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Cycloserine Capsules

» Cycloserine Capsules contain not less than 90.0 percent and not more than 120.0 percent of the labeled amount of cycloserine ($C_3H_6N_2O_2$).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Cycloserine RS

Identification—Shake a quantity of the contents of Capsules, equivalent to about 10 mg of cycloserine, with 100 mL of 0.1 N sodium hydroxide, and filter: 1 mL of the filtrate so obtained responds to the *Identification* test under *Cycloserine.*

Dissolution ⟨711⟩—

Medium: pH 6.8 Phosphate buffer (see *Buffer Solutions* under *Solutions* in the section *Reagents, Indicators, and Solutions*); 900 mL.

Apparatus 1: 100 rpm.

Time: 30 minutes.

Determine the amount of $C_3H_6N_2O_2$ dissolved by employing the following method.

pH 6.8 Phosphate buffer, *Mobile phase*, and *Chromatographic system*—Proceed as directed in the *Assay*.

Standard solution—Quantitatively dissolve an accurately weighed quantity of USP Cycloserine RS in *pH 6.8 Phosphate buffer* to obtain a solution having a known concentration of about 0.25 mg per mL.

Test solution—Use a filtered portion of the solution under test.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses for cycloserine. Calculate the quantity, in mg, of cycloserine ($C_3H_6N_2O_2$) dissolved by the formula:

$$900C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Cycloserine RS in the *Standard solution;* and r_U and r_S are the peak responses for cycloserine obtained from the *Test solution* and the *Standard solution*, respectively.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_3H_6N_2O_2$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Loss on drying ⟨731⟩—Dry about 100 mg of the contents of Capsules in a capillary-stoppered bottle in vacuum at 60° for 3 hours: it loses not more than 1.0% of its weight.

Assay—

pH 6.8 Phosphate buffer, *Mobile phase*, *Standard preparation*, and *Chromatographic system*—Proceed as directed in the *Assay* under *Cycloserine.*

Assay preparation—Remove, as completely as possible, the contents of not fewer than 20 Capsules. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of cycloserine, to a 250-mL volumetric flask, dilute with *pH 6.8 Phosphate buffer* to volume, mix, and filter.

Procedure—Proceed as directed in the *Assay* under *Cycloserine.* Calculate the quantity, in mg, of cycloserine ($C_3H_6N_2O_2$) in the portion of Capsules taken by the formula:

$$250C(r_U/r_S)$$

in which the terms are as defined therein.

Topic/Question	Contact	Expert Committee
CYCLOSERINE CAPSULES	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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