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Ondansetron Injection

DEFINITION
Ondansetron Injection is a sterile solution of Ondansetron Hydrochloride in Water for Injection or of Ondansetron in Water for Injection prepared with the aid of Hydrochloric Acid. It may contain suitable buffers and/or tonicity adjusting agents. It contains an amount of Ondansetron Hydrochloride equivalent to NLT 95.0% and NMT 105.0% of the labeled amount of ondansetron (C₁₈H₁₉N₃O).

IDENTIFICATION
• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
Add the following:
▲ • **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*. ▲ (USP 1-May-2024)

ASSAY
Change to read:
• **PROCEDURE**
▲ **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
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: Nominally 0.1 mg/mL of ondansetron from Injection in *Diluent*
Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))
Mode: LC

Detector: UV 216 nm. For *Identification B*, use a diode array detector in the range of 200–400 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 1.0%▲ (USP 1-May-2024)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ondansetron (C₁₈H₁₉N₃O) in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

- r_U = peak response of ondansetron from the *Sample solution*
- r_S = peak response of ondansetron from the *Standard solution*
- C_S = concentration▲ (USP 1-May-2024) of [USP Ondansetron Hydrochloride RS](#) in the *Standard solution* (mg/mL)
- C_U = nominal concentration of ondansetron in the *Sample solution* (mg/mL)
- M_{r1} = molecular weight of ondansetron, ▲293.37▲ (USP 1-May-2024)
- M_{r2} = molecular weight of anhydrous ondansetron hydrochloride, 329.83

Acceptance criteria: 95.0%–105.0%

IMPURITIES

Delete the following:

▲• **LIMIT OF ONDANSETRON RELATED COMPOUND D**▲ (USP 1-MAY-2024)

Change to read:

- **ORGANIC IMPURITIES**
- ▲**Solution A, Solution B, Mobile phase, Diluent, and Chromatographic system:** Proceed as directed in the Assay.
- System suitability solution:** 1 mg/mL of [USP Ondansetron Hydrochloride RS](#) and 0.002 mg/mL of [USP Ondansetron Related Compound G](#) in *Diluent*
- Standard solution:** 0.002 mg/mL each of [USP Ondansetron Hydrochloride RS](#) and [USP Ondansetron Related Compound D RS](#) in *Diluent*
- Sensitivity solution:** 0.001 mg/mL each of [USP Ondansetron Hydrochloride RS](#) and [USP Ondansetron Related Compound D RS](#) from the *Standard solution* in *Diluent*
- Sample solution:** Nominally 1.0 mg/mL of ondansetron from Injection in *Diluent*
- System suitability**
- Samples:** *System suitability solution, Standard solution, and Sensitivity solution*
- [NOTE—The relative retention times in [Table 2](#) are provided as information that could aid in peak assignment.]

Table 2

Name	Relative Retention Time
Imidazole ^a	0.28

Name	Relative Retention Time
Ondansetron related compound F ^b	0.33
Ondansetron related compound A ^c	0.94
Ondansetron	1.00
Ondansetron related compound G	1.04
Ondansetron related compound C ^d	1.1
Ondansetron related compound D	1.2

^a 1H-Imidazole.

^b 2-Methyl-1H-imidazole.

^c 3-[(Dimethylamino)methyl]-9-methyl-1,2,3,9-tetrahydro-4H-carbazol-4-one hydrochloride.

^d 9-Methyl-1,2,3,9-tetrahydro-4H-carbazol-4-one.

Suitability requirements

Resolution: NLT 2.0 between ondansetron and ondansetron related compound G, *System suitability solution*

Relative standard deviation: NMT 5.0% for ondansetron, *Standard solution*

Signal-to-noise ratio: NLT 10 for ondansetron, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ondansetron related compound D in the portion of Injection taken:

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

r_U = peak response of ondansetron related compound D from the *Sample solution*

r_S = peak response of ondansetron related compound D from the *Standard solution*

C_S = concentration of [USP Ondansetron Related Compound D RS](#) in the *Standard solution* (mg/mL)

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

Calculate the percentage of any other specified or unspecified degradation product in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of any other specified or any unspecified degradation product 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 = nominal concentration of ondansetron in the *Sample solution* (mg/mL)

F = relative response factor (see [Table 3](#))

M_{r1} = molecular weight of ondansetron, 293.37

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

Acceptance criteria: See [Table 3](#). The reporting threshold is 0.1%.

Table 3

Name	Relative Response Factor	Acceptance Criteria, NMT (%)
Ondansetron related compound A	1.0	0.2
Ondansetron related compound C	1.5	0.2
Ondansetron related compound D	—	0.12
Any unspecified degradation product	1.0	0.2
Total degradation products	—	0.5

▲ (USP 1-May-2024)

SPECIFIC TESTS

Change to read:

- [BACTERIAL ENDOTOXINS TEST \(85\)](#): ▲Meets the requirements▲ (USP 1-May-2024)

Add the following:

- ▲• [STERILITY TESTS \(71\)](#): Meets the requirements▲ (USP 1-May-2024)
- [pH \(791\)](#): 3.3–4.0
- [PARTICULATE MATTER IN INJECTIONS \(788\)](#): Meets the requirements for small-volume injections
- **OTHER REQUIREMENTS**: It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE**: Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, at a temperature between 2° and 30°, protected from light.

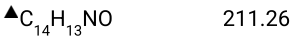
Change to read:

- [USP REFERENCE STANDARDS \(11\)](#)
[USP Ondansetron Hydrochloride RS](#)

▲ (USP 1-May-2024)

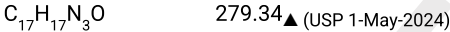
[USP Ondansetron Related Compound D RS](#)

9-Methyl-3-methylene-1,2,3,9-tetrahydro-4H-carbazol-4-one.



[USP Ondansetron Related Compound G](#)

3-[(1H-Imidazole-1-yl)methyl]-9-methyl-1,2,3,9-tetrahydro-4H-carbazol-4-one.



Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ONDANSETRON INJECTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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