100.000<br>107.304 |
| MUPIROCIN CALCIUM                     | CHEMICAL INFORMATION                                    | USPNF Online                       | Online                      | 29-Apr-2022                      | 1-May-2022                           | NA                                              | NA                                            | Change<br>1075.34<br>to:<br>1075.35                                                                                                                                 |
| LANSOPRAZOLE DELAYED-RELEASE CAPSULES | IMPURITIES/Organic Impurities                           | USPNF Online                       | Online                      | 30-Sep-2022                      | 1-Oct-2022                           | NA                                              | NA                                            | Delete<br><b>Blank:</b><br>Methanol and Diluent (1:9)                                                                                                               |
| ERYTHROMYCIN DELAYED-RELEASE TABLETS  | PERFORMANCE TESTS/Dissolution ?711?                     | USPNF Online                       | Online                      | 31-Mar-2023                      | 1-Apr-2023                           | NA                                              | NA                                            | In Test 1:<br>Change<br><b>Buffer stage</b><br><b>Medium:</b> 0.05 M pH 6.8 phosphate buffer (see Reagents,                                                         |

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| BOTANICAL EXTRACTS              | PREPARATIONS            | USPNF Online                       | Online                      | 27-May-2022                      | 1-Jun-2022                           | NA                                              | NA                                            |                                   | <p><i>Indicators, and Solutions—Buffer Solutions)</i></p> <p>to:</p> <p><b>Buffer stage</b></p> <p><b>Medium:</b> 0.05 M pH 6.8 phosphate buffer (see <i>Reagents, Indicators, and Solutions—Buffer Solutions)</i>;</p> <p>900 mL</p> <p>In <i>General Pharmacopeial R equ irement s/Pesticide Residues:</i></p> <p>Change where <i>L</i> is the limit in the original article as listed in <i>Table 4</i> (see <i>Pesticide Residue</i></p> |

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| DOXORUBICIN IM<br>HYDROCHLOR PUR<br>IDE FOR<br>INJECTION | USPNF Online<br>Online<br>ITIES/ <i>Organic Impurities</i> |                             | 28-Oct-2022                      | 1-Nov-2022                           | NA                                              | NA                                                                                 | <p><i>Analysis under Articles of Botanical Origin &lt;561&gt;)</i></p> <p>to:</p> <p>where <i>L</i> is the limit in the original article as listed in <i>Table 5</i> (see <i>Pesticide Residue Analysis under Articles of Botanical Origin &lt;561&gt;)</i></p> <p>In <i>Analysis</i>:<br/>Change<br/><i>P</i> = potency of doxorubicin in USP<br/>Doxorubicin Hydrochloride RS (µg/mg)<br/>to:<br/><i>P</i> = potency of doxorubicin hydrochloride in USP<br/>Doxorubicin</p> |

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| LEVORPHANOL TARTRATE TABLETS    | PERFORMANCE TESTS/<br><i>Uniformity of Dosage Units</i><br>?905? | USPNF Online                       | Online                      | 31-Mar-2023                      | 1-Aug-2023                           | NA                                              | NA                                                                                 | Hydrochloride RS (µg/mg)<br>In <i>Sample solution</i> :<br>Change<br>Nominally about 80 µg/mL of levorphanol tartrate in <i>Diluent</i> prepared as follows.<br>to:<br>Nominally about 80 µg/mL of levorphanol tartrate in <i>Diluent</i> prepared as follows. |
| OCTOCRYLENE                     | IDENTIFICATION                                                   | USPNF Online                       | Online                      | 25-Aug-2023                      | 1-Sep-2023                           | NA                                              | NA                                                                                 | In <i>A./ Acceptance criteria</i> : Change NMT 3.0%, calculated on the as-is basis to:<br>Absorptivities, calculated on the as-is basis,                                                                                                                       |

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| POWDERED FORSKOHLII EXTRACT     | COMPOSITION<br><i>/Content of Forskolin</i>                           | USPNF Online                       | Online                      | 29-Jul-2022                      | 1-Aug-2022                           | NA                                              | NA                                                                                 | do not differ by more than 3.0%.<br>In <i>Chromatographic system</i> :<br>Change Column: 4.6-mm × 25-cm; 5-μm, 100 Å<br>to:<br>Column: 4.6-mm × 25-cm; 5-μm, 100 Å; packing L1 |
| MESO-ZEAXANTHIN                 | ADDITIONAL REQUIREMENT<br><i>S/USP Reference Standards &lt;11&gt;</i> | USPNF Online                       | Online                      | 27-Jan-2023                      | 1-Jun-2023                           | NA                                              | NA                                                                                 | In USP <i>meso</i> -Zeaxanthin RS: Change (3 <i>R</i> ,3' <i>S</i> - <i>meso</i> )-Zeaxanthin.<br>to:<br>(3 <i>R</i> ,3' <i>S</i> )-Zeaxanthin.                                |
| ATORVASTATIN CALCIUM TABLETS    | PERFORMANCE TESTS/                                                    | USPNF Online                       | Online                      | 30-Jun-2023                      | 1-Jul-2023                           | NA                                              | NA                                                                                 | In <i>Test 1, Test 3, Test 4, Test 5, and Test</i>                                                                                                                             |

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| <i>Dissolution</i><br>?711?                                                  |                                    |                             |                                  |                                      |                                                 |                                                                                    | 6/ <i>Analysis:</i><br>Change<br>$M_{r1}$ = molecular weight of atorvastatin, 558.64<br>$M_{r2}$ = molecular weight of atorvastatin calcium, 1155.34<br>to:<br>$M_{r1}$ = molecular weight of atorvastatin, 558.65<br>$M_{r2}$ = molecular weight of atorvastatin calcium, 1155.36 |
| PANTOPRAZO PERFORMANC<br>LE SODIUM DEE TESTS<br>LAYED-<br>RELEASE<br>TABLETS | USPNF Online Online                |                             | 17-Nov-2023                      | 1-Dec-2023                           | NA                                              | NA                                                                                 | In <i>Dissolution</i><br>?711?/ <i>Test</i><br>2/ <i>Acid stage:</i><br>Change<br><b>Acid stage standard solution:</b> (L/10) mg/mL of USP Pantoprazole                                                                                                                            |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | Sodium RS from the <i>Standard stock solution</i> in <i>Acid stage medium</i> , where <i>L</i> is the label claim in mg/Tablet to:<br><b>Acid stage standard solution:</b><br>( <i>L</i> /10000) mg/mL of USP Pantoprazole Sodium RS from the <i>Standard stock solution</i> in <i>Acid stage medium</i> , where <i>L</i> is the label claim in mg/Tablet AND<br>In <i>Dissolution &lt;711&gt;/Test 2/Buffer stage</i> :<br>Change <b>Buffer stage standard</b> |

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| DOXYCYCLINE TABLETS             | ADDITIONAL REQUIREMENT S/USP Reference Standards <11> | USPNF Online                       | Online                      | 24-Jun-2022                      | 1-Jul-2022                           | NA                                              | NA                                            |                                   | <b>solution:</b><br>(L/1000) of USP<br>Pantoprazole<br>Sodium RS<br>where <i>L</i> is the<br>label claim in<br>mg/Tablet<br>to:<br><b>Buffer stage<br/> standard<br/> solution:</b><br>(L/1000) mg/mL<br>of USP<br>Pantoprazole<br>Sodium RS<br>from the<br><i>Standard stock<br/> solution in<br/> Buffer stage<br/> medium</i> , where<br><i>L</i> is the label<br>claim in<br>mg/Tablet<br>In USP<br>Doxycycline<br>Related<br>Compound A<br>RS: Change<br>444.43 |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>to:<br/>444.44<br/>AND<br/>Change<br/>(4S,4aR,5S<br/>,5aR,6S<br/>,12aS<br/>)-4-(Dimethylam<br/>ino)-1,4,4a,5,5a<br/>,6,11,12a-octah<br/>ydro-3,5,10,12,<br/>12a-pentahydro<br/>xy-6-methyl-1,1<br/>1-dioxo-2-napht<br/>hacenecarboxa<br/>mide, monohydr<br/>ochloride.<br/>C<sub>22</sub>H<sub>24</sub>N<sub>2</sub>O<sub>8</sub> ·<br/>HCl 480.13<br/>to:<br/>(4S,4aR,5S<br/>,5aR,6S<br/>,12aS<br/>)-4-(Dimethylam<br/>ino)-1,4,4a,5,5a<br/>,6,11,12a-octah<br/>ydro-3,5,10,12,<br/>12a-pentahydro<br/>xy-6-methyl-1,1<br/>1-dioxo-2-napht</p> |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                               |                                   | hacenecarboxamide hydrochloride.<br>C <sub>22</sub> H <sub>24</sub> N <sub>2</sub> O <sub>8</sub> · HCl 480.90 |

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