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Naratriptan Compounded Oral Suspension

DEFINITION

Naratriptan Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of naratriptan ($C_{17}H_{25}N_3O_2S$). 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, *NF* (regular or sugar-free), and Vehicle for Oral Suspension, *NF*, 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 ($C_{17}H_{25}N_3O_2S$) in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

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