

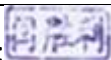
**QINGDAO BRIGHT MOON SEAWEED GROUP CO., LTD.**67, Haibin 1<sup>st</sup> Road, Jiaonan, Qingdao, China**CERTIFICATE OF ANALYSIS****Name of Product: MANNITOL IP/USP37/BP/EP/JP (PYROGEN FREE)INJECTABLE GRADE****Batch No:H361602022****Date of Mfg: MAR.,2016****Date of Expiry: MAR.,2019**

Test	Specifications	Observations	
Characters			
Appearance	White, Crystalline powder or free-flowing granules, odorless and sweet compound	Comply	
Solubility	Freely solution in water for Injections, solutions in alkaline solutions, slightly soluble in Pyridine, very slightly soluble in Ether (96%)	Comply	
Identification by IR	Conforms (As per USP)	Comply	
Melting Range	Between 165°C - 170°C	166.6	
Specific Rotation	Between +137.00° - +145.00° (as per USP)	140.1°	
Acidity	Not more than 0.30ml of 0.020 N sodium hydroxide should required for neutralizations (as per USP)	<0.20	
Loss on Drying	Not more than 0.30% w/w	0.1%	
Chloride	Not more than 0.007% (as per USP/IP)	<0.003%	
Reducing Sugar	NMT 0.1%, expressed as glucose; NMT 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 s.	Comply	
Sulphate	Not more than 0.01%	<0.01%	
Arsenic	Not more than 1ppm/2ppm (As per USP/IP)	<1.0ppm	
Assay of Mannitol	Between 97.0% w/w and 102% w/w of Mannitol, calculated on the anhydrous basis (As per USP37)	99.45%	
Residual Solvents	Conforms to USP<467>	Comply	
	Specific Optical Rotation	Between +23.00° to +25.00° calculated on anhydrous basis (As per BP/Ph.Eur/IP)	23.8°
Identification	Melting Point	Between 165°C - 170°C (As per BP/Ph.Eur/IP)	166.6
	I.R.	Comply (As per BP/Ph.Eur/IP)	Comply
	By TLC	The principal spot in the chromatogram obtained with the sample solution should be similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution(a) (As per BP/Ph.Eur)	Comply
	Iden.B as per I.P.	A clear solution is obtained	Comply
	Iden.C as per I.P.	A pink colour is produced	Comply
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 (As per	Comply	

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	BP/Ph.Eur/IP/USP37)	
Conductivity	Not more than 20 $\mu$ S/cm	<20 $\mu$ S/cm
Reducing Sugars	Not less than 12.8ml of 0.05M Sodium Thiosulphate should be required	>12.8
Related Substance	Impurity – A: Not more than 2.0%	<2.0%
	Impurity – B: Not more than 2.0%	<2.0%
	Impurity – C: Not more than 2.0%	<2.0%
	Any Other Impurities : Not More than 0.1%	<0.1%
	Total Impurities: Not More than 2.0% (As per BP/Ph.Eur)	<2.0%
Lead	Not more than 0.5ppm (As per BP/Ph.Eur)	<0.5ppm
Nickel	NMT 1 $\mu$ g/g	Comply
Water	Not more than 0.50% w/w	<0.50%
Bacteria Endotoxins	Not more than 2.5iu/g	<2.5iu/g
Microbial Contamination	Bacteria: Not more than 50CFU/g	<50
	Fungus: Should be absent	Comply
	Escherichia Coli: Should be absent	Comply
	Salmonella: Should be absent (As per BP/Ph.Eur)	Comply
Assay	Between 98.0% w/w and 102.0% w/w, calculated with reference to the anhydrous basis (As per BP/Ph.Eur/IP)	99.45%
Acidity or Alkalinity	Not more than 0.2ml of 0.01M of NaOH required & Not more than 0.3ml of 0.01 M HCL required	Comply
Sorbitol	By TLC: Any spot corresponding to Sorbitol in the chromatogram obtained with the test solution in not more than the spot in the chromatogram obtained with the reference solution (As per I.P.)	Comply
Sulphate Ash	Not more than 0.1%	0.02%
Particle Size (By Sieve)	Not more than 10% retained on 80 mesh.	Comply
Extraneous Matter	To be free from any extraneous matter	Comply
Tapped density g/cc	0.40-0.65	0.60
Angle of repose	Not more than 30°	20°
Conformity: As per IP/USP/BP/EP/JP		

DIRECTOR:



CHECKER:



LAB. TECHNICIAN:

