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Granisetron Hydrochloride Tablets

DEFINITION

Granisetron Hydrochloride Tablets contain an amount of Granisetron Hydrochloride equivalent to NLT 92.0% and NMT 108.0% of the labeled amount of granisetron ($C_{18}H_{24}N_4O$).

IDENTIFICATION

Delete the following:

▲ • A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#).

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Developing solvent: Prepare a mixture of methylene chloride, alcohol, water, and ammonium hydroxide (60:40:5:2).

Standard solution: 0.44 mg/mL of [USP Granisetron Hydrochloride RS](#) in 0.1 N hydrochloric acid

Sample solution: Transfer a number of Tablets, equivalent to about 2 mg of granisetron, to a suitable container. Add 5.0 mL of 0.1 N hydrochloric acid, and sonicate for about 3 min. Pass through a 0.45-µm filter.

Application volume: 20 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Dry the spots under a current of warm air for about 5 min, and develop the plate in a paper-lined chromatographic chamber equilibrated with *Developing solvent*. Allow the chromatogram to develop until the solvent front has moved about 15 cm. Remove the plate, dry the plate under a cold air stream for about 10 min, and examine the plate under short-wavelength UV light.

Acceptance criteria: The principal spot from the *Sample solution* corresponds in appearance and R_f value to that of the *Standard solution*. ▲

(USP 1-May-2021)

Add the following:

▲ • A. 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-2021)

• 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

Change to read:

• PROCEDURE

▲ [NOTE—Protect all solutions containing granisetron from light.] ▲ (USP 1-May-2021)

Solution A: 15.6 g/L of [sodium phosphate monobasic dihydrate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.0, prior to final dilution.

Mobile phase: [Methanol](#), [tetrahydrofuran](#), and *Solution A* (24: 1.1: 75)

System suitability solution: 0.1 mg/mL of [USP Granisetron Hydrochloride RS](#) and 0.01 mg/mL each of [USP Granisetron Related Compound B RS](#), [USP Granisetron Related Compound C RS](#), and [USP Granisetron Related Compound D RS](#) in *Solution A*

Standard solution: 0.11 mg/mL of [USP Granisetron Hydrochloride RS](#) in *Solution A*

Sample solution: ▲ Nominally ▲ (USP 1-May-2021) 0.1 mg/mL of granisetron (base), based on the label claim, prepared as follows. Fill a suitable volumetric flask with *Solution A*, add 5 Tablets and sonicate for approximately 20 min until the Tablets disintegrate completely. Pass a portion of this solution through a membrane filter of 0.45-µm pore size, discarding the first few milliliters.

Chromatographic system

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

Mode: LC

Detector: UV 300 nm. ▲ For *Identification A*, use a diode array detector in the range of 200–400 nm. ▲ (USP 1-May-2021)

Column: 4.6-mm × 15-cm; 4-µm packing [L1](#)

Flow rate: 1.2 mL/min

Injection volume: 20 µL

System suitability

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

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

▲▲ (USP 1-May-2021)

Resolution: NLT 2 between the granisetron and granisetron related compound C peaks, *System suitability solution*

Tailing factor: 0.8–1.5 for the granisetron peak, *System suitability solution*

Relative standard deviation: NMT 2.0% for 6 replicate injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of granisetron ($C_{18}H_{24}N_4O$) in each Tablet taken:

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

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

M_{r1} = molecular weight of granisetron, 312.41

M_{r2} = molecular weight of granisetron hydrochloride, 348.87

Acceptance criteria: 92.0%–108.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: pH 6.5 phosphate buffer (6.8 g/L of [monobasic potassium phosphate](#) in [water](#); adjusted with [1 N sodium hydroxide](#) to a pH of 6.5 prior to final dilution); 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Solution A and Mobile phase ▲▲ (USP 1-May-2021) : Prepare as directed in the Assay.

Standard stock solution: Use *Standard solution* from the Assay.

Standard solution: 0.002 mg/mL of [USP Granisetron Hydrochloride RS](#) in *Solution A* from *Standard stock solution*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. If necessary, further dilute 5 mL of this solution with *Solution A* to $(5 \times L)$ mL, where L is the label claim in mg/Tablet.

Chromatographic system: Proceed as directed in the Assay, except for the *Injection volume*.

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.8–1.5

Relative standard deviation: NMT 2.0% for 6 replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of granisetron ($C_{18}H_{24}N_4O$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times (M_{r1}/M_{r2}) \times V \times (1/L) \times D \times 100$$

r_U = peak response of granisetron from the *Sample solution*