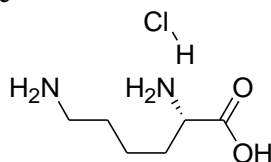


Lysine Hydrochloride

L- Lysine Hydrochloride



$C_6H_{14}N_2O_2$, HCl

Mol. Wt. 182.7

Lysine Hydrochloride contains not less than 98.5 per cent and not more than 101.5 per cent of $C_6H_{14}N_2O_2$, HCl calculated on the dried basis.

Category. pH modifier (acidifying agent/ alkalizing agent/ buffering agent)

Description. A white odourless powder.

Identification

Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *L- lysine hydrochloride RS* or with the reference spectrum of lysine hydrochloride.

Tests

Specific optical rotation (2.4.22). $+20.4^\circ$ to $+21.4^\circ$, determined in a 8.0 per cent w/v solution in 6 *M* hydrochloric acid.

Related substance. Determine by thin-layer chromatography (2.4.17), coating the plate with *silica gel G*.

Mobile phase. A mixture of 70 volumes of *isopropyl alcohol* and 30 volumes of *ammonia*.

Test solution. A 1.0 per cent w/v solution of the substance under examination in *water*.

Reference solution (a). A 0.005 per cent w/v solution of *L- lysine hydrochloride RS* in *water*.

Reference solution (b). A solution containing 0.04 per cent w/v, each of *L-lysine hydrochloride RS* and *arginine hydrochloride RS* in *water*.

Apply to the plate 5 μ l of each solution. After development, dry the plate at 105° until the ammonia completely disappears, cool and spray with a 0.2 per cent w/v solution of *ninhydrin* in a mixture of 95 volumes of *butyl alcohol* and 5 volume of 2*M* *acetic acid*. Heat at 105° for 15 minutes and examine under day light. Any secondary spot in the chromatogram obtained with the test solution is not more intense and larger than the principal spot in the chromatogram obtained with reference solution (a) (0.5 per cent). The test is not valid unless the chromatogram obtained with reference solution (b) shows two clearly separated spots.

Heavy metals (2.3.13). 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).

Iron (2.3.14). 1.33 g complies with the limit test for iron (30 ppm).

Chlorides. 19.0 per cent to 19.6 per cent.

Dissolve 0.35 g in 140 ml of *water* and 1 ml of 2,7 *dichlorofluorescein solution* in a porcelain casserole. Titrate with 0.1 *M silver nitrate* until the silver chloride flocculates and the mixture acquires a faint pink colour. Carry out a blank titration.

1 ml of 0.1 *M silver nitrate* is equivalent to 0.003545 g of chloride.

Sulphates (2.3.17). 0.5 g complies with the limit test for sulphates (300 ppm).

Sulphated ash (2.3.18). Not more than 0.1 per cent.

Loss on drying (2.4.19). Not more than 0.4 per cent, determined on 1.0 g by drying in an oven at 105° for 3 hours.

Assay. Dissolve 90 mg in a mixture of 3 ml of *formic acid* and 50 ml of *anhydrous glacial acetic acid*, add 10 ml of *mercuric acetate solution* and titrate with 0.1 M *perchloric acid*. Carry out a blank titration.

1 ml of 0.1 M *perchloric acid* is equivalent to 0.09133 g of $\text{C}_6\text{H}_{14}\text{N}_2\text{O}_2 \cdot \text{HCl}$.

Solubility: Freely soluble in *water*.

Draft For Comments