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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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NATEGLINIDE	CHEMICAL	USP43–NF38	Online	30-Oct-2020	1-Nov-2020	NA	NA	This erratum

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INFORMATION									
OIL-SOLUBLE VITAMINS WITH MINERALS TABLETS	CONTAMINANTS	USP43–NF38	5378	30-Oct-2020		1-Nov-2020	NA	NA	applies to the USP-NF ONLINE platform only. See <a href="http://uspnf.com/nateglinide-err-img-20201030">http://uspnf.com/nateglinide-err-img-20201030</a> for correction Change <i>Absence of Specified Microorganisms &lt;2022&gt;, Test Procedures, Test for Absence of Salmonella Species and Absence of Specified Microorganisms &lt;2022&gt;, Test Procedures, Test for Absence of Salmonella Species:</i> to: <i>Absence of Specified</i>

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LOSS ON IGNITION	INTRODUCTIO N	USP43–NF38	Online	30-Oct-2020		1-Nov-2020	NA	NA	<p><i>Microorganisms &lt;2022&gt;, Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli:</i></p> <p>In paragraph 3: Change Upon completion of each ignition, cover the crucible, and allow it to cool in a desiccator to room temperature before weighing. to: Upon completion of each ignition, cover the crucible, and allow it to cool in a desiccator</p>

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OXYGEN	IMPURITIES	USP43–NF38	3347	30-Oct-2020		1-Nov-2020	NA	NA	to room temperature before weighing accurately. Change <i>Impurities Testing in Medical Gases Assay ?413?</i> to: <i>Impurities Testing in Medical Gases ?413?</i>
LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE TABLETS	ASSAY/ Procedure	<i>First Supplement to USP43–NF38</i>	Online	30-Oct-2020		1-Nov-2020	NA	NA	In <i>Buffer A</i> : Change monobasic potassium phosphate to: monobasic sodium phosphate
PRAZQUANTEL TABLETS	PERFORMANCE TESTS/ Dissolution <711>	USP43–NF38	3650	30-Oct-2020		1-Nov-2020	NA	NA	In <i>For products for veterinary use/Apparatus 2</i> : Change peak vessels to: apex vessels
CELL-BASED	ANALYTICAL	USP43–NF38	7400	30-Oct-2020		1-Nov-2020	NA	NA	In <i>In-Process</i>

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ADVANCED THERAPIES AND TISSUE-BASED PRODUCTS	METHODS							<p><i>Control</i> s/paragraph 2: Change Refer to <i>Risk Assessment</i> for discussion on critical process parameters (CPP). to: Refer to <i>Quality Systems</i> for discussion on critical process parameters (CPP). AND In <i>Final Product Release Specifications/Dose-Defining Assays</i> /paragraph 3: Change relay to: rely In paragraph 3: Change and then touched against</p>
VOLUMETRIC APPARATUS	STANDARDS OF ACCURACY	<i>First Supplement to USP43–NF38</i>	Online	30-Oct-2020	1-Nov-2020	NA	NA	

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OXYGEN 93 PERCENT	IMPURITIES	USP43–NF38	3347	30-Oct-2020		1-Nov-2020	NA	NA	the wall of the receiving vessel to drain the tips. to: and then touched against the wall of the receiving vessel to drain the pipet tip. Change <i>Impurities Testing in Medical Gases Assay ?413?</i> to: <i>Impurities Testing in Medical Gases ?413?</i>
GALANTAMINE EXTENDED-RELEASE CAPSULES	ADDITIONAL REQUIREMENT S/USP Reference Standards <11>	<i>First Supplement to USP43–NF38</i>	Online	30-Oct-2020		1-Nov-2020	NA	NA	In USP Galantamine Hydrobromide Related Compounds Mixture RS: Change Anhydrogalantamine; (4aS,8aS)-3-Methoxy-11-

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							methyl-9,10,11,12-tetrahydro-4aH-benzo[2,3]benzofuro[4,3-cd]azepine. C <sub>17</sub> H <sub>19</sub> NO <sub>2</sub> to: Anhydrogalantamine; (4aS,8aS)-3-Methoxy-11-methyl-9,10,11,12-tetrahydro-4aH-benzo[2,3]benzofuro[4,3-cd]azepine. C <sub>17</sub> H <sub>19</sub> NO <sub>2</sub> 269.34
GALANTAMINE PERFORMANCE TABLETS E TESTS/ <i>Dissolution</i> <711>	USP43–NF38	2081	30-Oct-2020	1-Nov-2020	NA	NA	In Test 3/Apparatus 2: Change peak vessels to: apex vessels
DACTINOMYCIN IDENTIFICATION N/A.	USP43–NF38	1227	25-Sep-2020	1-Oct-2020	NA	NA	Change <i>Spectroscopic Identification Tests</i> ?197?, <i>Ultraviolet</i>

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TELMISARTAN IDENTIFICATIO TABLETS	USP43–NF38 N/A.	4240	25-Sep-2020	1-Oct-2020	NA	NA	<i>Spectroscopy: 197U to: Spectroscopic Identification Tests ?197?, Ultraviolet-Visible Spectroscopy: 197U Change Spectroscopic Identification Tests ?197?, Ultraviolet Spectroscopy: 197U: to: Spectroscopic Identification Tests ?197?, Ultraviolet-Visible Spectroscopy: 197U:</i>
NICOTINE TRA PERFORMANC NSDERMAL SYSTEM	USP43–NF38 E TESTS/ <i>Drug Release &lt;724&gt;</i>	3153	25-Sep-2020	1-Oct-2020	NA	NA	<i>In Tests 1, 2, 4, and 5/ Tolerances: Change conform to Dissolution</i>



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CEFTIOFUR H IM YDROCHLORI PURITIES/ <i>High</i> DE <i>Molecular Weight Impurities</i>	USP43–NF38	875	25-Sep-2020	1-Oct-2020	NA	NA	<711>, <i>Acceptance Table 1.</i> to: conform to <i>Acceptance Table 1.</i> In <i>Mobile phase</i> : Change 10 g/L of electrophoresis grade sodium dodecyl sulfate in <i>Solution A.</i> to: 10 g/L of electrophoresis grade sodium dodecyl sulfate in <i>Solution B.</i>
DESVENLAFAXINE SUCCINATE	IDENTIFICATIO N/A.	USP43–NF38 1283	25-Sep-2020	1-Oct-2020	NA	NA	Change <i>Infrared Absorption</i> ?197?: [ Note—Methods described in ?197K? or ?197A? may be used.] to: <i>Spectroscopic</i>

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DESVENLAFAXINE FUMARATE	IDENTIFICATIO N/A.	USP43–NF38	1281	25-Sep-2020		1-Oct-2020	NA	NA	<i>Identification Tests ?197?, Infrared Spectroscopy: 197K or 197A Change Infrared Absorption ?197?: [ Note—Methods described in ?197K? or ?197A? may be used.] to: Spectroscopic Identification Tests ?197?, Infrared Spectroscopy: 197K or 197A Change Organic Impurities</i>
METAXALONE TABLETS	IMPURITIES	<i>Revision Bulletin (Official September 01, 2020)</i>	Online	25-Sep-2020		1-Oct-2020	NA	NA	<i>to: IMPURITIES Organic Impurities Change Infrared Absorption</i>
DALFAMPRIDINE	IDENTIFICATIO N/A.	USP43–NF38	1228	25-Sep-2020		1-Oct-2020	NA	NA	<i>Change Infrared Absorption</i>

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TILETAMINE H IDENTIFICATIO YDROCHLORI N/B. DE	USP43–NF38	4382	25-Sep-2020	1-Oct-2020	NA	NA	?197?: [ Note— Methods described in ?197K? or ?197A? may be used.] to: <i>Spectroscopic Identification Tests ?197?, Infrared Spectroscopy:</i> 197K or 197A Change <i>Spectroscopic Identification Tests ?197?, Ultraviolet Spectroscopy:</i> 197U— to: <i>Spectroscopic Identification Tests ?197?, Ultraviolet- Visible Spectroscopy:</i> 197U—
AMIODARONE IDENTIFICATIO HYDROCHLOR N/A. IDE	USP43–NF38	Online	25-Sep-2020	1-Oct-2020	NA	NA	This erratum applies to the <i>USP-NF</i> online

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									platform only. Change <i>Infrared Absorption</i> ?197K? to: <i>Spectroscopic Identification Tests</i> ?197?, <i>Infrared Spectroscopy</i> : 197K
CLOMIPHENE CITRATE	IDENTIFICATIO N/B.	USP43–NF38	1088	25-Sep-2020		1-Oct-2020	NA	NA	Change <i>Spectroscopic Identification Tests</i> ?197?, <i>Ultraviolet Spectroscopy</i> : 197U to: <i>Spectroscopic Identification Tests</i> ?197?, <i>Ultraviolet-Visible Spectroscopy</i> : 197U
ETIDRONATE DISODIUM	IDENTIFICATIO N/A.	USP43–NF38	1782	25-Sep-2020		1-Oct-2020	NA	NA	Change <i>Infrared Absorption</i> ?197?

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ZONISAMIDE	IDENTIFICATIO N/A.	USP43–NF38	4718	25-Sep-2020		1-Oct-2020	NA	NA	to: <i>Spectroscopic Identification Tests ?197?, Infrared Spectroscopy</i> Change <i>Infrared Absorption ?197K?</i> to: <i>Spectroscopic Identification Tests ?197?, Infrared Spectroscopy: 197K</i> Change <i>Infrared Absorption ?197?: [</i> Note—Methods described in ?197K? or ?197A? may be used.] to: <i>Spectroscopic Identification Tests ?197?, Infrared</i>
DESVENLAFAXINE	IDENTIFICATIO N/A.	USP43–NF38	1280	25-Sep-2020		1-Oct-2020	NA	NA	

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VORICONAZOLE	IDENTIFICATION	USP43–NF38	4643	25-Sep-2020		1-Oct-2020	NA	NA	<i>Spectroscopy: 197K or 197A Change Infrared Absorption ?197K? to: Spectroscopic Identification Tests ?197?, Infrared Spectroscopy: 197K</i>
AMLODIPINE BESYLATE TABLETS	IDENTIFICATION	USP43–NF38	286	25-Sep-2020		1-Oct-2020	NA	NA	<i>Change Spectroscopic Identification Tests ?197?, Ultraviolet Spectroscopy: 197U to: Spectroscopic Identification Tests ?197?, Ultraviolet-Visible Spectroscopy: 197U</i>
CLOMIPRAMINE HYDROCHLORIDE	ADDITIONAL REQUIREMENT	<i>Revision Bulletin (Official July 08, 2020)</i>	Online	28-Aug-2020		1-Sep-2020	NA	NA	In USP Clomipramine Related

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CAPSULES	<i>Reference Standards &lt;11&gt;</i>								Compound A RS: Change 458.89 to: 458.90
THEOPHYLLIN Assay E TABLETS		<i>USP43–NF38</i>	4328	28-Aug-2020		1-Sep-2020	NA	NA	Change <i>Mobile phase, Internal standard solution, and Standard preparation</i> —Prepare as directed in the Assay under <i>Theophylline</i> . to: <i>Buffer solution</i> —Transfer 2.72 g of sodium acetate trihydrate to a 2000-mL volumetric flask, add about 200 mL of water, and shake until dissolution is complete. Add 10.0 mL of

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							<p>glacial acetic acid, dilute with water to volume, and mix.</p> <p><i>Mobile phase</i>—Transfer 70.0 mL of acetonitrile to a 1000-mL volumetric flask, dilute with <i>Buffer solution</i> to volume, and mix. Degas, and filter before using. Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> &lt;621&gt;).</p> <p><i>Internal standard solution</i>—Transfer about 50 mg of theobromine, accurately weighed, to a</p>



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							<p>100-mL volumetric flask, dissolve in 10.0 mL of 6 N ammonium hydroxide, dilute with <i>Mobile phase</i> to volume, and mix.</p> <p><i>Standard preparation</i></p> <p>—Dissolve an accurately weighed quantity of USP Theophylline RS in <i>Mobile phase</i>, and dilute quantitatively, and stepwise if necessary, with <i>Mobile phase</i> to obtain a solution having a known concentration of about 1 mg per mL. Transfer</p>

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							<p>10.0 mL of this solution to a 100-mL volumetric flask, add 20.0 mL of <i>Internal standard solution</i>, dilute with <i>Mobile phase</i> to volume, and mix to obtain a solution having a known concentration of about 0.1 mg of USP Theophylline RS per mL.</p> <p>AND</p> <p>Change <i>Chromatographic system</i></p> <p>—Proceed as directed in the <i>Assay under Theophylline</i>.</p> <p>to:</p> <p>(see <i>Chromatograph</i></p>

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							<p>y &lt;621&gt;—The liquid chromatograph is equipped with a 280-nm detector and a 4-mm × 30-cm column that contains packing L1. The flow rate is about 1.0 mL per minute. Chromatograph the <i>Standard preparation</i>, and record the peak responses as directed for <i>Procedure</i>: the resolution, <i>R</i>, between the theophylline and theobromine peaks is not less than 2.0, the tailing factor for the theophylline peak is not</p>

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							<p>more than 2.0, and the relative standard deviation for replicate injections is not more than 1.5%.  AND  Change  <i>Proce</i>  <i>dure</i>—Proceed as directed for <i>Procedure</i> in the <i>Assay</i> under <i>Theophylline</i>.  to:  <i>Proce</i>  <i>dure</i>  —Separately inject equal volumes (between 10 µL and 25 µL) of the <i>Standard preparation</i> and the <i>Assay preparation</i> into the chromatograph, and measure</p>

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SODIUM IODIDE I 123 CAPSULES	<i>Radiochemical purity</i>	USP43–NF38 2365	28-Aug-2020	1-Sep-2020	NA	NA	<p>the peak responses for the major peaks. The retention time of theophylline relative to that of theobromine is about 1.6.</p> <p>Change Homogenize 1 Capsule in 3 mL of water, add 3 mL of methanol, and centrifuge: the supernatant so obtained meets the requirements of the test for <i>Radiochemical purity</i> under <i>Sodium Iodide I 123 Solution</i>.</p> <p>to: Place a measured volume of a solution, containing 100 mg of</p>

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							<p>potassium iodide, 200 mg of potassium iodate, and 1 g of sodium bicarbonate in each 100 mL, 25 mm from one end of a 25- x 300-mm strip of chromatographic paper (see <i>Chromatography</i> &lt;621&gt;), and allow to dry. To the same area add a similar volume of the sample solution prepared as follows: homogenize the content from 1 Capsule in 3 mL of water and 3 mL of methanol and centrifuge. The supernatant should be</p>

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							diluted so that it provides a count rate of about 20,000 counts per minute. Allow the spots to dry. Develop the chromatogram over a period of about 4 hours by ascending chromatography, using dilute methanol (7 in 10). Dry the chromatogram in air, and determine the radioactivity distribution by scanning with a suitable collimated radiation detector: the radioactivity of the iodide <sup>123</sup> I band is not less than 95.0% of the total

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							radioactivity, and its $R_F$ value falls within $\pm 5.0\%$ of the value found for sodium iodide when determined under similar conditions. Confirmation of the identity of the iodide band is made by the addition to the suspected iodide band of 6 drops of acidified hydrogen peroxide solution (prepared by adding 6 drops of 1 N hydrochloric acid to 10 mL of hydrogen peroxide solution) followed by the



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SODIUM IODIDE I 123 CAPSULES	<i>Radionuclide identification</i>	USP43–NF38 2365	28-Aug-2020	1-Sep-2020	NA	NA	<p>dropwise addition of starch TS: the development of a blue color indicates the presence of iodide.</p> <p>Change A solution or suspension of 1 or more Capsules in water responds to the test for <i>Radionuclide identification</i> under <i>Sodium Iodide I 123 Solution</i>.</p> <p>to: (see <i>Radioactivity</i> &lt;821&gt;)</p> <p>The gamma-ray spectrum of a solution or suspension of 1 or more Capsules in water is</p>

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CARTEOLOL H Assay YDROCHLORIDE OPHTHALMIC SOLUTION	USP43–NF38	789	28-Aug-2020	1-Sep-2020	NA	NA	<p>identical to that of a specimen of <sup>123</sup>I of known purity that exhibits a major photoelectric peak having an energy of 0.159 MeV.</p> <p>Change <i>pH 6.0 buffer, Mobile phase, Diluent, Standard preparation, Resolution solution, and Chromatographic system</i>—Proceed as directed in the Assay under <i>Carteolol Hydrochloride</i>. to: <i>Buffer, Mobile phase, Standard stock solution, Standard</i></p>

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							<p><i>solution, System suitability stock solution, System suitability solution, Chromatographic system, and System suitability—</i></p> <p>Proceed as directed in the Assay under <i>Carbetolol Hydrochloride</i>.</p> <p>AND</p> <p>Add</p> <p><i>Diluent</i>—Prepare a mixture of <i>Buffer</i> and methanol (1:1).</p> <p>AND</p> <p>In all instances in <i>Procedure</i>: Change <i>Standard preparation</i> to: <i>Standard solution</i></p>

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SODIUM IODIDE I 123 CAPSULES	<i>Other requirements</i>	USP43–NF38	2365	28-Aug-2020		1-Sep-2020	NA	NA	Change <i>Other requirements</i> A solution or suspension prepared by homogenizing 1 or more Capsules in water to yield a concentration of not less than 1 MBq (25 µCi) per mL meets the requirements of the <i>Assay for radioactivity under Sodium Iodide I 123 Solution</i> . to: <i>Assay for radioactivity</i> Prepare a solution or suspension by homogenizing 1 or more Capsules in water to yield a

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SODIUM IODIDE I 123 CAPSULES	<i>Radionuclidic purity</i>	USP43–NF38 2365	28-Aug-2020	1-Sep-2020	NA	NA	<p>concentration of not less than 1 MBq (25 µCi) per mL.</p> <p>Determine the radioactivity of the resulting solution using a suitable counting assembly, by use of a calibrated system as directed under <i>Radioactivity &lt;821&gt;</i>.</p> <p>Change A solution or suspension of 1 or more Capsules in water responds to the test for <i>Radionuclidic purity</i> under <i>Sodium Iodide I 123 Solution</i>.</p> <p>to: (see <i>Radioactivity</i></p>

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VITAMIN D ASSAY	ASSAY/ <i>Chromatographic Methods</i>	<i>USP43–NF38</i>	6808	28-Aug-2020		1-Sep-2020	NA	NA	<p>&lt;821&gt;) Using a suitable counting assembly, determine the radionuclidic purity of a solution or suspension of 1 or more Capsules in water: not less than 90% of the total radioactivity is present as I 123.</p> <p>In the second Calculate statement in <i>Procedure 7/ Analysis/ Precholecalciferol and pre-ergocalciferol response factor.</i> Change pre-ergolecalciferol</p>

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FUROSEMIDE TABLETS	<i>Limit of furosemide related compound B</i>	USP43–NF38	2056	31-Jul-2020		1-Aug-2020	NA	NA	to: pre-ergocalciferol Change <i>Mobile phase, Diluting solution, System suitability solution, and Chromatographic system</i> —Prepare as directed in the test for <i>Related compounds</i> under <i>Furosemide</i> . to: <i>Mobile phase</i> —Prepare a filtered and degassed mixture of water, tetrahydrofuran, and glacial acetic acid (70:30:1). Make adjustments if

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							<p>necessary (see <i>System Suitability</i> under <i>Chromatography</i> &lt;621&gt;).  <i>Diluting solution</i>—Dilute 22 mL of glacial acetic acid with a mixture of acetonitrile and water (50:50) to 1000 mL, and mix.  <i>System suitability solution</i>—Dissolve suitable quantities of USP Furosemide RS and USP Furosemide Related Compound A RS in <i>Diluting solution</i> to obtain a solution containing</p>



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							<p>about 20 µg per mL and 12 µg per mL, respectively.</p> <p><i>Chromatographic system (see Chromatography &lt;621&gt;)</i>—The liquid chromatograph is equipped with a detector capable of recording at both 254 nm and 272 nm and a 4.6-mm x 25-cm column that contains packing L1.</p> <p>[NOTE—The 2,4-dichloro-5-sulfamoylbenzoic acid impurity does not respond at 272 nm and the 2,4-bis(furfurylamino)-5-sulfamoylbenzoic acid impurity has a</p>

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							<p>very intense absorbance at 254 nm.] The flow rate is about 1.0 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 furosemide and furosemide related compound A is not less than 2.5; and the relative standard deviation determined from furosemide is not more than 2.0%. [NOTE—The response for</p>

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NUCLEIC ACID-BASED TECHNIQUES—GENERAL <i>Appendix 1</i>	USP43–NF38	7865	31-Jul-2020	1-Aug-2020	NA	NA	furosemide is at 254 nm.] In footnote 1: Change <a href="http://ts.nist.gov/measurements/services/referencematerials/index.cfm">http://ts.nist.gov/measurements/services/referencematerials/index.cfm</a> . to: <a href="https://www.nist.gov/srm">https://www.nist.gov/srm</a> .
METOPROLOL ADDITIONAL REQUIREMENTS SUCCINATE ESTER EXTENDED-RELEASE TABLETS	USP43–NF38	2918	31-Jul-2020	1-Aug-2020	NA	NA	In <i>Labeling</i> : Change as metoprolol succinate [(C <sub>15</sub> H <sub>25</sub> NO <sub>3</sub> ) <sub>2</sub> · C <sub>4</sub> H <sub>6</sub> O <sub>6</sub> ]. to: as metoprolol tartrate [(C <sub>15</sub> H <sub>25</sub> NO <sub>3</sub> ) <sub>2</sub> · C <sub>4</sub> H <sub>6</sub> O <sub>6</sub> ].
FUROSEMIDE Assay INJECTION	USP43–NF38	2054	31-Jul-2020	1-Aug-2020	NA	NA	Change <i>Mobile phase</i> , <i>Diluting solution</i> , <i>System suitability solution</i> , and <i>Chromatography</i>

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							<p><i>c</i>  <i>system</i>—Prepare as directed in the test for <i>Related compounds</i> under <i>Furosemide</i>.  to:  <i>Mobile phase</i>—Prepare a filtered and degassed mixture of water, tetrahydrofuran, and glacial acetic acid (70:30:1). Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> &lt;621&gt;).  <i>Diluting solution</i>—Dilute 22 mL of glacial acetic acid with a mixture of acetonitrile and</p>

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							<p>water (50:50) to 1000 mL, and mix.</p> <p><i>System suitability solution</i></p> <p>—Dissolve suitable quantities of USP Furosemide RS and USP Furosemide Related Compound A RS in <i>Diluting solution</i> to obtain a solution containing about 20 µg per mL and 12 µg per mL, respectively.</p> <p><i>Chromatographic system</i> (see <i>Chromatography</i> &lt;621&gt;)—The liquid chromatograph is equipped with</p>

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							<p>a detector capable of recording at both 254 nm and 272 nm and a 4.6-mm x 25-cm column that contains packing L1. [NOTE—The 2,4-dichloro-5-sulfamoylbenzoic acid impurity does not respond at 272 nm and the 2,4-bis(furfurylamino)-5-sulfamoylbenzoic acid impurity has a very intense absorbance at 254 nm.] The flow rate is about 1.0 mL per minute. Chromatograph the <i>System suitability solution</i>, and record the peak</p>

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METHYLDOPA IDENTIFICATION HYDROCHLORIDE	USP43–NF38	2880	31-Jul-2020	1-Aug-2020	NA	NA	<p>responses as directed for <i>Procedure</i>: the resolution, <i>R</i>, between furosemide and furosemide related compound A is not less than 2.5; and the relative standard deviation determined from furosemide is not more than 2.0%.  [NOTE—The response for furosemide is at 254 nm.]  In <i>C</i>: Change It responds to <i>Identification</i> test <i>C</i> under Methyldopa. to:  <i>Sample</i>: 10 mg  <i>Analysis</i>: To the <i>Sample</i> add</p>

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FUROSEMIDE Assay TABLETS	USP43–NF38	2056	31-Jul-2020	1-Aug-2020	NA	NA	<p>0.15 mL of a solution of ninhydrin in sulfuric acid (1 in 250): a dark purple color is produced within 5–10 min. Add 0.15 mL of water.</p> <p><i>Acceptance criteria:</i> The color changes to pale brownish yellow.</p> <p>Change: <i>Mobile phase, Diluting solution, System suitability solution, and Chromatographic system</i>—Prepare as directed in the test for <i>Related compounds</i> under</p>



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							<p><i>Furosemide.</i></p> <p>to:</p> <p><i>Mobile phase</i>—Prepare a filtered and degassed mixture of water, tetrahydrofuran, and glacial acetic acid (70:30:1). Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> &lt;621&gt;).</p> <p><i>Diluting solution</i>—Dilute 22 mL of glacial acetic acid with a mixture of acetonitrile and water (50:50) to 1000 mL, and mix.</p> <p><i>System suitability solution</i>—Dissolve</p>

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							<p>suitable quantities of USP Furosemide RS and USP Furosemide Related Compound A RS in <i>Diluting solution</i> to obtain a solution containing about 20 µg per mL and 12 µg per mL, respectively.</p> <p><i>Chromatographic system (see Chromatography &lt;621&gt;)</i>—The liquid chromatograph is equipped with a detector capable of recording at both 254 nm and 272 nm and a 4.6-mm x 25-cm column</p>

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							<p>that contains packing L1. [NOTE—The 2,4-dichloro-5-sulfamoylbenzoic acid impurity does not respond at 272 nm and the 2,4-bis(furfurylamino)-5-sulfamoylbenzoic acid impurity has a very intense absorbance at 254 nm.] The flow rate is about 1.0 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 furosemide and furosemide</p>

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DIBASIC CALCIUM PHOSPHATE DIHYDRATE	IMPURITIES	USP43–NF38	708	31-Jul-2020		1-Aug-2020	NA	NA	related compound A is not less than 2.5; and the relative standard deviation determined from furosemide is not more than 2.0%. [NOTE—The response for furosemide is at 254 nm.] In <i>Chloride and Sulfate, Chloride</i> <221>: Change <i>Sample</i> : 0.2 g of of Dibasic Calcium Phosphate Dihydrate to: <i>Sample</i> : 0.2 g of Dibasic Calcium Phosphate Dihydrate
SOTALOL HYD	<i>Identification</i>	USP43–NF38	4105	31-Jul-2020		1-Aug-2020	NA	NA	Change

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ROCHLORIDE TABLETS							Weigh and powder a quantity of the Tablets, equivalent to about 250 mg of sotalol hydrochloride, and transfer to a 50-mL volumetric flask. Add 25 mL of methanol, and shake for 10 minutes. Dilute with methanol to volume, mix, and filter: the filtrate so obtained meets the requirements for <i>Identification</i> test B under <i>Sotalol Hydrochloride</i> . to: <i>Thin-Layer Chromatographic Identification</i> <i>Test &lt;201&gt;—</i>

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							<p><i>Test solution</i>—Weigh and powder a quantity of the Tablets, equivalent to about 250 mg of sotalol hydrochloride, and transfer to a 50-mL volumetric flask. Add 25 mL of methanol, and shake for 10 minutes. Dilute with methanol to volume, mix, and filter. Use the filtrate.</p> <p><i>Developing solvent system:</i> a mixture of chloroform and methanol (70:30).</p> <p><i>Procedure</i>—Proceed as directed in the chapter, except to place</p>

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ANTI-FACTOR <i>Anti-Factor Xa</i> XA AND ANTI- <i>and Anti-Factor</i>	USP43–NF38	6611	31-Jul-2020	1-Aug-2020	NA	NA	two 25-mL beakers, each containing about 10 mL of ammonium hydroxide, on the bottom of the chromatographic chamber that is lined with filter paper and contains the <i>Developing solvent system</i> , allow to equilibrate for 15 minutes, then place the plate in the chamber, and develop the chromatograms until the solvent front has moved about two-thirds of the length of the plate: meets the requirements. Change <i>Anti-Factor Xa</i>

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FACTOR IIA ASSAYS FOR UNFRACTIONA TED AND LOW MOLECULAR WEIGHT HEPARINS	<i>Ila Assays for Low Molecular Weight Heparins</i>						<p><i>Activity for Low Molecular Weight Heparin to:</i></p> <p>The following procedure is used where specified in the individual monographs. This assay can be performed manually in plastic tubes utilizing heated block stations or water bath. Microtiter plate equipment with a reader and automated coagulometer can improve reproducibility and throughput. Acetic acid solution (stopping solution) is used for manual and microtiter plate</p>



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DESIGN AND ANALYSIS OF BIOLOGICAL ASSAYS	COMBINATION OF INDEPENDENT ASSAYS	USP43–NF38	6543	31-Jul-2020		1-Aug-2020	NA	NA	assay. Automated coagulometers measure initial kinetic rate, and because of that, stopping of the reaction is not needed. <i>Anti-Factor Xa Activity for Low Molecular Weight Heparin</i> In the second bullet in <i>Alternate weights</i> for inter-assay component of variation: Delete the duplicate equation
MINOCYCLINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS	PERFORMANCE TESTS/ <i>Dissolution</i> <711>	Revision <i>Bulletin (Official September 01, 2019)</i>	Online	31-Jul-2020		1-Aug-2020	NA	NA	In <i>Test 4/ Table 5</i> : Change 45/ Tablet and 90 mg/ Tablet to: 45 mg/ Tablet and 90 mg/ Tablet
FUROSEMIDE	<i>Limit of</i>	USP43–NF38	2054	31-Jul-2020		1-Aug-2020	NA	NA	Change

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INJECTION		<i>furosemide related compound B</i>							<p><i>Mobile phase, Diluting solution, System suitability solution and Chromatographic system—Prepare as directed in the test for Related compounds under Furosemide. to: Mobile phase—Prepare a filtered and degassed mixture of water, tetrahydrofuran, and glacial acetic acid (70:30:1). Make adjustments if necessary (see System Suitability under Chromatograph</i></p>

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							<p>y &lt;621&gt;).</p> <p><i>Diluting solution</i>—Dilute 22 mL of glacial acetic acid with a mixture of acetonitrile and water (50:50) to 1000 mL, and mix.</p> <p><i>System suitability solution</i>—Dissolve suitable quantities of USP Furosemide RS and USP Furosemide Related Compound A RS in <i>Diluting solution</i> to obtain a solution containing about 20 µg per mL and 12 µg per mL, respectively.</p>

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							<p><i>Chromatographic system (see Chromatography &lt;621&gt;)</i>—The liquid chromatograph is equipped with a detector capable of recording at both 254 nm and 272 nm and a 4.6-mm x 25-cm column that contains packing L1. [NOTE—The 2,4-dichloro-5-sulfamoylbenzoic acid impurity does not respond at 272 nm and the 2,4-bis(furfurylamino)-5-sulfamoylbenzoic acid impurity has a very intense absorbance at 254 nm.] The flow rate is</p>

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ETHAMBUTOL IM HYDROCHLOR PURITIES/ <i>Limit</i>	USP43–NF38	1762	31-Jul-2020	1-Aug-2020	NA	NA	<p>about 1.0 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 furosemide and furosemide related compound A is not less than 2.5; and the relative standard deviation determined from furosemide is not more than 2.0%. [NOTE—The response for furosemide is at 254 nm.] In <i>Acceptance criteria</i>: Change</p>

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IDE		<i>of Aminobutanol</i>							The fluorescence intensity of the solution from the <i>Sample solution</i> is NMT 1.0% of the difference between the intensities of the two solutions. to: The fluorescence intensity of the solution from the <i>Sample solution</i> is NMT the difference between the intensities of the two solutions (NMT 1.0%).
ATORVASTATIN CALCIUM	ADDITIONAL REQUIREMENT S/USP Reference Standards <11>	USP43–NF38	414	26-Jun-2020		1-Jul-2020	NA	NA	In USP Atorvastatin Related Compound B RS: Change 3S,5R Isomer, or

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							<p>(3<i>S</i>,5<i>R</i>)-7-[3-(phenylcarbamoyl)-5-(4-fluorophenyl)-2-isopropyl-4-phenyl]-1<i>H</i>-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid, calcium salt.</p> <p>to:</p> <p>Calcium (3<i>S</i>,5<i>R</i>)-7-[2-(4-fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)]-1<i>H</i>-pyrrol-1-yl]-3,5-dihydroxyheptanoate (1:2); also known as 3<i>S</i>,5<i>R</i> Isomer, or (3<i>S</i>,5<i>R</i>)-7-[3-(phenylcarbamoyl)-5-(4-fluorophenyl)-2-isopropyl-4-phenyl]-1<i>H</i>-pyrrol-1-yl]-3,5-</p>

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DIPHENOXYLA Assay TE HYDROCHL ORIDE AND ATROPINE SULFATE TABLETS	USP43–NF38	1439	26-Jun-2020	1-Jul-2020	NA	NA	dihydroxyhepta noic acid, calcium salt. In <i>Procedure</i> : Change 694.83/676.83)( 250) $C_A(r_U/r_S)$ in which 694.83 and 676.83 are the molecular weights of atropine sulfate monohydrate and anhydrous atropine sulfate, respectively; to: (694.84/676.82) (250) $C_A(r_U/r_S)$ in which 694.84 and 676.82 are the molecular weights of atropine sulfate monohydrate and anhydrous atropine sulfate, respectively;

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