

Naratriptan Compounded Oral Suspension

DEFINITION
Naratriptan Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of naratriptan (C₁₇H₂₅N₃O₂S). Prepare Naratriptan Compounded Oral Suspension containing 0.5 mg/mL of *Naratriptan* as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Naratriptan (as Naratriptan Hydrochloride)	50 mg (55.43 mg)
Vehicle: a 1:1 mixture of Vehicle for Oral Solution, <i>NF</i> (regular or sugar-free), and Vehicle for Oral Suspension, <i>NF</i> , a sufficient quantity to make	100 mL

Calculate the required quantity of each ingredient for the total amount to be prepared. If using tablets, place the required number of tablets in a suitable mortar, and comminute the tablets to a fine powder or add *Naratriptan Hydrochloride* powder. Add the *Vehicle* in small portions and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a naratriptan suspension that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY

• **PROCEDURE**

Mobile phase: 2-Propanol and 12 mM triethylamine phosphate buffer (1:10). Make adjustments if necessary.

Standard stock solution: 0.5 mg/mL of [USP Naratriptan Hydrochloride RS](#) in *Mobile phase*

Standard solution: Transfer 1.0 mL of *Standard stock solution* to a 25-mL volumetric flask, dilute with *Mobile phase* to volume to obtain a solution containing 20 µg/mL of naratriptan hydrochloride, and pass through a suitable filter of 0.22-µm pore size.

Sample solution: Shake the Oral Suspension thoroughly by hand. Pipet 0.4 mL into a 10-mL volumetric flask. Add 1 mL of 0.1 N sodium hydroxide solution by pipet, and sonicate for 5 min. Dilute with *Mobile phase* to volume, and mix to obtain a nominal concentration of 20 µg/mL of naratriptan. Centrifuge, and pass the naratriptan solution through a suitable filter of 0.22-µm pore size.

Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 25-cm; 5-µm packing L11

Flow rate: 1.4 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Retention time: 9.7 min for the naratriptan peak

Relative standard deviation: NMT 4.9% for the replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of naratriptan (C₁₇H₂₅N₃O₂S) in the portion of Oral Suspension taken:

Result = (r_U/r_S) × (C_S/C_U) × (M_{r1}/M_{r2}) × 100

r_U = peak response from the *Sample solution*

r_s = peak response from the *Standard solution*

C_s = concentration of [USP Naratriptan Hydrochloride RS](#) in the *Standard solution* (µg/mL), on the anhydrous basis

C_u = nominal concentration of naratriptan in the *Sample solution* (µg/mL)

M_{r1} = molecular weight of naratriptan, 335.47

M_{r2} = molecular weight of naratriptan hydrochloride, 371.93

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH** (791): 4.0–4.5

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.
- **BEYOND-USE DATE:** NMT 7 days after the date on which it was compounded when stored at controlled room temperature, and NMT 90 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 Naratriptan Hydrochloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
NARATRIPTAN 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. PF 40(6)

Current DocID: GUID-B94700E3-4ACD-470A-AB99-F8F7A3B575E2_1_en-US

DOI: https://doi.org/10.31003/USPNF_M1787_01_01

DOI ref: [96sv9](#)