Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Dec-2020
Document Type: USP Monographs
DocId: GUID-3176EF7D-6591-43B1-B6FC-4F7CC953EB9F_4_en-US
DOI: https://doi.org/10.31003/USPNF_M25140_04_01
DOI Ref: w1wlb

Dicyclomine Hydrochloride Injection

DEFINITION

Dicyclomine Hydrochloride Injection is a sterile, isotonic solution of Dicyclomine Hydrochloride in Water for Injection. It contains NLT 93.0% and NMT 107.0% of the labeled amount of dicyclomine hydrochloride ($C_{19}H_{35}NO_2 \cdot HCl$).

IDENTIFICATION

• **A.**

Sample: Transfer a portion of Injection, equivalent to 100 mg of dicyclomine hydrochloride, to a separator containing 10 mL of water and 1 mL of hydrochloric acid. Shake with 25 mL of ether, and discard the ether layer. Extract the aqueous acid solution with two 30-mL portions of chloroform, transfer the chloroform extracts to a second separator containing 20 mL of water and 1 mL of sodium hydroxide solution (1 in 10), and shake. Filter the chloroform layer through anhydrous sodium sulfate into a suitable container. Add 3 mL of a freshly prepared 1-in-20 solution of acetyl chloride in anhydrous methanol, prepared by cautiously adding acetyl chloride dropwise to anhydrous methanol with stirring. Evaporate under reduced pressure at room temperature until the residue has been thoroughly dried. Use the residue so obtained to prepare a potassium bromide dispersion.

Standard: Use a similarly prepared potassium bromide dispersion of USP Dicyclomine Hydrochloride RS.

Acceptance criteria: The IR absorption spectrum of the *Sample* exhibits maxima and minima at the same wavelengths as those of the *Standard*.

• **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**

Buffer: Dissolve 2.72 g of monobasic potassium phosphate in 900 mL of water, adjust with 10% sodium hydroxide to a pH of 7.5 ± 0.1, and dilute with water to 1000 mL.

Mobile phase: Acetonitrile and *Buffer* (70:30)

Diluent: Acetonitrile and water (70:30)

Standard solution: 0.4 mg/mL of USP Dicyclomine Hydrochloride RS in *Diluent*. [Note—This solution is stable for ▲at least▲ (USP 1-Dec-2020) 2 days.]

Sample solution: Prepare a composite sample of at least 5 ampules or 2 vials. Transfer a volume of the composite sample, equivalent to 20.0 mg of dicyclomine hydrochloride, to a 50-mL volumetric flask, and dilute with *Diluent* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 15-cm; 3.5-µm packing L7

Flow rate: ▲1▲ (USP 1-Dec-2020) mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dicyclomine hydrochloride ($C_{19}H_{35}NO_2 \cdot HCl$) in the portion of Injection taken:

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

r_U = peak area of dicyclomine from the *Sample solution*

r_S = peak area of dicyclomine from the *Standard solution*

C_S = concentration of USP Dicyclomine Hydrochloride RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 93.0%–107.0%

IMPURITIES

Add the following:

▲• **Limit of Dicyclomine Related Compound A**

Buffer: Dissolve 2.72 g of monobasic potassium phosphate in 900 mL of water, adjust with phosphoric acid to a pH of 3.5, and dilute with water to 1000 mL.

Mobile phase: Acetonitrile and *Buffer* (55:45)

Diluent: Acetonitrile and water (70:30)

Standard stock solution: 0.1 mg/mL of USP Dicyclomine Related Compound A RS in *Diluent*. Sonication may be used.

Standard solution: 4.0 µg/mL of USP Dicyclomine Related Compound A RS in *Diluent* from *Standard stock solution*

Sensitivity solution: 2.0 µg/mL of USP Dicyclomine Related Compound A RS in *Diluent* from *Standard solution*

Sample solution: Nominally 2.0 mg/mL of dicyclomine hydrochloride in *Diluent* prepared as follows. Prepare a composite sample of NLT 5 vials. Transfer a volume of the composite sample, equivalent to 20 mg of dicyclomine hydrochloride, to a 10-mL volumetric flask, and dilute with *Diluent* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 15-cm; 3.5-µm packing L7

Flow rate: 1 mL/min

Injection volume: 100 µL

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dicyclomine related compound A in the portion of Injection taken:

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

r_U = peak response of dicyclomine related compound A from the *Sample solution*

r_S = peak response of dicyclomine related compound A from the *Standard solution*

C_S = concentration of USP Dicyclomine Related Compound A RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: NMT 0.2%▲ (USP 1-Dec-2020)

SPECIFIC TESTS

Change to read:

• **Bacterial Endotoxins Test ⟨85⟩:** ▲Meets the requirements▲ (USP 1-Dec-2020)

Add the following:

▲• **Sterility Tests ⟨71⟩:** Meets the requirements▲ (USP 1-Dec-2020)

• **Other Requirements:** It meets the requirements in Injections and *Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass. ▲Store at controlled room temperature. Protect from freezing.▲ (USP 1-Dec-2020)

Change to read:

• **USP Reference Standards ⟨11⟩**

USP Dicyclomine Hydrochloride RS

▲ USP Dicyclomine Related Compound A RS

[1,1'-Bi(cyclohexane)]-1-carboxylic acid.

$C_{13}H_{22}O_2$ 210.32▲ (USP 1-Dec-2020)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DICYCLOMINE HYDROCHLORIDE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 43(6)

Current DocID: GUID-3176EF7D-6591-43B1-B6FC-4F7CC953EB9F_4_en-US

DOI: https://doi.org/10.31003/USPNF_M25140_04_01

DOI ref: w1wlb