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# Cyclizine Hydrochloride Tablets

## DEFINITION

Cyclizine Hydrochloride Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of cyclizine hydrochloride ($C_{18}H_{22}N_2 \cdot HCl$).

## IDENTIFICATION

***Change to read:***

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

**Sample:** Extract a quantity of powdered Tablets containing 100 mg of cyclizine hydrochloride with 10 mL of ethanol. Filter, evaporate to dryness, and use the dried residue.

**Acceptance criteria:** Meet the requirements

## ASSAY

• **Procedure**

**Analysis:** Proceed with Tablets as directed in *Salts of Organic Nitrogenous Bases ⟨501⟩*. Dilute the *Standard Preparation* and the *Assay Preparation*, respectively, with an equal volume of dilute sulfuric acid (1 in 100), and determine the absorbance at the wavelength of maximum absorbance at about 264 nm.

Calculate the percentage of the labeled amount of cyclizine hydrochloride ($C_{18}H_{22}N_2 \cdot HCl$) in the portion of Tablets taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

$A_U$ = absorbance of the *Assay Preparation*

$A_S$ = absorbance of the *Standard Preparation*

$C_S$ = concentration of USP Cyclizine Hydrochloride RS in the *Standard Preparation* (mg/mL)

$C_U$ = nominal concentration of cyclizine hydrochloride in the *Assay Preparation* (mg/mL)

**Acceptance criteria:** 93.0%–107.0%

## PERFORMANCE TESTS

• **Dissolution, *Procedure for a Pooled Sample ⟨711⟩***

**Medium:** Water; 900 mL

**Apparatus 2:** 50 rpm

**Time:** 45 min

**Analysis:** Determine the amount of cyclizine hydrochloride ($C_{18}H_{22}N_2 \cdot HCl$) dissolved by proceeding as directed in the *Assay*, making any necessary modifications.

**Tolerances:** NLT 75% (*Q*) of the labeled amount of cyclizine hydrochloride ($C_{18}H_{22}N_2 \cdot HCl$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

## IMPURITIES

• **Organic Impurities**

**Diluent:** Methanol

**Standard solution 1:** 0.05 mg/mL of USP Cyclizine Hydrochloride RS in *Diluent*

**Standard solution 2:** 0.05 mg/mL of USP Cyclizine Related Compound A RS in *Diluent*

**System suitability solution:** 1 mg/mL of USP Cyclizine Hydrochloride RS and 1 mg/mL of USP Hydroxyzine Hydrochloride RS in *Diluent*

**Sample solution:** Triturate a quantity of powdered Tablets containing 100 mg of cyclizine hydrochloride with 10 mL of methanol, and filter.

**Chromatographic system**

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

**Mode:** TLC

**Adsorbent:** 0.25-mm layer of chromatographic silica gel mixture

**Application volume:** 20 µL

**Developing solvent system:** Mix methylene chloride, methanol, and ammonium hydroxide (90:8:2). Allow the layers to separate, and use the lower layer.

**System suitability**

**Sample:** *System suitability solution*

**Suitability requirements**

**Resolution:** The chromatogram shows two clearly visible and separated spots.

**Analysis**

**Samples:** *Standard solution 1*, *Standard solution 2*, and *Sample solution*

Proceed as directed in *Chromatography ⟨621⟩, Thin-Layer Chromatography*. Air-dry the plate for several min, expose it to iodine vapor for 20 min, and examine the plate under short-wavelength UV light.

**Acceptance criteria**

**Cyclizine related compound A:** The spot corresponding to cyclizine related compound A in the *Sample solution* is not more intense than the principal spot obtained from *Standard solution 2* (NMT 0.5%).

**Any unspecified impurity:** Any other secondary spot in the chromatogram from the *Sample solution* is not more intense than the principal spot obtained from *Standard solution 1* (NMT 0.5%).

## ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers.
- **USP Reference Standards ⟨11⟩**

USP Cyclizine Hydrochloride RS

USP Cyclizine Related Compound A RS

1-Methylpiperazine.

$C_5H_{12}N_2$ 100.16

USP Hydroxyzine Hydrochloride RS

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| CYCLIZINE HYDROCHLORIDE TABLETS | Documentary Standards Support | SM32020 Small Molecules 3 |

**Chromatographic Database Information:** Chromatographic Database

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