



88539

## Lactose Monohydrate sterile (gamma irradiated)

Part D

CAS : 10039-26-6, 64044-51-5

### Specifications

Appearance (Colour)	White crystalline
Appearance (Form)	Free flowing, fine powder
Solubility	10% aq. solution is completely soluble
Clarity of solution	10% w/v aqueous solution is clear and colourless
pH (25°C)	(10% aq.) 4.00 - 6.00
Residue on ignition	Max 0.03%
Chloride (Cl)	Max 0.005%
Sulphate (SO <sub>4</sub> )	Max 0.005%
Heavy Metals (Pb)	Max 0.0001%
Dextrose	Passes test
Sucrose	Passes test
Acidity	Max. 0.25 ml
Nitrogen Compounds (N)	Max. 0.02%
Water (KF)	4.8 - 5.4%
Absorbance (A) of 1% aq. solution in a 1cm cell v/s H <sub>2</sub> O	@210 - 220 nm...max. 0.25 @270 - 300 nm...max. 0.07
Sterility (Bacterial count)	No growth is observed after 14 days for bacteria at 30-35°C and for fungi at 20-25°C
Cultural Response	Cultural response observed after an incubation at 35 ± 2°C for 18 - 24 hours by preparing Phenol Red Broth Base (14517) using 0.5% of Lactose monohydrate, Sterile (Gamma Irradiated)
Organism	Enterobacter aerogenes ATCC 13048
Inoculum (cfu) 10-100	Growth: Good, Acid: + , Gas production: +
Organism	Escherichia coli ATCC 25922
Inoculum (cfu) 10-100	Growth: Good, Acid: + , Gas production: +
Organism	Proteous vulgaris ATCC 13315
Inoculum (cfu) 10-100	Growth: Good, Acid: -- , Gas production: --
Organism	Salmonella typhimurium ATCC 14028
Inoculum (cfu) 10-100	Growth: Good, Acid: -- , Gas production: --
Organism	Pseudomonas aeruginosa ATCC 27853
Inoculum (cfu) 10-100	Growth: Good, Acid: -- , Gas production: --

## Other Information

### Applications

Lactose monohydrate, Sterile (Gamma Irradiated) is used for Media Fill Runs in dry injectable in pharmaceutical industry.

## General Information

Storage	25 to 40°C (Room Temperature)
Shelf Life	36 Months
IMDG Identification	Not Regulated for Transport (Non-Haz)
HSN Code	
5 Kg	17021110 (GST 18%)
500 Gms	17021110 (GST 18%)
Type of Packing	
5 Kg	Plastic Jar
500 Gms	Plastic Bottle

## Available Packages

500 Gms

5 Kg

### Disclaimer

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608-B, Satellite Gazebo, Andheri Ghatkopar Link Road, Chakala, Andheri (E), Mumbai - 400 099, Maharashtra, India. Telephone: +91-22-4268 5800, Email: info@srchem.com, website www.srchem.com