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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 (C₁₄H₂₁N₃O₂S).
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 (C₁₄H₂₁N₃O₂S) in the portion of Oral Suspension taken:

Result = (r_U/r_S) × (C_S/C_U) × 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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