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Isosorbide Mononitrate Tablets

DEFINITION

Isosorbide Mononitrate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of isosorbide mononitrate ($C_6H_9NO_6$).

IDENTIFICATION

Change to read:

- **A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#).**

Standard solution: 0.5 mg/mL of isosorbide mononitrate in [absolute alcohol](#) from [USP Diluted Isosorbide Mononitrate RS](#)

Sample stock solution: Nominally 2.4 mg/mL of isosorbide mononitrate prepared as follows. Finely powder NLT 20 Tablets and transfer a suitable portion of the powder to a suitable container. Add a suitable volume of [absolute alcohol](#), sonicate for 10 min, and centrifuge. Use the supernatant.

Sample solution: Nominally 0.48 mg/mL of isosorbide mononitrate in [absolute alcohol](#) from the *Sample stock solution*

Chromatographic system

▲**Adsorbent:** 0.25-mm layer of [chromatographic silica gel mixture](#)▲ (USP 1-May-2024)

Application volume: 20 µL

Developing solvent system: [Chloroform](#) and [methanol](#) (95:5)

Spray reagent: Dissolve 1 g of [soluble starch](#) in 100 mL of boiling [water](#). Cool and add 0.5 g of [potassium iodide](#).

Analysis

Samples: *Standard solution* and *Sample solution*

Examine the plate under short-wave UV light, marking any observed spots. Visualize nitrates on the plate by spraying with *Spray reagent* and illuminating with short-wave UV light for about 10 min.

Acceptance criteria: Isosorbide mononitrate and other nitrates appear as a violet spot on a white-to-light violet background.

- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

PROCEDURE

Mobile phase: [Methanol](#) and [water](#) (30:70)

System suitability solution: 0.5 µg/mL each of isosorbide mononitrate and isosorbide mononitrate related compound A ▲ in [water](#)▲ (USP 1-May-2024) from [USP Diluted Isosorbide Mononitrate RS](#) and [USP Diluted Isosorbide Mononitrate Related Compound A RS](#)

Standard solution: 0.1 mg/mL of isosorbide mononitrate in [water](#) from [USP Diluted Isosorbide Mononitrate RS](#). Pass a portion of the solution through a suitable filter of 0.45-µm or finer pore size, and use the filtrate.

Sample solution: Nominally 0.1 mg/mL of isosorbide mononitrate prepared as follows. Finely powder NLT 20 Tablets and transfer a suitable portion of the powder to a suitable volumetric flask. Add 50% of the final volume of [water](#), and sonicate for about 10 min. Dilute with [water](#) to volume. Pass a portion of the solution through a suitable filter of 0.45-µm or finer pore size, and use the filtrate.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; ▲5-µm▲ (USP 1-May-2024) packing [L1](#)

Flow rate: ▲1 mL/min▲ (USP 1-May-2024)

Injection volume: 50 µL

▲**Run time:** NLT 6 times the retention time of isosorbide mononitrate▲ (USP 1-May-2024)

System suitability

Samples: *System suitability solution* and *Standard solution*

▲[NOTE—The relative retention times for isosorbide mononitrate related compound A and isosorbide mononitrate are 0.9 and 1.0, respectively.]▲ (USP 1-MAY-2024)

Suitability requirements

Resolution: NLT 1.5 between isosorbide mononitrate related compound A and isosorbide mononitrate in *system suitability solution*

Relative standard deviation: NMT $\blacktriangle$ 1.0%, $\blacktriangle$ (USP 1-May-2024) *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of isosorbide mononitrate ($C_6H_9NO_6$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of isosorbide mononitrate from the *Sample solution*

r_S = peak response of isosorbide mononitrate from the *Standard solution*

C_S = concentration of isosorbide mononitrate in the *Standard solution* (mg/mL)

C_U = nominal concentration of isosorbide mononitrate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#).

Medium: Water; 900 mL, deaerated

Apparatus 2: 50 rpm

Time: 15 min

Mobile phase and **Chromatographic system:** Proceed as directed in the Assay.

Standard solution: 0.02 mg/mL of $\blacktriangle$ isosorbide mononitrate from [USP Diluted Isosorbide Mononitrate RS](#) in *Medium* $\blacktriangle$ (USP 1-May-2024)

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size. Discard the first few milliliters of the filtrate.

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of isosorbide mononitrate ($C_6H_9NO_6$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

r_U = peak response of isosorbide mononitrate from the *Sample solution*

r_S = peak response of isosorbide mononitrate from the *Standard solution*

C_S = concentration of isosorbide mononitrate in the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of isosorbide mononitrate ($C_6H_9NO_6$) is dissolved

Change to read:

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements $\blacktriangle$ (USP 1-May-2024)

IMPURITIES

Add the following:

$\blacktriangle$ • **LIMIT OF NITRATE**

[NOTE—Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.]

Mobile phase: 20 mM [potassium hydroxide](#) in [water](#). [NOTE—*Mobile phase* can be generated electrolytically using an automatic eluant generator.]

Sensitivity solution: 0.5 μ g/mL of [USP Potassium Nitrate RS](#) in [water](#)

Standard solution: 1.0 μ g/mL of [USP Potassium Nitrate RS](#) in [water](#)

Sample solution: Nominally 200 μ g/mL of isosorbide mononitrate prepared as follows. Finely powder NLT 20 Tablets and transfer a suitable portion of the powder to a suitable volumetric flask. Add [water](#) to about 80% of the final flask volume. Sonicate for about 10 min with intermittent shaking, cool to ambient temperature, and dilute with [water](#) to volume. Centrifuge a portion of the solution and use the clear supernatant.

Chromatographic system