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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.
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ISOSORBIDE	Assay	USP41–NF36	2272	27-Apr-2018	1-May-2018	USP42–NF37	Second	Change

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DINITRATE SUBLINGUAL TABLETS						<i>Supplement to USP41–NF36</i>	<i>Buffer solution, Mobile phase, Internal standard solution, Standard preparation, and Chromatographic system—Prepare as directed in the Assay under Diluted Isosorbide Dinitrate.</i> to: <i>Buffer solution</i> —Dissolve 15.4 g of ammonium acetate in water, add 11.5 mL of glacial acetic acid, dilute with water to 1000 mL, and mix to obtain a solution having a pH of about 4.7.

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							<p><i>Mobile phase</i>—Mix 350 mL of water, 100 mL of <i>Buffer solution</i>, and 550 mL of methanol. Cool to room temperature, dilute with water to 1000 mL, mix, degas, and filter. Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> &lt;621&gt;).</p> <p><i>Internal standard solution</i>—Transfer a quantity of diluted nitroglycerin to a suitable volumetric flask, add about 60% of the flask volume of</p>

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							<p>methanol, sonicate for 5 minutes, and shake for 30 minutes. Dilute with methanol to volume to obtain a solution having a concentration of about 3 mg of nitroglycerin per mL, and mix. Allow any undissolved material to settle, filter, and store the filtrate in an airtight container.</p> <p><i>Standard preparation</i></p> <p>—Transfer about 125 mg of recently mixed USP Diluted Isosorbide Dinitrate RS, accurately weighed, to a</p>

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							50-mL volumetric flask, add about 30 mL of <i>Mobile phase</i> , shake for 30 minutes, dilute with <i>Mobile phase</i> to volume, and mix. Pipet 10 mL of the resulting solution into a 25-mL volumetric flask, and add 4.0 mL of <i>Internal standard solution</i> and 4 mL of dilute <i>Buffer solution</i> (1 in 10). Cool to room temperature, dilute with <i>Mobile phase</i> to volume, and mix to obtain a solution having a known concentration of

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							<p>about 0.25 mg of isosorbide dinitrate per mL, based on the quantity of USP Diluted Isosorbide Dinitrate RS weighed and the labeled content of isosorbide dinitrate. Pass a portion of this solution through a 0.45-<math>\mu</math>m filter. AND Add</p> <p><i>Chromatographic system (see Chromatography &lt;621&gt;)</i>—The liquid chromatograph is equipped with a 220-nm detector and a 4-mm x 25-cm column that contains packing L1. The</p>

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							<p>flow rate is about 1 mL per minute.</p> <p>Chromatograph the <i>Standard preparation</i>, and record the peak responses as directed for <i>Procedure</i>: the resolution, <i>R</i>, between isosorbide dinitrate and nitroglycerin is not less than 2.0; and the relative standard deviation for replicate injections determined from the peak response ratios is not more than 2%. [Note—The relative retention times are about 0.75 for isosorbide</p>

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							<p>dinitrate and 1.0 for nitroglycerin. The relative retention times for isosorbide mononitrates, if present, are about 0.38.]</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>Diluted Isosorbide Dinitrate</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</p>



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REAGENTS	SOLUTIONS/Volumetric Solutions	USP41–NF36	5769	27-Apr-2018		1-May-2018	USP42–NF37	Second Supplement to USP41–NF36	chromatograms, and measure the responses for the major peaks. Line 1 of 0.1 N Potassium Hydroxide VS: Change Transfer 100 mL of potassium hydroxide to a 1000-mL volumetric flask. to: Transfer 100 mL of 1 N Potassium Hydroxide VS to a 1000-mL volumetric flask.
REPOSITORY CORTICOTROPIN INJECTIONS	ADDITIONAL REQUIREMENT	USP41–NF36	1097	27-Apr-2018		1-May-2018	USP42–NF37	Second Supplement to USP41–NF36	In USP Reference Standards <11>: Add USP Ascorbic Acid RS Change
ISOSORBIDE DINITRATE CHEWABLE	Assay	USP41–NF36	2270	27-Apr-2018		1-May-2018	USP42–NF37	Second Supplement to USP41–NF36	Buffer solution, Mobile phase,

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TABLETS							<p><i>Internal standard solution, Standard preparation, and Chromatographic system—Prepare as directed in the Assay under Diluted Isosorbide Dinitrate.</i></p> <p>to:</p> <p><i>Buffer solution</i></p> <p>—Dissolve 15.4 g of ammonium acetate in water, add 11.5 mL of glacial acetic acid, dilute with water to 1000 mL, and mix to obtain a solution having a pH of about 4.7.</p> <p><i>Mobile phase—Mix 350</i></p>

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							<p>mL of water, 100 mL of <i>Buffer solution</i>, and 550 mL of methanol. Cool to room temperature, dilute with water to 1000 mL, mix, degas, and filter. Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> &lt;621&gt;.)</p> <p><i>Internal standard solution</i></p> <p>—Transfer a quantity of diluted nitroglycerin to a suitable volumetric flask, add about 60% of the flask volume of methanol, sonicate for 5</p>

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							<p>minutes, and shake for 30 minutes. Dilute with methanol to volume to obtain a solution having a concentration of about 3 mg of nitroglycerin per mL, and mix. Allow any undissolved material to settle, filter, and store the filtrate in an airtight container.</p> <p><i>Standard preparation</i></p> <p>—Transfer about 125 mg of recently mixed USP Diluted Isosorbide Dinitrate RS, accurately weighed, to a 50-mL volumetric flask,</p>

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							add about 30 mL of <i>Mobile phase</i> , shake for 30 minutes, dilute with <i>Mobile phase</i> to volume, and mix. Pipet 10 mL of the resulting solution into a 25-mL volumetric flask, and add 4.0 mL of <i>Internal standard solution</i> and 4 mL of dilute <i>Buffer solution</i> (1 in 10). Cool to room temperature, dilute with <i>Mobile phase</i> to volume, and mix to obtain a solution having a known concentration of about 0.25 mg of isosorbide

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							<p>dinitrate per mL, based on the quantity of USP Diluted Isosorbide Dinitrate RS weighed and the labeled content of isosorbide dinitrate. Pass a portion of this solution through a 0.45-<math>\mu</math>m filter.</p> <p>AND</p> <p>Add</p> <p><i>Chromatographic system (see Chromatography &lt;621&gt;)</i>—The liquid chromatograph is equipped with a 220-nm detector and a 4-mm x 25-cm column that contains packing L1. The flow rate is about 1 mL per</p>

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							<p>minute.</p> <p>Chromatograph the <i>Standard preparation</i>, and record the peak responses as directed for <i>Procedure</i>: the resolution, <i>R</i>, between isosorbide dinitrate and nitroglycerin is not less than 2.0; and the relative standard deviation for replicate injections determined from the peak response ratios is not more than 2%. [Note—The relative retention times are about 0.75 for isosorbide dinitrate and 1.0 for nitroglycerin.</p>

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							<p>The relative retention times for isosorbide mononitrates, if present, are about 0.38.]  AND  Line 1 of  <i>Procedure:</i>  Change  Proceed as directed for  <i>Procedure</i> in the Assay under  <i>Diluted Isosorbide Dinitrate.</i>  to:  Separately inject equal volumes (about 20 µL) of the  <i>Standard preparation</i> and the Assay  <i>preparation</i> into the chromatograph, record the chromatograms, and measure</p>



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REAGENTS	REAGENT SPECIFICATIONS	USP41–NF36	5680	27-Apr-2018		1-May-2018	USP42–NF37	Second Supplement to USP41–NF36	the responses for the major peaks. Line 1 of Carbon Disulfide, CS: Change Carbon Disulfide, CS to: Carbon Disulfide, CS <sub>2</sub>
COLCHICINE	IM PURITIES/Limit of Ethyl Acetate/System suitability/Suitability requirements	First Supplement to USP41–NF36	8314	27-Apr-2018		1-May-2018	USP42–NF37	Second Supplement to USP41–NF36	Delete Tailing factor. NMT 2.0 for the menthol peak
ARGATROBAN	IM PURITIES/Organic Impurities	USP41–NF36	346	27-Apr-2018		1-May-2018	USP42–NF37	Second Supplement to USP41–NF36	Footnote b of Table 2: Change Ethyl (2R,4R)-1-[N <sup>8</sup> -nitro-L-arginyl]-4-methylpiperidine-2-carboxylate hydrochloride. to: Ethyl (4R)-1-[N <sup>8</sup> -nitro-

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ISOSORBIDE Assay DINITRATE TABLETS	USP41–NF36	2270	27-Apr-2018	1-May-2018	USP42–NF37	Second Supplement to USP41–NF36	L-arginyl]-4-methylpiperidine-2-carboxylate. Change Buffer solution, Mobile phase, Internal standard solution, Standard preparation, and Chromatographic system—Prepare as directed in the Assay under Diluted Isosorbide Dinitrate. to: Buffer solution —Dissolve 15.4 g of ammonium acetate in water, add 11.5 mL of glacial acetic acid, dilute with water to 1000 mL, and

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							<p>mix to obtain a solution having a pH of about 4.7.</p> <p><i>Mobile phase</i>—Mix 350 mL of water, 100 mL of <i>Buffer solution</i>, and 550 mL of methanol. Cool to room temperature, dilute with water to 1000 mL, mix, degas, and filter. Make adjustments if necessary (see <i>System Suitability</i> under <i>Chromatography</i> &lt;621&gt;).</p> <p><i>Internal standard solution</i> —Transfer a quantity of diluted nitroglycerin to a suitable</p>

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							<p>volumetric flask, add about 60% of the flask volume of methanol, sonicate for 5 minutes, and shake for 30 minutes. Dilute with methanol to volume to obtain a solution having a concentration of about 3 mg of nitroglycerin per mL, and mix. Allow any undissolved material to settle, filter, and store the filtrate in an airtight container.</p> <p><i>Standard preparation</i></p> <p>—Transfer about 125 mg of recently mixed USP Diluted</p>

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							<p>Isosorbide Dinitrate RS, accurately weighed, to a 50-mL volumetric flask, add about 30 mL of <i>Mobile phase</i>, shake for 30 minutes, dilute with <i>Mobile phase</i> to volume, and mix. Pipet 10 mL of the resulting solution into a 25-mL volumetric flask, and add 4.0 mL of <i>Internal standard solution</i> and 4 mL of dilute <i>Buffer solution</i> (1 in 10). Cool to room temperature, dilute with <i>Mobile phase</i> to volume, and</p>

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							<p>mix to obtain a solution having a known concentration of about 0.25 mg of isosorbide dinitrate per mL, based on the quantity of USP Diluted Isosorbide Dinitrate RS weighed and the labeled content of isosorbide dinitrate. Pass a portion of this solution through a 0.45-<math>\mu</math>m filter.</p> <p>AND</p> <p>Add</p> <p><i>Chromatographic system (see Chromatography &lt;621&gt;)</i>—The liquid chromatograph is equipped with a 220-nm detector and a</p>

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							<p>4-mm x 25-cm column that contains packing L1. The flow rate is about 1 mL per minute.</p> <p>Chromatograph the <i>Standard preparation</i>, and record the peak responses as directed for <i>Procedure</i>: the resolution, <i>R</i>, between isosorbide dinitrate and nitroglycerin is not less than 2.0; and the relative standard deviation for replicate injections determined from the peak response ratios is not more than 2%. [Note—The</p>

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							<p>relative retention times are about 0.75 for isosorbide dinitrate and 1.0 for nitroglycerin. The relative retention times for isosorbide mononitrates, if present, are about 0.38.]</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>Diluted Isosorbide Dinitrate</i>. to: Separately inject equal volumes (about 20 µL) of the <i>Standard preparation</i> and the <i>Assay</i></p>



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ZONISAMIDE CAPSULES	PERFORMANCE TESTS/ <i>Dissolution</i> <711>	USP41–NF36	4410	27-Apr-2018		1-May-2018	USP42–NF37	<i>Second Supplement to USP41–NF36</i>	<p><i>preparation</i> into the chromatograph, record the chromatograms, and measure the responses for the major peaks.</p> <p>Line 1 of <i>Apparatus 2</i>: Change 75 rpm, with sinkers (see <i>Dissolution</i> &lt;711&gt;, <i>Figure 2a</i>) to: 75 rpm. Use suitable sinkers, if necessary.</p>
REAGENTS/INDICATORS AND SOLUTIONS	SOLVENTION <i>S/Volumetric Solutions/0.01 M Sodium Thiosulfate VS</i>	USP41–NF36	5772	27-Apr-2018		1-May-2018	USP42–NF37	<i>Second Supplement to USP41–NF36</i>	<p>In the equation in <i>Standardization</i>: Change N = mg <math>K_2Cr_2O_7/49.04 \times mL Na_2S_2O_3</math> to: M = mg K</p>

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DESLORATADINE TABLETS	USP41–NF36	1178	27-Apr-2018	1-May-2018	USP42–NF37	Second Supplement to USP41–NF36	$2\text{Cr}_2\text{O}_7/49.04 \text{ x mL Na}_2\text{S}_2\text{O}_3$ Organic Impurities: Add Protect all solutions containing desloratadine from light.
ISOSORBIDE DINITRATE SUBLINGUAL TABLETS	USP41–NF36	2272	27-Apr-2018	1-May-2018	USP42–NF37	Second Supplement to USP41–NF36	Identification Line 1: Change Tablets respond to the Identification test under Isosorbide Dinitrate Tablets. to: Transfer a suitable quantity of finely powdered Tablets to a glass-stoppered centrifuge tube. Add 10 mL of sodium hydroxide solution (1 in 250), shake to wet the powder,

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							<p>then add 15 mL of solvent hexane, and again shake. Centrifuge the mixture, and transfer the upper phase to a beaker. Evaporate the solvent, and dry the residue in vacuum over anhydrous calcium chloride at room temperature for 16 hours: the IR absorption spectrum of a suitable solution in chloroform of the residue so obtained exhibits maxima only at the same wavelengths as that of a similar preparation from the residue</p>

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HYDROGENATED VEGETABLE OIL DEFINITION	USP41–NF36	5649	27-Apr-2018	1-May-2018	USP42–NF37	Second Supplement to USP41–NF36	obtained from USP Diluted Isosorbide Dinitrate RS. Line 2: Change The melting range, heavy metals limit, iodine value, and saponification value differ, to: The melting range, iodine value, and saponification value differ,
PEMETREXED ASSAY/ FOR INJECTION	First Supplement to USP41–NF36 <i>Procedure/Analysis</i>	Online	27-Apr-2018	1-May-2018	USP42–NF37	Second Supplement to USP41–NF36	Line 8 of the variable definition list: Change $M_{r2}$ = molecular weight of pemetrexed disodium (anhydrous), 473.37 to: $M_{r2}$ = molecular weight of

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SALMETEROL INHALATION POWDER	ADDITIONAL REQUIREMENT S/USP Reference Standards <11>	USP40–NF35	6096	30-Mar-2018		1-Apr-2018	USP42–NF37	USP42–NF37	pemetrexed disodium (anhydrous), 471.38 Line 2 of USP Salmeterol Related Compound H RS: Change 1-Hydroxy-4-[2-hydroxy-5-(1-hydroxy-2-[[6-(4-p henylbutoxy)he xyl]amino}ethyl) benzyl]-2-napht hoic acid. $C_{36}H_{43}NO_6$ 585.73 to: 1-Hydroxy-4-[2-hydroxy-5-(1-hydroxy-2-[[6-(4-p henylbutoxy)he xyl]amino}ethyl) benzyl]-2-napht hoic acid, monohydrate. $C_{36}H_{43}NO_6 \cdot H_2O$ 603.76
FLUTICASONE PROPIONATE	ADDITIONAL REQUIREMENT	USP40–NF35	4309	30-Mar-2018		1-Apr-2018	USP42–NF37	USP42–NF37	Line 2 of USP Salmeterol

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AND SALMETEROL INHALATION POWDER	<i>S/USP Reference Standards &lt;11&gt;</i>								Related Compound H RS: Change 1-Hydroxy-4-[2-hydroxy-5-(1-hydroxy-2-[[6-(4-p henylbutoxy)he xyl]amino}ethyl) benzyl]-2-napht hoic acid. $C_{36}H_{43}NO_6$ 585.73 to: 1-Hydroxy-4-[2-hydroxy-5-(1-hydroxy-2-[[6-(4-p henylbutoxy)he xyl]amino}ethyl) benzyl]-2-napht hoic acid, monohydrate. $C_{36}H_{43}NO_6 \cdot H_2O$ 603.76
PLASTIC MATERIALS OF CONSTRU CTION	TEST METHODS/ <i>Tin in Non-Tin-Stabilized Materials</i>	<i>USP41–NF36</i>	6403	30-Mar-2018		1-Apr-2018	<i>USP42–NF37</i>	<i>USP42–NF37</i>	Line 3 of <i>Sample solution</i> : Change If the solution is not colorless, add the sodium sulfate

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PERINDOPRIL IM ERBUMINE PURITIES/ <i>Limit of Perindopril Related Compound //System suitability</i>	USP40–NF35	5644	30-Mar-2018	1-Apr-2018	USP42–NF37	USP42–NF37	to: If the solution is not colorless, add the sodium sulfite Line 3: Add [Note—The relative retention times for perindopril and perindopril related compound I are 1.0 and 1.6, respectively.]
CHLORHEXIDI NE GLUCONATE ORAL RINSE	USP40–NF35	3367	23-Feb-2018	1-Mar-2018	USP42–NF37	Second Supplement to USP41–NF36	Line 1 of C: Change Undiluted Oral Rinse used as the test solution meets the requirements for <i>Identification</i> test <i>B</i> under <i>Calcium Gluconate</i> , except that a Standard solution containing about 0.6 mg of

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							<p>USP Potassium Gluconate RS per mL is used and 15 ?L of the test solution and the Standard solution are applied to the thin-layer chromatographic plate.</p> <p>to:</p> <p>Use undiluted Oral Rinse as the test solution and prepare a Standard solution of USP Potassium Gluconate RS in water containing 0.6 mg/mL. Apply separate 15-?L portions of the test solution and the Standard solution to a suitable thin-</p>



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							<p>layer chromatographic plate (see <i>Chromatography</i> &lt;621&gt;) coated with a 0.25-mm layer of chromatographic silica gel, and allow to dry. Develop the chromatogram in a solvent system consisting of a mixture of alcohol, water, ammonium hydroxide, and ethyl acetate (50:30:10:10) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and dry at 110° for 20 minutes.</p>

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							<p>Allow to cool and spray with a spray reagent prepared as follows.</p> <p>Dissolve 2.5 g of ammonium molybdate in about 50 mL of 2 N sulfuric acid in a 100-mL volumetric flask, add 1.0 g of ceric sulfate, swirl to dissolve, dilute with 2 N sulfuric acid to volume, and mix. Heat the plate at 110° for about 10 minutes: the principal spot obtained from the test solution corresponds in color, size, and <math>R_F</math> value to that obtained from the Standard solution.</p>

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REAGENTS	REAGENT SPECIFICATIONS	USP41–NF36	5724	23-Feb-2018		1-Mar-2018	USP42–NF37	Second Supplement to USP41–NF36	Line 2 of 9Z-Retinoic Acid: Change Acidalitretinoin), to: Alitretinoin),
AMLODIPINE AND ATORVASTATIN TABLETS	IMPURITIES/Organic Impurities Related to Atorvastatin	First Supplement to USP41–NF36	8270	23-Feb-2018		1-Mar-2018	USP42–NF37	Second Supplement to USP41–NF36	In the variable definition list in Analysis: Change $M_{r2}$ = molecular weight of atorvastatin calcium, 1209.39 to: $M_{r2}$ = molecular weight of atorvastatin calcium, 1155.34
PIPERACILLIN AND TAZOBACTAM FOR INJECTION	IMPURITIES/Organic Impurities, Procedure 2/ Table 3	USP40–NF35	5728	23-Feb-2018		1-Mar-2018	USP42–NF37	Second Supplement to USP41–NF36	Footnote m: Change (2S,5R,6R)-Ethyl 6-((R)-2-((2S,5R,6R)-6-((R)-2-(4-ethyl-2,3-dioxopiperazine-1-carboxamido

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AMLODIPINE ASSAY/ AND ATORVAS Procedure TATIN	<i>First Supplement to USP41–NF36</i>	8270	23-Feb-2018	1-Mar-2018	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	)-2-phenylaceta mido]-3,3-dimet hyl-7-oxo-4-thia -1-azabicyclo[3. 2.0]heptane-2-c arboxamido}-2- phenylacetamid o)-3,3-dimethyl- 7-oxo-4-thia-1-a zabicyclo[3.2.0] heptane-2-carb oxylate. to: 2-(((3-Acetyl-4-( ethoxycarbonyl) -5,5-dimethylthi azolidin-2-yl)me thyl)amino)-2-ox o-1-phenylethyl 6-(2-(4-ethyl-2,3 -dioxopiperazin e-1-carboxamid o)-2-phenylacet amido)-3,3-dim ethyl-7-oxo-4-thi a-1-azabicyclo[ 3.2.0]heptane-2 -carboxylate. In the variable definition list of the second

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TABLETS									
NOREPINEPH RINE BITARTRATE	IDENTIFICATIO N/B. Procedure	USP40–NF35	5380	23-Feb-2018		1-Mar-2018	USP42–NF37	Second Supplement to USP41–NF36	equation in <i>Analysis</i> : Change $M_{r2}$ = molecular weight of atorvastatin calcium, 1209.39 to: $M_{r2}$ = molecular weight of atorvastatin calcium, 1155.34 Line 1 of <i>Analysis</i> : Change Add 1 drop of ferric chloride TS. to: Add 1 drop of ferric chloride TS to 2 mL of <i>Sample solution</i> .
INHALATION AND NASAL DRUG PRODUCTS: AEROSOLS,	C. AERODYNA MIC SIZE DIST RIBUTION—INH ALATION AEROSOLS,	USP41–NF36	6327	23-Feb-2018		1-Mar-2018	USP42–NF37	Second Supplement to USP41–NF36	<i>Figure 6</i> : Change Boquilla del Inhalador to:

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SPRAYS, AND SPRAYS, AND POWDERS—PERFORMANCE QUALITY TESTS									Inhaler Mouthpiece AND Change Tubo de Admisión to: Induction Port AND Change Cono de Ingreso to: Entrance Cone
ANTIBIOTICS—CALCULATION MICROBIAL ASSAYS	<i>S/Turbidimetric Assay/Sample Data</i>	<i>USP40–NF35</i>	143	23-Feb-2018		1-Mar-2018	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	Second equation in <i>Step 1</i> : Change 0.0125 = to: 0.0062 = AND Third equation in <i>Step 1</i> : Change 0.0325 = to: 0.0322 =
PAROXETINE HYDROCHLORIDE ADDITIONAL REQUIREMENT	<i>R S/USP Reference</i>	<i>First Supplement to USP40–NF35</i>	Online	23-Feb-2018		1-Mar-2018	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	Line 1 of USP Paroxetine Related Compound F

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<i>Standards &lt;11&gt;</i>									
AMLODIPINE AND ATORVASE TATIN TABLETS	PERFORMANC TESTS/ <i>Dissolution</i> <711>	<i>First Supplement to USP41–NF36</i>	8270	23-Feb-2018		1-Mar-2018	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	RS: Change <i>trans</i> (?) -1-Methyl-3-[1,3-benzodioxol-5-yloxy)methyl]-4-(fluorophenyl)piperidine. to: (3 <i>S</i> ,4 <i>R</i> )-3-[(Benzodioxol-5-yloxy)methyl]-4-(4-fluorophenyl)-1-methylpiperidine. In the variable definition list of the second equation in <i>Analysis</i> : Change $M_{r2}$ = molecular weight of atorvastatin calcium, 1209.39 to: $M_{r2}$ = molecular weight of atorvastatin calcium, 1155.34

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NOREPINEPHRINE BITARTRATE	ASSAY/ <i>Procedure</i>	USP40–NF35	5380	23-Feb-2018		1-Mar-2018	USP42–NF37	<i>Second Supplement to USP41–NF36</i>	Line 1 of <i>Sample solution</i> : Change 25 mg/mL of Norepinephrine Bitartrate in glacial acetic acid. If necessary warm slightly to effect solution. to: Dissolve 500 mg of Norepinephrine Bitartrate in 20 mL of glacial acetic acid, warming slightly if necessary to effect solution.
STATISTICAL TOOLS FOR PROCEDURE VALIDATION	3. ACCURACY AND PRECISION/3.1 <i>Methods for Estimating Accuracy and Precision</i>	USP41–NF36	7622	23-Feb-2018		1-Mar-2018	USP42–NF37	<i>Second Supplement to USP41–NF36</i>	Paragraph 4: Change For example, with $\alpha = 0.05$ and $n = 9$ , $t_{0.95;8} = 1.860$ provides a $100(1 - 2 \times 0.05)\%$



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POWDERED ECHINACEA PALLIDA EXTRACT	IDENTIFICATIO N	USP40–NF35	6935	26-Jan-2018		1-Feb-2018	USP42–NF37	Second Supplement to USP41–NF36	<p>to:  For example, with <math>\alpha = 0.05</math> and <math>n = 9</math>, <math>t_{0.95;8} = 1.860</math> provides a <math>100(1 - \alpha)^2 \times 0.05\%</math> Line 5 of A. <i>Thin-Layer Chromatography/Presence of echinacoside and absence of dicaffeoylquinic acid/System suitability.</i> Change <i>Standard solution B</i> shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower <math>R_F</math>) and chlorogenic acid (higher <math>R_F</math>) that are clearly</p>

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							<p>separated, to:  <i>Standard solution B</i> shows two major blue bands at about the middle of the chromatogram due to caftaric acid (higher <math>R_F</math>) and chlorogenic acid (lower <math>R_F</math>) that are clearly separated, AND            Lines 3 and 6 of C.: Change <i>Standard solution B</i>, to:  <i>Standard solution C</i>, AND            Change <i>Standard solution C</i>) to:  <i>Standard solution D</i>)</p>

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PHENYTOIN ORAL SUSPENSION	PERFORMANCE TESTS/ <i>Dissolution</i> <711>	USP41–NF36	3286	26-Jan-2018		1-Feb-2018	USP42–NF37	<i>Second Supplement to USP41–NF36</i>	In the <i>Analysis</i> : Change $C_S$ = concentration of USP Phenytoin RS in the <i>Standard solution</i> to: $C_S$ = concentration of USP Phenytoin RS in the <i>Standard solution</i> (mg/mL)
ESZOPICLONE TABLETS	ADDITIONAL REQUIREMENT S/USP Reference Standards <11>	<i>Revision Bulletin (Official August 01, 2017)</i>	Online	26-Jan-2018		1-Feb-2018	USP42–NF37	<i>Second Supplement to USP41–NF36</i>	Line 2 of USP Eszopiclone Related Compound A RS: Change 6-(5-Chloropyridin-2-yl)-7-oxo-6,7-dihydro-5H-pyridolo[3,4-b]pyrazin-5-yl 4-methylpiperazine-1-carboxylate 4-oxide.

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							<p>C<sub>17</sub>H<sub>17</sub>ClN<sub>6</sub>O<sub>4</sub> 404.81 to: [Note—This material may be available in the free base or salt form.] 6-(5-Chloropyridin-2-yl)-7-oxo-6,7-dihydro-5H-pyrido[3,4-b]pyrazin-5-yl 4-methylpiperazine-1-carboxylate 4-oxide.</p> <p>C<sub>17</sub>H<sub>17</sub>ClN<sub>6</sub>O<sub>4</sub> 404.81 6-(5-Chloropyridin-2-yl)-7-oxo-6,7-dihydro-5H-pyrido[3,4-b]pyrazin-5-yl 4-methylpiperazine-1-carboxylate 4-oxide, 3-chlorobenzoic</p>

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POWDERED DIGITALIS	IDENTIFICATION N/B. <i>Thin-Layer Chromatographic Identification Test</i>	USP40–NF35	3762	26-Jan-2018		1-Feb-2018	USP42–NF37	<i>Second Supplement to USP41–NF36</i>	<p>salt (1:1).  <math>C_{17}H_{17}ClN_6O_4 \cdot C_7H_5ClO</math> 561.38</p> <p>Line 3 of <i>Standard solution A</i>:  Change lead acetate, to:  lead acetate TS,  AND</p> <p>Line 11 of <i>Analysis</i>:  Change  Locate the two prominent bands from <i>Standard solution A</i> corresponding in <math>R_F</math> value to the two bands from <i>Standard solution B</i>.  to:  Locate the prominent bands from <i>Standard solution A</i></p>

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NEVIRAPINE TABLETS	IMPURITIES/ <i>Organic Impurities</i>	USP40–NF35	5333	26-Jan-2018		1-Feb-2018	USP42–NF37	Second Supplement to USP41–NF36	corresponding in $R_F$ value to the band from <i>Standard solution B</i> . Line 1 of <i>Standard solution</i> : Change 0.125 ?g/mL of USP Nevirapine Anhydrous RS from <i>Standard stock solution A</i> in <i>Diluent</i> to: 0.125 ?g/mL of USP Nevirapine Anhydrous RS in <i>Diluent</i>
ECHINACEA PALLIDA	IDENTIFICATION	USP40–NF35	6931	26-Jan-2018		1-Feb-2018	USP42–NF37	Second Supplement to USP41–NF36	Line 5 of <i>A</i> . <i>Thin-Layer Chromatography/Presence of echinacoside and absence of dicaffeoylquinic acid/System suitability</i> . Change <i>Standard</i>

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							<p><i>solution B</i> shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower <math>R_F</math>) and chlorogenic acid (higher <math>R_F</math>) that are clearly separated, to:</p> <p><i>Standard solution B</i> shows two major blue bands at about the middle of the chromatogram due to caftaric acid (higher <math>R_F</math>) and chlorogenic acid (lower <math>R_F</math>) that are clearly separated, AND  Lines 3 and 6 of C.: Change</p>

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POWDERED ECHINACEA PURPUREA	IDENTIFICATION	USP40–NF35	6942	26-Jan-2018		1-Feb-2018	USP42–NF37	Second Supplement to USP41–NF36	<p>Standard solution B, to: Standard solution C, AND Change Standard solution C) to: Standard solution D)</p> <p>Line 3 of A. Thin-Layer Chromatography/ Presence of chicoric acid and absence of echinacoside/System suitability: Change Standard solution B shows two major blue bands at about the middle of the</p>



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ECHINACEA SPECIES POWDER CAPSULES	IDENTIFICATIO N	USP41–NF36	4595	26-Jan-2018		1-Feb-2018	USP42–NF37	Second Supplement to USP41–NF36	<p>chromatogram due to caftaric acid (lower <math>R_F</math>) and chlorogenic acid (higher <math>R_F</math>) that are clearly separated, to:</p> <p><i>Standard solution B</i> shows two major blue bands at about the middle of the chromatogram due to caftaric acid (higher <math>R_F</math>) and chlorogenic acid (lower <math>R_F</math>) that are clearly separated,</p> <p>Line 4 of A. HPTLC for Articles of Botanical Origin &lt;203&gt;/For Capsules containing <i>Echinacea angustifolia</i></p>

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							<p><i>powder prepared from dried rhizome and roots/System suitability.</i></p> <p>Change <i>Standard solution B</i> shows two major blue bands at about the middle section due to caftaric acid (lower <math>R_F</math>) and chlorogenic acid (higher <math>R_F</math>) that are clearly separated, to:</p> <p><i>Standard solution B</i> shows two major blue bands at about the middle section due to caftaric acid (higher <math>R_F</math>) and chlorogenic acid</p>

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TIMOLOL MALEATE	ADDITIONAL R EQUIREMENT S/USP Reference Standards <11>	<i>First Supplement to USP40–NF35</i>	8416	26-Jan-2018		1-Feb-2018	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	(lower $R_F$ ) that are clearly separated, Line 2 of USP Timolol Related Compound A RS: Change <i>(R)</i> -1-( <i>tert</i> -Butylamino)-3-(4-morpholino-1,2,5-thiadiazol-3-yloxy)propan-2-ol. $C_{13}H_{24}N_4O_3S$ 316.42 to:  <i>(R)</i> -1-( <i>tert</i> -Butylamino)-3-(4-morpholino-1,2,5-thiadiazol-3-yloxy)propan-2-ol maleate. $C_{13}H_{24}N_4O_3S \cdot C_4H_4O_4$ 432.49 AND Line 2 of USP Timolol Related Compound C RS: Change <i>N</i> -( <i>tert</i>

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							<p>-Butyl)-2,3-bis(4-morpholino-1,2,5-thiadiazol-3-yl)propan-1-amine.</p> <p><math>C_{19}H_{31}N_7O_4S_2</math> 485.19</p> <p>to:</p> <p><i>N</i>-(<i>tert</i>-Butyl)-2,3-bis(4-morpholino-1,2,5-thiadiazol-3-yl)propan-1-amine maleate.</p> <p><math>C_{19}H_{31}N_7O_4S_2</math> ? <math>C_4H_4O_4</math> 601.69 AND Line 3 of USP Timolol Related Compound D RS: Change <math>C_6H_9N_7O_4S</math> to: <math>C_6H_9N_3O_2S</math> AND Line 2 of USP Timolol Related Compound E RS: Change (<i>S</i>)-3-(<i>tert</i>-Butylamino)-1-(</p>

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IMMUNOLOGICAL TEST METHODS—ENZYMELINKED IMMUNOSORBENT ASSAY (ELISA)	USP40—NF35	1344	26-Jan-2018	1-Feb-2018	USP42—NF37	Second Supplement to USP41—NF36	<p>4-morpholino-1,2,5-thiadiazol-3-yl)oxy]propan-2-yl hydrogen maleate.  <math>C_{17}H_{26}N_4O_6S</math>  414.48  to:</p> <p>(S,Z)-4-({1-(tert-Butylamino)-3-[(4-morpholino-1,2,5-thiadiazol-3-yl)oxy]propan-2-yl}oxy)-4-oxobut-2-enoic acid maleate salt (1:1)  <math>C_{17}H_{26}N_4O_6S</math> ?  <math>C_4H_4O_4</math> 530.55  Line 7 of <i>Coating the Solid Phase—Immobilization of Capture Reagent.</i>  Change  1–10 µg/well  to:  1–10 µg/mL</p>

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ESZOPICLONE ADDITIONAL REQUIREMENT S/USP Reference Standards <11>	USP40–NF35	4090	26-Jan-2018	1-Feb-2018	USP42–NF37	Second Supplement to USP41–NF36	Line 2 of USP Eszopiclone Related Compound A RS: Change 6-(5-Chloropyridin-2-yl)-7-oxo-6,7-di hydro-5H -pyr rolo[3,4 -b]pyrazin-5-yl 4 -methylpiperazine-1-carboxylate 4-oxide. $C_{17}H_{17}ClN_6O_4$ 404.81 to: [Note—This material may be available in the free base or salt form.] 6-(5-Chloropyridin-2-yl)-7-oxo-6,7-di hydro-5H -pyr rolo[3,4 -b]pyrazin-5-yl 4 -methylpiperazi

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POWDERED IDENTIFICATION ECHINACEA ANNUA ANGUSTIFOLIA	USP40–NF35	6926	26-Jan-2018	1-Feb-2018	USP42–NF37	Second Supplement to USP41–NF36	ne-1-carboxylate 4-oxide. C <sub>17</sub> H <sub>17</sub> ClN <sub>6</sub> O <sub>4</sub> 404.81 6-(5-Chloropyridin-2-yl)-7-oxo-6,7-dihydro-5H-pyridolo[3,4-b]pyrazin-5-yl 4-methylpiperazine-1-carboxylate 4-oxide, 3-chlorobenzoic salt (1:1). C <sub>17</sub> H <sub>17</sub> ClN <sub>6</sub> O <sub>4</sub> · C <sub>7</sub> H <sub>5</sub> ClO 561.38 Line 5 of A. <i>Thin-Layer Chromatography/Presence of echinacoside and dicaffeoylquinic acid/System suitability.</i> Change Standard solution B shows two

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							<p>major blue bands at about the middle of the chromatogram due to caftaric acid (lower <math>R_F</math>) and chlorogenic acid (higher <math>R_F</math>) that are clearly separated, to:</p> <p><i>Standard solution B</i> shows two major blue bands at about the middle of the chromatogram due to caftaric acid (higher <math>R_F</math>) and chlorogenic acid (lower <math>R_F</math>) that are clearly separated, AND</p> <p>Line 3 of C.: Change <i>Standard solution B,</i></p>



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ECHINACEA PURPUREA AERIAL PARTS	IDENTIFICATIO N	USP40–NF35	6937	26-Jan-2018		1-Feb-2018	USP42–NF37	Second Supplement to USP41–NF36	to: Standard solution C, Line 3 of A. Thin-Layer Chromatography/ Presence of chicoric acid and absence of echinacoside/ System suitability. Change Standard solution B shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower $R_f$ ) that are clearly separated, to: Standard solution B shows two

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ECHINACEA IDENTIFICATIO SPECIES DRY N EXTRACT CAPSULES	USP41–NF36	4590	26-Jan-2018	1-Feb-2018	USP42–NF37	Second Supplement to USP41–NF36	major blue bands at about the middle of the chromatogram due to caftaric acid (higher $R_F$ ) and chlorogenic acid (lower $R_F$ ) that are clearly separated, Line 4 of A. HPTLC for Articles of Botanical Origin <203>/For Capsules containing Echinacea angustifolia Dry Extract/System suitability. Change Standard solution B shows two major blue bands at about the middle section due to caftaric acid

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QUETIAPINE E IM XTENDED- RELEASE TABLETS	PUR ITIES/ <i>Organic Impurities</i>	Revision <i>Bulletin (Official November 01, 2017)</i>	Online	26-Jan-2018	1-Feb-2018	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	(lower $R_F$ ) and chlorogenic acid (higher $R_F$ ) that are clearly separated, to: <i>Standard solution B</i> shows two major blue bands at about the middle section due to caftaric acid (higher $R_F$ ) and chlorogenic acid (lower $R_F$ ) that are clearly separated, Footnote a of <i>Table 5:</i> Change total impurities. to: total degradation products. AND Footnote b: Change total impurities.

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DOBUTAMINE IN DEXTROSE INJECTION	<i>Identification</i>	<i>USP40–NF35</i>	3843	26-Jan-2018		1-Feb-2018	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	to: total degradation products. Line 1 of <i>B</i> : Change It meets the requirements for the <i>Identification</i> test under <i>Dextrose</i> . to: Add a few drops of a solution (1 in 20) to 5 mL of hot alkaline cupric tartrate TS. A copious red precipitate of cuprous oxide is formed.
TIMOLOL MALEATE TABLETS	ADDITIONAL REQUIREMENT S/USP Reference Standards <11>	<i>USP40–NF35</i>	6481	26-Jan-2018		1-Feb-2018	<i>USP42–NF37</i>	<i>Second Supplement to USP41–NF36</i>	Line 3 of USP Timolol Related Compound D RS: Change $C_6H_9N_7O_4S$ to: $C_6H_9N_3O_2S$
POWDERED ECHINACEA	IDENTIFICATION	<i>USP40–NF35</i>	6933	26-Jan-2018		1-Feb-2018	<i>USP42–NF37</i>	<i>Second Supplement to</i>	Line 5 of <i>A</i> . <i>Thin-Layer Chro</i>

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PALLIDA						USP41–NF36	<p>matography/Pre sence of echinacoside and absence of dicaffeoylquinic acid/System suitability. Change Standard solution B shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower <math>R_F</math>) and chlorogenic acid (higher <math>R_F</math>) that are clearly separated, to: Standard solution B shows two major blue bands at about the middle of the chromatogram</p>

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POWDERED ECHINACEA PURPUREA EXTRACT	IDENTIFICATION	USP40–NF35	6944	26-Jan-2018		1-Feb-2018	USP42–NF37	Second Supplement to USP41–NF36	<p>due to caftaric acid (higher <math>R_F</math>) and chlorogenic acid (lower <math>R_F</math>) that are clearly separated, AND Lines 3 and 6 of C.: Change <i>Standard solution B</i>, to: <i>Standard solution C</i>, AND Change <i>Standard solution C</i>) to: <i>Standard solution D</i>) Line 3 of A. <i>Thin-Layer Chromatography/Presence of chicoric acid and absence of echinacoside/System suitability.</i></p>

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BRETYLIUM	Identification	USP40–NF35	3049	26-Jan-2018		1-Feb-2018	USP42–NF37	Second	<p>Change <i>Standard solution B</i> shows two major blue bands at about the middle of the chromatogram due to caftaric acid (lower <math>R_F</math>) and chlorogenic acid (higher <math>R_F</math>) that are clearly separated, to:</p> <p><i>Standard solution B</i> shows two major blue bands at about the middle of the chromatogram due to caftaric acid (higher <math>R_F</math>) and chlorogenic acid (lower <math>R_F</math>) that are clearly separated,</p> <p>Line 1 of <i>B</i>:</p>

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TOSYLATE IN DEXTROSE INJECTION						<i>Supplement to USP41–NF36</i>	Change It responds to the <i>Identification test</i> under <i>Dextrose</i> . to: Add a few drops of a solution (1 in 20) to 5 mL of hot alkaline cupric tartrate TS. A copious red precipitate of cuprous oxide is formed.

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