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Hydroxyzine Hydrochloride Oral Solution

DEFINITION

Hydroxyzine Hydrochloride Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of hydroxyzine hydrochloride ($C_{21}H_{27}ClN_2O_2 \cdot 2HCl$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the hydroxyzine peak of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• **PROCEDURE**

Solution A: [Trifluoroacetic acid](#) and water (0.1:99.9)

Solution B: [Trifluoroacetic acid](#) and [acetonitrile](#) (0.05: 99.95)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
4	90	10
12	60	40
16	60	40
21	20	80
25	20	80
26	90	10
30	90	10

Diluent: [Acetonitrile](#) and [water](#) (30:70)

Standard solution: 0.05 mg/mL of [USP Hydroxyzine Hydrochloride RS](#) in *Diluent*

Sample stock solution: Nominally 0.5 mg/mL of hydroxyzine hydrochloride from Oral Solution in *Diluent* prepared as follows. Transfer a portion of Oral Solution, equivalent to 25 mg of hydroxyzine hydrochloride, to a 50-mL volumetric flask. Dissolve and dilute with *Diluent* to volume.

Sample solution: Nominally 0.05 mg/mL of hydroxyzine hydrochloride from the *Sample stock solution* in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 230 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 2.1-mm × 15-cm; 1.8-μm packing [L1](#)

Column temperature: 30°

Flow rate: 0.3 mL/min

Injection volume: 2 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of hydroxyzine hydrochloride ($C_{21}H_{27}ClN_2O_2 \cdot 2HCl$) in the portion of Oral Solution taken:

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

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

r_S = peak response of hydroxyzine from the *Standard solution*

C_S = concentration of [USP Hydroxyzine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#)

For single-unit containers

Acceptance criteria: Meets the requirements

• [DELIVERABLE VOLUME \(698\)](#)

For multiple-unit containers

Acceptance criteria: Meets the requirements

IMPURITIES

• ORGANIC IMPURITIES

Solution A, Solution B, Mobile phase, and Diluent: Prepare as directed in the Assay.

Standard stock solution: 25.0 µg/mL each of [USP Hydroxyzine Hydrochloride RS](#), [USP Hydroxyzine Related Compound A RS](#), and [USP 4-Chlorobenzophenone RS](#) in *Diluent*

Standard solution: 1.0 µg/mL each of [USP Hydroxyzine Hydrochloride RS](#), [USP Hydroxyzine Related Compound A RS](#), and [USP 4-Chlorobenzophenone RS](#) from the *Standard stock solution* in *Diluent*

Sample solution: Nominally 500 µg/mL of hydroxyzine hydrochloride from Oral Solution in *Diluent* prepared as follows. Transfer a portion of Oral Solution, equivalent to 25 mg of hydroxyzine hydrochloride, to a 50-mL volumetric flask. Dissolve and dilute with *Diluent* to volume.

Chromatographic system

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

Mode: LC

Detectors

Hydroxyzine related compound A and hydroxyzine hydrochloride: UV 230 nm

4-Chlorobenzophenone: UV 254 nm

Column: 2.1-mm × 15-cm; 1.8-µm packing [L1](#)

Column temperature: 30°

Flow rate: 0.3 mL/min

Injection volume: 2 µL

System suitability

Sample: *Standard solution*

[NOTE—See [Table 2](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 5.0 between hydroxyzine related compound A and hydroxyzine

Relative standard deviation: NMT 3.0% for hydroxyzine related compound A, hydroxyzine, and 4-chlorobenzophenone

Analysis

Samples: *Standard solution* and *Sample solution*

For impurities detected at UV 230 nm

Calculate the percentage of any individual unspecified degradation product in the portion of Oral Solution taken:

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

r_U = peak response of any individual unspecified degradation product from the *Sample solution*

r_S = peak response of hydroxyzine from the *Standard solution*

C_S = concentration of [USP Hydroxyzine Hydrochloride RS](#) in the *Standard solution* (µg/mL)