Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-5D7F7AE1-81F8-425B-8848-6ABE0DE3BCCE_3_en-US
DOI: https://doi.org/10.31003/USPNF_M39470_03_01
DOI Ref: m9m09

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:
Pharmacopeial Forum: Volume No. PF 41(1)

Current DocID: GUID-5D7F7AE1-81F8-425B-8848-6ABE0DE3BCCE_3_en-US
Previous DocID: GUID-5D7F7AE1-81F8-425B-8848-6ABE0DE3BCCE_1_en-US
DOI: https://doi.org/10.31003/USPNF_M39470_03_01
DOI ref: m9m09