RAWPHARMA BIZ PRIVATE LIMITED
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SPECIFICATION

Product Name: Lactose Monohydrate BP Grade
Chemical Formula: $C_{12}H_{22}O_{11} * H_2O$
CAS Number: 10039-26-6
Molecular Weight: 360.31 g/mol
Appearance: White or almost white crystalline powder
Odor: Odorless

Chemical Composition

Parameter	Unit	Typical Value	Specification (Min./Max.)
Appearance of solution	-	Complies	The solution is clear and not more than intensely coloured than reference solution BYS7 (method II).
Particle size distribution (200#)	-	Passing should be 80% min.	Passing should be 80% min.
Bulk density	g/ml	0.68	--
Moisture	%	4.94%	Max. 4.4 – 5.5
Acidity	ml	0.20	NMT 0.4ml(0.1M NaOH/6g)
Sulphated Ash	%	0.088%	Max. 0.1%
Identification: A. IR B. TLC C. Colour development D. Test for water	 - - - -	 Complies Complies Complies Complies	 Shall pass the test Shall pass the test A red colour develops Shall pass the test
Specific rotation	°	+54.8°	+54.4° to +55.9°
Light Absorption Analysis			
210nm – 220nm (1%)	%	0.054	NMT 0.25

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270nm – 300nm (1%)	%	0.012	NMT 0.07
400 nm (10%)	%	0.002	NMT 0.04
Bacteriological Characteristics			
Total plate count	cfu/g	40	Max. 100
E. coli	g	Absent	Absent

Physical Properties

- Solubility: Soluble in water. Insoluble in ethanol. Inoluble in ether. Insoluble in chloroform.

Shelf Life & Storage

- Shelf Life: 3 years from date of manufacture under recommended storage.
- Storage Conditions: Store in a cool, dry place at 15–30°C. Protect from moisture, excessive humidity, heat, and direct sunlight. Keep the container tightly closed in the original, properly labeled container and store in a well-ventilated area to prevent moisture absorption and maintain product quality and stability.

Applications

- Use: Widely used as a pharmaceutical excipient in the manufacture of tablets, capsules, sachets, and dry powder formulations. It functions as a diluent (filler), binder, carrier, and bulking agent, improving tablet compressibility, content uniformity, and powder flow. It is also used in dry powder inhalers (DPIs) as a carrier and in nutraceutical formulations where a stable, water-soluble excipient is required.
-Dosage: Depends on intended formulation, dosage form, manufacturing process, and the properties of the active pharmaceutical ingredient (API). As a pharmaceutical excipient, it is used in quantities required to achieve the desired tablet or capsule weight, flowability, compressibility, and content uniformity.

Packaging

- Standard Packing: 25 Kgs woven pp bag with inner liner or as per customer requirement.
- Labeling: Product name, batch number, net weight, manufacture date, expiry date, and manufacturer details.

* Specifications are based on the manufacturer’s provided specifications.