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Ondansetron Compounded Topical Gel

Change to read:

DEFINITION
Ondansetron Compounded Topical Gel contains NLT 90.0% and NMT 110.0% of the labeled amount of ondansetron ($C_{18}H_{19}N_3O$).

Prepare Ondansetron Compounded Topical Gel, 20 mg/mL, as follows (see *Pharmaceutical Compounding—Nonsterile Preparations (795)*).

Ondansetron (as Ondansetron Hydrochloride)	200 mg (249.4 mg)
Propylene Glycol	▲3▲ (RB 1-Jun-2018) mL
Lipoderm,[a] a sufficient quantity to make	10 mL

[a] PCCA, Houston, TX.

Wet the *Ondansetron Hydrochloride* with the *Propylene Glycol* in a suitable container. Add the *Lipoderm* stepwise and quantitatively. Bring to final volume and mix well.

ASSAY

• **Procedure**

Mobile phase: Dissolve 2.72 g of monobasic potassium phosphate in 750 mL of water and adjust to a pH of 6.0. Mix with 250 mL of acetonitrile.

Diluent: Methanol and water (50:50)

Standard solution: 0.1 mg/mL of ondansetron (free base) prepared from USP Ondansetron Hydrochloride RS in *Diluent* (approximately equal to 0.1247 mg/mL of ondansetron hydrochloride)

Sample solution: Fill a 1-mL syringe with Topical Gel and weigh. Transfer the sample to a 200-mL volumetric flask, add about 150 mL of *Diluent*, and sonicate until the gel has broken down. Dilute with *Diluent* to final volume.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1.8 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for ondansetron is about 5.3 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% 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 Topical Gel taken:

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

r_U = peak response of ondansetron from the *Sample solution*

r_S = peak response of ondansetron from the *Standard solution*

C_S = concentration of ondansetron in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Package in a tight, light-resistant calibrated container dispenser. Store at controlled room temperature.
- **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature.
- **Labeling:** Label it to indicate that it is for external use only and to state the *Beyond-Use Date*.
- **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 TOPICAL GEL	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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