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Sumatriptan Compounded Oral Suspension

DEFINITION

Sumatriptan Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of sumatriptan ($C_{14}H_{21}N_3O_2S$).

Prepare Sumatriptan Compounded Oral Suspension containing 5 mg/mL of sumatriptan as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Sumatriptan (as Sumatriptan Succinate)	500 mg (700 mg)
Vehicle: a 1:1 mixture of Vehicle for Oral Solution (regular or sugar-free), *NF*, and Vehicle for Oral Suspension, *NF*, a sufficient quantity to make	100 mL

Place the required number of tablets in a suitable mortar, and comminute to a fine powder, or add *Sumatriptan Succinate* powder to the mortar. Add 25 mL of *Vehicle* in portions, mixing thoroughly after each addition. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add sufficient *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and 0.01 M dibutylamine in 0.025 M aqueous monobasic sodium phosphate dihydrate (25:75), adjusted with 1 N sodium hydroxide to a pH of 8.0. Filter and degas.

Standard stock solution: 4.0 mg/mL of USP Sumatriptan Succinate RS in *Mobile phase*

Standard solution: 0.12 mg/mL of sumatriptan prepared with *Standard stock solution* and *Mobile phase*

Sample solution: 0.15 mg/mL of sumatriptan prepared from Oral Suspension and 0.1 M hydrochloric acid. Pass through a 0.22-µm syringe filter into a 0.3-mL polypropylene sample vial.

Chromatographic system

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

Mode: LC

Detector: UV 282 nm

Column: 4.6-mm × 10-cm; 5-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for sumatriptan is about 11 min.]

Suitability requirements

Relative standard deviation: NMT 1.5% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sumatriptan ($C_{14}H_{21}N_3O_2S$) 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 sumatriptan in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.6–4.6

ADDITIONAL REQUIREMENTS

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

• **Beyond-Use Date:** NMT 14 days after the date on which it was compounded when stored in a refrigerator

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

• **USP Reference Standards** ⟨11⟩

USP Sumatriptan Succinate RS

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

Topic/Question	Contact	Expert Committee
SUMATRIPTAN 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

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