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Cysteine Hydrochloride Injection

» Cysteine Hydrochloride Injection is a sterile solution of Cysteine Hydrochloride in Water for Injection. It contains not less than 85.0 percent and not more than 115.0 percent of the labeled amount of $C_3H_7NO_2S \cdot HCl \cdot H_2O$.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

USP REFERENCE STANDARDS (11)—
[USP L-Cysteine Hydrochloride RS](#)

Identification—

- A:** To 2 mL of Injection add 3 mL of water, and mix. Add 10 mL of cupric sulfate TS: a bluish-gray precipitate is formed.
- B:** To 2 mL of Injection add 3 mL of water, and mix. Add 2 mL of 3 N sodium hydroxide and 2 drops of sodium nitroferricyanide solution (1 in 20): a red-purple color is produced, and it rapidly changes to yellow.

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 0.7 USP Endotoxin Unit per mg of cysteine hydrochloride.

pH (791): between 1.0 and 2.5.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—

Standard stock preparation—Dissolve an accurately weighed quantity of [USP L-Cysteine Hydrochloride RS](#) in nitrogen-saturated water to obtain a solution having a known concentration of about 1 mg per mL.

Standard preparation—Transfer 20.0 mL of *Standard stock preparation* to a 200-mL volumetric flask, dilute with nitrogen-saturated 1.0 N sodium hydroxide to volume, and mix.

Assay preparation—Dilute an accurately measured volume of Injection, equivalent to about 250 mg of cysteine hydrochloride, quantitatively and stepwise with nitrogen-saturated 1.0 N sodium hydroxide, to obtain a solution having a concentration of about 0.1 mg per mL.

Procedure—Transfer a suitable amount of *Standard preparation* to a polarographic cell. With mercury dropping from the electrode, lower the dropping mercury electrode of a polarograph so that the end is submerged in the liquid. Bubble oxygen-free, water-saturated nitrogen through the liquid for 15 minutes. Record the polarogram from -0.2 volt to -1.10 volts, using a saturated calomel electrode as the reference electrode. In a similar manner, record the polarograms obtained using portions of the *Assay preparation* and of the nitrogen-saturated 1.0 N sodium hydroxide. Determine the height of the diffusion current wave at -0.4 volt. Calculate the quantity, in mg, of $C_3H_7NO_2S \cdot HCl \cdot H_2O$ in each mL of the Injection taken by the formula:

$$2500(C/V)[(i_d)_U/(i_d)_S]$$

in which C is the concentration, in mg per mL, of [USP L-Cysteine Hydrochloride RS](#). In the *Standard preparation*, V is the volume, in mL, of Injection taken; and $(i_d)_U$ and $(i_d)_S$ are the observed diffusion currents, corrected for the diffusion current of the 0.1 N sodium hydroxide, of the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
CYSTEINE HYDROCHLORIDE INJECTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

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