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Ondansetron Compounded Oral Suspension

DEFINITION

Ondansetron Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of ondansetron ($C_{18}H_{19}N_3O$), calculated on the anhydrous basis.

Prepare Ondansetron Compounded Oral Suspension containing 1.0 mg/mL of ondansetron hydrochloride (dihydrate) equivalent to 0.8 mg/mL of ondansetron as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Ondansetron (as ondansetron hydrochloride dihydrate)	80 mg (100 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 glass mortar, and comminute to a fine powder, or add *Ondansetron* hydrochloride powder. Add 50 mL of the *Vehicle* in 5-mL portions, and mix well with each addition. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add sufficient *Vehicle* to bring the preparation to final volume, and mix well.

ASSAY

• **Procedure**

Mobile phase: 43 mM of monobasic potassium phosphate buffer adjusted with a mixture of 1 N sodium hydroxide and acetonitrile (85:15) to a pH of 5.4

Standard solution: Dissolve USP Ondansetron Hydrochloride RS in *Mobile phase* to obtain a solution with a nominal concentration of 4 µg/mL of ondansetron.

Sample solution: Bring each bottle of Oral Suspension to room temperature. Pipet 500 µL of Oral Suspension from each bottle into a 100-mL volumetric flask, and dilute with *Mobile phase* to volume. Pass through a filter of 0.45-µm pore size, and keep frozen at −70° until assayed.

Chromatographic system

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

Mode: LC

Detector: UV 216 nm

Columns

Guard: 3.9-mm × 20-cm; 4-µm packing L10

Analytical: 4.6-mm × 25-cm; 5-µm packing L10

Flow rate: 1 mL/min

Injection volume: 80 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for ondansetron is about 30 min.]

Suitability requirements

Relative standard deviation: NMT 1.6% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ondansetron ($C_{18}H_{19}N_3O$) 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 ondansetron in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0% on the anhydrous basis

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.6–4.6

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature, or in a refrigerator.

• **Beyond-Use Date:** NMT 42 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator

• **Labeling:** Label it to state that it is to be well shaken before use, and to state the *Beyond-Use Date*. Label to indicate that it contains 0.8 mg/mL of ondansetron equivalent to 1 mg/mL of ondansetron hydrochloride (dihydrate).

• **USP Reference Standards** ⟨11⟩

USP Ondansetron Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
ONDANSETRON 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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