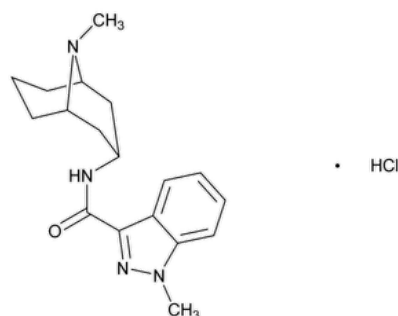


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## Granisetron Hydrochloride



$C_{18}H_{24}N_4O \cdot HCl$  348.87

1*H*-Indazole-3-carboxamide, 1-methyl-*N*-(9-methyl-9-azabicyclo[3.3.1]non-3-yl)-, monohydrochloride, *endo*-;

1-Methyl-*N*-(9-methyl-*endo*-9-azabicyclo[3.3.1]non-3-yl)-1*H*-indazole-3-carboxamide monohydrochloride CAS RN®: 107007-99-8; UNII: 318F6L70J8.

### DEFINITION

Granisetron Hydrochloride contains NLT 97.0% and NMT 102.0% of granisetron hydrochloride ( $C_{18}H_{24}N_4O \cdot HCl$ ), calculated on the dried basis.

### IDENTIFICATION

- **A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#):** 197M
- **B. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#):** Meets the requirements

### ASSAY

#### • PROCEDURE

**Mobile phase:** [Acetonitrile](#), [water](#), [phosphoric acid](#), and [hexylamine](#) (200: 800: 1.6: 1.0). Adjust with [triethylamine](#) to a pH of  $7.5 \pm 0.05$  (about 4 mL is needed). Make adjustments if necessary. (See [Chromatography \(621\)](#), [System Suitability](#).)

**Standard solution:** 1.0 mg/mL of [USP Granisetron Hydrochloride RS](#) in *Mobile phase*

**System suitability solution:** Transfer 2 mL of *Standard solution* to a colorless glass vial, stopper it, and either expose the solution to sunlight for 4 h or place it under a UV lamp for 16 h (granisetron undergoes partial degradation to granisetron related compound C). A degradation of at least about 0.3% of granisetron to granisetron related compound C must be obtained as shown by the appearance of a corresponding peak in the chromatogram. If it is not obtained, again expose the solution to sunlight or place it under a UV lamp.

**Sample solution:** 1.0 mg/mL of Granisetron Hydrochloride in *Mobile phase*

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 305 nm

**Column:** 4.6-mm × 25-cm; 5-μm packing [L1](#)

**Column temperature:** 40°

**Flow rate:** 1.5 mL/min

**Injection volume:** 10 μL

#### System suitability

**Samples:** *Standard solution* and *System suitability solution*

#### Suitability requirements

**Resolution:** NLT 3.5 between granisetron related compound C and granisetron, *System suitability solution*

**Tailing factor:** NMT 2.0 for the granisetron peak, *System suitability solution*

**Relative standard deviation:** NMT 2.0%, *Standard solution*



**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of granisetron hydrochloride ( $C_{18}H_{24}N_4O \cdot HCl$ ) in the portion of Granisetron Hydrochloride taken:

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

 $r_U$  = peak response of granisetron from the *Sample solution* $r_S$  = peak response of granisetron from the *Standard solution* $C_S$  = concentration of [USP Granisetron Hydrochloride RS](#) in the *Standard solution* (mg/mL) $C_U$  = concentration of Granisetron Hydrochloride in the *Sample solution* (mg/mL)**Acceptance criteria:** 97.0%–102.0% on the dried basis**IMPURITIES**• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%• **ORGANIC IMPURITIES**

[NOTE—Protect all solutions containing Granisetron Hydrochloride from light.]

**Mobile phase, System suitability solution, and Sample solution:** Prepare as directed in the Assay.**Peak identification solution:** 0.01 mg/mL of [USP Granisetron Related Compound A RS](#) and 0.005 mg/mL of [USP Granisetron Related Compound B RS](#) in *Mobile phase***Standard solution:** 0.005 mg/mL of [USP Granisetron Hydrochloride RS](#) in *Mobile phase***Chromatographic system:** Proceed as directed in the Assay, except for the *Run time*.**Run time:** NLT 2 times the retention time of granisetron**System suitability****Samples:** *System suitability solution* and *Standard solution***Suitability requirements****Resolution:** NLT 3.5 between granisetron related compound C and granisetron, *System suitability solution***Tailing factor:** NMT 2.0 for the granisetron peak, *System suitability solution***Relative standard deviation:** NMT 10%, *Standard solution***Analysis****Samples:** *Peak identification solution*, *Standard solution*, and *Sample solution*

Calculate the percentage of each impurity in the portion of Granisetron Hydrochloride taken:

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

 $r_U$  = peak response of each impurity from the *Sample solution* $r_S$  = peak response of granisetron from the *Standard solution* $C_S$  = concentration of [USP Granisetron Hydrochloride RS](#) in the *Standard solution* (mg/mL) $C_U$  = concentration of Granisetron Hydrochloride in the *Sample solution* (mg/mL) $F$  = relative response factor (see [Table 1](#))**Acceptance criteria:** See [Table 1](#). Discard any peaks observed in the blank. The reporting threshold is 0.05%.**Table 1**

| Name                                        | Relative Retention Time | Relative Response Factor | Acceptance Criteria, NMT (%) |
|---------------------------------------------|-------------------------|--------------------------|------------------------------|
| Granisetron related compound D <sup>a</sup> | 0.4                     | 1.0                      | 0.1                          |