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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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| DROSPIRENO IM                                           | USP37–NF32                                            | 2739                        | 26-Sep-2014                                                                                           | 1-Oct-2014                                              | USP39–NF34                                                         | First                                                            | Line 2 of   |

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| NE AND ETHINYL ESTRADIOL TABLETS                        | PURITIES/ <i>Organic Impurities/Chromatographic system</i> |                                    |                             |                                                                 |                                      |                                                 | <i>Supplement to USP38–NF33</i>               | <i>Detector 2: Change Monitor the signal at 344 nm between 37 and 42 min. to:</i>                               |
|                                                         |                                                            |                                    |                             |                                                                 |                                      |                                                 |                                               | <i>Monitor the signal at 344 nm for ethinyl estradiol related compound B (typically between 37 and 42 min).</i> |
|                                                         |                                                            |                                    |                             |                                                                 |                                      |                                                 |                                               | <i>Line 2 of System suitability solution:</i>                                                                   |
| PSEUDOEPHEDRINE HYDROCHLORIDE                           | ASSAY/ <i>Procedure</i>                                    | <i>USP37–NF32</i>                  | 4481                        | 26-Sep-2014                                                     | 1-Oct-2014                           | <i>USP39–NF34</i>                               | <i>First Supplement to USP38–NF33</i>         | <i>Change 0.02 mg/mL of USP Ephedrine Sulfate RS to: 0.002 mg/mL of USP Ephedrine Sulfate RS</i>                |
| STERILE WATER FOR INJECTION                             | CHEMICAL INFORMATION                                       | <i>USP37–NF32</i>                  | 5175                        | 26-Sep-2014                                                     | 1-Oct-2014                           | <i>USP39–NF34</i>                               | <i>First Supplement to USP38–NF33</i>         | <i>Add the chemical formula and molecular</i>                                                                   |

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| STERILE PURIFIED WATER          | ADDITIONAL REQUIREMENTS                                     | USP37–NF32                         | 5176                        | 26-Sep-2014                      |                                       | 1-Oct-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | weight:<br>H <sub>2</sub> O 18.02<br>Add a section:<br><i>USP Reference Standards &lt;11&gt;</i><br>USP 1,4-Benzoquinone RS<br>USP Sucrose RS                     |
| DEXCHLORPHENIRAMINE MALEATE     | IMPURITIES/Organic Impurities                               | First Supplement to USP37–NF32     | 6626                        | 26-Sep-2014                      |                                       | 1-Oct-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Line 1 of Standard solution:<br>2.2 ?g/mL of USP Dexchlorpheniramine Maleate RS in Diluent,<br>to:<br>2.8 ?g/mL of USP Dexchlorpheniramine Maleate RS in Diluent, |
| AMIFOSTINE                      | ASSAY/Procedure/System suitability/Suitability requirements | USP37–NF32                         | 1717                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Line 1 of Column efficiency:<br>Change NLT 100 to:<br>NLT 1000                                                                                                    |
| TIZANIDINE                      | ASSAY/                                                      | Second                             | Online                      | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | First                                         | Change                                                                                                                                                            |

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| TABLETS                         | <i>Procedure/System suitability</i> | <i>Supplement to USP37–NF32</i>    |                             |                                  |                                |                                      |                                                 | <i>Supplement to USP38–NF33</i>               | <i>Sample: Standard solution to:</i><br><i>Samples: System suitability solution and Standard solution AND Change Resolution: NLT 4.0 between tizanidine and tizanidine related compound C; NLT 4.0 between tizanidine and tizanidine related compound B</i><br><i>Tailing factor: NMT 2.0</i><br><i>Relative standard deviation: NMT 2.0%</i><br><i>to:</i> |

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|                                 |                             |                                    |                             |                                                                 |                                      |                                                 |                                               | <i>Resolution:</i> NLT 4.0 between tizanidine and tizanidine related compound C; NLT 4.0 between tizanidine and tizanidine related compound B, <i>System suitability solution</i><br><i>Tailing factor:</i> NMT 2.0, <i>Standard solution</i><br><i>Relative standard deviation:</i> NMT 2.0%, <i>Standard solution</i> |
| CEFUROXIME FOR INJECTION        | <i>Constituted solution</i> | USP37–NF32                         | 2246                        | 25-Jul-2014                                                     | 1-Aug-2014                           | USP39–NF34                                      | <i>First Supplement to USP38–NF33</i>         | Line 3: Change meets the requirements for <i>Constituted Solutions</i> under <i>Labeling</i> under <i>Injections</i> <1>.                                                                                                                                                                                               |

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| DULOXETINE DELAYED-RELEASE CAPSULES | IDENTIFICATION          | USP37–NF32                         | 2743                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | to:<br>meets the requirements for <i>Constituted Solutions</i> under <i>Injections</i> <1>. Change<br>A. <i>Infrared Absorption</i> <197S><br>to:<br>A. <i>Infrared Absorption</i> <197F>  |
| LEVODOPA                            | IMPURITIES              | USP37–NF32                         | 3533                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Row 6 of Column 1 of <i>Table 1</i> : Change<br>1-Veratrylglycine<br>to:<br>L-Veratrylglycine <sup>a</sup><br>AND<br>Add a footnote:<br><sup>a</sup><br>3-(3,4-Dimethoxyphenyl)-L-alanine. |
| VINBLASTINE SULFATE                 | IDENTIFICATION          | USP37–NF32                         | 5150                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to                           | Line 1 of <i>Sample</i> :                                                                                                                                                                  |

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|                                                                                            |                                                                                                                                 |                                       |                             |                                  |                                       |                                      |                                                 | USP38–NF33                                    | Change 100 mg/mL in water to: 10 mg/mL in water                                                                                                                                      |
| CEFADROXIL                                                                                 | ASSAY/<br>Procedure                                                                                                             | <i>First Supplement to USP37–NF32</i> | 6602                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | <i>First Supplement to USP38–NF33</i>         | Line 3 of Sample solution: Change USP Cefadroxil RS to: Cefadroxil                                                                                                                   |
| METHODS FOR THE DETERMINATION OF PARTICULATE MATTER IN INJECTIONS AND OPHTHALMIC SOLUTIONS | LIGHT OBSCURATION PARTICLE COUNT TEST/<br><i>Instrument Standardization Tests/Particle Counting Accuracy—System Suitability</i> | USP37–NF32                            | 1301                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | <i>First Supplement to USP38–NF33</i>         | Line 26 of Method 1—MWHC Instruments: Change $P_B$ is the average particle count obtained from the suspension; to: $P_S$ is the average particle count obtained from the suspension; |
| TERBINAFINE                                                                                | ADDITIONAL R                                                                                                                    | <i>First</i>                          | 6704                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | <i>First</i>                                  | Line 2 of USP                                                                                                                                                                        |

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| HYDROCHLORIDE                   | EQUIREMENT              | <i>Supplement to S/USP Reference Standards &lt;11&gt;</i> | <i>USP37–NF32</i>           |                                  |                                |                                      |                                                 | <i>Supplement to USP38–NF33</i>               | Terbinafine Related Compound A RS: Change <i>N</i> -Methyl-C -(naphthalen-1-yl)methanamine . to: <i>N</i> -Methyl-C -(naphthalen-1-yl)methanamine hydrochloride. AND Line 2 of USP Terbinafine Related Compound B RS: Change (2 <i>Z</i> )- <i>N</i> , 6, 6-Tr imethyl- <i>N</i> -(naphthalen-1-ylmethyl)hept-2-en-4-yn-1-amine. to: |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | (2Z)-N<br>,<br>6,<br>6-Tr<br>imethyl-N<br>-(naphthalen-1-ylmethyl)hept-2-en-4-yn-1-amine hydrochloride.<br>AND<br>Line 2 of USP<br>Terbinafine<br>Related<br>Compound C:<br>Change<br>(2E)-N<br>,<br>6,<br>6-Tr<br>imethyl-N<br>-(naphthalen-2-ylmethyl)hept-2-en-4-yn-1-amine.<br>to:<br>(2E)-N<br>,<br>6,<br>6-Tr<br>imethyl-N<br>-(naphthalen-2- |

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| CEFTIZOXIME FOR                 | Constituted solution    | USP37–NF32                         | 2240                        | 25-Jul-2014                      |                                | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to                           | ylmethyl)hept-2-en-4-yn-1-amine hydrochloride.<br>AND<br>Line 2 of Terbinafine Related Compound D RS: Change (2E)-N<br>,<br>6,<br>6-Tr<br>imethyl-N<br>-[(4-methylnaphthalen-1-yl)methyl]hept-2-en-4-yn-1-amine.<br>to:<br>(2E)-N<br>,<br>6,<br>6-Tr<br>imethyl-N<br>-[(4-methylnaphthalen-1-yl)methyl]hept-2-en-4-yn-1-amine hydrochloride.<br>Line 1: Change At the time of |

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| INJECTION                                                 |                                    |                             |                                                                 |                                      |                                                 | USP38–NF33                                    | use, it meets the requirements for <i>Constituted Solutions</i> under <i>Labeling</i> under <i>Injections</i> <1>. to:<br>At the time of use, it meets the requirements for <i>Constituted Solutions</i> under <i>Injections</i> <1>. |
| DOXAPRAM H ASSAY/<br>YDROCHLORI Procedure<br>DE INJECTION | USP37–NF32                         | 2708                        | 25-Jul-2014                                                     | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Line 7 of Analysis: Change $R_U$ = peak response ratio of the doxapram to the internal standard from the <i>Sample solution</i> $R_S$ = peak response ratio of the doxapram to the internal standard from the <i>Sample</i>           |

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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                                      | First Supplement to USP38–NF33                | <p><i>solution</i><br/>to:<br/><math>R_U</math> = peak response ratio of doxapram to the internal standard from the <i>Sample solution</i><br/><math>R_S</math> = peak response ratio of doxapram to the internal standard from the <i>Standard solution</i></p> <p>Line 3 of <i>Analysis</i>:<br/>Change<br/>[Note—Disregard any peak with an area less than the leflunomide peak from the <i>System suitability solution</i>.<br/>to:<br/>[Note—Disregard any peak with</p> |

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| NALTREXONE Assay<br>HYDROCHLOR<br>IDE                   | USP37–NF32                         | 3922                           | 25-Jul-2014                                                     | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | an area less than the leflunomide peak from the <i>Sensitivity solution</i> .<br>Line 7 of <i>Procedure</i> :<br>Change (377.86/341.41) $10C(r_U/r_S)$ in which 377.86 and 341.41 are the molecular weights of naltrexone hydrochloride and naltrexone to:<br>(377.86/341.40) $10C(r_U/r_S)$ in which 377.86 and 341.40 are the molecular weights of naltrexone hydrochloride and naltrexone |                                                |
| VITAMIN E<br>ASSAY                                      | ASSAY/<br><i>Procedure 4/</i>      | First Supplement to USP37–NF32 | 6338                                                            | 25-Jul-2014                          | 1-Aug-2014                                      | USP39–NF34                                    | First Supplement to USP38–NF33                                                                                                                                                                                                                                                                                                                                                               | Line 1 of <i>Flow rate</i> : Change 1.5 mL/min |

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| GENERAL NOTICES TO USP-NF       | Chromatographic system<br>6. TESTING PRACTICES AND PROCEDURES/6.50.<br><i>Preparation of Solutions</i> | <i>First Supplement to USP37–NF32</i> | 6291                        | 25-Jul-2014                      |                                | 1-Aug-2014                           | USP38–NF33                                      | USP38–NF33                                    | to:<br>1 mL/min<br>Line 6 of 6.50.20.<br><i>Solutions:</i><br>Change<br>An expression such as “(1 in 10)” means that 1 part <i>by volume</i> of a liquid shall be diluted with a sufficient quantity of the diluent or solvent to make the volume of the finished solution 10 parts <i>by volume</i> . An expression such as “(20:5:2)” means that the respective numbers of parts, by volume, of the designated liquids shall be |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>mixed, unless otherwise indicated.</p> <p>to:</p> <p>An expression such as “(1 in 10)” means that 1 part <i>by volume</i> of a liquid shall be diluted with, or 1 part <i>by weight</i> of a solid shall be dissolved in, a sufficient quantity of the diluent or solvent to make the volume of the finished solution 10 parts <i>by volume</i>. An expression such as “(20:5:2)” means that the respective numbers of parts, by volume, of the designated</p> |

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| SUFENTANIL CITRATE                                      | ASSAY/<br><i>Procedure/System suitability requirements</i>     | <i>First Supplement to USP37–NF32</i>            | 6701                        | 25-Jul-2014                                                     | 1-Aug-2014                           | <i>USP39–NF34</i>                               | <i>First Supplement to USP38–NF33</i>         | liquids shall be mixed, unless otherwise indicated.<br>Line 1 of <i>Relative standard deviation</i> : Change NMT 0.7% to:<br>NMT 0.73%                               |
| BUMETANIDE                                              | IMPURITIES                                                     | <i>USP37–NF32</i>                                | 2024                        | 25-Jul-2014                                                     | 1-Aug-2014                           | <i>USP39–NF34</i>                               | <i>First Supplement to USP38–NF33</i>         | Row 4 of Column 1 of <i>Table 1</i> : Change Paroxetine butyl 3-(butylamino)-4-phenoxy-5-sulfamoylbenzoate to:<br>Butyl 3-(butylamino)-4-phenoxy-5-sulfamoylbenzoate |
| ROPINIROLE HYDROCHLORIDE                                | HIMPURITIES/Organic Impurities, Procedure 1/System suitability | <i>Revision Bulletin (Official May 01, 2014)</i> | Online                      | 25-Jul-2014                                                     | 1-Aug-2014                           | <i>USP39–NF34</i>                               | <i>First Supplement to USP38–NF33</i>         | Line 1 of <i>Tailing factor</i> : Change NLT 2.0 for the ropinirole peak to:<br>NMT 2.0 for the                                                                      |

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| ility/Suitability requirements                                                  |                                    |                             |                                                                 |                                      |                                                 |                                               | ropinirole peak                                                                                                                                                                                                                                                     |
| CHLORDIAZEP Constituted<br>OXIDE HYDRO solution<br>CHLORIDE<br>FOR<br>INJECTION | USP37–NF32                         | 2290                        | 25-Jul-2014                                                     | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Line 1: Change At the time of use, it meets the requirements for <i>Constituted Solutions</i> under <i>Labeling</i> under <i>Injections</i> <1>. to:<br>At the time of use, it meets the requirements for <i>Constituted Solutions</i> under <i>Injections</i> <1>. |
| ERGOTAMINE Identification<br>TARTRATE                                           | USP37–NF32                         | 2826                        | 25-Jul-2014                                                     | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Line 4:Change value as the principal spot of <i>Standard solution A</i> . to:<br>values as the corresponding spots of the <i>Standard preparation</i> .                                                                                                             |
| LEVOTHYROXI IM                                                                  | USP37–NF32                         | 3548                        | 25-Jul-2014                                                     | 1-Aug-2014                           | USP39–NF34                                      | First                                         | Line 1 of                                                                                                                                                                                                                                                           |

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| NE SODIUM TABLETS               | PURITIES/Organic Impurities/Procedure: Limit of Liothyronine Sodium |                                    |                             |                                  |                                       |                                      |                                                 | Supplement to USP38–NF33                      | Acceptance criteria: Change NMT 2.0% of liothyronine to: NMT 2.0% of liothyronine sodium                                                                        |
| VITAMIN E                       | IDENTIFICATION N/A./Sample solutions                                | USP37–NF32                         | 5163                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Lines 4 and 7 of Alpha tocopheryl acetate: Change dilute sulfuric acid to: diluted sulfuric acid                                                                |
| CEFADROXIL CAPSULES             | ADDITIONAL REQUIREMENTS/USP Reference Standards <11>                | First Supplement to USP37–NF32     | 6604                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Line 2 of USP Cefadroxil Related Compound I RS: Change (6R,7R)-7-[(R)-2-Amino-2-(4-hydroxyphenyl)acetamido]-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene- |

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| ALLOPURINOL <i>USP Reference standards &lt;11&gt;</i>   | <i>USP37–NF32</i>                  | 1649                        | 25-Jul-2014                                                     | 1-Aug-2014                           | <i>USP39–NF34</i>                               | <i>First Supplement to USP38–NF33</i>         | 2-carboxylic acid monohydrate. to: (6 <i>R</i> ,7 <i>R</i> )-7-[( <i>R</i> )-2-Amino-2-(4-hydroxyphenyl)acetamido]-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-3-ene-2-carboxylic acid.<br>Line 2 of USP Allopurinol Related Compound C RS: Change <i>N</i> -(4 <i>H</i> -1,2,4-Triazol-4-yl)-1 <i>H</i> -pyrazole-4-carboxamide. to: 5-(4 <i>H</i> -1,2,4-Triazol-4-yl)-1 <i>H</i> -pyrazole-4-carboxamide.<br>Line 2 of USP |
| RISPERIDONE ADDITIONAL R                                | <i>Second</i>                      | Online                      | 25-Jul-2014                                                     | 1-Aug-2014                           | <i>USP39–NF34</i>                               | <i>First</i>                                  | Line 2 of USP                                                                                                                                                                                                                                                                                                                                                                                                                  |

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| ORAL SOLUTION                   | EQUIREMENT S/USP Reference Standards <11> | Supplement to USP37–NF32           |                             |                                  |                                |                                      |                                                 | Supplement to USP38–NF33                      | Risperidone Related Compounds Mixture RS: Change Contains a mixture of the following four compounds: 98.9% of <i>Risperidone</i> . 0.5% of <i>Risperidone cis-N-oxide: cis</i> -3-[2-[4-(6-Fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-N-oxide. 0.3% of <i>Bicyclorisperidone</i> : 3-(4-Fluoro-2-hydroxyphenyl)-1-[2-(6,7,8,9-t |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>etrahydro-2-methyl-4-oxo-4H-pyrido[1,2-a]pyrimidin-3-yl)ethyl]-1-aza-2-azoniabicyclo[2.2.2]oct-2-ene iodide.<br/> 0.3% of Z-<i>Oxime</i>:<br/> (Z)-3-[2-[4-(2,4-Difluorophenyl)(hydroxyimino)methyl]-1-piperidinylethyl]-6,7,8,9-tetrahydro-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one<br/> .<br/> to:<br/> Contains a mixture of the following four compounds:<br/> Risperidone.</p> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | Risperidone<br><i>cis</i> - <i>N</i> -oxide:<br><i>cis</i><br>-3-[2-[4-(6-Fluor<br>o-1,2-benzisoxa<br>zol-3-yl)-1-piperi<br>diny]ethyl]-6,7,<br>8,9-tetrahydro-2<br>-methy<br>l-4 <i>H</i><br>-pyri<br>do[1,2- <i>a</i><br>]pyrimidin-4-one<br>, <i>N</i> -oxide.<br>Bicyclorisperido<br>ne: 3-(4-Fluoro-<br>2-hydroxypheny<br>l)-1-[2-(6,7,8,9-t<br>etrahydro-2-met<br>hyl-4<br>-oxo-4 <i>H</i><br>-pyr<br>ido-[1,2<br>- <i>a</i><br>]pyrimidin-3-yl)e<br>thyl]-2-aza-1-az<br>oniabicyclo[2.2.<br>2]oct-2-ene<br>iodide.<br><i>Z</i> -Oxime:<br>( <i>Z</i> |

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| CEFTRIAXONE Assay INJECTION                             | USP37–NF32                         | 2241                        | 25-Jul-2014                                                     | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | <p>)-3-[2-[4-(2,4-Difluorophenyl)(hydroxyimino)methyl]-1-piperidinylethyl]-6,7,8,9-tetrahydro-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one</p> <p>Change pH 7.0 Buffer, pH 5.0 Buffer, Mobile phase, Standard preparation, Resolution solution, and Chromatographic system—Prepare as directed in the Assay under Ceftriaxone Sodium.</p> <p>to:</p> <p>pH 7.0 Buffer—Dissolve 13.6 g of dibasic</p> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>potassium phosphate and 4.0 g of monobasic potassium phosphate in water to obtain 1000 mL of solution. Adjust this solution with phosphoric acid or 10 N potassium hydroxide to a pH of <math>7.0 \pm 0.1</math>.</p> <p><i>pH 5.0</i></p> <p><i>Buffer</i>—Dissolve 25.8 g of sodium citrate in 500 mL of water, adjust with citric acid solution (1 in 5) to a pH of <math>5.0 \pm 0.1</math>, and dilute with water to a volume of 1000 mL.</p> <p><i>Mobile phase</i>—Dissolve 3.2 g of tetrahe</p> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | ptylammonium<br>bromide in 400<br>mL of<br>acetonitrile, add<br>44 mL of <i>pH 7.0</i><br><i>Buffer</i> and 4 mL<br>of <i>pH 5.0</i><br><i>Buffer</i> , and add<br>water to make<br>1000 mL. Pass<br>through a<br>membrane filter<br>of 0.5-?m or<br>finer porosity,<br>and degas.<br>Make<br>adjustments if<br>necessary (see<br><i>System</i><br><i>Suitability</i> under<br><i>Chromatograph</i><br><i>y &lt;621&gt;</i> ).<br><i>Standard</i><br><i>prep</i><br><i>aration</i><br>—Dissolve an<br>accurately<br>weighed<br>quantity of USP<br>Ceftriaxone<br>Sodium RS in |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p><i>Mobile phase</i> to obtain a solution having a known concentration of about 0.2 mg per mL. Use this solution promptly after preparation.</p> <p><i>Resolution solution</i><br/>—Dissolve a suitable quantity of USP Ceftriaxone Sodium <i>E</i>-Isomer RS in <i>Standard preparation</i>, and dilute with <i>Mobile phase</i> to obtain a solution containing about 160 µg of USP Ceftriaxone Sodium <i>E</i>-Isomer RS per mL and 160 µg</p> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>of USP Ceftriaxone Sodium RSper mL. Use this solution promptly after preparation.</p> <p><i>Chromatographi c system (see Chromatograph y &lt;621&gt;)</i>—The liquid chromatograph is equipped with a 270-nm detector and a 4.0-mm × 15-cm column that contains 5-?m packing L1. The flow rate is about 2 mL per minute. Chromatograph the <i>Resolution solution</i>, and record the peak responses as directed for <i>Procedure</i>. The resolution, <i>R</i>,</p> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>between the ceftriaxone <i>E</i>-isomer and ceftriaxone peaks is not less than 3. Chromatograph the <i>Standard preparation</i>, and record the peak responses as directed under <i>Procedure</i>. The column efficiency determined from the analyte peak is not less than 1500 theoretical plates, the tailing factor for the analyte is not more than 2, and the relative standard deviation for replicate injections is not</p> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>more than 2%.<br/>AND<br/>Change<br/><i>Proce</i><br/><i>dure</i>—Proceed<br/>as directed for<br/><i>Procedure</i> in<br/>the Assay under<br/><i>Ceftriaxone</i><br/><i>Sodium</i>.<br/>Calculate the<br/>quantity, in mg,<br/>of ceftriaxone<br/>(C<sub>18</sub>H<sub>18</sub>N<sub>8</sub>O<sub>7</sub>S<sub>3</sub>)<br/>in each mL of<br/>the Injection<br/>taken by the<br/>formula:<br/><math display="block">200(C / V)(r_U / r_S)</math><br/>in which V is the<br/>volume, in mL,<br/>of Injection<br/>taken; and the<br/>other terms are<br/>as defined<br/>therein.<br/>to:<br/><i>Proce</i><br/><i>dure</i><br/>—Separately</p> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>inject equal volumes (about 20 µL) of the <i>Standard preparation</i> and the <i>Assay preparation</i> into the chromatograph, record the chromatograms, and measure the responses for the major peaks.</p> <p>Calculate the quantity, in mg, of ceftriaxone (C<sub>18</sub>H<sub>18</sub>N<sub>8</sub>O<sub>7</sub>S<sub>3</sub>) in each mL of Injection taken by the formula:</p> $200(C / V)(r_U / r_S)$ <p>in which C is the concentration, in mg per mL, of USP Ceftriaxone Sodium RS in</p> |

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| DOXEPIN HYD PERFORMANC<br>ROCHLORIDE E TESTS<br>CAPSULES | USP37–NF32                         | 2712                        | 25-Jul-2014                                                     | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | <p>the <i>Standard preparation</i>; <math>V</math> is the volume, in mL, of Injection taken; and <math>r_U</math> and <math>r_S</math> are the ceftriaxone peak responses obtained from the Assay <i>preparation</i> and the <i>Standard preparation</i>, respectively.</p> <p>Change <i>Uniformity of Dosage Units, Content Uniformity &lt;905&gt;</i> to: <i>Uniformity of Dosage Units &lt;905&gt;</i>: Meet the requirements. The following procedure is used where the test for <i>Content Uniformity</i> is</p> |

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| LEVALBUTEROL HYDROCHLORIDE      | ADDITIONAL REQUIREMENTS | USP37–NF32<br>S/USP<br>Reference<br>Standards <11> | 3513                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | required.<br><i>Procedure for Content Uniformity AND Delete a subsection: Acceptance criteria:</i> Meet the requirements<br>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:<br>4-[2-( <i>tert</i> -Butylamino)-1-methoxyethyl]-2-(hydroxymethyl)phenol acetate.<br>C <sub>14</sub> H <sub>23</sub> NO <sub>3</sub> · C |

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| TICLOPIDINE HYDROCHLORIDE                           | IMPURITIES                                                      | USP37–NF32                         | 4958                        | 25-Jul-2014                      |                                | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Change Residue on Ignition <231> to:<br>Residue on Ignition <281>                                                                                                                          |
| ATROPINE SULFATE                                    | ASSAY/<br>Procedure/System suitability/Suitability requirements | First Supplement to USP37–NF32     | 6591                        | 25-Jul-2014                      |                                | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Line 1 of Relative standard deviation:<br>Change NMT 1.0 to:<br>NMT 1.0%                                                                                                                   |
| PHARMACEUTICAL COMPOUNDING—NON STERILE PREPARATIONS | DEFINITIONS                                                     | USP37–NF32                         | 403                         | 25-Jul-2014                      |                                | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Line 1 of Beyond-Use Date (BUD):<br>Change The date after which a compounded preparation should not to be used;<br>to:<br>The date after which a compounded preparation shall not be used; |

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| TERBINAFINE IMPURITIES<br>HYDROCHLOR<br>IDE             | <i>First Supplement to USP37–NF32</i> | 6704                        | 25-Jul-2014                                                     | 1-Aug-2014                           | <i>USP39–NF34</i>                               | <i>First Supplement to USP38–NF33</i>         | Footnotes b, c, and d of <i>Table 2</i> : Change <sup>b</sup> <i>trans</i> -Isoterbinafine or ( <i>E</i> )- <i>N</i> ,6,6-trimethyl- <i>N</i> -(naphthalen-2-ylmethyl)hept-2-en-4-yn-1-amine. <sup>c</sup> <i>cis</i> -Terbinafine or ( <i>Z</i> )- <i>N</i> ,6,6-trimethyl- <i>N</i> -(naphthalen-1-ylmethyl)hept-2-en-4-yn-1-amine. <sup>d</sup> 4-Methylterbinafine or ( <i>E</i> )- <i>N</i> ,6,6-trimethyl- <i>N</i> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>           -((4-methylnaphthalen-1-yl)methyl)hept-2-en-4-yn-1-amine.<br/>           to:<br/> <sup>b</sup><i>trans</i>-Isoterbinafine or (2<i>E</i>)-<i>N</i>,<br/>           6,6-Trimethyl-<i>N</i>-(naphthalen-2-ylmethyl)hept-2-en-4-yn-1-amine.<br/> <sup>c</sup><i>cis</i>-Terbinafine or (2<i>Z</i>)-<i>N</i>,<br/>           6,6-Trimethyl-<i>N</i>-(naphthalen-1-ylmethyl)hept-2-en-4-yn-1-amine.<br/> <sup>d</sup>4-Methylterbinafine or         </p> |

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| CEFAZOLIN INJECTION             | Assay                   | USP37–NF32                         | 2190                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | (2E)-N<br>,<br>6,<br>6-Tr<br>imethyl-N<br>-((4-methylnaphthalen-1-yl)methyl)hept-2-en-4-yn-1-amine.<br>Change<br>pH 3.6 Buffer,<br>pH 7.0 Buffer,<br>Mobile phase,<br>Internal standard solution,<br>Standard preparation, and<br>Chromatographic system—Prepare as directed in the Assay under Cefazolin.<br>to:<br>pH 3.6 Buffer—Dissolve 0.900 g of anhydrous dibasic sodium |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | phosphate and 1.298 g of citric acid monohydrate in water to make 1000 mL. <i>pH 7.0 Buffer</i> —Dissolve 5.68 g of anhydrous dibasic sodium phosphate and 3.63 g of monobasic potassium phosphate in water to make 1000 mL. <i>Mobile phase</i> —Prepare a suitable mixture of <i>pH 3.6 Buffer</i> and acetonitrile (9:1). Pass through a membrane filter having a 10-?m or finer porosity, and degas. Make |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> &lt;621&gt;).</p> <p><i>Internal standard solution</i></p> <p>—Transfer 750 mg of salicylic acid to a 100-mL volumetric flask, dissolve in 10 mL of methanol, dilute with <i>pH 7.0 Buffer</i> to volume, and mix.</p> <p><i>Standard preparation</i></p> <p>—Transfer about 25 mg of USP Cefazolin RS, accurately weighed, to a 25-mL volumetric flask, dissolve in and</p> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>dilute with <i>pH 7.0 Buffer</i> to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, add 5.0 mL of <i>Internal standard solution</i>, dilute with <i>pH 7.0 Buffer</i> to volume, and mix.</p> <p><i>Chromatographic system</i> (see <i>Chromatography</i> &lt;621&gt;)—The liquid chromatograph is equipped with a 254-nm detector and a 4.0-mm × 30-cm column that contains 10-<math>\mu</math>m packing L1. The flow rate is about 2</p> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>mL per minute. Chromatograph the <i>Standard preparation</i>, and record the peak responses as directed for <i>Procedure</i>. The relative retention times are about 0.7 for salicylic acid and 1.0 for cefazolin; the resolution, <i>R</i>, between the analyte and internal standard peaks is not less than 4.0; the column efficiency is not less than 1500 theoretical plates; the tailing factor is not more than 1.5; and the relative standard deviation for</p> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>replicate injections is not more than 2.0%.<br/> AND<br/> Change<br/> <i>Proce</i><br/> <i>dure</i>—Proceed as directed for <i>Procedure</i> in the Assay under <i>Cefazolin</i>.<br/> Calculate the quantity, in mg, of cefazolin (<math>C_{14}H_{14}N_8O_4S_3</math>) in each mL of the Injection taken by the formula:<br/> <math display="block">(1000C / V)(R_U / R_S)</math> in which V is the volume, in mL, of Injection taken, and the other terms are as defined therein.<br/> to:<br/> <i>Proce</i></p> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p><i>dure</i></p> <p>—Separately inject equal volumes (about 10 ?L) of the <i>Standard preparation</i> and the Assay <i>preparation</i> into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of cefazolin (<math>C_{14}H_{14}N_8O_4S_3</math>) in each mL of Injection taken by the formula: <math>(1000C / V)(R_U / R_S)</math> in which C is the concentration, in mg per mL, of USP Cefazolin</p> |

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| CLOPIDOGREL ASSAY/<br>BISULFATE <i>Procedure</i>        | USP37–NF32                         | 2422                        | 25-Jul-2014                                                     | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | RS, calculated on the anhydrous basis, in the <i>Standard preparation</i> ; $V$ is the volume, in mL, of Injection taken; and $R_U$ and $R_S$ are the peak response ratios of cefazolin to the internal standard obtained from the <i>Assay preparation</i> and the <i>Standard preparation</i> , respectively. Line 1 of <i>System suitability solution</i> : Change 25 µg/mL of USP Clopidogrel Bisulfate RS and 50 µg/mL of |

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| FLAVOXATE H IMPURITIES<br>YDROCHLORI<br>DE              | USP37–NF32                         | 2988                        | 25-Jul-2014                                                     | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | USP<br>Clopidogrel<br>Related<br>Compound B<br>RS<br>to:<br>2.5 µg/mL of<br>USP<br>Clopidogrel<br>Bisulfate RS<br>and 5.0 µg/mL<br>of USP<br>Clopidogrel<br>Related<br>Compound B<br>RS<br>Row 3 of<br>Column 1 of<br><i>Impurity Table 1</i> : Change<br>Flavoxate<br>related<br>compound A <sup>a,*</sup><br>to:<br>Flavoxate<br>related<br>compound A <sup>a</sup><br>AND<br>Row 4 of<br>Column 1 of<br><i>Impurity Table</i> |

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|                                 |                         |                                    |                             |                                                                    |                                      |                                                 |                                               | <p>1: Change Flavoxate related compound B<sup>b,*</sup> to: Flavoxate related compound B<sup>b</sup> AND Row 5 of Column 1 of <i>Impurity Table 1</i>: Change Flavoxate related compound C<sup>c,*</sup> to: Flavoxate related compound C<sup>c</sup> AND Delete footnote *</p> |
| MITOTANE TABLETS                | Assay                   | USP37–NF32                         | 3858                        | 25-Jul-2014                                                        | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Line 1 of <i>Procedure</i> : Change Proceed as directed in the Assay under <i>Mitotane</i> ,                                                                                                                                                                                    |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | <p>beginning with “Concomitantly determine the absorbances of both solutions.” to:</p> <p>Concomitantly determine the absorbances of the Assay <i>preparation</i> and the <i>Standard preparation</i> in 1-cm cells at the wavelength of maximum absorbance at about 268 nm, with a suitable spectrophotometer, using methanol as the blank.</p> <p>Calculate the quantity, in mg, of <math>C_{14}H_{10}Cl_4</math> in the portion of Tablets taken by the formula:<br/> <math>0.5C(A_U/A_S)</math><br/> in which C is</p> |

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|                                 |                                                                       |                                    |                             |                                  |                                       |                                      |                                                 |                                               | the concentration, in mg/mL, of USP Mitotane RS in the <i>Standard preparation</i> , and $A_U$ and $A_S$ are the absorbances of the Assay <i>preparation</i> and the <i>Standard preparation</i> , respectively. |
| GELATIN                         | SPECIFIC TESTS/ <i>Sulfur Dioxide</i> Analysis                        | USP37–NF32                         | 5995                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Line 5 of the variable definition list: Change $m$ = actual molarity of the <i>Titrant</i> (mol/mL) to: $m$ = actual molarity of the <i>Titrant</i> (mol/L)                                                      |
| INSULIN ASPART                  | IDENTIFICATION/ <i>N/B. Physicochemical Analytical Procedures for</i> | First Supplement to USP37–NF32     | 6647                        | 25-Jul-2014                      |                                       | 1-Aug-2014                           | USP39–NF34                                      | First Supplement to USP38–NF33                | Line 1 of <i>Column</i> : Change 4.0-mm × 25-cm; 5-μm                                                                                                                                                            |

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| AMIODARONE IM<br>HYDROCHLOR PUR<br>IDE                     | <i>Insulins,<br/>Peptide<br/>Mapping &lt;121.1<br/>&gt;/Chromatograp<br/>hic system</i><br><br><i>ITIES/Organic<br/>Impuri<br/>ties/Procedure<br/>1</i> | USP37–NF32                         | 1750                        | 30-May-2014                      |                                       | 1-Jun-2014                           | USP38–NF33                                      | USP38–NF33                                    | packing L7<br>to:<br>4.6-mm ×<br>10-cm; 3-?m<br>packing L1<br>Line 3 of<br><i>Acceptance<br/>criteria: Change<br/>Standard<br/>solution B</i> is not<br>more intense<br>to:<br>the <i>Sample<br/>solution</i> is not<br>more intense |
| QUINIDINE<br>GLUCONATE E<br>XTENDED-<br>RELEASE<br>TABLETS | <i>ASSAY/<br/>Procedure</i>                                                                                                                             | USP37–NF32                         | 4515                        | 30-May-2014                      |                                       | 1-Jun-2014                           | USP38–NF33                                      | USP38–NF33                                    | Line 2 of<br><i>System<br/>suitability<br/>solution:</i><br>Change<br>dihydroquinidin<br>e chloride<br>to:<br>dihydroquinidin<br>e hydrochloride                                                                                     |
| DAPSONE<br>TABLETS                                         | <i>IDENTIFICATIO<br/>N/B. Ultraviolet<br/>Absorption<br/>&lt;197U&gt;</i>                                                                               | USP37–NF32                         | 2514                        | 30-May-2014                      |                                       | 1-Jun-2014                           | USP38–NF33                                      | USP38–NF33                                    | Line 1 of<br><i>Sample<br/>solution:</i><br>Delete<br>Nominally 0.01<br>?g/mL prepared                                                                                                                                               |

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| SULFACETAMI ASSAY/<br>DE SODIUM <i>Procedure</i><br>OPHTHALMIC<br>OINTMENT | USP37–NF32                         | 4765                        | 30-May-2014                                                     | 1-Jun-2014                           | USP38–NF33                                      | USP38–NF33                                    | as follows.<br>Line 1 of<br><i>Sample solution:</i><br>Change<br>USP<br>Sulfacetamide<br>Sodium RS<br>to:<br>sulfacetamide<br>sodium                                                                                                                              |
| GADOPENTET IDENTIFICATIO<br>ATE N/B.<br>DIMEGLUMINE<br>INJECTION           | USP37–NF32                         | 3113                        | 30-May-2014                                                     | 1-Jun-2014                           | USP38–NF33                                      | USP38–NF33                                    | Line 2: Change<br>364.8 nm<br>to:<br>368.4 nm                                                                                                                                                                                                                     |
| VALSARTAN IMPURITIES                                                       | USP37–NF32                         | 5115                        | 30-May-2014                                                     | 1-Jun-2014                           | USP38–NF33                                      | USP38–NF33                                    | Footnote a of<br><i>Table 1:</i><br>Change<br>(S)- <i>N</i> -<br>-Butyryl<br>- <i>N</i> -<br>-([2?-(1 <i>H</i><br>-tetrazole-5-yl)bi<br>phen-4-yl]methy<br>l)-valine.<br>to:<br><i>N</i> -<br>-Butyryl<br>- <i>N</i> -<br>-{[2?-(1 <i>H</i><br>-tetrazole-5-yl)bi |

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| STRONG IODINE SOLUTION                                  | ASSAY                              | USP37–NF32 3354             | 30-May-2014                                                     | 1-Jun-2014                           | USP38–NF33                                      | USP38–NF33                                    | <p>phenyl-4-yl]methyl}-L-valine.<br/>AND<br/>Footnote b of <i>Table 1</i>:<br/>Change<br/>(S)-N<br/>-Valeryl<br/>-N<br/>-([2?-(1H<br/>-tetrazole-5-yl)bi<br/>phen-4-yl]methy<br/>l)-valine benzyl<br/>ester.<br/>to:<br/>N<br/>-Valeryl<br/>-N<br/>-{[2?-(1H<br/>-tetrazole-5-yl)bi<br/>phenyl-4-yl]met<br/>hyl}-L-valine<br/>benzyl ester.<br/>Line 1 of<br/><i>Acceptance<br/>criteria</i> in<br/><i>Iodine</i>: Change<br/>of iodine (I)<br/>to:<br/>of iodine (I) in<br/>each 100 mL</p> |

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|                                                         |                                    |                             |                                                                 |                                      |                                                 |                                               | AND<br>Line 1 of<br><i>Acceptance criteria</i> in<br><i>Potassium Iodide</i> : Change<br>potassium<br>iodide (KI)<br>to:<br>potassium<br>iodide (KI) in<br>each 100 mL |

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