Trade Name: -					
Chemical Name: **Mannitol**					
CAS No.: [69-65-8]					
Raw material/ Excipient ■	Starting material/ Intermediate □	API product □	Semi-finished product □	Finished product□	
Method of analysis:	USP □	BP ■	EP □	JP □	In House □
Handling and storage:					

Chemical specification

No.	Item	Standard-Specification	Ref.	Recommendation
1	**Description**	White or free flowing granules.	BP2022	
2	**Identification**	IR	BP2022	
3	**Specific optical rotation**	+23 to +25 (dried substance)	BP2022	
4	**Assay**	97.0% to 102.0%, calculated on the dried basis	BP2022	
5	**Impurities**	Sorbitol: Not more than 2.0% Sum of isomalt and maltitol: Not more than 2.0% Unspecified impurities: Not more than 0.1% Total impurities: Not more than 2.0%	BP2022	
6	**Reducing sugars**	Not more than 0.1%	BP2022	
7	**Nickel**	Not more than 1µg/g	BP2022	
8	**Melting point**	165°C to 170°C	BP2022	
9	**Appearance of solution**	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.	BP2022	
10	**Loss on drying**	Not more than 0.5%	BP2022	
11	**Conductivity**	Not more than 20µS/cm at 25°C	BP2022	

Written by	Reviewed by		Approved by	
QC Supervisor	QC Manager	R&D Manager	QA Manager	Qualified Person
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Documentation stamp