

SPECIFICATION

Product Name: Mannitol
Chemical Formula: C ₆ H ₁₄ O ₆
CAS Number: 69-65-8
Molecular Weight: 182.17 g/mol
Appearance: White crystalline powder
Odor: Odorless

Chemical Composition

Parameter	Unit	Typical Value	Specification (Min./Max.)
Identification by IR	-	Comply	Conforms (as per USP)
Melting Range	°C	166.5 – 167.5	Between 165°C - 170°C
Specific Rotation	°	140.0°	Between +137.00° - +145.00° (as per USP)
Acidity	-	0.13	Not more than 0.30ml of 0.020 N sodium hydroxide should be required for neutralizations (as per USP)
Loss on Drying	%	0.05%	NMT 0.30%
Chloride	%	0.002%	NMT 0.005% (as per USP/IP)
Reducing Sugar	-	Comply	NMT 0.1%, expressed as glucose; NMT 3.2 mL of 0.02 M potassium permanganate VS is required to change the color of the solution. The green color turns to pink, and the color persists at least 10 s.
Sulphate	%	<0.01%	NMT 0.01%
Arsenic	PPM	<1.0 PPM	NMT 1PPM/2PPM (As per USP/IP)

Assay of Mannitol	%	99.90%	Between 97.0%w/w and 102% w/w of Mannitol, calculated on the anhydrous basis (As per USP37)
Residual Solvents	-	Comply	Conforms to USP<467>
Specific Optical Rotation	°	23.9°	Between +23.00° to +25.00° calculated on anhydrous basis (As per BP/Ph.Eur/IP)
Identification			
Melting Point	°C	166.5 - 167.5	Between 165°C - 170°C (As per BP/Ph.Eur/IP)
I.R.	-	Comply	Comply (As per BP/Ph.Eur/IP)
By TLC	-	Comply	The principal spot in the chromatogram obtained with the sample solution should be similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution(a) (As per BP/Ph.Eur)
Iden.B as per I.P.	-	Comply	A clear solution is obtained
Iden.C as per I.P.	-	Comply	A pink colour is produced
Appearance of solution	-	Comply	The Sample solution is clear and colorless: its clarity is the same as that of water, or its opalescence is not more pronounced than that of the Reference suspension, and it is not more intensely colored than the Standard solution (As per BP/Ph.Eur/IP/USP37)
Conductivity	μS/cm	1.50	NMT 20 μS/cm
Reducing Sugars	-	>12.8	Not less than 12.8ml of 0.05M Sodium Thiosulphate should be required
	-	0.021	Impurity – A: Not more than 2.0%

Related Substance	-	0.018	Sum Of Impurity B and C: Not more than 2.0%
	-	0.075	Any Other Impurities: Not More than 0.1%
	-	0.13	Total Impurities: Not More than 2.0% (As per BP/Ph.Eur)
Lead	PPM	0.4 PPM	NMT 0.5PPM (As per BP/Ph.Eur)
Nickel	µg/g	0.8	NMT 1µg/g
Water	%	0.03%	NMT 0.50%
Bacteria Endotoxins	iu/g	1.25iu/g	NMT 2.5iu/g
Total viable aerobic count	cfu/g	<100	NMT 100 cfu/g
Total combined yeast and moulds count	cfu/g	<10	NMT 10 cfu/g
Escherichia Coli	-	Absent	Should be absent
Salmonella	-	Absent	Should be absent (As per BP/Ph.Eur)
Assay	%	99.90%	Between 98.0% w/w and 102.0% w/w, calculated with reference to the anhydrous basis (As per BP/Ph.Eur/IP)
Acidity or Alkalinity	-	Comply	Not more than 0.2ml of 0.01M of NaOH required & Not more than 0.3ml of 0.01 M HCL required
Sorbitol	-	Comply	By TLC: Any spot corresponding to Sorbitol in the chromatogram obtained with the test solution in not more than the spot in the chromatogram obtained with the reference solution (As per I.P.)
Sulphate Ash	%	0.02%	NMT 0.1%
Particle Size (By Sieve)	-	Comply	Not more than 10% retained on 80 mesh.
Extraneous Matter	-	Comply	To be free from any extraneous matter

Tapped density g/cc	-	0.60	0.40-0.65
Angle of repose	°	20°	NMT 30°
Particle Size > 315microns	%	0.2	<10
Particle Size > 150microns	%	46	>45
Particle Size > 75microns	%	94.3	>90

Physical Properties

- Solubility: Soluble in water. Soluble in ethanol. Soluble in methanol. Insoluble in acetone. Insoluble in ether.

Shelf Life & Storage

- Shelf Life: 3 years from date of manufacture under recommended storage.
- Storage Conditions: Store in a cool, dry, and well-ventilated place at 15–30°C. Protect from moisture, excessive humidity, and contamination. Keep the container tightly closed in the original, properly labeled packaging. Store away from direct sunlight, excessive heat, and incompatible materials to maintain product quality, free-flowing properties, and stability. For pharmacopeial grades (USP/BP/EP/IP), store in accordance with Good Manufacturing Practice (GMP) to preserve product integrity.

Applications

- Use: Widely used in pharmaceutical, nutraceutical, food, and medical formulations as a diluent (filler), sweetening agent, bulking agent, anti-caking agent, and osmotic agent. It is commonly incorporated into tablets, capsules, chewable tablets, orally disintegrating tablets (ODTs), powders, sachets, syrups, sugar-free confectionery, chewing gum, and dietary supplements. Mannitol provides a pleasant cooling sensation and sweetness, improves tablet compressibility and stability, and is frequently used in formulations intended for diabetic or sugar-free products due to its low glycemic impact.
- Dosage: Depends on its intended use (excipient, food ingredient, or medicinal product).

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.