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Granisetron Hydrochloride Compounded Oral Suspension

DEFINITION

Granisetron Hydrochloride Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of granisetron ($C_{18}H_{24}N_4O$). Prepare Granisetron Hydrochloride Compounded Oral Suspension containing 0.05 mg/mL of granisetron as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Granisetron (as Granisetron Hydrochloride)	5 mg (5.6 mg)
Vehicle: a 1:1 mixture of Vehicle for Oral Solution, *NF*, 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 with a pestle, or add *Granisetron Hydrochloride* powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a *Granisetron Hydrochloride* suspension that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and 50 mM monobasic sodium dihydrogen phosphate (3:17). Adjust with phosphoric acid to a pH of 7.0. Make adjustments if necessary (see *Chromatography* ⟨621⟩, *System Suitability*).

Standard stock solution: 1.0 mg/mL of USP Granisetron Hydrochloride RS

Standard solution: Transfer 2.5 mL of *Standard stock solution* to a 100-mL volumetric flask, and dilute with *Mobile phase* to volume to obtain a solution containing 25 µg/mL of granisetron hydrochloride.

Sample solution: Shake the Oral Suspension thoroughly by hand. Pipet 5.0 mL into a 10-mL volumetric flask. Dilute with *Mobile phase* to volume, and mix.

Chromatographic system

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

Mode: LC

Detector: UV 300 nm

Column: 4.6-mm × 15-cm; 5-µm packing L10

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time of the granisetron peak is 7.0 min.]

Suitability requirements

Relative standard deviation: NMT 2.0% for the replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of granisetron ($C_{18}H_{24}N_4O$) in the volume 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 Granisetron Hydrochloride RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of granisetron in the *Sample solution* (µg/mL)

M_{r1} = molecular weight of granisetron, 312.41

M_{r2} = molecular weight of granisetron hydrochloride, 348.87

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 90 days after the date on which it was compounded when stored at controlled room temperature or 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 Granisetron Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
GRANISETRON HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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