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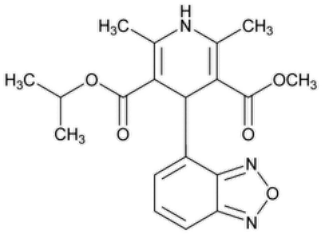
Isradipine



$C_{19}H_{21}N_3O_5$ 371.39

3,5-Pyridinedicarboxylic acid, 4-(4-benzofurazanyl)-1,4-dihydro-2,6-dimethyl-, methyl 1-methylethyl ester, (±)-;

Isopropyl methyl (±)-4-(4-benzofurazanyl)-1,4-dihydro-2,6-dimethyl-3,5-pyridinedicarboxylate CAS RN®: 75695-93-1; UNII: YO1UK1S598.

DEFINITION

Isradipine contains NLT 98.0% and NMT 102.0% of isradipine ($C_{19}H_{21}N_3O_5$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

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

ASSAY

• **Procedure**

Use low-actinic glassware throughout this procedure, and otherwise protect the test specimen, the Reference Standard, and all solutions containing them from unnecessary exposure to light.

Mobile phase: Methanol, tetrahydrofuran, and water (400:100:500)

Standard solution: 0.2 mg/mL of USP Isradipine RS and 0.01 mg/mL of USP Isradipine Related Compound A RS in *Mobile phase*. If necessary, use sonication and/or add 1 mL of methanol per 20 mL of *Mobile phase* to dissolve the Reference Standards.

Sample solution: 0.2 mg/mL of Isradipine prepared as follows. Transfer 20 mg of Isradipine to a 100-mL volumetric flask. Add sufficient methanol to dissolve, and sonicate if necessary. Dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 326 nm

Column: 4.6-mm × 10-cm; packing L1

Flow rate: 1.7 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between isradipine and isradipine related compound A

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of isradipine ($C_{19}H_{21}N_3O_5$) in the portion of Isradipine taken:

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

r_U = peak response of isradipine from the *Sample solution*

r_S = peak response of isradipine from the *Standard solution*

C_S = concentration of USP Isradipine RS in the *Standard solution* (mg/mL)

C_U = concentration of Isradipine in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Organic Impurities**

Use low-actinic glassware throughout this procedure, and otherwise protect the test specimen, the Reference Standard, and all solutions containing them from unnecessary exposure to light.

Mobile phase: Prepare as directed in the *Assay*.

System suitability solution: 0.2 mg/mL of USP Isradipine RS and 0.01 mg/mL of USP Isradipine Related Compound A RS in *Mobile phase*. If necessary, use sonication and/or add 1 mL of methanol per 20 mL of *Mobile phase* to dissolve the Reference Standards.

Standard solution: 6 µg/mL of USP Isradipine RS in *Mobile phase*. If necessary, use sonication and/or add 1 mL of methanol per 20 mL of *Mobile phase* to dissolve the Reference Standards.

Sample solution: 2 mg/mL of Isradipine prepared as follows. Transfer 50 mg of Isradipine to a 25-mL volumetric flask, and add 5.0 mL of methanol to dissolve. Sonicate if necessary, and dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 10-cm; packing L1

Flow rate: 1.7 mL/min

Injection volume: 25 µL

Run time: NLT 3 times the retention time of isradipine for the *Sample solution*

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 1.5 between isradipine and isradipine related compound A

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Acceptance criteria: The sum of the peak responses, other than that of isradipine, of the *Sample solution* is NMT 4 times the isradipine response from the *Standard solution* (NMT 1.2%); the response of the largest peak, other than that of isradipine, of the *Sample solution* is NMT 1.6 times greater than the isradipine response from the *Standard solution* (NMT 0.5%); no other peak response, other than that of isradipine, is greater than the isradipine response from the *Standard solution* (NMT 0.3%).

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 0.2%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Isradipine RS

USP Isradipine Related Compound A RS

Isopropyl methyl 4-(4-benzofurazanyl)-2,6-dimethyl-3,5-pyridinedicarboxylate.

$C_{19}H_{19}N_3O_5$ 369.38

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ISRADIPINE	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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