19 Specific References

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2 ScienceLab.com. Material data safety sheet: *L-Lysine acetate*, January 2010.
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5 Sweetman SC, ed. *Martindale: The Complete Drug Reference*, 37th edn. London: Pharmaceutical Press, 2011; 2114.

20 General References

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21 Authors

ME Quinn, RC Rowe.

22 Date of Revision

4 May 2017.

Lysine Hydrochloride

L

1 Nonproprietary Names

BP: Lysine Hydrochloride
JP: L-Lysine Hydrochloride
PhEur: Lysine Hydrochloride
USP–NF: Lysine Hydrochloride

2 Synonyms

Darvyl; (2*S*)-2,6-diaminohexanoic acid hydrochloride; E642; *Enisyl*; L-lysine monohydrochloride; lysine monohydrochloride; lysini hydrochloridum.

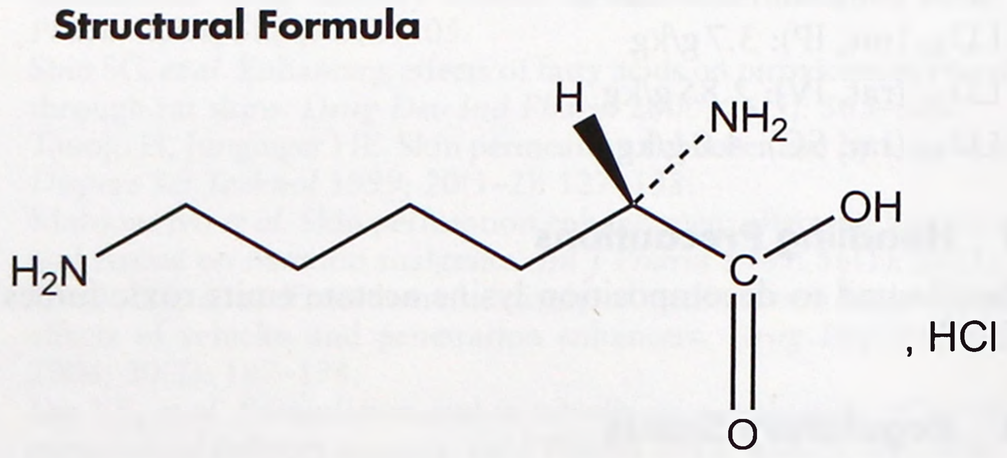
3 Chemical Name and CAS Registry Number

L-Lysine, hydrochloride (1 : 1) [657-27-2]

4 Empirical Formula and Molecular Weight

$C_6H_{14}N_2O_2HCl$ 182.65

5 Structural Formula



6 Functional Category

Buffering agent.

7 Applications in Pharmaceutical Formulation or Technology

Lysine hydrochloride is used as a buffering agent in pharmaceutical formulations. It is widely used as a food additive and as a dietary supplement.

8 Description

Lysine hydrochloride occurs as an odorless, white or almost white crystalline powder.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for lysine hydrochloride.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+	+
Characters	+	+	–
Appearance of solution	+	+	–
Ninhydrin-positive substances	–	+	–
Chlorides	+	–	19.0–19.6%
Residue on ignition	≤0.1%	–	≤0.1%
Sulfated ash	–	≤0.1%	–
Sulfates	≤0.028%	≤300 ppm	≤0.03%
Ammonium	≤0.02%	+	–
Iron	–	≤30 ppm	≤30 ppm
Arsenic	≤2 ppm	–	–
Heavy metals	≤10 ppm	–	≤15 ppm
Chromatographic purity	+	+	+
Optical rotation	+19.0° to +21.5°	+21.0° to +22.5°	+20.4° to +21.4°
Loss on drying	≤1.0%	≤0.5%	≤0.4%
pH	5.0–6.0	–	–
Related substances	+	–	–
Assay (dried basis)	≥ 98.5%	98.5–101.0%	98.5–101.5%

10 Typical Properties

Melting point 263–264°C
Dissociation constant

$pK_{a1} = 2.18$;
$pK_{a2} = 8.95$;
$pK_{a3} = 10.53$ at 25.9°C.