



**SHIJIAZHUANG HUAXU PHARMACEUTICAL CO., LTD**  
**HEBEI HUAXU PHARMACEUTICAL CO., LTD**

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### Mannitol specification

ITEM	CP2015	BP2016	EP8	USP39
Assay	98.0~102.0%	97.0~102.0%	98.0~102.0%	98.0~102.0%
Appearance	White crystalline powder or free-flowing granules			
Solubility	Freely soluble in water, very slightly soluble in ethanol, insoluble in ether.			—
Melting point	166°C~170°C	165°C~170°C		
Specific optical rotation	+137°~+145°	+23°~+25°		—
Identification:FeCl <sub>3</sub>	Positive			
Identification Infrared absorption spectrophotometry	Conformity			
Identification: TLC	—	Conformity		—
Acidity	Conformity	—		Conformity
Appearance of solution	Clear and colourless			
Related substances:	≤2.0%	Conformity		
Reducing sugars	—	—	≤0.1	≤0.1
Chloride	≤0.003%	—	—	—
Sulphate	≤0.01%	—	—	—
Oxalate	≤0.01%	—	—	—
Loss on drying	≤0.5%	≤0.5%	≤0.5%	≤0.5%
Residue on ignition	≤0.1%	—	—	—
Heavy metals	≤10ppm	≤10ppm	≤10ppm	≤10ppm
Arsenic	≤2ppm	—	—	—
Conductivity	—	≤20us/cm	≤20us/cm	≤20us/cm
Nickel	—	≤1ppm	≤1ppm	—
Bacterial endotoxins	—	≤2.5IU/g	≤2.5 IU/g	≤2.5IU/g
The total viable aerobic count	—	≤100cfu/g	≤100cfu/g	≤100cfu/g
Molds and yeasts	—	≤100cfu/g	≤100cfu/g	≤100cfu/g
Escherichia coli	—	Negative/g	Negative/g	Negative/g
Salmonella	—	Negative/10g	Negative/10g	Negative/10g