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Dolasetron Mesylate Compounded Oral Suspension

DEFINITION

Dolasetron Mesylate Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of dolasetron mesylate ($C_{19}H_{20}N_2O_3 \cdot CH_4O_3S$).

Prepare Dolasetron Mesylate Compounded Oral Suspension 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Dolasetron Mesylate	1 g
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

If using tablets, place the required number in a suitable mortar, and comminute to a fine powder, or add *Dolasetron Mesylate* powder to the mortar. Add 20 mL of *Vehicle*, and mix to a uniform paste. Add the *Vehicle* in small portions, and mix well after each addition. Transfer, stepwise and quantitatively, to a calibrated bottle. Add the *Vehicle* in portions to rinse the mortar, add sufficient *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: 0.05 M ammonium acetate adjusted with diluted ammonium hydroxide to a pH of 7.5

Mobile phase: Acetonitrile and *Solution A* (24:76). Filter and degas.

Diluent: Acetonitrile and water (24:76)

Standard stock solution: 500 µg/mL of USP Dolasetron Mesylate RS in *Diluent*

Standard solution: 10 µg/mL of USP Dolasetron Mesylate RS prepared from the *Standard stock solution* in *Mobile phase*

Sample solution: 10 µg/mL of dolasetron mesylate prepared from Oral Suspension and *Diluent*. Shake each sample thoroughly by hand for 15 s, centrifuge at 1000 rpm for 2 min, and use the supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

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

Column temperature: 30°

Flow rate: 0.8 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for dolasetron mesylate is about 6.9 min.]

Suitability requirements

Relative standard deviation: NMT 1.4% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dolasetron mesylate ($C_{19}H_{20}N_2O_3 \cdot CH_4O_3S$) 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 USP Dolasetron Mesylate RS in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

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 90 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*.

• **USP Reference Standards** ⟨11⟩

USP Dolasetron Mesylate RS

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

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

Chromatographic Database Information: Chromatographic Database

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