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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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| LEFLUNOMIDE IM<br>PUR<br>ITIES/ <i>Organic Impurities/Procedure 2</i> |                                         | USP37–NF32                         | 3502                        | 25-Jul-2014                      | 1-Aug-2014                           | USP39–NF34                                      | <i>First Supplement to USP38–NF33</i>                                              | Line 3 of <i>Analysis</i> : Change [Note—Disregard any peak with an area less than the leflunomide peak from the <i>System suitability solution</i> . to: [Note—Disregard any peak with an area less than the leflunomide peak from the <i>Sensitivity solution</i> . |
| POWDERED<br>CELLULOSE                                                 | IDENTIFICATION<br><i>N/B. Procedure</i> | USP37–NF32                         | 5923                        | 26-Sep-2014                      | 1-Oct-2014                           | USP39–NF34                                      | <i>First Supplement to USP38–NF33</i>                                              | Fourth equation in <i>Analysis</i> : Change Result = $95 \times [?]_c / W_s \times [(100 - \% \text{LOD}) / 100]$ to: Result = $[95 \times [?]]$                                                                                                                      |

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| ATROPINE SULFATE                | ASSAY/<br>Proce<br>dure/System<br>suitabil<br>ity/Suitability<br>requirements | <i>First Supplement to USP37–NF32</i> | 6591                        | 25-Jul-2014                      | 1-Aug-2014                           | <i>USP39–NF34</i>                               | <i>First Supplement to USP38–NF33</i>                                              | $\frac{c}{W_s} \times [(100 - \%LOD)/100]$ Line 1 of<br><i>Relative standard deviation:</i><br>Change NMT 1.0 to:<br>NMT 1.0%                                                                                                                                                                        |
| CALCIUM GLUCONATE INJECTION     | <i>Identification</i>                                                         | <i>USP37–NF32</i>                     | 2089                        | 26-Sep-2014                      | 1-Oct-2014                           | <i>USP39–NF34</i>                               | <i>First Supplement to USP38–NF33</i>                                              | Line 1 of<br><i>Identification test A:</i> Change A volume of Injection diluted, if necessary, with water to obtain a test solution of calcium gluconate (1 in 100) responds to Identification test <i>B</i> under <i>Calcium Gluconate</i> .<br>to:<br>Dissolve a quantity of it in water to obtain |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>a test solution containing 10 mg per mL, heating in a water bath at 60° if necessary. Similarly, prepare a Standard solution of USP Potassium Gluconate RS in water containing 10 mg per mL. Apply separate 5-μL portions of the test solution and the Standard solution to a suitable thin-layer chromatographic plate (see <i>Chromatography</i> &lt;621&gt;) coated with a 0.25-mm layer of chromat</p> |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>ographic 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 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, spray with a spray reagent prepared as follows. Dissolve 2.5 g of ammonium</p> |

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| CEFTIZOXIME FOR INJECTION                               | <i>Constituted solution</i>        | USP37–NF32 2240             | 25-Jul-2014                      | 1-Aug-2014                           | USP39–NF34                                      | <i>First Supplement to USP38–NF33</i>                                              | <p>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 principal spot obtained from the test solution corresponds in color, size, and <math>R_F</math> value to that obtained from the Standard solution.</p> <p>Line 1: Change At the time of use, it meets the requirements for <i>Constituted</i></p> |

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|                                 |                                                                |                                    |                             |                                  |                                      |                                                 |                                               |                                   | <i>Solutions under Labeling under Injections &lt;1&gt;.</i><br>to:<br>At the time of use, it meets the requirements for <i>Constituted Solutions under Injections &lt;1&gt;.</i>                      |
| WATER FOR INJECTION             | CHEMICAL INFORMATION                                           | USP37–NF32                         | 5173                        | 26-Sep-2014                      | 1-Oct-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                |                                   | Add the chemical formula and molecular weight:<br>H <sub>2</sub> O 18.02                                                                                                                              |
| LEVALBUTEROL HYDROCHLORIDE      | ADDITIONAL REQUIREMENT<br>S/USP<br>Reference<br>Standards <11> | USP37–NF32                         | 3513                        | 25-Jul-2014                      | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                |                                   | Line 2 of USP Levalbuterol Related Compound H RS: Change 4-[2-( <i>tert</i> -Butylamino)-1-methoxyethyl]-2-(hydroxymethyl)phenol.<br>C <sub>14</sub> H <sub>23</sub> NO <sub>3</sub><br>253.34<br>to: |

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| METHACRYLIC ASSAY/<br>ACID AND <i>Procedure</i><br>METHYL METH<br>ACRYLATE<br>COPOLYMER | USP38–NF33                         | 6755                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | <i>First Supplement to USP39–NF34</i>                                              | 4-[2-( <i>tert</i> -Butylamino)-1-methoxyethyl]-2-(hydroxymethyl)phenol acetate.<br>$C_{14}H_{23}NO_3 \cdot C_2H_4O_2$ 313.39<br>Line 3 of <i>Acceptance criteria</i> : Delete on the dried basis<br>AND<br>Line 5 of <i>Acceptance criteria</i> : Delete on the dried basis |
| CHLOROXYLE IM<br>NOL<br>PURITIES/ <i>Limit of Tetrachloroethylene</i>                   | USP38–NF33                         | 2774                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | <i>First Supplement to USP39–NF34</i>                                              | Row 3 of Column 1 of <i>Table 2</i> : Change 210 to: 70<br>Row 3 of Column 2 of <i>Table 2</i> : Change 0                                                                                                                                                                    |

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| RIVASTIGMINE IM<br>PUR<br>ITIES/ <i>Organic Impurities</i>                      | USP38–NF33                         | 5212                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | <i>First Supplement to USP39–NF34</i>                                              | to:<br>35<br>Row 3 of Column 1 of Table 1:<br>Change Nor impurity (rivastigmine related compound B) to:<br>Nor impurity <sup>a</sup><br>AND<br>Add footnote a:<br><sup>a</sup> (S )?3?[1?(Dimethylamino)ethyl]phenyl dimethylcarbamate (racemic mixture is rivastigmine related compound B).<br>Line 15 of Analysis:<br>Change methotrexate related compound E |
| METHOTREXATE IM<br>PUR<br>ITIES/ <i>Organic Impurities/Procedure 1: Related</i> | USP38–NF33                         | 4318                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | <i>First Supplement to USP39–NF34</i>                                              |                                                                                                                                                                                                                                                                                                                                                                |

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| <i>Compounds</i>                                        |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>free acid to: methotrexate related compound E free base AND Line 8 of the second variable definition list for <i>Analysis</i>: Change methotrexate related compound E free acid to: methotrexate related compound E free base AND Row 5 of Column 1 of <i>Impurity Table 1</i>: Change Methotrexate related compound E free acid<sup>c</sup></p> |

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| PURIFIED STEARIC ACID           | ASSAY/<br><i>Procedure/System suitability/Suitability requirements</i> | USP38–NF33                         | 6919                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | <i>First Supplement to USP39–NF34</i>                                              | to:<br>Methotrexate related compound E free base <sup>c</sup><br>Line 2 of <i>Relative standard deviation</i> :<br>Change six replicate injections of <i>Sample solution</i> ;<br>to:<br>six replicate injections;<br>Line 11: Change weight, in mg, on the anhydrous basis, of the portion of Ethotoin taken;<br>to:<br>weight, in mg, of the portion of Ethotoin taken;<br>Line 2 of USP Rivastigmine |
| ETHOTOIN                        | <i>Related compounds/ Procedure</i>                                    | USP38–NF33                         | 3415                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | <i>First Supplement to USP39–NF34</i>                                              |                                                                                                                                                                                                                                                                                                                                                                                                         |
| RIVASTIGMINE TARTRATE           | ADDITIONAL REQUIREMENT                                                 | USP38–NF33                         | 5213                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | <i>First Supplement to</i>                                                         |                                                                                                                                                                                                                                                                                                                                                                                                         |

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| <i>S/USP Reference Standards &lt;11&gt;</i>             |                                    |                             |                                  |                                      |                                                 | <i>USP39–NF34</i>                                                                  | Related Compound B<br>RS: Change <i>N,N</i> -Dimethylcarbamate acid-3-[1-(dimethylamino)ethyl]phenyl ester.<br>to:<br>( <i>RS</i> )?3?[1?(Dimethylamino)ethyl]phenyl dimethylcarbamate.                       |
| METOLAZONE ASSAY/<br>TABLETS <i>Procedure</i>           | <i>USP38–NF33</i>                  | 4368                        | 31-Jul-2015                      | 1-Aug-2015                           | <i>USP40–NF35</i>                               | <i>First Supplement to USP39–NF34</i>                                              | Change the subsection <i>Standard solution</i> : 5 µg/mL of USP Metolazone RS in methanol to:<br><i>Standard stock solution</i> : 0.25 mg/mL of USP Metolazone RS in methanol<br><i>Standard solution</i> : 5 |

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| ALMOTRIPTAN IM<br>MALATE        | PURITIES/Limit<br>of Almotriptan<br>Related<br>Compound D<br>and Almotriptan<br>N-Dimer | <i>First Supplement to<br/>USP38–NF33</i> | 7325                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | <i>First Supplement to<br/>USP39–NF34</i>     |                                   | <p>µg/mL of USP Metolazone RS in <i>Mobile phase</i> from <i>Standard stock solution</i> AND</p> <p>Line 2 of <i>Sample solution</i>: Change of metolazone from the <i>Sample stock solution</i> in methanol to: of metolazone in <i>Mobile phase</i> from the <i>Sample stock solution</i></p> <p>Line 1 of <i>Internal standard solution</i>: Change 4-hydroxy-phenylpiperidine to: 4-hydroxy-4-phenylpiperidine</p> |

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| HYDROXYZINE PAMOATE ORAL SUSPENSION | ADDITIONAL REQUIREMENT S/USP Reference Standards <11> | USP38–NF33                         | 3817                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                | Delete USP Hydroxyzine Hydrochloride RS                                                                                                                                                                                                           |             |
| RIVASTIGMINE IM TARTRATE            | PURITIES/Organic Impurities/Procedure 1               | USP38–NF33                         | 5213                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                | Footnote c of Impurity Table 1: Change (S)-3-[1-(Dimethylamino)ethyl]phenyl dimethylcarbamate (rivastigmine related compound B). to: (S)-3-[1-(Dimethylamino)ethyl]phenyl dimethylcarbamate (racemic mixture is rivastigmine related compound B). |             |
| OXAPROZIN TABLETS                   | IM PURITIES/Organic                                   | USP38–NF33                         | 4681                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                | Delete the subsection Signal-to-noise                                                                                                                                                                                                             |             |

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|                                 |                                                                                                                             |                                              |                             |                                  |                                      |                                                 |                                               |                                   | ratio: NLT 3000                                                                                                                                                                                                                                                                                                                                     |
| DOXAZOSIN MESYLATE              | <p><i>Impurities/System suitability/Suitability requirements</i></p> <p>IM PUR ITIES/Organic <i>Impurities/Analysis</i></p> | <p><i>First Supplement to USP38–NF33</i></p> | 7387                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | <i>First Supplement to USP39–NF34</i>         |                                   | <p>Line 3 of the variable definition list: Change <math>r_S</math> = peak response of each impurity from the <i>Standard solution</i> to: <math>r_S</math> = peak response of each impurity or doxazosin mesylate (for calculating unspecified impurities) from the <i>Standard solution</i> AND</p> <p>Line 5 of the variable definition list:</p> |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | Change<br>C <sub>S</sub> =<br>concentration of<br>USP Doxazosin<br>Mesylate RS in<br>the <i>Standard<br/>solution</i><br>(mg/mL)<br>to:<br>C <sub>S</sub> =<br>concentration of<br>the<br>corresponding<br>USP Doxazosin<br>Related<br>Compound RS<br>or USP<br>Doxazosin<br>Mesylate RS<br>(for calculating<br>unspecified<br>impurities) in<br>the <i>Standard<br/>solution</i><br>(mg/mL) |
| IPRATROPIUM DEFINITION<br>BROMIDE                       | USP38–NF33                         | 3932                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First<br>Supplement to<br>USP39–NF34                                               | Line 2: Change<br>(C <sub>20</sub> H <sub>30</sub> BrNO <sub>3</sub> ·<br>H <sub>2</sub> O)<br>to:<br>(C                                                                                                                                                                                                                                                                                     |

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| RIVASTIGMINE<br>TARTRATE<br>CAPSULES  | ADDITIONAL REQUIREMENT<br>S/USP<br>Reference<br>Standards <11> | USP38–NF33                         | 5215                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                                                     | Line 2 of USP Rivastigmine Related Compound B RS: Change N,N-Dimethylcarbamate acid-3-[1-(dimethylamino)ethyl]phenyl ester.<br>to:<br>(RS)-3-[1-(Dimethylamino)ethyl]phenyl dimethylcarbamate. |
| TETRACAINE<br>HYDROCHLORIDE INJECTION | Identification                                                 | USP38–NF33                         | 5507                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                                                     | Line 1 of A: Change It responds to Identification test B under Tetracaine Hydrochloride.<br>to:<br>Dissolve 100 mg in 10 mL of water, and add 1 mL of potassium                                |

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| STEARIC ACID ASSAY/<br>Proce<br>dure/System<br>suitabil<br>ity/Suitability<br>requirements | Harmonization Online<br>(Official May 01,<br>2015) |                             | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | First<br>Supplement to<br>USP39–NF34                                               | thiocyanate<br>solution (1 in 4):<br>a crystalline<br>precipitate is<br>formed.<br>Recrystallize<br>the precipitate<br>from water, and<br>dry at 80° for 2<br>hours: it melts<br>between 130°<br>and 132°.<br>Line 3 of<br>Relative<br>standard<br>deviation:<br>Change<br>peaks (from<br>six replicate<br>injections of<br>Sample<br>solution);<br>to:<br>peaks, from<br>six replicate<br>injections; |
| IPRATROPIUM ASSAY/<br>BROMIDE Procedure                                                    | USP38–NF33                                         | 3932                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First<br>Supplement to<br>USP39–NF34                                               | Line 4 of<br>Analysis:<br>Change<br>(C                                                                                                                                                                                                                                                                                                                                                                 |

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| ROPIVACAINE ADDITIONAL REQUIREMENT<br>IDE               | USP38–NF33<br>S/USP<br>Reference<br>Standards <11> | 5225                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                                                     | $^{20}\text{H}_{30}\text{BrNO}_3 \cdot \text{H}_2\text{O}$<br>to:<br>$(\text{C}_{20}\text{H}_{30}\text{BrNO}_3)$<br>Line 2 of USP<br>Ropivacaine<br>Related<br>Compound B<br>RS: Change<br>(R)-ropivacaine<br>hydrochloride<br>monohydrate;<br>(R<br>)-(?)-1-propylpip<br>eridine-2-carbox<br>ylic acid (2,6-di<br>methylphenyl)-a<br>mide<br>hydrochloride<br>monohydrate.<br>to:<br>(R<br>)-Ropivacaine<br>hydrochloride<br>monohydrate;<br>(R<br>)-(+)-1-propylpip<br>eridine-2-carbox<br>ylic acid (2,6-di<br>methylphenyl)-a |

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| TETRACAINE <i>Identification</i><br>HYDROCHLOR<br>IDE FOR<br>INJECTION | USP38–NF33                            | 5508                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | <i>First Supplement to USP39–NF34</i>                                              | mide hydrochloride monohydrate. Line 1 of <i>B</i> : Change It responds to <i>Identification</i> test <i>B</i> under <i>Tetracaine Hydrochloride</i> . to:<br>Dissolve 100 mg in 10 mL of water, and add 1 mL of potassium thiocyanate solution (1 in 4): a crystalline precipitate is formed. Recrystallize the precipitate from water, and dry at 80° for 2 hours: it melts between 130° and 132°. |
| BIOTECHNOL INTRODUCTION<br>OGY-DERIVED N                               | <i>Harmonization Online (Official</i> |                             | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | <i>First Supplement to</i>                                                         | A paragraph before the                                                                                                                                                                                                                                                                                                                                                                               |

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| ARTICLES -- P<br>OLYACRYLAMIDE GEL ELECTROPHORESIS | <i>December 01, 2015)</i>          |                             |                                  |                                      |                                                 | USP39–NF34                                                                         | Introduction was deleted: This chapter provides guidance and procedures used for characterization of biotechnology-derived articles by polyacrylamide gel electrophoresis. Portions of the chapter that are not harmonized with the other two pharmacopeias are marked by the symbol ?. This chapter is harmonized with the corresponding chapter in <i>JP</i> and <i>EP</i> . Other characterization tests, also |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | harmonized, are shown in <i>Biotechnology-Derived Articles—Amino Acid Analysis</i> <1052>, <i>Biotechnology-Derived Articles—Capillary Electrophoresis</i> <1053>, <i>Biotechnology-Derived Articles—Isoelectric Focusing</i> <1054>, <i>Biotechnology-Derived Articles—Peptide Mapping</i> <1055>, and <i>Biotechnology-Derived Articles—Total Protein Assay</i> <1057>. |
| METHOHEXITACHEMICAL<br>L INFORMATION                    | USP38–NF33                         | 4316                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                                                     | Line 5: Change [18652-93-2] to:                                                                                                                                                                                                                                                                                                                                           |

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| ROPIVACAINE <i>USP Reference Standards</i> <11><br>HYDROCHLORIDE INJECTION | USP38–NF33                         | 5227                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                                                     | [151-83-7]<br>Line 2 of USP Ropivacaine Related Compound B RS: Change (R)-ropivacaine hydrochloride monohydrate; (R)-(?)-1-propylpiperidine-2-carboxylic acid (2,6-dimethylphenyl)-amide hydrochloride monohydrate. to: (R)-Ropivacaine hydrochloride monohydrate; (R)-(+)-1-propylpiperidine-2-carboxylic acid (2,6-dimethylphenyl)-amide hydrochloride monohydrate. |

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| TETRACAINE <i>Chromatographi</i><br>HYDROCHLOR <i>c purity</i><br>IDE FOR<br>INJECTION | USP38–NF33                         | 5508                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | <i>First Supplement to USP39–NF34</i>                                              | Line 1: Change Dissolve an accurately weighed quantity of <i>Tetracaine Hydrochloride for Injection</i> in water to obtain a test solution containing 50 mg per mL, and proceed as directed in the test for <i>Chromatographi c purity</i> under <i>Tetracaine</i> , beginning with “Prepare a Standard solution.” to:<br>Dissolve an accurately weighed quantity of <i>Tetracaine Hydrochloride for Injection</i> in |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>water to obtain a test solution containing 50 mg per mL. Prepare a Standard solution of 4-(butylamino) benzoic acid in methanol containing 0.2 mg per mL. Apply separate 5-μL portions of the test solution and the Standard solution to a suitable thin-layer chromatographic plate (see <i>Chromatography</i> &lt;621&gt;) coated with a 0.25-mm layer of chromatographic silica gel mixture. Develop the plate in a</p> |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>suitable chromatographic chamber containing a solvent system consisting of a mixture of chloroform, methanol, and isopropylamine (98:7:2) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and dry in a current of warm air. Examine the plate under short-wavelength UV light: any spot obtained from the test solution, other than the principal spot, is</p> |

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| MUCOSAL DRUG PRODUCTS—PRODUCT QUALITY TESTS FOR T QUALITY TESTS | PRODUCT QUALITY TESTS FOR MUCOSAL DRUG PRODUCTS /General Necessary Tests/Impurities | USP38–NF33                         | 76                          | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                |                                   | not more intense than the principal spot obtained from the Standard solution (0.4%), and the sum of the intensities of any such spots is not greater than 0.8%.<br>Line 1 of footnote 2: Change<br><a href="http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q3B_R2/Step4/Q3B_R2_Guideline.pdf">http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q3B_R2/Step4/Q3B_R2_Guideline.pdf</a> .<br>to:<br><br><a href="http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html">http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html</a> . |
| NALOXONE HYIM                                                   |                                                                                     | USP38–NF33                         | 4486                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First                                         |                                   | Add                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

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| DROCHLORID E                         | PUR ITIES/<br>Noroxymorphon<br>e Hydrochloride<br>[(?)-4,5?-Epoxy-<br>3,14-Dihydroxy<br>morphinan-6-on<br>e-hydrochloride]<br>and Other<br>Impuri<br>ties/<br>Chromatographi<br>c system |                                    |                             |                                  |                                      |                                                 | Supplement to<br>USP39–NF34                   | Application<br>volume: 5 µL                                                                                                                                                                                                                                                |
| VALGANCICLO<br>VIR HYDROCH<br>LORIDE | Assay                                                                                                                                                                                    | USP38–NF33                         | 5729                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First<br>Supplement to<br>USP39–NF34          | Line 4 of<br>Procedure:<br>Change<br>Calculate the<br>percentage, on<br>the anhydrous<br>and solvent-free<br>basis, of<br>$C_{14}H_{22}N_6O_5 \cdot HCl$<br>to:<br>Calculate the<br>percentage of<br>valganciclovir<br>hydrochloride<br>( $C_{14}H_{22}N_6O_5 \cdot HCl$ ) |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <p>AND</p> <p>Line 8 of<br/><i>Procedure:</i><br/>Change<br/> <math>100[(r_U / W_U)(C_F) / (100 - S_U)]</math><br/> to:<br/> <math>100[(r_U / W_U)(C_F) / (100)]</math></p> <p>AND</p> <p>Line 12 of<br/><i>Procedure:</i><br/>Change<br/> <math>C_F</math> is the correction factor; and <math>S_U</math> is the total percent of solvent and water in the test sample.<br/> to:<br/> and <math>C_F</math> is the correction factor.</p> <p>AND</p> <p>Line 16 of<br/><i>Procedure:</i><br/>Change<br/> <math>(W</math></p> |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | $s/R_S][(100 - S_S)/100]$ <p>to:</p> $(W_S/R_S)/100$ <p>AND</p> <p>Line 18 of <i>Procedure</i>:</p> <p>Change</p> <p><math>R_S</math> is the area response (sum of two peaks for valganciclovir diastereomers) obtained from the <i>Standard preparation</i>; and <math>S_S</math> is the total percent of solvent and water in USP Valganciclovir Hydrochloride RS.</p> <p>to:</p> <p>and <math>R_S</math> is the area response (sum of two peaks for valganciclovir diastereomers)</p> |

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| TETRACAINE IDENTIFICATION IN DEXTROSE INJECTION                                                                   | USP38–NF33                         | 5509                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                                                     | obtained from the <i>Standard preparation</i> .<br>Line 1 of <i>B</i> :<br>Change<br>It responds to <i>Identification</i> test <i>C</i> under <i>Tetracaine Hydrochloride</i> .<br>to:<br>A solution of 100 mg in 5 mL of water meets the requirements of the tests for <i>Chloride</i> <191>. |
| ANTIBIOTICS—MICROBIAL ASSAYS—APPENDIX 1. FORMULAS FOR MANUAL CALCULATION S OF REGRESSION AND SAMPLE CONCENTRATION | USP38–NF33                         | 133                         | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                                                     | Line 19:<br>Change<br>$b = [(4 \times 17.222) + (2 \times 16.511) \div (2 \times 14.989) \div (4 \times 14.020)] / \{5[\ln(7.81)] \div \ln(3.2)\} = 3.551$<br>to:<br>$b = [(4 \times 17.222) + (2 \times$                                                                                      |

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| NOREPINEPH<br>RINE<br>BITARTRATE | CHEMICAL<br>INFORMATION                                                               | USP38–NF33                         | 4582                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First<br>Supplement to<br>USP39–NF34          | 16.511) ? (2 ×<br>14.989) ? (4 × 1<br>4.020)]/{5[ln(7.8<br>1) ? ln(3.2)]} =<br>3.551<br>Line 6: Change<br>[69815-49-2].<br>to:<br>[108341-18-0].                                                                                                                                                                             |
| SODIUM<br>STEARYL<br>FUMARATE    | SPECIFIC<br>TESTS/ <i>Fats<br/>and Oils,<br/>Saponification<br/>Value &lt;401&gt;</i> | USP38–NF33                         | 6877                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First<br>Supplement to<br>USP39–NF34          | Line 6 of<br><i>Analysis</i> :<br>Change<br>Rinse the<br>condenser with<br>two 10-mL<br>portions of 70%<br>alcohol, add<br>phenolphthalein<br>TS,<br>to:<br>Rinse the<br>condenser with<br>10 mL of 70%<br>alcohol,<br>followed by<br>three 10-mL<br>portions of<br>water, collecting<br>the rinsings in<br>the flask. Cool, |

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| METHACRYLIC DEFINITION ACID AND ETHYL ACRYLATE COPOLYMER |                         | USP38–NF33                         | 6753                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                |                                   | rinse the sides of the flask with two 10-mL portions of 70% alcohol, add phenolphthalein TS,<br>Line 4: Change Methacrylic acid units in Methacrylic Acid and Ethyl Acrylate Copolymer are NLT 46.0% and NMT 50.6%, calculated on the dried basis. to:<br>Methacrylic acid units in Methacrylic Acid and Ethyl Acrylate Copolymer, previously dried, are NLT 46.0% and NMT 50.6%. |
| BOVINE                                                   | APPENDIX 1              | USP38–NF33                         | 719                         | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First                                         |                                   | Line 2 of bullet                                                                                                                                                                                                                                                                                                                                                                  |

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| SERUM                                                   |                                    |                             |                                  |                                      |                                                 | <i>Supplement to USP39–NF34</i>                                                    | <p>1 of International Regulations and Guidance Documents in second paragraph: Change<br/> <a href="http://www.emea.europa.eu/pdfs/human/bwp/026895en.pdf">http://www.emea.europa.eu/pdfs/human/bwp/026895en.pdf</a></p> <p>to:</p> <p><a href="http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003684.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003684.pdf</a></p> <p>AND</p> <p>Line 2 of bullet 2 of International Regulations and Guidance Documents in second paragraph:</p> |

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|                                                         |                                    |                             |                                  |                                      |                                                 |                                                                                    | <a href="#">en_GB/document_library/Scientific_guideline/2009/10/WC500004575.pdf</a><br>AND<br>Delete bullet 4 of International Regulations and Guidance Documents in second paragraph<br>AND<br>Line 2 of bullet 5 of International Regulations and Guidance Documents in second paragraph:<br>Change<br><a href="#">http://www.ema.europa.eu/pdfs/human/bwp/TSE%20NFG%20410-rev2.pdf</a><br>to:<br><a href="#">http://www.ema.</a> |

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|                                               |                                                                  |                                    |                             |                                  |                                      |                                                 | <a href="#">Sort descending</a>               | <a href="http://www.oie.int/doc/ged/D10905.pdf">http://www.oie.int/doc/ged/D10905.pdf</a>              |
| OXAZEPAM                                      | SPECIFIC TESTS/ <i>pH</i> <791>                                  | USP38–NF33                         | 4683                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                | Line 1: Change Sample solution: 20 mg/mL to:<br>Sample: A suspension of 1 g of Oxazepam in 50 mL water |
| CHLORPHENIRAMINE MALEATE                      | SPECIFIC TESTS/ <i>Optical Rotation, Specific Rotation</i> <781> | Second Supplement to USP38–NF33    | Online                      | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                | Line 1: Delete Specific Rotation                                                                       |
| METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER | ASSAY/ <i>Procedure</i>                                          | USP38–NF33                         | 6753                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                | Line 1 of Acceptance criteria: Delete on the dried basis                                               |
| BROMPHENIRAMINE MALEATE                       | SPECIFIC TESTS/ <i>Optical Rotation, Specific Rotation</i> <781> | USP38–NF33                         | 2475                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                | Line 1: Delete Specific Rotation AND<br>Line 1 of Sample: Change 100 mg/mL in                          |

| <a href="#">Monograph Title</a>          | <a href="#">Section</a>                            | <a href="#">Source Publication</a> | <a href="#">Page Number</a> | <a href="#">Errata Post Date</a> | <a href="#">Errata Official Date</a> | <a href="#">Target Errata Print Publication</a> | <a href="#">Target Online Fix Publication</a> | <a href="#">_Sort descending_</a> | Description                                                                                                                                                                     |
|------------------------------------------|----------------------------------------------------|------------------------------------|-----------------------------|----------------------------------|--------------------------------------|-------------------------------------------------|-----------------------------------------------|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RIBAVIRIN TABLETS                        | IMPURITIES/ <i>Organic Impurities, Procedure 1</i> | USP38–NF33                         | 5162                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                |                                   | water to: 100 mg/mL in water at 20° Footnote e of Table 2: Change 1-?-D-Ribofuranosyl-1H-1,2,4-triazole-3-carboxamide. to: 1-?-D-Ribofuranosyl-1H-1,2,4-triazole-5-carboxamide. |
| AMOXICILLIN TABLETS FOR ORAL SUSPENSION  | ASSAY/ <i>Procedure</i>                            | USP38–NF33                         | 2225                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                |                                   | Line 6 of Analysis: Change Result = $(r_U/r_S) \times (C_S/C_U) \times P \times (1/F) \times 100$ to: Result = $(r_U/r_S) \times (C_S/C_U) \times P \times F \times 100$        |
| METHACRYLIC ACID AND METHYL METHACRYLATE | DEFINITION                                         | USP38–NF33                         | 6755                        | 31-Jul-2015                      | 1-Aug-2015                           | USP40–NF35                                      | First Supplement to USP39–NF34                |                                   | Methacrylic acid units in Methacrylic Acid and Methyl                                                                                                                           |

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|---------------------------------|----------------------------|------------------------------------|-----------------------------|----------------------------------|--------------------------------------|-------------------------------------------------|-----------------------------------------------|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| COPOLYMER                       |                            |                                    |                             |                                  |                                      |                                                 |                                               |                                   | Methacrylate Copolymer are NLT 27.6% and NMT 50.6%, calculated on the dried basis. to:<br>Methacrylic acid units in Methacrylic Acid and Methyl Methacrylate Copolymer, previously dried, are NLT 27.6% and NMT 50.6%. |
| CALCIUM LACTATE TABLETS         | ASSAY/<br><i>Procedure</i> | USP38–NF33                         | 2553                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | <i>First Supplement to USP39–NF34</i>         |                                   | Line 3 of <i>Analysis</i> : Change While stirring, add 30 mL of <i>Titrant</i> from a 50-mL buret. to:<br>While stirring, add 15 mL of <i>Titrant</i> from a 50-mL buret.                                              |
| RIVASTIGMINE                    | ADDITIONAL R               | USP38–NF33                         | 5212                        | 25-Sep-2015                      | 1-Oct-2015                           | USP40–NF35                                      | <i>First</i>                                  |                                   | Line 2 of USP                                                                                                                                                                                                          |

| <a href="#">Monograph Title</a>             | <a href="#">Section</a>                                             | <a href="#">Source Publication</a> | <a href="#">Page Number</a> | <a href="#">Errata Post Date</a> | <a href="#">Errata Official Date</a> | <a href="#">Target Errata Print Publication</a> | <a href="#">Target Online Fix Publication</a>                        | <a href="#">Description</a>                                                                                                                                                                                   |
|---------------------------------------------|---------------------------------------------------------------------|------------------------------------|-----------------------------|----------------------------------|--------------------------------------|-------------------------------------------------|----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                             | EQUIREMENT<br><i>SI/USP Reference Standards &lt;11&gt;</i>          |                                    |                             |                                  |                                      |                                                 | <a href="#">_Sort descending_</a><br><i>Supplement to USP39–NF34</i> | Rivastigmine Related Compound B RS: Change Nor impurity; (S)-3-[1-(Dimethylamino)ethyl]phenyl dimethylcarbamate. to: Nor impurity (racemic mixture); (RS)-3-[1-(Dimethylamino)ethyl]phenyl dimethylcarbamate. |
| ESTRADIOL AND NORETHINDRONE ACETATE TABLETS | IM PURITIES/ <i>Organic Impurities/Procedure/System suitability</i> | <i>USP38–NF33</i>                  | 3385                        | 31-Jul-2015                      | 1-Aug-2015                           | <i>USP40–NF35</i>                               | <i>First Supplement to USP39–NF34</i>                                | Line 2 of the Note: Change 1.0, 1.4, and 3.0, to: 1.0, 1.1, and 1.7,                                                                                                                                          |

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