



RAW MATERIAL SPECIFICATION

Title : Mannitol USP (Item No. 41032310)	Spec. No. : SP-AK30-M007
Reference(s) : USP 41 page 2527 – 2529	Rev. No. : 03
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USP 41	Description	: White, crystalline powder or free-flowing granules; odorless.
	Solubility	: Freely soluble in water; soluble in alkaline solutions; slightly soluble in pyridine; very slightly soluble in alcohol; practically insoluble in ether.
	Identification	: Infrared Absorption.
	Related Substances	
	- Sorbitol	: Not more than 2.0%.
	- Sum of isomalt and maltitol	: Not more than 2.0%.
	- Unspecified impurities	: Not more than 0.10% for each impurity.
	- Total impurities	: Not more than 2.0%.
	Reducing sugars	: Not more than 0.1%, expressed as glucose; Not more than 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 seconds.
	Nickel	: Not more than 1 µg/g.
	Melting point	: 165 °C to 170 °C.
	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.

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THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

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Loss on drying	: Not more than 0.5%.
Conductivity	: Not more than 20 μ S/cm at 25 °C.
Assay	: It contains not less than 97.0% and not more than 102.0% of Mannitol ($C_6H_{14}O_6$), calculated on the dried basis.
Microbial enumeration tests and tests for specified microorganisms	: The total aerobic microbial count (TAMC) is not more than 10^3 cfu/g, and the total combined molds and yeasts count is not more than 10^2 cfu/g. It meets the requirements of the test for absence of Escherichia coli.

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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Mannitol USP (Item No. 41032310).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-M007, WI-AK62-T41 and WI-AK62-T11.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in well-closed containers.
Retest period	2 years after first testing date.

History of changes

Rev. No.	Description	Effective Date
02	Update ข้อกำหนดตาม USP 36	19/04/12
03	Update ข้อกำหนดตาม USP 41	01/10/18

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