Lysine Acetate

1 Nonproprietary Names

BP: Lysine Acetate

JP: L-Lysine Acetate

PhEur: Lysine Acetate

USP–NF: Lysine Acetate

2 Synonyms

(2*S*)-2,6-Diaminohexanoic acid acetate; lysini acetas; L-lysine acetate; L-lysine monoacetate.

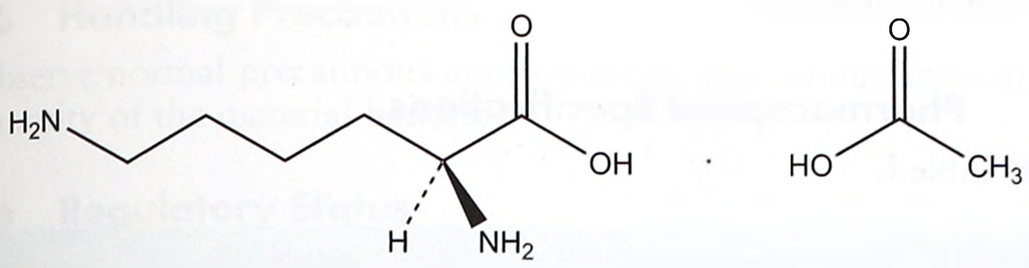
3 Chemical Name and CAS Registry Number

L-Lysine monoacetate [57282-49-2]

4 Empirical Formula and Molecular Weight

$C_8H_{18}N_2O_4$ 206.24

5 Structural Formula



6 Functional Category

Buffering agent.

7 Applications in Pharmaceutical Formulation or Technology

Lysine acetate is used as a buffering agent and neutralizing agent for antipyretics and analgesics such as acetylsalicylic acid and ibuprofen. It has been investigated as a component of vaginal sponge-like dressings for treatment of vaginal infections and delivery of peptidic drugs.[1]

8 Description

Lysine acetate occurs as a white or almost white, crystalline powder or colorless crystals.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for lysine acetate.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+	+
Characters	—	+	—
Appearance of solution	+	+	—
Specific rotation	+8.5° to +10.0°	+8.5° to +10.0°	+8.4° to +9.9°
Ninhydrin-positive substances	—	≤0.5%	–
Loss on drying	≤0.3%	≤0.5%	≤0.2%
Residue on ignition	≤0.1%	≤0.1%	≤0.4%
Chloride	≤0.021%	≤200 ppm	≤0.05%
Sulfate	≤0.028%	≤300 ppm	≤0.03%
Ammonium	≤0.02%	≤200 ppm	—
Iron	≤10 ppm	≤30 ppm	≤0.003%
Heavy metals	≤10 ppm	≤10 ppm	≤0.0015%
Chromatographic purity	—	—	+
Assay	98.5–101.0%	98.5–101.0%	98.0–102.0%

10 Typical Properties

Melting point 281°C[2]

Solubility Freely soluble in water; very slightly soluble in ethanol (96%).

11 Stability and Storage Conditions

Store in well-closed containers protected from light.

12 Incompatibilities

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13 Method of Manufacture

L-Lysine is manufactured by fermentation from carbohydrate sources. The solution is mixed with acetic acid to produce L-lysine acetate.[3]

14 Safety

Lysine acetate in pure form is moderately toxic by IP, IV, and SC routes, and mildly toxic by ingestion.[4]

LD_{50} (mouse, oral): 14.4 g/kg[4]

LD_{50} (mouse, IP): 5.1 g/kg

LD_{50} (mouse, IV): 3.7 g/kg

LD_{50} (mouse, SC): 5.8 g/kg

LD_{50} (rat, oral): 11.4 g/kg

LD_{50} (rat, IP): 3.7 g/kg

LD_{50} (rat, IV): 2.85 g/kg

LD_{50} (rat, SC): 4.0 g/kg

15 Handling Precautions

When heated to decomposition lysine acetate emits toxic fumes of NO_x.[4]

16 Regulatory Status

Included in the FDA Inactive Ingredient Database (IV injections).

17 Related Substances

Lysine hydrochloride.

18 Comments

The PhEur 9.2 states that lysine acetate exhibits polymorphism.

Therapeutically, lysine acetate is an essential amino acid and is used as a dietary supplement.[5] It is also used for the treatment of mouth and genital lesions caused by herpes zoster viruses.[3]

The EINECS number for lysine acetate is 260-664-4.