Cyclophosphamide / Official Monographs for Part I

(100:60:23:17) to a distance of about 10 cm, and air-dry the plate. Spray evenly a solution of sulfuric acid in ethanol (99.5) (1 in 10) on the plate, and heat at 120°C for 30 minutes. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

**Loss on drying** Not more than 0.5% (1 g, 105°C, 4 hours).

**Residue on ignition** Not more than 0.05% (1 g).

**Assay** Weigh accurately about 0.5 g of Cyclopentolate Hydrochloride, previously dried, dissolve in 50 mL of a mixture of acetic anhydride and acetic acid (100) (4:1), and titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from purple through blue-green to yellow-green (indicator: 2 drops of crystal violet TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS = 32.785 mg of Cl₃H₂N₂NO₃.HCl

**Containers and storage** Containers—Tight containers.

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**Cycloserine**

サイクロセリン

\[
\text{C}_9\text{H}_8\text{N}_2\text{O}_5\cdot\text{H}_2\text{O}: 102.09
\]

(4R)-4-Aminoisoaxazolidin-3-one [68-41-7]

Cycloserine contains not less than 900 μg (potency) per mg, calculated on the dried basis. The potency of Cycloserine is expressed as mass (potency) of cycloserine (C₉H₈N₂O₅).

**Description** Cycloserine occurs as white to light yellowish white, crystals or crystalline powder.

It is soluble in water, and sparingly soluble in ethanol (95%).

**Identification** (1) Dissolve 0.1 g of Cycloserine in 10 mL of water, and add 5 mL of silver nitrate TS: no precipitate is produced. Then boil this solution: a white precipitate is produced. Collect the precipitate, and add dilute nitric acid to a portion of this precipitate: it does not dissolve. Add excess ammonia TS to another portion of the precipitate: it dissolves.

(2) Add 1 mL of diluted sulfuric acid (1 in 25) to 0.02 g of Cycloserine, and heat until white fumes are evolved. After cooling, add 5 mL of water, and shake. Neutralize with ammonia TS, then acidify with dilute nitric acid: this solution responds to the Qualitative Tests (2) for phosphate.

**Purity** (1) Clarity and color of solution—Dissolve 0.20 g of Cycloserine in 10 mL of water: the solution is clear and colorless.

(2) Chloride—Perform the test with 0.40 g of Cyclophosphamide at a temperature not exceeding 20°C. Prepare the control solution with 0.40 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.036%).

(3) Heavy metals—Proceed with 1.0 g of Cyclophosphamide according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

**Water** 5.5 - 7.0% (0.5 g, direct titration).

**Containers and storage** Containers—Tight containers.

Storage—Not exceeding 30°C.
Cycloheptadine Hydrochloride, when dried, contains not less than 98.5% of $C_{21}H_{29}N\cdot HCl$: 323.86

**Description** Cycloheptadine Hydrochloride occurs as a white to pale yellow, crystalline powder. It is odorless, and has a slightly bitter taste.

It is freely soluble in methanol and in acetic acid (100), soluble in chloroform, sparingly soluble in ethanol (95), slightly soluble in water, and practically insoluble in diethyl ether.

**Identification**

1. Dissolve 0.1 g of Cycloheptadine Hydrochloride in 10 mL of methanol, apply 1 drop of this solution on filter paper, air-dry, and examine under ultraviolet light (main wavelength: 254 nm): the solution shows a pale blue fluorescence.

2. Weigh 0.1 g of Cycloheptadine Hydrochloride, transfer to a separator, dissolve in 5 mL of chloroform, add 4 mL of water and 1 mL of sodium carbonate TS, and shake. Transfer the chloroform layer to another separator, and wash with 4 mL of water by shaking well. Filter the chloroform layer through absorbent cotton moistened previously with chloroform, and evaporate the filtrate to dryness. Dissolve the residue in 8 mL of dilute ethanol by warming at 65°C. Rub the inner wall of the container with a glass rod while cooling until crystallization begins, and allow to stand for 30 minutes. Collect the crystals, and dry at 80°C for 2 hours: the crystals melt between 111°C and 115°C.

3. Determine the absorption spectrum of a solution of Cycloheptadine Hydrochloride in ethanol (95) (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

4. A saturated solution of Cycloheptadine Hydrochloride responds to the Qualitative Tests (2) for chloride.

**Purity**

1. Acid—Dissolve 2.0 g of Cycloheptadine Hydrochloride in 25 mL of methanol, and add 1 drop of methyl red TS and 0.30 mL of 0.1 mol/L sodium hydroxide VS: a yellow color develops.

2. Heavy metals—Proceed with 1.0 g of Cycloheptadine Hydrochloride according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

**Loss on drying** 7.0 - 9.0% (1 g, in vacuum at a pressure not exceeding 0.67 kPa, 100°C, 5 hours).

**Residue on ignition** Not more than 0.10% (1 g).

**Assay** Weigh accurately about 0.5 g of Cycloheptadine Hydrochloride, previously dried, and dissolve in 20 mL of acetic acid (100) by warming at 50°C. After cooling, add 40 mL of acetic anhydride, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS = 32.387 mg of $C_{21}H_{29}N\cdot HCl$

**Containers and storage** Containers—Well-closed containers.

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Cycloheptadine Hydrochloride

C$_{21}$H$_{29}$N$\cdot$HCl,$\frac{1}{2}$H$_2$O: 350.88

4-(5H-Dibenzo[a,d]cyclohepten-5-ylidene)-1-methylpiperidine monohydrochloride sesquihydrate

$\{41354-29-4\}$

Containers and storage  Containers—Tight containers.