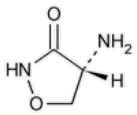
Status: Currently Official on 17-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-374775C8-4F44-4EE9-8739-CF234A5DD929_1_en-US
DOI: https://doi.org/10.31003/USPNF_M21450_01_01
DOI Ref: qao2o

Cycloserine



$C_3H_6N_2O_2$ 102.09

3-Isoxazolidinone, 4-amino-, (*R*)-.

(+)-4-Amino-3-isoxazolidinone CAS RN®: 68-41-7; UNII: 95IK5KI84Z.

» Cycloserine has a potency of not less than 900 µg of $C_3H_6N_2O_2$ per mg.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Cycloserine RS

Identification—Dissolve about 1 mg in 10 mL of 0.1 N sodium hydroxide. To 1 mL of the resulting solution add 3 mL of 1 N acetic acid and 1 mL of a mixture, prepared 1 hour before use, of equal parts of sodium nitroprusside solution (1 in 25) and 4 N sodium hydroxide: a blue color gradually develops.

Condensation products—Its absorptivity (see *Ultraviolet-Visible Spectroscopy* ⟨857⟩) at 285 nm, determined in a 0.1 N sodium hydroxide solution containing 0.40 mg per mL is not more than 0.80.

Specific rotation ⟨781S⟩: between 108° and 114°.

Test solution: 50 mg per mL, in 2 N sodium hydroxide.

Crystallinity ⟨695⟩: meets the requirements.

pH ⟨791⟩: between 5.5 and 6.5, in a solution (1 in 10).

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

Residue on ignition ⟨281⟩: not more than 0.5%, the charred residue being moistened with 2 mL of nitric acid and 5 drops of sulfuric acid.

Assay—

pH 6.8 Phosphate buffer—Prepare as directed in *Buffer Solutions* under *Solutions* in the section *Reagents, Indicators, and Solutions.*

Mobile phase—Dissolve 0.5 g of sodium 1-decanesulfonate in 800 mL of water, add 50 mL of acetonitrile and 5 mL of glacial acetic acid, and mix. Adjust with 1 N sodium hydroxide to a pH of 4.4. Filter, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—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 0.4 mg per mL.

Assay preparation—Transfer about 20 mg of Cycloserine, accurately weighed, to a 50-mL volumetric flask, dissolve in and dilute with *pH 6.8 Phosphate buffer* to volume, and mix.

Chromatographic system (see Chromatography ⟨621⟩)—The liquid chromatograph is equipped with a 219-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L1. The flow rate is about 1 mL per minute. The column temperature is maintained at about 30°. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the tailing factor is not more than 1.8; and the relative standard deviation for replicate injections is not more than 2.0%.

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

$$50{,}000(C/W)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Cycloserine RS in the *Standard preparation; W* is the quantity, in mg, of Cycloserine taken to prepare the *Assay preparation;* and r_U and r_S are the peak responses for cycloserine obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Topic/Question	Contact	Expert Committee
CYCLOSERINE	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 27(5)

Current DocID: GUID-374775C8-4F44-4EE9-8739-CF234A5DD929_1_en-US

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