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Ondansetron Tablets

DEFINITION

Ondansetron Tablets contain Ondansetron Hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of ondansetron ($C_{18}H_{19}N_3O$).

IDENTIFICATION

• **A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)**

Sample: Transfer a portion of the powder from finely powdered Tablets, equivalent to 100 mg of ondansetron hydrochloride, to a suitable conical flask. Add 50 mL of alcohol, and swirl. Pass the liquid through a PTFE filter of 0.45- μ m pore size into a 50-mL beaker. Evaporate the solvent on a rotary evaporator. Dry the precipitate in an air oven for 1 h at 105°. Prepare a suitable dispersion of the residue in potassium bromide, and record the spectra of the *Sample* and the standard specimen in the spectral range 3800–650 cm^{-1} . [NOTE—It is recommended that a solution of [USP Ondansetron Hydrochloride RS](#) in alcohol be prepared at a concentration of 2 mg/mL before the evaporation, followed by the drying steps.]

Acceptance criteria: The *Sample* shows strong bands at 1621, 1481, 1281, and 758 cm^{-1} , similar to the potassium bromide dispersion of [USP Ondansetron Hydrochloride RS](#).

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• **PROCEDURE**

Buffer: 2.7 g/L of monobasic potassium phosphate. Adjust with 1 N sodium hydroxide to a pH of 5.4.

Mobile phase: Acetonitrile and *Buffer* (1:4)

Diluent: Acetonitrile and *Buffer* (1:1)

Standard solution: 0.05 mg/mL of ondansetron (free base) in *Diluent* from [USP Ondansetron Hydrochloride RS](#)

Sample stock solution: Weigh and finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 50 mg of ondansetron, based on the label claim, to a 100-mL volumetric flask. Add 70 mL of *Diluent*, and sonicate for about 20 min. Dilute with *Diluent* to volume. Centrifuge a portion of the solution.

Sample solution: Quantitatively dilute the supernatant with *Diluent* to obtain a solution having a nominal concentration of 0.05 mg/mL of ondansetron, based on the label claim. Pass through a suitable nylon filter of 0.45- μ m pore size, and use the filtrate.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 216 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing L10

Flow rate: 1.5 mL/min

Injection size: 10 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the label claim of ondansetron ($C_{18}H_{19}N_3O$) in the portion of Tablets 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 (free base) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Medium: Water; 500 mL, deaerated

Apparatus 2: 50 rpm

Time: 15 min

Standard solution: [USP Ondansetron Hydrochloride RS](#) in *Medium* in a concentration similar to the one expected in the *Sample solution*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size, and dilute, if necessary, with *Medium*.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: 310 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ondansetron ($C_{18}H_{19}N_3O$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times (M_{r1}/M_{r2}) \times V \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

L = label claim (mg/Tablet)

M_{r1} = molecular weight of ondansetron, 293.36

M_{r2} = molecular weight of ondansetron hydrochloride (anhydrous), 329.83

V = volume of *Medium*, 500 mL

Tolerances: NLT 80% (Q) of the labeled amount of $C_{18}H_{19}N_3O$ is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium, Apparatus 2, Standard solution, Sample solution, Instrumental conditions, and Analysis: Proceed as directed for *Test 1*.

Time: 30 min

Tolerances: NLT 80% (Q) of the labeled amount of $C_{18}H_{19}N_3O$ is dissolved.

Test 3: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

Medium: 0.01 N hydrochloric acid; 500 mL, deaerated

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: Known concentration of [USP Ondansetron Hydrochloride RS](#) in *Medium*, close to the expected concentration of the *Sample solution*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size, and dilute, if necessary, with *Medium*.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV