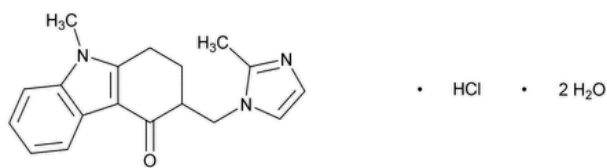


Ondansetron Hydrochloride

Change to read:



$C_{18}H_{19}N_3O \cdot HCl \cdot 2H_2O$ Δ 365.86 Δ (USP 1-Aug-2024)
4*H*-Carbazol-4-one, 1,2,3,9-tetrahydro-9-methyl-3-[(2-methyl-1*H*-imidazol-1-yl)methyl]-, monohydrochloride, (±), dihydrate;
 Δ 9-Methyl-3-[(2-methyl-1*H*-imidazol-1-yl)methyl]-1,2,3,9-tetrahydro-4*H*-carbazol-4-one hydrochloride dihydrate Δ (USP 1-Aug-2024) CAS RN[®]:
103639-04-9; UNII: NMH84OZK2B.

DEFINITION

Ondansetron Hydrochloride contains NLT 98.0% and NMT 102.0% of ondansetron hydrochloride ($C_{18}H_{19}N_3O \cdot HCl$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#):** Δ 197A, 197K, or Δ (USP 1-Aug-2024) 197M
- **B. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#)**
Sample solution: Dissolve 20 mg in 2 mL of [water](#), add 1 mL of [2 M nitric acid](#), and filter.
Acceptance criteria: Meets the requirements.

Add the following:

- Δ • **C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. Δ (USP 1-Aug-2024)

ASSAY

Change to read:

- **PROCEDURE**
 Δ **Solution A:** 2.4 g/L of [monobasic sodium phosphate, anhydrous](#) and 0.6 g/L of [sodium 1-heptanesulfonate](#) in [water](#). Adjust with [0.5 N sodium hydroxide](#) to a pH of 5.4.
Solution B: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
5	95	5
8	80	20

Time (min)	Solution A (%)	Solution B (%)
25	35	65
27	30	70
33	30	70
35	95	5
40	95	5

Diluent: [Acetonitrile](#) and [water](#) (30:70). To each liter of this solution, add 1 mL of [formic acid](#).

Standard solution: 0.1 mg/mL of [USP Ondansetron Hydrochloride RS](#) in *Diluent*

Sample solution: 0.1 mg/mL of Ondansetron Hydrochloride in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 216 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L11](#)

Temperatures

Autosampler: 15°

Column: 40°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%▲ (USP 1-Aug-2024)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ondansetron hydrochloride (C₁₈H₁₉N₃O · HCl) in the portion of Ondansetron Hydrochloride 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 [USP Ondansetron Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Ondansetron Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Delete the following:

▲ • **ORGANIC IMPURITIES, METHOD I**▲ (USP 1-Aug-2024)

Add the following:

▲ • **LIMIT OF METHYLENE BISONDANSETRON**

Buffer: 2.4 g/L of [monobasic sodium phosphate, anhydrous](#) in [water](#). Adjust with [0.5 N sodium hydroxide](#) to a pH of 6.5.

Mobile phase: [Acetonitrile](#) and *Buffer* (65:35)

Peak identification solution: 1 mg/mL of [USP Ondansetron Resolution Mixture RS](#) in *Mobile phase*

Standard solution: 0.002 mg/mL of [USP Ondansetron Hydrochloride RS](#) in *Mobile phase*