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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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| ELEMENTAL I <i>Drug Substance</i>                       | <i>Second</i>   | 5633                        | 31-Jan-2013   | 1-Feb-2013  | <i>USP37–NF32</i>  | <i>Second</i>  | Row 16 of   |

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| MPURITIES--LI<br>MITS   | <i>and Excipients</i>  | <i>Supplement to USP35–NF30</i>    |                             |                                  |                                |                                      |   | <i>Supplement to USP36–NF31</i>               | Column 4 of Table 2: Change 7 to: 10  |
| VIRAL SAFETY EVALUATION OF BIOTECHNOLOGY PRODUCTS DERIVED FROM CELL LINES OF HUMAN OR ANIMAL ORIGIN | <i>VI. Evaluation and Characterization of Viral Clearance Procedures</i> | <i>USP35–NF30</i>                  | 553                         | 31-Jan-2013                      |                                | 1-Feb-2013                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | Row 10 (Reovirus 3) of Column 5 (Genome) of Table A-1: Change DNA to: RNA   |
| MYRISTYL ALCOHOL  | <i>SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value &lt;401&gt;</i>    | <i>USP35–NF30</i>                  | 1873                        | 31-Jan-2013                      |                                | 1-Feb-2013                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | Line 7 of Analysis: Change Result = $[(V_U ? V_B) \times F]/W$<br>$V_U$ = volume of 1 N sodium hydroxide consumed by the <i>Sample</i> (mL)<br>$V_B$ = volume of 1 N sodium |

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| ONDANSETRO USP Reference<br>N INJECTION Standards       | USP35–NF30                         | 4120                        | 31-Jan-2013   | 1-Feb-2013                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | hydroxide consumed by the <i>Blank</i> (mL) to:<br>$\text{Result} = [(V_B - V_U) \times F] / W$ $V_B = \text{volume of 1 N sodium hydroxide consumed by the } Blank \text{ (mL)}$ $V_U = \text{volume of 1 N sodium hydroxide consumed by the } Sample \text{ (mL)}$ Line 7: Delete USP Ondansetron Related Compound B RS 6,6'-Methylene bis-[(1,2,3,9-tetrahydro-9-methyl-3-[(2-methyl-1H |

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| ZINC GLUCONATE                  | IM PURITIES/ <i>Limit of Cadmium</i>                               | USP35–NF30                         | 5070                        | 31-Jan-2013                      |                                | 1-Feb-2013                           | USP37–NF32                                      | <i>Second Supplement to USP36–NF31</i>        | -imidazol-1-yl)-methyl]-4 <i>H</i> -carbazol-4-one<br>.<br>Line 22 of <i>Analysis</i> :<br>Change <i>W</i> = weight of Calcium Gluconate taken to prepare <i>Sample solution A</i> (g) to:<br><i>W</i> = weight of Zinc Gluconate taken to prepare <i>Sample solution A</i> (g) |
| TACROLIMUS ORAL SUSPENSION      | ASSAY/ <i>Chromatographic system</i>                               | USP36–NF31                         | 5261                        | 31-Jan-2013                      |                                | 1-Feb-2013                           | USP37–NF32                                      | <i>Second Supplement to USP36–NF31</i>        | After line 1 of <i>Column</i> : Add a new section <i>Column temperature</i> : 70°   |
| GLYCERYL MONOOLEATE             | SPECIFIC TESTS/ <i>Fats and Fixed Oils, Fatty Acid Composition</i> | USP35–NF30                         | 1814                        | 31-Jan-2013                      |                                | 1-Feb-2013                           | USP37–NF32                                      | <i>Second Supplement to USP36–NF31</i>        | Column 3 of <i>Table 1</i> :<br>Change in Row 1 Percentage,   |

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| <401>   |                                    |                             |   |                                      |   |   | NMT (%)<br>to:<br>Percentage (%)<br>Change in Row<br>2<br>12.0<br>to:<br>NMT 12.0<br>Change in Row<br>3<br>6.0<br>to:<br>NMT 6.0<br>Change in Row<br>4<br>60.0<br>to:<br>NLT 60.0<br>Change in Row<br>5<br>35.0<br>to:<br>NMT 35.0<br>Change in Row<br>6<br>2.0<br>to:<br>NMT 2.0<br>Change in Row<br>7<br>2.0 |

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| LORATADINE<br>ORALLY-DISINTEGRATING<br>TABLETS | ADDITIONAL REQUIREMENT<br>S/USP<br>Reference<br>Standards | USP35–NF30                         | 3714                        | 31-Jan-2013                      |                                | 1-Feb-2013                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | to:<br>NMT 2.0<br>Change in Row 8<br>2.0<br>to:<br>NMT 2.0<br>Line 4 of USP Reference Standards:<br>Change<br>8-Chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine.<br>to:<br>8-Chloro-5,6-dihydro-11-(piperidylidene)-5H-benzo[5,6]cyclohepta[1,2-b] |

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|   |                                    |                             |   |                                      |   |   | <p>]pyridine.<br/> AND<br/> Line 6: Change<br/> 310.83<br/> to:<br/> 310.82<br/> AND<br/> Line 8: Change<br/> 8-Chloro-6,11-di<br/> hydro<br/> -11-(<i>N</i><br/> -methyl-4-piperi<br/> dylid<br/> ene)-5<i>H</i><br/> -benzo[5,6]cycl<br/> ohe<br/> pta[1,2-<i>b</i><br/> ]pyridine.<br/> to:<br/> 8-Chloro-5,6-dih<br/> ydro-1<br/> 1-(<i>N</i><br/> -methylpiperidin<br/> -4<br/> -ylid<br/> ene)-11<i>H</i><br/> -benzo[5,6]cycl<br/> ohe<br/> pta[1,2-<i>b</i><br/> ]pyridine.<br/> AND</p> |

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| TRIAZOLAM TABLETS               | Assay                   | USP35–NF30                         | 4936                        | 31-Jan-2013                      |                                | 1-Feb-2013                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | <p>Line 10:<br/>Change 324.88 to: 324.85</p> <p>Line 2: Change <i>Mobile phase</i> and <i>Chromatographic system</i>—Proceed as directed in the Assay under <i>Triazolam</i>. to: <i>Mobile phase</i>—Prepare a filtered and degassed mixture of acetonitrile, chloroform, butyl alcohol, water, and glacial acetic acid (850:80:50:20:0.5). Make adjustments if necessary (see <i>System</i></p> |



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|   |                                    |                             |   |                                      |   |   | <p><i>Suitability under Chromatography &lt;621&gt;).</i><br/> AND<br/> After the Assay preparation subsection: Add a new subsection<br/> <i>Chromatographic system (see Chromatography &lt;621&gt;)</i>—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm x 30-cm column that contains packing L3. The flow rate is about 2.0 mL per minute. Chromatograph the <i>Standard preparation</i>, and record the peak responses as directed</p> |

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|   |                                    |                             |   |                                      |   |   | <p>under<br/> <i>Procedure:</i> the relative retention times are 1 for triazolam and about 1.4 for the internal standard, the resolution, <i>R</i>, between the internal standard and triazolam is not less than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%.</p> <p>AND<br/> Line 4 of<br/> <i>Procedure:</i><br/> Change<br/> Calculate the quantity, in mg, of C<sub>17</sub>H<sub>12</sub>Cl<sub>2</sub>N<sub>4</sub> in the portion of Triazolam taken</p> |

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|   |                                    |                             |   |                                      |   |   | <p>by the formula:<br/>to:<br/>Calculate the quantity, in mg, of <math>C_{17}H_{12}Cl_2N_4</math> in the portion of Tablets taken by the formula:<br/>AND<br/>Line 9 of <i>Procedure</i>:<br/>Change <math>R_U</math> and <math>R_S</math> are the ratios of the internal standard peak area to the triazolam peak area obtained from the <i>Assay preparation</i> and the <i>Standard preparation</i>, respectively.<br/>to:<br/><math>R_U</math> and <math>R_S</math> are the ratios of the triazolam peak area to the internal standard peak</p> |

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| AZITHROMYCI<br>N FOR<br>INJECTION                     | IM<br>PURITIES/ <i>Limit Supplement to of Aminoazithro mycin, Formamido Analog, Methylformamido Analog, and 3'-De(dimethylamino)-3'-oxoazithromycin (if present)</i> | <i>Second Supplement to USP35–NF30</i> | 5910                        | 31-Jan-2013                      |                                | 1-Feb-2013                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | area obtained from the <i>Assay preparation</i> and the <i>Standard preparation</i> , respectively.<br>Line 1 of <i>Buffer</i> .<br>Change 3.5 g/mL to:<br>3.5 g/L  |
| Esomeprazole<br>Magnesium Delayed-Release<br>Capsules | ASSAY/<br><i>Procedure</i>   | <i>First Supplement to USP35–NF30</i>  | 5473                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | Line 1 of <i>Standard solution</i> :<br>Change<br>Transfer 10 mg of USP Omeprazole RS to a 250-mL volumetric flask, and dissolve in about 10 mL of methanol.<br>to: |

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| Carisoprodol Tablets            | ADDITIONAL REQUIREMENT S/USP Reference Standards <11> | <i>Second Supplement to USP35–NF30</i>            | 5921                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | Transfer 10 mg of USP Omeprazole RS to a 250-mL volumetric flask, and dissolve in about 10 mL of alcohol.<br>Line 5: At end of USP Reference Standards, add USP Meprobamate RS |
| Olanzapine Tablets              | ADDITIONAL REQUIREMENT S/USP Reference Standards <11> | <i>Revision Bulletin (Official July 01, 2012)</i> | Online                      | 30-Nov-2012                      |                                | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | Lines 3 and 6: Change USP Olanzapine Related Compound A RS<br>5-Methyl-2-((2-nitrophenyl)amino)-3-thiophene carbonitrile.<br>USP Olanzapine Related Compound B RS              |

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|   |                                    |                             |   |                                      |   |   | 2-M ethyl-10 <i>H</i> -thi eno-[2, 3- <i>b</i> ][1,5]benzodiazepin-4[5 <i>H</i> ]-one.<br>to:<br>USP<br>Olanzapine Related Compound A<br>RS<br>5-Methyl-2-((2-nitrophenyl)amino)-3-thiophenecarbonitrile.<br>$C_{12}H_9N_3O_2S$<br>259.28<br>USP<br>Olanzapine Related Compound B<br>RS<br>2-M ethyl-10 <i>H</i> -thi eno-[2, 3- <i>b</i> ][1,5]benzodiazepin-4[5 <i>H</i> ]-one. |

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| Aminosalicylate Sodium<br><i>Limit of m-aminophenol</i> | USP35–NF30                         | 2177                        | 30-Nov-2012   | 1-Dec-2012                           | USP37–NF32                                      | <i>Second Supplement to USP36–NF31</i>        | <p>C<sub>12</sub>H<sub>10</sub>N<sub>2</sub>O<sub>5</sub><br/>230.29</p> <p>Line 1 of <i>Test preparation</i>:<br/>Change<br/>Use the <i>Assay preparation</i>, prepared as directed in the <i>Assay</i>.<br/>to:<br/>Transfer about 69 mg of Aminosalicylate Sodium, accurately weighed, to a 100-mL low-actinic volumetric flask, add 50 mL of <i>Mobile phase</i>, and swirl to dissolve. Add 10.0 mL of <i>Internal standard solution</i>, dilute with <i>Mobile phase</i> to volume, and</p> |

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| Dibasic Calcium Phosphate Dihydrate ASSAY               | USP35–NF30                                | 2463                        | 30-Nov-2012   | 1-Dec-2012                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | mix.<br>Line 14 of Analysis:<br>Change $W = \text{Sample weight (mg)}$<br>to:<br>$W = \text{Sample weight (mg)}$ in 20.0 mL of the Sample solution  |
| Glimepiride Tablets                                     | PERFORMANCE TESTS/<br>Dissolution/ Test 1 | USP35–NF30 3335             | 30-Nov-2012   | 1-Dec-2012                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | Line 3 of Analysis:<br>Change Result = $(r_U/r_S) \times (C_S/L) \times V \times 100$<br>to:<br>Result = $(r_U/r_S) \times (C_S/L) \times V \times D \times 100$<br>AND after Line 8 of Analysis:<br>Add<br>$D = \text{dilution factor of the Sample solution}$ |
| Compound Undecylenic Acid Ointment                      | Assay for zinc undecylenate               | USP35–NF30 4978             | 30-Nov-2012   | 1-Dec-2012                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | Line 17 of Procedure:<br>Change A   |



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| Itraconazole                    | IM<br>PUR<br>ITIES/Organic<br>Impurities | <i>First Supplement to USP35–NF30</i>             | 5508                        | 30-Nov-2012                      |                                       | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | $u$ , $A_H$ , and $A_L$<br>to:<br>$A_U$ , $A_{S1}$ , and $A_{S2}$<br>Line 1 of<br><i>Standard solution:</i><br>Change<br>1.0 $\mu\text{g/mL}$ of<br>USP<br>Itraconazole RS<br>in <i>Diluent</i><br>to:<br>10.0 $\mu\text{g/mL}$ of<br>USP<br>Itraconazole RS<br>in <i>Diluent</i> |
| Olanzapine<br>Tablets           | ASSAY/<br>Procedure                      | <i>Revision Bulletin (Official July 01, 2012)</i> | Online                      | 30-Nov-2012                      |                                       | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | Line 10 of<br><i>Analysis:</i><br>Change<br>$C_U =$<br>concentration of<br>olanzapine in<br>the <i>Sample solution</i><br>(mg/mL)<br>to:<br>$C_U =$ nominal<br>concentration of<br>olanzapine in<br>the <i>Sample solution</i>  |

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| Polysorbate 80                      | SPECIFIC TESTS/ <i>Fats and Fixed Oils, Peroxide Value</i> <401> | USP35–NF30                         | 1920                        | 30-Nov-2012                      |                                       | 1-Dec-2012                           | USP37–NF32                                      | <i>Second Supplement to USP36–NF31</i>        | (mg/mL)<br>Line 5 of <i>Analysis</i> :<br>Change<br>0.01 M sodium thiosulfate<br>to:<br>0.01 M sodium thiosulfate VS  |
| Ampicillin Sodium                   | SPECIFIC TESTS/ <i>pH</i> <791>                                  | USP35–NF30                         | 2213                        | 30-Nov-2012                      |                                       | 1-Dec-2012                           | USP37–NF32                                      | <i>Second Supplement to USP36–NF31</i>        | Line 2: Change text of <i>Sample solution</i> from<br>10.0 mg/mL<br>to:<br>10.0 mg/mL of ampicillin   |
| Anhydrous Dibasic Calcium Phosphate | IM PUR ITIES/ <i>Heavy Metals, Method I</i> <231>                | USP35–NF30                         | 2464                        | 30-Nov-2012                      |                                       | 1-Dec-2012                           | USP37–NF32                                      | <i>Second Supplement to USP36–NF31</i>        | Line 1 of <i>Test preparation</i> :<br>Change<br>Warm 1.3 g with<br>3 mL of 3 N hydrochloric acid to<br>completely dissolve.<br>to:<br>Warm 1.3 g with<br>3 mL of 3 N hydrochloric acid until no<br>more dissolves. |

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| Tramadol Hydrochloride Tablets                  | IM PUR ITIES/ <i>Organic Impurities/Procedure</i> | <i>USP35–NF30</i>                     | 4905                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | Line 5 of <i>Analysis:</i><br>Change<br>Result = $(r_U/r_S) \times (C_S/C_U) \times (1/F) \times 0.1$<br>to:<br>Result = $(r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$  |
| Esomeprazole Magnesium Delayed-Release Capsules | PERFORMANCE TESTS/ <i>Dissolution &lt;711&gt;</i> | <i>First Supplement to USP35–NF30</i> | 5473                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | Change<br><i>Buffer, Diluent, Mobile phase, System suitability, and Chromatographic system:</i><br>Proceed as directed in the Assay.<br>to:<br><i>Buffer, Mobile phase, System suitability, and Chromatographic system:</i><br>Proceed as directed in the Assay. |
| Cefepime Hydrochloride                          | IM PUR  | <i>Second Supplement to</i>           | 5923                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to</i>                   | Line 5 of <i>Chromatographic</i>   |

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|                                 | ITIES/Organic Impurities/Procedure 1: Limit of N-Methylpyrrolidine | USP35–NF30                         |                             |                                  |                                |                                      |   | USP36–NF31                                    | c system: Change Column: 4.0-mm x 25-cm; 5-µm packing L## <sup>1</sup> to: Column: 4.0-mm x 25-cm; 5-µm packing L76 AND Delete corresponding footnote: "Available as Metrosep C4-250." |
| Antibiotics—Microbial Assays    | Turbidimetric Method   | USP35–NF30                         | 74                          | 30-Nov-2012                      |                                | 1-Dec-2012                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | Line 8 of Analysis: Change Include in each rack 1–2 control tubes containing 1 mL of the inoculum medium (see Table 8) but no antibiotic. to: Include in each                          |

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| Aminosalicylate Limit of m-Sodium Tablets <i>aminophenol</i> | USP35–NF30                         | 2178                        | 30-Nov-2012   | 1-Dec-2012                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | rack 1–2 control tubes containing 1 mL of the test diluent (see <i>Table 7</i> ) but no antibiotic.<br>Line 1 of <i>Test solution</i> :<br>Change<br>Use the <i>Assay preparation</i> , prepared as directed in the <i>Assay</i> .<br>to:<br>Weigh and finely powder not fewer than 20 Tablets.<br>Transfer an accurately weighed portion of the powder, equivalent to about 690 mg of aminosalicylate sodium, to a 100-mL low-actinic volumetric flask. |

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| Dibasic Calcium IM<br>Phosphate PUR<br>Dihydrate ITIES/ <i>Heavy<br/>Metals, Method<br/>I &lt;231&gt;</i> | USP35–NF30                             | 2463                        | 30-Nov-2012   | 1-Dec-2012                               | USP37–NF32  | <i>Second<br/>Supplement to<br/>USP36–NF31</i>    | <p>Add 50 mL of <i>Mobile phase</i>, and shake for about 5 minutes. Dilute with <i>Mobile phase</i> to volume, and mix. Filter, and transfer 10.0 mL of the clear filtrate to a low-actinic, 100-mL volumetric flask containing 10.0 mL of <i>Internal standard solution</i>, dilute with <i>Mobile phase</i> to volume, and mix.</p> <p>Line 1 of <i>Test preparation</i>: Change Warm 1.3 g with 3 mL of 3 N hydrochloric acid to completely dissolve.</p> |

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| Moxifloxacin Ophthalmic Solution | <i>Related com pounds/Test 1</i>                     | <i>USP35–NF30</i>                     | 3960                        | 30-Nov-2012                      | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | to:<br>Warm 1.3 g with 3 mL of 3 N hydrochloric acid until no more dissolves.<br>Line 4 of <i>Chromatographic system:</i><br>Delete<br>The flow rate is about 0.5 mL per minute.  |
| Containers—Glass                 | <i>SPECIFIC TESTS/ Hydrolytic Resi stance/Method</i> | <i>First Supplement to USP35–NF30</i> | 5150                        | 30-Nov-2012                      | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | In the Note in line 11 of <i>Titration:</i><br>Change<br>Rinse the grains by swirling with three 15-mL portions of Purified Water, and add the washings to the main solution.<br>to:<br>Rinse the grains by swirling with three 15-mL portions of Carbon Dioxide- |

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| Omega-3-Acid Ethyl Esters Capsules | SPECIFIC TESTS/<br><i>Microbial Enumeration</i><br><61> | <i>First Supplement to USP35–NF30</i>             | 5524                        | 30-Nov-2012                      |                                       | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>First Supplement to USP36–NF31</i>         | Free Water, and add the washings to the main solution.<br>Line 2: Change $10^3$ to:<br>$10^3$ cfu/g<br>AND<br>Line 3: Change $10^2$ to:<br>$10^2$ cfu/g  |
| Olanzapine Tablets                 | IM<br>PUR<br>ITIES/ <i>Organic Impurities</i>           | <i>Revision Bulletin (Official July 01, 2012)</i> | Online                      | 30-Nov-2012                      |                                       | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | Line 11 of <i>Analysis</i> :<br>Change $C_U$ = concentration of olanzapine in the <i>Sample solution</i> (mg/mL)<br>to:<br>$C_U$ = nominal concentration of olanzapine in the <i>Sample solution</i> (mg/mL) |
| Polysorbate 80                     | SPECIFIC TESTS/ <i>Fats</i>                             | <i>USP35–NF30</i>                                 | 1920                        | 30-Nov-2012                      |                                       | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to</i>                   | Line 3 of <i>Analysis</i> :  |



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|                                 |                         |                                    |                             |                                  |                                |                                      |   | USP36–NF31                                    | Change 0.5 N alcoholic potassium hydroxide to: 0.5 N alcoholic potassium hydroxide VS<br><br>Line 6 of <i>Analysis</i> : Change 0.5 N hydrochloric acid to: 0.5 N hydrochloric acid VS |
| Budesonide                      | ASSAY/<br>Procedure     | USP35–NF30                         | 2394                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | Line 2 of <i>Acceptance criteria</i> : Change <i>Epimer A</i> : 40.0%–51.0% on the dried basis to: <i>Epimer A</i> : 40.0%–51.0%   |
| Cod Liver Oil                   | ASSAY/ <i>Vitamin D</i> | USP35–NF30                         | 2756                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | USP37–NF32                                      | Second Supplement to                          | Line 1 of <i>Aqueous</i>   |

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|                                 |                          |                                       |                             |                                  |                                |                                      |   | <i>USP36–NF31</i>                             | <i>potassium hydroxide solution:</i><br>Change Dissolve 800 mg of potassium hydroxide in 1000 mL of freshly boiled water, mix, and cool.<br>to:<br>Dissolve 800 g of potassium hydroxide in 1000 mL of freshly boiled water, mix, and cool. |
| Triclosan                       | <i>Related compounds</i> | <i>USP35–NF30</i>                     | 4939                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | Line 1 of <i>Procedure:</i><br>Change Inject a volume (about 0.5 µL)<br>to:<br>Inject a volume (about 2.0 µL)   |
| Esterified Estrogens Tablets    | <i>ASSAY/ Procedure</i>  | <i>First Supplement to USP35–NF30</i> | 5485                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | Line 3 of <i>Analysis:</i><br>Change  |

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| Cefepime for Injection          | IM<br>PUR<br>ITIES/Organic<br>Impurities/Procedure<br>1: Limit of N-Me | <i>Second Supplement to USP35–NF30</i> | 5925                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | <i>USP37–NF32</i>                               | <i>Second Supplement to USP36–NF31</i>        | Separately calculate the percentage of the labeled amount of sodium estrone sulfate and sodium equilin sulfate in the portion of Conjugated Estrogens taken:<br>to:<br>Separately calculate the percentage of the labeled amount of sodium estrone sulfate and sodium equilin sulfate in the portion of Tablets taken:<br>Line 5 of <i>Chromatographic system:</i><br>Change <i>Column:</i><br>4.0-mm x |

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|                                 |  |                                    |                             |                                  |                                |                                      |   |   | 25-cm; 5- $\mu$ m packing L## <sup>1</sup> to:<br><i>Column:</i><br>4.0-mm x 25-cm; 5- $\mu$ m packing L76 AND<br>Delete corresponding footnote:<br>Available as Metrosep C4-250. |
| Polysorbate 80                  | SPECIFIC TESTS/ <i>Fats and Fixed Oils, Hydroxyl Value &lt;401&gt;</i> | USP35–NF30                         | 1920                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | Line 13 of <i>Analysis:</i><br>Change 0.5 N alcoholic potassium hydroxide to:<br>0.5 N alcoholic potassium hydroxide VS   |
| Aminosalicyclic Acid Tablets    | <i>Limit of m-aminophenol</i>  | USP35–NF30                         | 2179                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | Change the subsection: <i>Mobile phase and Internal standard solution</i><br>—Prepare as  |

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|   |                                    |                             |   |                                      |   |   | <p>directed in the Assay under <i>Aminosalicyclic Acid</i>.</p> <p>to:</p> <p><i>Mobile phase</i>—Prepare as directed in the Assay under <i>Aminosalicyclic Acid</i>.</p> <p><i>Internal standard solution</i></p> <p>—Prepare a solution of sulfanilamide in <i>Mobile phase</i> having a concentration of about 5 µg per mL.</p> <p>Line 1 of <i>Test solution</i>:<br/>Change<br/>Use the Assay <i>preparation</i>, prepared as directed in the Assay.</p> |

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|   |                                    |                             |   |                                      |   |   | <p>to:</p> <p>Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 500 mg of aminosalicyclic acid, to a 100-mL low-actinic volumetric flask. Add 50 mL of <i>Mobile phase</i>, and shake for about 5 minutes. Dilute with <i>Mobile phase</i> to volume, and mix. Filter, and transfer 10.0 mL of the clear filtrate to a 100-mL low-actinic volumetric flask</p> |

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|                                     |   |                                    |                             |                                  |                                |                                      |   |   | containing 10.0 mL of <i>Internal standard solution</i> , dilute with <i>Mobile phase</i> to volume, and mix.   |
| Anhydrous Dibasic Calcium Phosphate | ASSAY                                   | USP35–NF30                         | 2464                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | In line 14 of <i>Analysis</i> : Change <i>W = Sample weight (mg)</i> to:<br><i>W = Sample weight (mg) in 20.0 mL of the Sample solution</i>                 |
| Metronidazole                       | ASSAY                                   | USP36–NF31                         | 4352                        | 30-Nov-2012                      |                                | 1-Dec-2012                           | USP37–NF32                                      | Second Supplement to USP36–NF31               | Line 8 of <i>Chromatographic system</i> : Add new subsection after <i>Injection volume</i> :<br><i>Run time</i> : Twice the retention time of metronidazole |
| DESCRIPTION AND SOLUBILITY          | <i>Ethylcellulose Dispersion Type B</i> | USP35–NF30                         | 1118                        | 28-Sep-2012                      |                                | 1-Oct-2012                           | USP37–NF32                                      | First Supplement to USP36–NF31                | Lines 3 and 4: Change in toluene, in  |

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|                                 |  |                                       |                             |                                  |                                |                                      |   |   | chloroform, and in ethyl acetate; insoluble in water, in glycerin, and in propylene glycol.<br>to:<br>in tetrahydrofuran, and in ethyl acetate; insoluble in water and in chloroform. |
| DELIVERABLE VOLUME              | ACCEPTANCE CRITERIA/For Multiple-Unit Containers | <i>First Supplement to USP35–NF30</i> | 5154                        | 28-Sep-2012                      |                                | 1-Oct-2012                           | <i>USP37–NF32</i>                               | <i>First Supplement to USP36–NF31</i>         | <i>Figure 1</i> , right branch, left box: Change Volume of 1 more containers is less than 95% LV to: Volume of 1 or more containers is less than 95% LV                               |
| MAGNESIUM STEARATE              | IMPURITIES/Chloride and Sulfate,                 | <i>USP35–NF30</i>                     | 1847                        | 28-Sep-2012                      |                                | 1-Oct-2012                           | <i>USP37–NF32</i>                               | <i>First Supplement to USP36–NF31</i>         | Line 3: Change 0.020 N sulfuric acid (1.0%) to:   |



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|                                 |                                    | <i>Sulfate</i> <221>                  |                             |                                  |                                |                                      |   |   | 0.020 M sulfuric acid (1.0%)  |
| TACROLIMUS                      | IM<br>PUR<br>ITIES/<br>Procedure 2 | <i>First Supplement to USP35–NF30</i> | 5538                        | 28-Sep-2012                      |                                | 1-Oct-2012                           | <i>USP37–NF32</i>                               | <i>First Supplement to USP36–NF31</i>         | Footnote h of Table 3: Change (3 <i>S</i> ,4 <i>R</i> ,5 <i>S</i> ,8 <i>S</i> ,9 <i>E</i> ,12 <i>S</i> ,14 <i>S</i> ,15 <i>R</i> ,16 <i>S</i> ,18 <i>R</i> ,19 <i>R</i> ,26 <i>aS</i> )-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26 <i>a</i> -hexadecahydro-5,19-dihydroxy-3- <i>{(E)</i> -2-[(1 <i>R</i> ,3 <i>R</i> ,4 <i>R</i> )-4-hydroxy-3-methoxycyclohexyl]-1-methylvinyl}-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-8-propyl-3 <i>H</i> -pyrido[2,1- <i>c</i> ][1,4]oxaazacyclotricosine-1,7,20,21(4 <i>H</i> ,23 <i>H</i> )-trone. |

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| SODIUM HYDROXIDE  | ASSAY/<br>Procedure                | USP35–NF30 1955             | 28-Sep-2012   | 1-Oct-2012                           | USP37–NF32                                      | First Supplement to USP36–NF31                | <p>to:<br/> (3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-((E)-2-[(1R,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylvinyl)-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-8-propyl-3H-pyridod[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone.</p> Line 10 of Analysis: Change Result = {(V |

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|  |  |                             |   |   |  |  | $s_1?$<br>$V_B) \times N \times F_1]/W\}$<br>$\times 100$<br>to:<br>Result = $\{[(V_{S2} ?$<br>$V_B) \times N \times F_1]/W\}$<br>$\times 100$<br>AND<br>Line 11 of<br><i>Analysis:</i><br>Change<br>$V_{S1}$<br>to:<br>$V_{S2}$<br>Row 13 of<br><i>Column 4 of</i><br><i>Table 1:</i><br>Change<br>250<br>to:<br>10<br>Change the<br>subsection<br><i>Buffer and</i><br><i>Diluent.</i> Prepare<br>as directed in<br>the Assay.<br>to:<br><i>Diluent.</i> Prepare<br>as directed in<br>the Assay. |
| ELEMENTAL I DRUG<br>MPURITIES—LIP<br>MITS RO<br>DUCTS/ <i>Large</i><br><i>Volume</i><br><i>Parenterals</i> | <i>Second</i><br><i>Supplement to</i><br><i>USP35–NF30</i> | 5633                        | 28-Sep-2012   | 1-Oct-2012  | <i>USP37–NF32</i>  | <i>First</i><br><i>Supplement to</i><br><i>USP36–NF31</i>        |  |
| ALPRAZOLAM IM<br>ORALLY-DISIN PUR<br>TEGRATING ITIES/<br>TABLETS <i>Procedure</i>                          | <i>USP35–NF30</i>  | 2106                        | 28-Sep-2012   | 1-Oct-2012  | <i>USP37–NF32</i>  | <i>First</i><br><i>Supplement to</i><br><i>USP36–NF31</i>        |  |

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| INDINAVIR SULFATE               | OTHER COMP ONE          | USP35–NF30                         | 3489                        | 28-Sep-2012                      |                                | 1-Oct-2012                           | USP37–NF32                                      | First Supplement to USP36–NF31                | <p>Buffer: 6.8 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid to a pH of 3.0.</p> <p>Line 6 of <i>Chromatographic system</i> in the subsection <i>Column</i>:<br/>Change G14 to: G16</p> |

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