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Hydroxyzine Hydrochloride Injection

DEFINITION

Hydroxyzine Hydrochloride Injection is a sterile solution of Hydroxyzine Hydrochloride in Water for Injection. It 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.

Standard solution: 20 µg/mL of [USP Hydroxyzine Hydrochloride RS](#) in 0.1 N hydrochloric acid

Sample solution: Nominally 20 µg/mL of hydroxyzine hydrochloride from Injection in 0.1 N hydrochloric acid

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as that of the *Standard solution*, concomitantly measured.

• B. The retention time of the main peak in the *Sample solution* corresponds to that of the hydroxyzine peak from the *Standard solution* as obtained in the Assay.

ASSAY

• PROCEDURE

Protect the *Standard solution* and *Sample solution* from light.

Buffer: 2 g/L of dibasic potassium phosphate and 8 g/L of monobasic potassium phosphate adjusted with 10 N potassium hydroxide to a pH of 6.6

Mobile phase: Methanol and *Buffer* (65:35)

Standard solution: 0.25 mg/mL of [USP Hydroxyzine Hydrochloride RS](#) and 0.5 µg/mL of [USP 4-Chlorobenzophenone RS](#) in *Mobile phase*

Sample solution: Nominally 0.25 mg/mL of hydroxyzine hydrochloride from Injection in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for 4-chlorobenzophenone and hydroxyzine are 0.75 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the 4-chlorobenzophenone and hydroxyzine peaks

Tailing factor: NMT 2.5 for the 4-chlorobenzophenone and hydroxyzine peaks

Relative standard deviation: NMT 2.0% for the hydroxyzine peak

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 Injection 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%

IMPURITIES

• LIMIT OF 4-CHLOROBENZOPHENONE

Mobile phase, Standard solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of 4-chlorobenzophenone in the portion of Injection taken:

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

r_U = peak response of 4-chlorobenzophenone in the *Sample solution*

r_S = peak response of 4-chlorobenzophenone in the *Standard solution*

C_S = concentration of [USP 4-Chlorobenzophenone RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: NMT 0.2%

SPECIFIC TESTS

- **pH** (791): 3.5–6.0
- **BACTERIAL ENDOTOXINS TEST** (85): NMT 3.6 USP Endotoxin Units/mg of hydroxyzine hydrochloride
- **OTHER REQUIREMENTS:** Meets the requirements in [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose or multiple-dose containers, protected from light. Store at controlled room temperature.

- **USP REFERENCE STANDARDS** (11).

[USP 4-Chlorobenzophenone RS](#) $C_{13}H_9ClO$ 216.66

[USP Hydroxyzine Hydrochloride RS](#)

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

Topic/Question	Contact	Expert Committee
HYDROXYZINE HYDROCHLORIDE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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