Sodium Lactate

1 Nonproprietary Names

BP: Sodium Lactate
JP: Sodium L-Lactate
PhEur: Sodium Lactate
USP–NF: Sodium Lactate

2 Synonyms

E325; 2-hydroxypropanoic acid monosodium salt; *Lacolin*; lactic acid monosodium salt; lactic acid sodium salt; natrii lactatis solutio; *Patlac*; *Purasal*; *Ritalac NAL*; sodium α-hydroxypropionate.

3 Chemical Name and CAS Registry Number

Sodium lactate [72-17-3]

4 Empirical Formula and Molecular Weight

$C_3H_5NaO_3$ 112.06

5 Structural Formula

The PhEur 9.2 and USP 40–NF 35 S1 describe sodium lactate solution as a mixture of the enantiomers of sodium 2-hydroxypropanoate in approximately equal proportions.

6 Functional Category

Antimicrobial preservative; buffering agent; emulsifying agent; flavoring agent; humectant.

7 Applications in Pharmaceutical Formulation or Technology

Sodium lactate is widely used in cosmetics,[1,2] food products, and pharmaceutical applications including parenteral and topical formulations.

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8 Description

Sodium lactate occurs as a clear, colorless, slightly syrupy liquid. It is odorless, or has a slight odor with a characteristic saline taste. It is hygroscopic.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for sodium lactate solution.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Characters	–	+	–
Identification	+	+	+
Appearance of solution	+	+	–
Specific rotation	-38° to -44°	–	–
pH	6.5–7.5	6.5–9.0	5.0–9.0
Reducing sugars and sucrose	+	+	+
Methanol	≤0.025%	≤50 ppm[a]	–
Methanol and methyl esters	–	–	≤0.025%
Chlorides	≤0.014%	≤50 ppm	≤0.05%
Oxalates and phosphates	–	+	–
Citrate, oxalate, phosphate or tartrate	+	–	+
Cyanide	+	–	–
Sulfates	≤0.01%	≤100 ppm	+
Aluminum	–	≤0.1 ppm[a]	–
Barium	–	+	–
Arsenic	≤4 ppm	–	–
Iron	≤5 ppm	≤10 ppm	–
Heavy metals	≤10 ppm	–	≤0.001%
Bacterial endotoxins	–	≤5 IU/g[b]	–
Volatile fatty acids	+	–	–
Assay	95.0–105.0%	96.0–104.0%[c]	98.0–102.0%

(a) If intended for use in the manufacture of parenteral dosage forms, hemodialysis, or hemofiltration solutions.
(b) If intended for use in the manufacture of parenteral dosage forms without a further appropriate procedure for the removal of bacterial endotoxins.
(c) PhEur 9.2 also lists sodium (S) lactate solution, which has an additional requirement for the content of the (S)-enantiomer of ≤95%.

10 Typical Properties

Acidity/alkalinity pH = 7 for an aqueous solution.
Boiling point 112°C
Hygroscopicity Very hygroscopic.
Melting point 17°C with decomposition at 140°C.
Solubility Miscible with ethanol (95%), and with water.
Specific gravity 1.31–1.34

11 Stability and Storage Conditions

Sodium lactate should be stored in a well-closed container in a cool, dry place. Sodium lactate is combustible and decomposes upon heating.

12 Incompatibilities

See Lactic Acid.

13 Method of Manufacture

See Lactic Acid.

14 Safety

Sodium lactate occurs naturally in the body and is involved in physiological processes. It is generally regarded as a relatively nontoxic and nonirritant material when used as an excipient. Low concentrations are well tolerated by skin and eye mucosa, although higher concentrations should be avoided.

LD_{50} (rat, IP): 2 g/kg[3]

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Sodium lactate may cause eye irritation. When heated to decomposition, sodium lactate emits toxic fumes of Na_2O.[3]

16 Regulatory Status

GRAS listed (not for infant formulas). Included in the FDA Inactive Ingredient Database (epidural, IM, IV, and SC injections; oral suspensions; topical gels and solutions). Included in nonparenteral