Mannitol

$C_6H_{14}O_6$ · CAS 69-65-8 · D-Mannitol, crystalline powder or granules

SPECIMEN — LIMITS ONLY · BATCH RESULTS ISSUED WITH THE LOT

PRODUCT	IDENTITY / FORM	CAS	SPECIFICATION VERSION
Mannitol	D-Mannitol, crystalline powder or granules	69-65-8	Catalog · confirmed at quotation
BATCH NUMBER	**MANUFACTURE DATE**	**RETEST DATE**	**RELEASE DECISION**
Issued with the lot	Issued with the lot	Issued with the lot	Issued with the lot

RELEASE SPECIFICATION

PARAMETER	SPECIFICATION	METHOD
Assay (dried basis)	98.0–101.0% (HPLC-RI)	As stated
Appearance	White crystalline powder or granules	As stated
Moisture	≤0.5%	As stated
pH (5% solution)	5.0–7.5	As stated
Solubility	Soluble in water; less hygroscopic than sorbitol	As stated
Particle size	≥95% through 60 mesh; spray-dried on request	As stated
Bulk density	0.50–0.80 g/mL	As stated
Reducing sugars	≤0.1%	As stated
Heavy metals	Pb ≤0.5 · As ≤0.5 · Cd ≤0.5 · Hg ≤0.1 mg/kg	As stated
Microbiology	APC ≤1,000 cfu/g · yeast and mould ≤100 cfu/g · E. coli and Salmonella absent	As stated
Marker / profile	Mannitol 98.0–101.0%, reducing sugars ≤0.1%	Identity
Solubility	Soluble in water; low hygroscopicity and a cooling effect, with good tablet compaction in the right grade.	Matrix dependent

LOT FIELDS

A batch-specific certificate replaces the fields above with the measured result, the method actually used, the batch number, the manufacture and retest dates, and the release signature. The catalog limits on this page are the release window, not a result.

STATEMENT

This specimen shows the format and the release specification. It is not a batch COA and must not be presented as one. The COA that ships with a lot is issued from the released batch and is available before dispatch.

Pack and storage. 1 kg foil pouch · 25 kg fiber drum. Store closed in a cool, dry place, away from direct sunlight and moisture. The lot-specific retest

date is shown on the batch certificate.