Ondansetron Compounded Topical Gel

Type of Posting	Revision Bulletin
Posting Date	25–May–2018
Official Date	01–Jun–2018
Expert Committee	Compounding
Reason for Revision	Compliance

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Compounding Expert Committee has revised the Ondansetron Compounded Topical Gel monograph. The purpose for the revision is to correct the formulation described in the *Definition* section of the monograph.

- The assay was validated and stability testing performed in a formulation containing 30% propylene glycol as the solubilizing agent.

The Ondansetron Compounded Topical Gel Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Brian Serumaga, Science Program Manager (CompoundingSL@usp.org).

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