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Lysine Hydrochloride

$C_6H_{12}N_2O_2 \cdot HCl$ 182.65

USP XXI I I

Reference No. LYSH-5021

~ Lysine Hydrochloride contains not less than 98.5 percent and not more than 101.5 percent of $C_6H_{12}N_2O_2 \cdot HCl$, as L-lysine hydrochloride, calculated on the dried basis.

Lysine Hydrochloride: White, odorless powder. Freely soluble in water.

Packaging and storage Preserve in well-closed containers.

USP Reference standards (11) ~ USP 'L-lysine Hydrochloride RS.

Identification, Infrared Absorption (1 97K).

Specific rotation (781S): between +20.4° and +21.4°. Test solution: 80 mg per mL, in 6 N hydrochloric acid.

Loss on drying (731) ~ Dry it at 105° for 3 hours: it loses not more than 0.4% of its weight.

Residue on ignition (281): not more than 0.1%.

Sulfate (221) ~ A solution containing 0.33 g shows no more sulfate than corresponds to 0.10 mL of 0.020 N sulfuric acid (0.03%).

Arsenic (211): 1.5 ppm.

Iron (241): 0.003%.

Heavy metals, Method I (231): 0.0015%.

Organic volatile impurities, Method I (467): meets the requirements.

Chloride content (221) Transfer about 350 mg, accurately weighed, to a porcelain casserole, and add 140 mL of water and 1 mL of dichlorofluorescein TS. Mix, and titrate with 0.1 N silver nitrate VS until the silver chloride flocculates and the mixture acquires a faint pink color. Each mL of 0.1 N silver nitrate is equivalent to 3.545 mg of chloride: between 19.0% and 19.6% is found.

Assay Transfer about 90 mg of Lysine Hydrochloride, accurately weighed, to a 125-mL flask, and dissolve in a mixture of 3 mL of formic acid and 50 mL of glacial acetic acid. Add 10

mL of mercuric acetate TS, and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 9.133 mg of C₆H₄7