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Isradipine Capsules

» Isradipine Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of isradipine ($C_{19}H_{21}N_3O_5$).

Packaging and storage—Store in a tight container at controlled room temperature. Protect from light.

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

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests ⟨197⟩, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Medium: methanol.

Solution—Transfer the contents of 1 Capsule into a suitable volumetric flask, dissolve the contents in the *Medium* by mechanical shaking for 15 minutes, and dilute with *Medium* to obtain a solution containing 25 µg of isradipine per mL.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

Dissolution ⟨711⟩—

Medium: 0.1% aqueous solution of lauryl dimethyl amine oxide (prepared by transferring 500 mL of deaerated water into the dissolution vessel, adding 1.65 mL of 30% lauryl dimethyl amine oxide, and mixing); 500 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{19}H_{21}N_3O_5$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 328 nm on filtered portions of the solution under test, suitably diluted with *Medium,* if necessary, in comparison with a Standard solution having a known concentration of USP Isradipine RS in the same *Medium.*

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{19}H_{21}N_3O_5$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩**:** meet the requirements.

[Note—Isradipine is light sensitive. Throughout the following procedures, protect test or assay specimens, the Reference Standards, and solutions containing them from unnecessary exposure to light. Use low-actinic glassware, unless otherwise directed.]

Chromatographic purity—

Mobile phase, Resolution solution, and *Chromatographic system*—Proceed as directed in the test for *Chromatographic purity* under *Isradipine.*

Standard solution—Dissolve an accurately weighed quantity of USP Isradipine RS in *Mobile phase,* with the aid of sonication if necessary, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 1 µg per mL. [Note—If necessary, use 1 mL of methanol per 20 mL of *Mobile phase* to dissolve the Reference Standard prior to diluting with *Mobile phase.*]

Test solution—Use the *Assay preparation.*

Procedure—Separately inject equal volumes (about 25 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for all the peaks: the sum of all peak responses, other than that of isradipine, from the *Test solution* is not more than four times the isradipine response obtained from the *Standard solution* (2.0%); and no single peak response is greater than that of the isradipine peak response obtained from the *Standard solution* (0.5%).

Assay—

Mobile phase, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Isradipine.*

Assay preparation—Remove, as completely as possible, the contents of not fewer than 20 Capsules, and mix the combined contents. Transfer an accurately weighed quantity, equivalent to about 25 mg of isradipine, to a 100-mL volumetric flask. Add 5.0 mL of methanol and 5.0 mL of *Mobile phase,* and sonicate at room temperature for 15 minutes. Shake for 15 minutes in a mechanical shaker. Dilute with *Mobile phase* to volume, mix, and filter, discarding the first 5 mL of the filtrate.

Procedure—Separately inject equal volumes (about 25 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of isradipine ($C_{19}H_{21}N_3O_5$) in the

portion of Capsules taken by the formula:

$$100C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Isradipine RS in the *Standard preparation;* and r_U and r_S are the isradipine peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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

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

Chromatographic Database Information: Chromatographic Database

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