

GALAFLOW SL INJECTABLE 60

SLPIL60 / *galactic ref.*

SODIUM LACTATE 60% INJECTABLE / *product name*

DESCRIPTION

GALAFLOW SL INJECTABLE 60 is the sodium salt of natural L(+) lactic acid made by fermentation from sugar. It has a mild taste, antimicrobial properties and is pH neutral.

PHYSICO-CHEMICAL PROPERTIES

Chemical name		2-Hydroxypropanoic acid, monosodium salt
Molecular weight	<i>g/mol</i>	112
Molecular formula		C ₃ H ₅ O ₃ Na
Density (@20°C/68°F)	<i>g/mL</i>	1.32- 1.34
pH (fresh solution)	-	6.5 - 8.5
pH (stability)	Δ pH	Max. 0.2 (thermostability)

SENSORY CHARACTERISTICS

Colour (fresh solution)	<i>Hazen</i>	Max. 50
Odour	-	Almost odorless
Taste	-	Mild saline taste

PURITY

Appearance of solution	-	Passes test
Positive test for lactate	-	Passes test
Positive test for sodium	-	Passes test
Sodium lactate content	<i>% w/w</i>	59 - 61
Sodium content	<i>% w/w</i>	12.1 - 12.6
Stereochemical purity	<i>% L(+)</i>	Min. 97
Heavy metals (as Pb)	<i>ppm</i>	Max. 5
Iron	<i>ppm</i>	Max. 5
Calcium	<i>ppm</i>	Max. 10
Chloride	<i>ppm</i>	Max. 25
Sulphate	<i>ppm</i>	Max. 20
Lead	<i>ppm</i>	Max. 2
Arsenic	<i>ppm</i>	Max. 1
Mercury	<i>ppm</i>	Max. 1
Barium	-	Passes test
Aluminium	<i>ppm</i>	Max. 0.1
Reducing substances (sugars) & sucrose	-	Passes test
Reducing substances (sugars)	-	Passes test
Oxalate and phosphate	-	Passes test
Citrate, oxalate, phosphate or tartrate	-	Passes test
Methanol and methyl esters	<i>ppm</i>	Max. 25
Ethanol	<i>ppm</i>	Max. 150
Bacterial endotoxins (LAL test)	<i>IU/g</i>	Max. 5
Mesophilic bacteria	<i>counts/g</i>	Max. 100
Moulds	<i>counts/g</i>	Max. 10
Yeasts	<i>counts/g</i>	Max. 100

REGISTRATION

Labeling		E 325
CAS number		867-56-1
GRAS status		Yes
Complies with		EP ⁽¹⁾ - USP ⁽¹⁾ Kosher - Halal

PACKAGING

See packaging list

STORAGE CONDITIONS

Dry, well ventilated room

SHELF-LIFE

48 months

LEGEND

⁽¹⁾ Latest edition