

Lactose Anhydrous / Monohydrate

Pharmaceutical filler for powder and parenteral use

Product Description

Lactose Anhydrous and Monohydrate are widely used pharmaceutical fillers in dry powder inhaler (DPI), tablet and sachet formulations. Available to BP/USP standards.

Certificate of Analysis

HSN Code: 1702.19

CAS Number: Monohydrate: 5989-81-1 / Anhydrous: 6033-07-8
Classification: Pharmaceutical Excipient — F

Parameter	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual
Assay	98.0–102.0%	Polarimetry / HPLC
Identification	Conforms to reference standard	IR
Loss on Drying (Monohydrate)	4.5–5.5%	USP <731>
Loss on Drying (Anhydrous)	"d 0 . 5 %	USP <731>
Acidity / Alkalinity	pH 4.0–6.5 (10% solution)	USP <791>
Clarity of solution	Passes test	Visual
Heavy Metals	"d 5 p p m	USP <231>

Physical Properties

Appearance: White to off-white crystalline powder

Molecular Formula: $C_6H_{12}O_6 \cdot H_2O$ (monohydrate)

Molecular Weight: 360.32 g/mol (monohydrate)

Solubility: Freely soluble in water; practically insoluble in ethanol

Melting Point: Monohydrate: 201–203°C (anhydrous equivalent)

Packing: 25 kg HDPE bags with polyethylene inner liner; fibre drums available

Storage: Store in a cool, dry, well-ventilated area. Below 25°C.

Safety & Handling

PPE: Gloves, safety goggles, dust mask, lab coat

Hazards:

- Milk sugar allergen
- Dust may cause respiratory irritation