

SHIJIAZHUANG HUAXU PHARMACEUTICAL CO., LTD

CERTIFICATE OF ANALYSIS

Commodity	Mannitol	Batch NO	2403060
Packing	25kg/Drum	MFG. date	Mar.26.2024
Quantity	7200kg	Expiry date	Mar.25.2026
Basis	Correspond to USP 43		
ITEM	STANDARD	RESULT	CONCLUSION
Appearance	White or almost white crystals or powder	White crystals	Conformity
Identification : Infrared absorption spectrophotometry	Conformity	Conformity	Conformity
Assay	97.0% ~ 102.0%	99.9%	Conformity
Related substances	Sorbitol $\leq 2.0\%$	0.2%	Conformity
	Sum of Maltitol and Isomalt $\leq 2.0\%$	Not detected	
	Unspecified impurities $\leq 0.10\%$	Not detected	
	Total impurities $\leq 2.0\%$	0.3%	
Reducing sugars	$\leq 0.1\%$	$< 0.1\%$	Conformity
Nickel	$\leq 1 \mu\text{g/g}$	$< 1 \mu\text{g/g}$	Conformity
Melting point	165 °C ~ 170 °C	166 °C ~ 168 °C	Conformity
Appearance of solution	Clear and colourless	Conformity	Conformity
Loss on drying	$\leq 0.5\%$	0.1%	Conformity
Conductivity	$\leq 20 \mu\text{S/cm}$	2.0 $\mu\text{S/cm}$	Conformity
Microbial contamination	TAMC $\leq 10^3$ CFU/g	30CFU/g	Conformity
	TYMC $\leq 10^2$ CFU/g	40CFU/g	
	Absence of Escherichia coli	Negative/g	
Bacterial endotoxins	≤ 2.5 IU/g	< 2.5 IU/g	Conformity
Residual solvents	The raw materials, manufacturing process and product do not contain any of the solvents listed in Residual Solvents (USP<467>)		
Conclusion	Conformity		

Address: No.33 Industrial Street, Economic Development Zone, Shijiazhuang City, Hebei, China