Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Dec-2016
Document Type: USP Monographs
DocId: GUID-06BA9140-6A00-43E5-9FC1-242C74EDD5D3_1_en-US
DOI: https://doi.org/10.31003/USPNF_M1391_01_01
DOI Ref: h0vir

Isradipine Compounded Oral Suspension

DEFINITION

Isradipine Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of isradipine ($C_{19}H_{21}N_3O_5$).

Prepare Isradipine Compounded Oral Suspension 1 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Isradipine capsules[a] or powder,[b] equivalent to	100 mg of isradipine
Glycerin, *USP*	3 mL
Syrup, *NF*, a sufficient quantity to make	100 mL

[a] DynaCirc 5-mg capsules, Sandoz Pharmaceuticals, East Hanover, NJ.

[b] Isradipine powder, Sandoz, East Hanover, NJ.

Calculate the required quantity of each ingredient for the total amount to be prepared. If using *Isradipine capsules*, empty the required number in a suitable mortar, or use *Isradipine powder*. Add sufficient *Glycerin* to wet the powder, and triturate to a fine paste. Add the *Syrup* in small portions. Add increasing volumes of the *Syrup* to make an isradipine liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Syrup* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Mobile phase: Methanol, tetrahydrofuran, and water (42:20:38). Filter, and degas.

Diluent: Prepare a solution of methanol and 95% ethanol (50:50).

Standard stock solution: 1.0 mg/mL of USP Isradipine RS in *Diluent*

Standard solution: Prepare 0.1 mg/mL of isradipine from *Standard stock solution* and *Diluent*, and pass through a filter of 0.22-µm pore size.

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Prepare 0.1 mg/mL of isradipine from Oral Suspension and *Diluent*, and pass through a filter of 0.22-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for isradipine is about 6.1 min.]

Suitability requirements

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of isradipine ($C_{19}H_{21}N_3O_5$) in the portion of Oral Suspension taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 5.5–6.5

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store in a refrigerator.

• **Beyond-Use Date:** NMT 30 days after the date on which it was compounded, when stored in a refrigerator

• **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Isradipine RS

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

Topic/Question	Contact	Expert Committee
ISRADIPINE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 49(6)

Current DocID: GUID-06BA9140-6A00-43E5-9FC1-242C74EDD5D3_1_en-US

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