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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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URSODIOL	IM	USP36–NF31	5520	27-Sep-2013	1-Oct-2013	USP38–NF33	First	Line 2 of

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TABLETS	PUR ITIES/ <i>Organic Impurities/Procedure</i>							<i>Supplement to USP37–NF32</i>	<i>Sample solution: Change Tablets, equivalent to about 25 mg of ursodiol, to: Tablets, equivalent to about 250 mg of ursodiol,</i>
SORBITAN MO IDENTIFICATIO NOPALMITATE N/A.		<i>USP36–NF31</i>	2213	27-Sep-2013		1-Oct-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	Line 1 of <i>Sample: Change 1 g of the residue obtained in the Assay for Fatty Acids to: Residue obtained in the Assay for Fatty Acids</i> AND Line 2 of <i>Acceptance criteria: Change 210–225 to:</i>

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BETHANECHOL CHLORIDE IM PURITIES/Heavy Metals, Method 1 <231>	<i>Second Supplement to USP36–NF31</i>	6568	27-Sep-2013	1-Oct-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	210–225 on 1-g sample Line 1 of <i>Test preparation</i> : Change Bethacholine Chloride to: Bethanechol Chloride
POWDERED STINGING NETTLE COMPOSITION /Content of Total Amino Acids	<i>USP36–NF31</i>	1606	26-Jul-2013	1-Aug-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	Line 1 of <i>Reagent solution</i> : Change Solution containing 1.00 g of ninhydrin, 1.50 g of hydrindantin, to: Solution containing 1.00 g of ninhydrin, 150 mg of hydrindantin,
MEPROBAMATE TABLETS ASSAY/ Procedure	<i>First Supplement to USP36–NF31</i>	6015	26-Jul-2013	1-Aug-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	Line 4 of <i>Standard solution</i> : Change Dissolve in 30% of the final flask

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BETAMETHASONE SODIUM PHOSPHATE	Identification/B. Thin-Layer Chromatographic Identification Test <201>	USP36–NF31	2645	26-Jul-2013		1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	<p>volume, and dilute with water to volume.</p> <p>to:</p> <p>Dissolve in 30% of the final flask volume of acetonitrile, and dilute with water to volume.</p> <p>Line 1 of <i>Test solution</i>: Change 1 mg per mL to: 1 mg per mL in methanol.</p>
DACARBAZINE FOR INJECTION	USP Reference standards <11>	USP36–NF31	3137	26-Jul-2013		1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	<p>Line 3 of USP Dacarbazine Related Compound B RS: Change <math>C_4H_3N_5O</math> 137.10 to: <math>C_4H_3N_5O \cdot H_2O</math> 155.12</p>
EDETATE DISODIUM	ASSAY/ Procedure	USP36–NF31	3370	26-Jul-2013		1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	<p>Line 5: Delete <i>Titrimetric system</i> (See <i>Titrimetry</i></p>

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LAMOTRIGINE TABLETS	PERFORMANCE TESTS/ Dissolution <711>/Test 1	USP36–NF31	4056	26-Jul-2013		1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	<541>.) Mode: Direct titration Titrant: 0.1 N sodium hydroxide VS Endpoint detection: Visual Line 3 of Standard solution: Change 0.028 µg/mL to: 0.028 mg/mL
TRAMADOL HYDROCHLORIDE EXTENDED-RELEASE TABLETS	IMPURITIES/Organic Impurities/ Table 2	USP36–NF31	5438	26-Jul-2013		1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	Footnote c: Change 1-(3-Methoxyphenyl)-2-(dimethylaminomethyl)cyclohex-1-ene hydrochloride (identified and reported as an individual unspecified impurity if present). to:

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							<p>1-(3-Methoxyphenyl)-2-(dimethylaminomethyl)cyclohex-6-ene hydrochloride (identified and reported as an individual unspecified impurity if present).  AND  Footnote d:  Change  1-(3-Methoxyphenyl)-2-(dimethylaminomethyl)cyclohex-6-ene hydrochloride (identified and reported as an individual unspecified impurity if present).  to:  1-(3-Methoxyphenyl)-2-(dimethylaminomethyl)cyclohex-1-ene</p>

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PURIFIED GYMNEMA EXTRACT	COMPOSITION /Content of <i>Gymnemic Acids</i>	<i>First Supplement to USP36–NF31</i>	5884	26-Jul-2013		1-Aug-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	hydrochloride (identified and reported as an individual unspecified impurity if present). Line 1 of <i>Acceptance criteria</i> : Change 90%–110% of the labeled amount to: 90.0%–110.0% of the labeled amount on the dried basis
SODIUM HYDROXIDE	ASSAY/ <i>Procedure</i>	<i>USP36–NF31</i>	2203	26-Jul-2013		1-Aug-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	Line 11 of <i>Analysis</i> : Change = volume of <i>Titrant</i> consumed by the <i>Sample</i> to the first endpoint (mL) to: = volume of <i>Titrant</i> consumed by

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CLARITHROM ASSAY/ YCIN FOR Procedure ORAL SUSPENSION	USP36–NF31	3018	26-Jul-2013	1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	the <i>Sample</i> to the second endpoint (mL) Change the subsection head <i>Buffer</i> : to: <i>Buffer A</i> : AND After the <i>Buffer A</i> subsection: Add <i>Buffer B</i> : 0.067 M dibasic potassium phosphate AND Line 1 of <i>Mobile phase</i> : Change Methanol and <i>Buffer</i> to: Methanol and <i>Buffer A</i> AND Line 4 of <i>Sample stock solution</i> : Change with the aid of



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DIPHENHYDR AMINE HYDRO CHLORIDE INJECTION	USP36–NF31	3276	26-Jul-2013	1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	330 mL of <i>Buffer</i> , to a 1000-mL volumetric flask containing 50 mL of <i>Buffer</i> . to: with the aid of 330 mL of <i>Buffer B</i> , to a 1000-mL volumetric flask containing 50 mL of <i>Buffer B</i> . Line 2: Change <i>Mobile phase, Standard preparation, System suitability solution, and Chromatographic system</i> —Prepare as directed in the Assay under <i>Diphenhydramine Hydrochloride</i> . to: <i>Mobile</i>

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							<p><i>phase</i>—Prepare a solution of acetonitrile, water, and triethylamine (50: 50: 0.5), adjust with glacial acetic acid to a pH of 6.5, filter, and degas. Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> &lt;621&gt;). <i>Standard preparation</i></p> <p>—Dissolve an accurately weighed quantity of USP Diphenhydramine Hydrochloride RS in water to obtain a solution having a known</p>

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							<p>concentration of about 0.5 mg per mL.</p> <p>AND</p> <p><i>After the Assay preparation subsection: Add System suitability solution</i></p> <p>—Dissolve about 5 mg of benzophenone in 5 mL of acetonitrile, dilute with water to 100 mL, and mix. Transfer 1.0 mL of this solution and 5 mg of diphenhydramine hydrochloride to a 10-mL volumetric flask, dilute with water to volume, and mix.</p> <p><i>Chromatographic system (see Chromatograph</i></p>

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							<p>y &lt;621&gt;—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm x 25-cm column that contains packing L10. The flow rate is about 1 mL per minute. Chromatograph the <i>System suitability solution</i>, and record the peak responses as directed for <i>Procedure</i>; the resolution, <i>R</i>, between the benzophenone and diphenhydramine peaks is not less than 2.0. Chromatograph replicate injections of the</p>

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							<p><i>Standard preparation, and record the peak responses as directed for Procedure; the relative standard deviation is not more than 2.0%, and the tailing factor for the diphenhydramine hydrochloride peak is not more than 2.0. AND</i></p> <p>Line 1 of <i>Procedure:</i> Change Proceed as directed for <i>Procedure</i> in the <i>Assay under Diphenhydramine Hydrochloride.</i> to: Separately inject equal</p>

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FEXOFENADIN ASSAY/ E HYDROCHL ORIDE TABLETS	<i>USP36–NF31</i>	3576	26-Jul-2013	1-Aug-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	volumes, about 10 ?L, 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. Line 6 of <i>Sample stock solution</i> : Change (equivalent to 80% of the total flask volume) to: (sufficient to fill the flask to 80% of its volume)
NIFEDIPINE EXPERFORMANC TENDED- RELEASE TABLETS	<i>USP36–NF31</i>	4509	26-Jul-2013	1-Aug-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	Line 1 of <i>Cell</i> : Change 0.5 cm to: 1 cm

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GYMNEMA	<i>conditions</i> IDENTIFICATIO N/B. <i>Thin-Layer Supplement to Chromatograph</i> <i>y/</i> <i>Chromatographi</i> <i>c system</i>	<i>First</i> USP36–NF31	5880	26-Jul-2013	1-Aug-2013	USP38–NF33	<i>First</i> <i>Supplement to</i> USP37–NF32	Line 2 of <i>Adsorbent:</i> Change 5m to: 5 µm
POWDERED STINGING NETTLE EXTRACT	COMPOSITION <i>/Content of</i> <i>Total Amino</i> <i>Acids</i>	USP36–NF31	1608	26-Jul-2013	1-Aug-2013	USP38–NF33	<i>First</i> <i>Supplement to</i> USP37–NF32	Line 1 of <i>Reagent</i> <i>solution:</i> Change Solution containing 1.00 g of ninhydrin, 1.50 g of hydrindantin, to: Solution containing 1.00 g of ninhydrin, 150 mg of hydrindantin,
OXCARBAZEPI NE	IM PUR ITIES/ <i>Organic</i> <i>Impurities,</i> <i>Procedure 1</i>	<i>First</i> <i>Supplement to</i> USP36–NF31	6035	26-Jul-2013	1-Aug-2013	USP38–NF33	<i>First</i> <i>Supplement to</i> USP37–NF32	Row 4 of Column 1 of <i>Table 1:</i> Change Dibenzazepinon e <sup>b</sup> to: Oxcarbazepine related

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CALCIUM CARBONATE	IMPURITIES	USP36–NF31	2747	26-Jul-2013		1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	<p>compound E AND Delete footnote b AND Reletter the following footnotes in both the table and footnote definitions: c to b d to c e to d</p> <p>Line 1 of <i>Acceptance criteria in Limit of Fluoride</i>: Change 50 ppm to: NMT 50 ppm AND Line 1 of <i>Acceptance criteria in Mercury, Method IIa</i> &lt;261&gt;: Change 0.5 ppm to:</p>



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CRYOPRESERVED HUMAN FIBROBLAST-DERIVED DERMAL SUBSTITUTE	USP36-NF31	3155	26-Jul-2013	1-Aug-2013	USP38-NF33	First Supplement to USP37-NF32	NMT 0.5 ppm Line 7 of <i>Collagen calibration standards:</i> Change by adding 25 mL, 50 mL, 100 mL, and 200 mL, to: by adding 25 ?L, 50 ?L, 100 ?L, and 200 ?L,
EDETATE DISODIUM ASSAY/ Procedure	USP36-NF31	3370	26-Jul-2013	1-Aug-2013	USP38-NF33	First Supplement to USP37-NF32	Line 16 of <i>Analysis:</i> Change Calculate the percentage of edetate disodium to: Calculate the weight of edetate disodium AND Line 19 of <i>Analysis:</i> Change Result = (V

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LEVOFLOXACIN	ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	USP36-NF31	4099	26-Jul-2013		1-Aug-2013	USP38-NF33	First Supplement to USP37-NF32	$\frac{T}{V_U} \times W \times (M_{r1}/M_{r2}) \times 100$ to: Result = $(V_T/V_U) \times W \times (M_{r1}/M_{r2})$ Line 2 of USP Levofloxacin Related Compound A RS: Change (S)-9-Fluoro-3-methyl-10-(piperazin-1-yl)-7-oxo-2,3-dihydro-7H-pyrido[1,2,3-de][1,4-benzoxazine-6-carboxylic acid. to: (S)-9-Fluoro-3-methyl-10-(piperazin-1-yl)-7-oxo-2,3-dihydro-7H

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							<p>-p yrido [1,2,3-<i>de</i> ][1,4]benzoxazi ne-6-carboxylic acid. AND Line 2 of USP Levofloxacin Related Compound B RS: Change (S )-9,10-Difluoro- 3-methyl-7-oxo- 2, 3-di hydro-7<i>H</i></p> <p>-p yrido [1,2,3-<i>de</i> ][1,4-benzoxazi ne-6-carboxylic acid. to: (S )-9,10-Difluoro- 3-methyl-7-oxo- 2, 3-di hydro-7<i>H</i></p>

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VENLAFAXINE ADDITIONAL REQUIREMENT	IDE	USP36–NF31	5551	26-Jul-2013		1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	-p yrido [1,2,3-de ][1,4]benzoxazi ne-6-carboxylic acid. Line 2 of Venlafaxine Related Compound A RS: Change 1-(1-(4-methoxy phenyl)-2-(meth ylamino)ethyl)cy clohexanol. C <sub>16</sub> H <sub>25</sub> NO <sub>2</sub> 263.38 to: 1-(1-(4-Methox yphenyl)-2-(met hylamino)ethyl) cyclohexanol hydrochloride. C <sub>16</sub> H <sub>25</sub> NO <sub>2</sub> · HCl 299.84
STINGING NETTLE	COMPOSITION /Content of Total Amino Acids	USP36–NF31	1604	26-Jul-2013		1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	Line 1 of Reagent solution: Change Solution

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GENTAMICIN SULFATE	IM	<i>First PurITIES/Limit of Methanol Supplement to USP36–NF31</i>	5990	26-Jul-2013		1-Aug-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	<p>containing 1.00 g of ninhydrin, 1.50 g of hydrindantin, to:</p> <p>Solution containing 1.00 g of ninhydrin, 150 mg of hydrindantin, Line 11 of <i>Analysis</i>: Change Result = <math>(R_U/R_S) \times (C_S/C_U) \times D \times F \times 100</math> to: Result = <math>(R_U/R_S) \times (C_S/C_U) \times D \times F</math> AND Line 18 of <i>Analysis</i>: Change <math>C_S =</math> percentage of methanol in the <i>Standard solution</i> (% v/v) to:</p>

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AMOXICILLIN	IM PUR ITIES/ <i>Organic Impurities/Procedure</i>	USP36–NF31	2477	26-Jul-2013		1-Aug-2013	USP38–NF33	<i>First Supplement to USP37–NF32</i>	<p><math>C_S</math> = percentage of methanol in the <i>Standard solution</i> AND Line 23 of <i>Analysis</i>: Change <math>F</math> = conversion factor, 0.001 g/mg to: <math>F</math> = conversion factor, 1000 mg/g</p> <p>Line 2 of <i>Acceptance criteria</i>: Change [Note—The reporting limit is 0.03% of the amoxicillin peak from the <i>Standard solution</i>. ] to: [Note—The reporting limit is 0.03 times the amoxicillin peak</p>

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CLARITHROM YCIN EXTENDED-RELEASE TABLETS	PERFORMANCE TESTS/ <i>Dissolution</i> <711>/Test 4	USP36–NF31	3019	26-Jul-2013		1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	from the <i>Standard solution.</i> ] Line 2 of <i>Standard solution:</i> Change and <i>Medium</i> (96:4). to: and <i>Medium</i> (4:96).
DIPHENHYDRAMINE HYDROCHLORIDE ORAL SOLUTION	Assay	USP36–NF31	3277	26-Jul-2013		1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	Line 2: Change <i>Mobile phase, Standard preparation, System suitability solution,</i> and <i>Chromatographic system</i> —Prepare as directed in the Assay under <i>Diphenhydramine Hydrochloride.</i> to: <i>Mobile phase</i> —Prepare a solution of

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							<p>acetonitrile, water, and triethylamine (50: 50: 0.5), adjust with glacial acetic acid to a pH of 6.5, filter, and degas. Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> &lt;621&gt;). <i>Standard preparation</i> —Dissolve an accurately weighed quantity of USP Diphenhydramine Hydrochloride RS in water to obtain a solution having a known concentration of about 0.5 mg</p>



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							<p>per mL.  AND  After the Assay preparation subsection: Add System suitability solution  —Dissolve about 5 mg of benzophenone in 5 mL of acetonitrile, dilute with water to 100 mL, and mix. Transfer 1.0 mL of this solution and 5 mg of diphenhydramine hydrochloride to a 10-mL volumetric flask, dilute with water to volume, and mix.  <i>Chromatographic system</i> (see <i>Chromatography</i> &lt;621&gt;)—The liquid</p>

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							<p>chromatograph is equipped with a 254-nm detector and a 4.6-mm x 25-cm column that contains packing L10. The flow rate is about 1 mL per minute.</p> <p>Chromatograph the <i>System suitability solution</i>, and record the peak responses as directed for <i>Procedure</i>; the resolution, <i>R</i>, between the benzophenone and diphenhydramine peaks is not less than 2.0.</p> <p>Chromatograph replicate injections of the <i>Standard preparation</i>,</p>

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							<p>and record the peak responses as directed for <i>Procedure</i>; the relative standard deviation is not more than 2.0%, and the tailing factor for the diphenhydramine hydrochloride peak is not more than 2.0.</p> <p>AND</p> <p>Line 1 of <i>Procedure</i>: Change Proceed as directed for <i>Procedure</i> in the <i>Assay</i> under <i>Diphenhydramine Hydrochloride</i>. to: Separately inject equal volumes, about 10 µL, of the</p>

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FLUPHENAZIN Assay E DECANOATE INJECTION	USP36–NF31	3639	26-Jul-2013	1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	<p><i>Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks.</i></p> <p>Line 11 of <i>Standard preparation:</i> Delete (1:5) AND Line 8 of <i>Assay preparation:</i> Delete (1:5)</p>
OLMESARTAN IM MEDOXOMIL PUR ITIES/ <i>Organic Impurities/Impurity Table</i>	USP36–NF31	4570	26-Jul-2013	1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	<p>Footnote d: Change ((5-Methyl-2-oxo-1,3-dioxol-4-yl)methyl 4-(2-hydroxypropan-2-yl)-2-propyl-1-((2'-(1-trityl-1H</p>

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									-tetrazol-5-yl)biphenyl-4-yl)methyl)-1H -imidazole-5-carboxylate. to: (5-Methyl-2-oxo-1,3-dioxol-4-yl)methyl 4-(2-hydroxypropan-2-yl)-2-propyl-1-((2'- 2-trityl-1H -tetrazol-5-yl)biphenyl-4-yl)methyl)-1H -imidazole-5-carboxylate.
POWDERED GYMNEMA	IDENTIFICATION/ N/B. Thin-Layer Chromatography/ Chromatographic system	<i>First Supplement to USP36–NF31</i>	5883	26-Jul-2013		1-Aug-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	Line 2 of Adsorbent. Change 5m to: 5 µm
GLYCERYL DISTEARATE	ASSAY/ Procedure/ Chromatographic system	<i>USP36–NF31</i>	2029	26-Jul-2013		1-Aug-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	Line 1 of Column temperature: Change Column temperature: 40°

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OXCARBAZEPINE	IMPURITIES/Organic Impurities, Procedure 2	<i>First Supplement to USP36–NF31</i>	6035	26-Jul-2013		1-Aug-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	to: Temperatures Detector: 40° Column: 40° Row 9 of Column 1 of Table 3: Change Oxcarbazepine related compound E <sup>9</sup> to: Oxcarbazepine related compound E AND Delete footnote g Row 16 of Column 1: Change Cefdinir impurity 2 <sup>e</sup> to: Cefdinir impurity 2 <sup>f</sup> AND Row 21 of Column 1: Change Cefdinir impurity
CEFDINIR CAPSULES	IMPURITIES/Organic Impurities/ Table 2	<i>USP36–NF31</i>	2850	26-Jul-2013		1-Aug-2013	<i>USP38–NF33</i>	<i>First Supplement to USP37–NF32</i>	

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DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES Assay	USP36–NF31	3276	26-Jul-2013	1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	3 <sup>e</sup> to: Cefdinir impurity 3 <sup>f</sup> Line 2: Change <i>Mobile phase, Standard preparation, System suitability solution, and Chromatographic system</i> —Prepare as directed in the Assay under <i>Diphenhydramine Hydrochloride</i> . to: <i>Mobile phase</i> —Prepare a solution of acetonitrile, water, and triethylamine (50: 50: 0.5), adjust with glacial acetic acid to a pH of 6.5, filter, and

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							<p>degas. Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> &lt;621&gt; ).</p> <p><i>Standard preparation</i></p> <p>—Dissolve an accurately weighed quantity of USP Diphenhydramine Hydrochloride RS in water to obtain a solution having a known concentration of about 0.5 mg per mL.</p> <p>AND</p> <p>After the <i>Assay preparation</i> subsection: Add <i>System suitability solution</i></p>



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							<p>—Dissolve about 5 mg of benzophenone in 5 mL of acetonitrile, dilute with water to 100 mL, and mix. Transfer 1.0 mL of this solution and 5 mg of diphenhydramine hydrochloride to a 10-mL volumetric flask, dilute with water to volume, and mix.</p> <p><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 25-cm column that contains packing L10.</p>

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							<p>The flow rate is about 1 mL per minute.</p> <p>Chromatograph the <i>System suitability solution</i>, and record the peak responses as directed for <i>Procedure</i>; the resolution, <i>R</i>, between the benzophenone and diphenhydramine peaks is not less than 2.0.</p> <p>Chromatograph replicate injections of the <i>Standard preparation</i>, and record the peak responses as directed for <i>Procedure</i>; the relative standard deviation is not more than</p>

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							<p>2.0%, and the tailing factor for the diphenhydramine hydrochloride peak is not more than 2.0.</p> <p>AND</p> <p>Line 1 of <i>Procedure:</i> Change Proceed as directed for <i>Procedure</i> in the <i>Assay</i> under <i>Diphenhydramine Hydrochloride</i>. to:</p> <p>Separately inject equal volumes, about 10 µL, of the <i>Standard preparation</i> and the <i>Assay preparation</i> into the chromatograph, record the chromatograms,</p>

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FELBAMATE TABLETS	IMPURITIES/ <i>Organic Impurities/System suitability/Suitability requirements</i>	USP36–NF31	3537	26-Jul-2013		1-Aug-2013	USP38–NF33	<i>First Supplement to USP37–NF32</i>	and measure the responses for the major peaks. Line 1 of <i>Resolution:</i> Change NMT 2 to: NLT 2
MOXIFLOXACIN OPTHALMIC SOLUTION	<i>Related compounds</i>	USP36–NF31	4414	26-Jul-2013		1-Aug-2013	USP38–NF33	<i>First Supplement to USP37–NF32</i>	Row 1 of Column 3 of <i>Table 2:</i> Change Relative Retention Time vs. Moxifloxacin to: Relative Retention vs. Moxifloxacin AND Row 1 of Column 3 of <i>Table 3:</i> Change Relative Retention Time vs. Moxifloxacin

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VENLAFAXINE TABLETS	ADDITIONAL REQUIREMENT S/USP Reference Standards <11>	USP36–NF31	5554	26-Jul-2013		1-Aug-2013	USP38–NF33	First Supplement to USP37–NF32	to: Relative Retention vs. Moxifloxacin Line 2 of Venlafaxine Related Compound A RS: Change 1-(1-(4-methoxy phenyl)-2-(methylamino)ethyl)cyclohexanol. C <sub>16</sub> H <sub>25</sub> NO <sub>2</sub> 263.38 to: 1-(1-(4-Methoxyphenyl)-2-(methylamino)ethyl)cyclohexanol hydrochloride. C <sub>16</sub> H <sub>25</sub> NO <sub>2</sub> · HCl 299.84
ALBUTEROL SULFATE	Chromatographic purity	USP36–NF31	2352	31-May-2013		1-Jun-2013	USP37–NF32	USP37–NF32	Line 1: Change It meets the requirements of the test for Chromatographic purity under Albuterol,

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							<p>except to read Albuterol Sulfate in place of Albuterol and to use water instead of methanol as the solvent to prepare the <i>Standard solution</i> and the <i>Test solution</i>.</p> <p>to:</p> <p>It meets the requirements of the test for <i>Organic Impurities</i> under <i>Albuterol</i>, except to read Albuterol Sulfate in place of Albuterol and to use water instead of methanol as the solvent to prepare the <i>Standard solution</i> and the <i>Sample</i></p>

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MINOCYCLINE Assay HYDROCHLOR IDE CAPSULES	USP36–NF31	4375	31-May-2013	1-Jun-2013	USP37–NF32	USP37–NF32	<p><i>solution.</i></p> <p>Line 2: Change <i>Mobile phase, Standard preparation, Resolution solution, and Chromatographic system</i>—Proceed as directed in the Assay under <i>Minocycline Hydrochloride</i>. to: <i>Mobile phase</i>—Prepare a mixture of 0.2 M ammonium oxalate, 0.01 M edetate disodium, dimethylformamide, and tetrahydrofuran (600:180:120:80). Adjust with ammonium hydroxide to a pH of 7.2, and</p>

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							<p>pass through a filter of 0.5-<math>\mu</math>m or finer pore size. Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> &lt;621&gt;). <i>Standard preparation</i></p> <p>—Dissolve an accurately weighed quantity of USP Minocycline Hydrochloride RS in water to obtain a solution having a known concentration of about 500 <math>\mu</math>g of minocycline (<math>C_{23}H_{27}N_3O_7</math>) per mL. Use this solution within 3 hours. <i>Resolution</i></p>



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							<p><i>solution</i>  —Transfer 10 mg of USP Minocycline Hydrochloride RS to a 25-mL volumetric flask, add 20 mL of 0.2 M ammonium oxalate, and swirl to dissolve. Heat on a water bath at 60° for 180 minutes, and allow to cool. Dilute with water to volume, and mix.</p> <p><i>Chromatographic system (see Chromatography &lt;621&gt;)</i>—The liquid chromatograph is equipped with a 280-nm detector and a 4.6-mm x</p>

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							<p>25-cm column that contains 5-<math>\mu</math>m packing L1, and is maintained at a constant temperature of about 40°. The flow rate is about 1.5 mL per minute. Chromatograph the <i>Standard preparation</i>, and record the peak responses as directed for <i>Procedure</i>: the capacity factor, <math>k'</math>, is not less than 5.0 and not more than 11.5; the tailing factor for the analyte peak is not less than 0.9 and not more than 2.0; and the relative standard deviation for</p>

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							<p>replicate injections is not more than 2.0%.  Chromatograph the <i>Resolution solution</i>, and record the peak responses as directed for <i>Procedure</i>: the relative retention times are about 0.7 for epiminocycline and 1.0 for minocycline; and the resolution, <i>R</i>, between epiminocycline and minocycline is not less than 4.6.  AND  Line 1 of <i>Procedure</i>:  Change  Proceed as directed for</p>

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NIFEDIPINE EXPERFORMANC TENDED- RELEASE TABLETS	USP36–NF31	4509	31-May-2013	1-Jun-2013	USP37–NF32	USP37–NF32	<p><i>Procedure in the Assay under Minocycline Hydrochloride. to: Separately inject equal volumes (about 20 µL) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks.</i></p> <p>Line 1 of <i>Solution A:</i> Change Dissolve 330.9 mg of sodium phosphate to: Dissolve 330.9 g of dibasic sodium</p>

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POTASSIUM Assay for BICARBONATE <i>potassium</i> AND POTASSIUM CHLORIDE FOR EFFERVE SCENT ORAL SOLUTION	USP36–NF31	4834	31-May-2013	1-Jun-2013	USP37–NF32	USP37–NF32	phosphate Line 2: Change <i>Potassium stock solution and Standard preparations—</i> to: <i>Standard stock solution and Standard solutions—</i> AND Line 1 of <i>Procedure:</i> Change for <i>Procedure</i> in the Assay under <i>Potassium Chloride Oral Solution.</i> to: for <i>Instrumental conditions and Analysis</i> in the Assay under <i>Potassium Chloride Oral Solution</i> , except use Assay <i>preparation</i>

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POTASSIUM CHLORIDE EX <711> TENDED-RELEASE TABLETS	<i>Dissolution</i> USP36–NF31	4841	31-May-2013	1-Jun-2013	USP37–NF32	USP37–NF32	<p>instead of <i>Sample solution</i>.</p> <p>Line 5: Change <i>Potassium stock solution</i>—to: <i>Standard stock solution</i>—AND</p> <p>Line 7: Change Prepare as directed for <i>Standard preparations</i> to: Prepare as directed for <i>Standard solutions</i> AND</p> <p>Line 7 of <i>Procedure</i>: Change for <i>Procedure</i> in the Assay under <i>Potassium Chloride Oral Solution</i>. to: for <i>Instrumental</i></p>

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THIMEROSAL TOPICAL AEROSOL	SPECIFIC TESTS/ <i>Alcohol Determination, Method II</i> <611>	USP36–NF31	5369	31-May-2013		1-Jun-2013	USP37–NF32	USP37–NF32	<p><i>conditions and Analysis in the Assay under Potassium Chloride Oral Solution.</i></p> <p>Line 4 of <i>Analysis:</i> Change Determine the alcohol content of the sample thus prepared by the <i>Gas–Liquid Chromatographic Method</i> (see <i>Method II</i> in <i>Alcohol Determination &lt;611&gt;</i>, using methyl ethyl ketone as the internal standard in place of acetone. to: Determine the alcohol content of the sample</p>

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									thus prepared by the <i>Gas Chromatographic Method</i> (see <i>Method II</i> in <i>Alcohol D ete rminat ion &lt;611&gt;</i> ), using methyl ethyl ketone as the internal standard in place of acetonitrile.
NORTRIPTYLIN NE HYDROCHLORIDE	IMPURITIES/ Organic Impurities	<i>First Supplement to USP36–NF31</i>	6027	31-May-2013		1-Jun-2013	<i>USP37–NF32</i>	<i>USP37–NF32</i>	Line 3 of <i>Acceptance criteria: Change Standard solution to: Sample solution</i>
CARAWAY OIL	DEFINITION	<i>USP36–NF31</i>	1924	31-May-2013		1-Jun-2013	<i>USP37–NF32</i>	<i>USP37–NF32</i>	Line 3: Change It contains NMT 50.0% of <i>d</i> -carvone (C <sub>10</sub> H <sub>14</sub> O). to: It contains NLT 50.0% of <i>d</i>



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FOSPHENYTOIN SODIUM INJECTION	<i>USP Reference standards &lt;11&gt;</i>	USP36–NF31 3680	31-May-2013	1-Jun-2013	USP37–NF32	USP37–NF32	-carvone (C <sub>10</sub> H <sub>14</sub> O). Line 6: Change C <sub>14</sub> H <sub>15</sub> NO <sub>2</sub> to: C <sub>14</sub> H <sub>13</sub> NO <sub>2</sub>
MINOCYCLINE HYDROCHLORIDE TABLETS	Assay	USP36–NF31 4378	31-May-2013	1-Jun-2013	USP37–NF32	USP37–NF32	Line 2: Change <i>Mobile phase, Standard preparation, Resolution solution, and Chromatographic system</i> —Proceed as directed in the Assay under <i>Minocycline Hydrochloride</i> . to: <i>Mobile phase</i> —Prepare a mixture of 0.2 M ammonium oxalate, 0.01 M edetate disodium, dimethylformamide, and tetrahydrofuran

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							(600:180:120:80). Adjust with ammonium hydroxide to a pH of 7.2, and pass through a filter of 0.5-µm or finer pore size. Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> <621>). <i>Standard preparation</i> —Dissolve an accurately weighed quantity of USP Minocycline Hydrochloride RS in water to obtain a solution having a known concentration of about 500 µg of minocycline

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							<p>(C<sub>23</sub>H<sub>27</sub>N<sub>3</sub>O<sub>7</sub>) per mL. Use this solution within 3 hours.</p> <p><i>Resolution solution</i></p> <p>—Transfer 10 mg of USP Minocycline Hydrochloride RS to a 25-mL volumetric flask, add 20 mL of 0.2 M ammonium oxalate, and swirl to dissolve. Heat on a water bath at 60° for 180 minutes, and allow to cool. Dilute with water to volume, and mix.</p> <p><i>Chromatographic system (see Chromatography &lt;621&gt;)</i>—The liquid</p>

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							<p>chromatograph is equipped with a 280-nm detector and a 4.6-mm x 25-cm column that contains 5-<math>\mu</math>m packing L1, and is maintained at a constant temperature of about 40°. The flow rate is about 1.5 mL per minute. Chromatograph the <i>Standard preparation</i>, and record the peak responses as directed for <i>Procedure</i>: the capacity factor, <math>k'</math>, is not less than 5.0 and not more than 11.5; the tailing factor for the analyte peak is not less</p>

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							<p>than 0.9 and not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%. Chromatograph the <i>Resolution solution</i>, and record the peak responses as directed for <i>Procedure</i>: the relative retention times are about 0.7 for epiminocycline and 1.0 for minocycline; and the resolution, <i>R</i>, between epiminocycline and minocycline is not less than 4.6.</p> <p>AND</p>

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PENTAZOCINE <i>Chemical</i> INJECTION <i>Information</i>	USP36–NF31	4734	31-May-2013	1-Jun-2013	USP37–NF32	USP37–NF32	<p>Line 1 of <i>Procedure</i>: Change Proceed as directed for <i>Procedure</i> in the <i>Assay</i> under <i>Minocycline Hydrochloride</i>. to: Separately 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>Line 1: Remove all chemical information.</p>

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