U.S. Pharmacist
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PUBLISHED SEPTEMBER 20, 2011

L-Cysteine Hydrochloride 50 mg/mL Injection

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US Pharm. 2011;36(9):41-42.

FORMULA

L-Cysteine Hydrochloride 50 mg/mL Injection

Rx:	Ingredient		
	L-Cysteine hydrochloride		5 g
	Hydrochloric acid 2N solution		qs to pH 1 to 2.5
	Sterile Water for Injection	qs	100 mL

Method of Preparation: Note: This formulation should be prepared according to strict aseptic compounding technique in a laminar airflow hood in a cleanroom or via isolation barrier technology by a compounding pharmacist who is validated in aseptic compounding. This is a high-risk preparation.

Calculate the quantity of each ingredient for the amount to be prepared. Accurately weigh or measure each ingredient. Mix the cysteine in about 40 mL of Sterile Water for Injection. Add sufficient hydrochloric acid 2N solution to a pH of 1 to 2.5 to form a clear solution. Add sufficient Sterile Water for Injection to final volume; mix well. Filter into sterile containers. Package and label.

Use: This injection solution is intended for use only after dilution as an additive to crystalline amino acid injections to meet the nutritional amino acid requirements of infants receiving total parenteral nutrition (TPN).

Packaging: Package in tight, light-resistant containers.

Labeling: Keep out of the reach of children. Discard after ____ [time period]. Protect from light. Discard if precipitation occurs. Store at controlled room temperature. Do not freeze.

Stability: A beyond-use date of up to 24 hours at room temperature or 3 days in the refrigerator may be used if not sterility tested. If sterility tested, a beyond-use date of up to 6 months may be used.[1]

Quality Control: Quality-control assessment can include weight/volume, physical observation, pH, specific gravity, osmolality, assay, color, clarity, particulate matter, sterility, and pyrogenicity.[2,3]

Discussion: Premature or sick infants may receive TPN before starting other feedings or when they cannot absorb nutrients through the gastrointestinal tract for a significant period of time. TPN confers a level of nutrition that is superior to standard IV feedings, which provide simply sugars and salts. L-Cysteine hydrochloride 50 mg/mL injection is used for TPN in infants.[4]

L-Cysteine hydrochloride 50 mg/mL injection has been in short supply. The formulation presented here can be compounded for use until the manufactured product is available.

Cysteine Hydrochloride Injection, USP, is a sterile solution of cysteine hydrochloride in water for injection. It is a clear, colorless solution with an odor of sulfide. It contains not less than 85.0% and not more than 115.0% of the labeled amount of cysteine hydrochloride. The product contains not more than 0.7 USP endotoxin units per mg of cysteine hydrochloride and has a pH between 1.0 and 2.5.[5]

L-Cysteine hydrochloride (L-cysteine, L-cysteine ethylester hydrochloride, $C_3H_7NO_2S.HCl.H_20$, MW 175.63) is a nonessential amino acid in human development. It is freely soluble in water, alcohol, acetic acid, and ammonia water, but is insoluble in ether, acetone, ethyl acetate, benzene, carbon disulfide, and carbon tetrachloride. In neutral or slightly alkaline aqueous solutions, it is oxidized to cystine by air. It is more stable in acidic solutions.

Hydrochloric acid (HCl, MW 36.46) occurs as a clear, colorless, fuming aqueous solution of hydrogen chloride that has a pungent odor. Concentrated hydrochloric acid is 36.5% to 38.0% w/w concentration. It has a specific gravity of 1.18 g/cm^3, is miscible with water, and is soluble in ethanol. The pH of a 10% v/v aqueous solution is 0.1. Hydrochloric acid should be stored in well-closed glass or other inert containers.[6]

Sterile Water for Injection is water for injection that has been sterilized and suitably packaged; it contains no added substances. Water for injection is water purified by distillation or reverse osmosis and contains no added substances. Water for injection is not prepared by an ion-exchange process. The term *water* is used to describe potable water from a public water supply that is suitable for drinking and is the beginning point of the official waters. It is a clear, colorless, odorless, and tasteless liquid. Purified water is obtained by distillation, ion exchange, reverse osmosis, or other suitable process. Water has a specific gravity of 0.9971 at room temperature, a melting point of 0°C, and a boiling point of 100°C. It is miscible with most polar solvents and is chemically stable in all physical states (ice, liquid, and steam).[7]

REFERENCES

1. *USP Pharmacists' Pharmacopeia.* 2nd ed. Rockville, MD: US Pharmacopeial Convention, Inc; 2008:775-779,797-831.
2. Allen LV Jr. Standard operating procedure for particulate testing for sterile products. *IJPC*. 1998;2:78.
3. Allen LV Jr. Standard operating procedure: quality assessment for injectable solutions. *IJPC*. 1999;3:406-407.
4. Total parenteral nutrition—infants. Medline Plus. www.nlm.nih.gov/medlineplus/ency/article/007239.htm. Accessed August 12, 2011.
5. *U.S. Pharmacopeia 34/National Formulary 29*. Rockville, MD: US Pharmacopeial Convention, Inc; 2011:2464.
6. Quinn ME, Sheskey PJ. Hydrochloric acid. In: Rowe RC, Sheskey PJ, Quinn ME, eds. *Handbook of Pharmaceutical Excipients*. 6th ed. London, England: Pharmaceutical Press; 2009:308-309.
7. Dubash D, Shah U. Water. In: Rowe RC, Sheskey PJ, Quinn ME, eds. *Handbook of Pharmaceutical Excipients*. 6th ed. London, England: Pharmaceutical Press; 2009:766-770.

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