



Mannitol USP/EP

Mannogem® Emerald Powder Mannitol USP/EP

Retest Date: 3 year(s) from the date of Mfg.

Product Code : 112-1211

CHARACTERISTICS

Description	White or almost white crystals or powder
Foreign Matter	No significant amount
Character: Solubility	Freely soluble in water and NaOH TS, practically insoluble in ethanol (96%)
Clarity, USP/EP/JP	The solution is clear
Color, USP/EP/JP	The solution is colorless
(1) Identification by IR, USP/EP/ JP	Matches mannitol Reference Spectra

PHYSICAL

Loss on Drying USP/EP/JP/IP	NMT 0.5 %
Melting Point, USP/EP/JP	165 - 170 °C
Microtrac S3550 Particle Analyzer D(10)	Report Results
Microtrac S3550 Particle Analyzer D(50)	Report Results
Microtrac S3550 Particle Analyzer D(90)	NMT 75 µm

CHEMICAL

Conductivity, USP/EP/JP	NMT 20 µS/cm
Reducing Sugars in Mannitol (Glucose), USP/EP/JP	NMT 0.1% Expressed as Glucose (equivalent to NMT 3.2mL)
Mannitol % db, USP/EP/JP/IP	97.0 - 102.0 %
Impurity A (Sorbitol), USP/EP/JP	NMT 2.0 %
Impurity B+C (Isomalt + Maltitol), USP/EP/JP	NMT 2.0 %
Total Impurities, USP/EP/JP	NMT 2.0 %
Unspecified Impurities, USP/EP/JP	NMT 0.10 %
(1) Nickel, USP/EP/JP	NMT 1 ppm

MICROBIAL

Total Aerobic Microbial Count	NMT 1000 cfu/g
Total Yeast and Mold Count	NMT 100 cfu/g

Company Name:

Signer's Name:

Signature:

Date:

(Company stamp if available)

Signed electronically by
SPI Pharma Quality Assurance

This product was manufactured under cGMP conditions.

(1) These tests are on reduced testing status.

(db) Results are reported on a dried basis

112-1211-00 Effective (dd.mm.yyyy) 14.02.2020

Effective Date 14 Feb 2020

SPI Pharma Inc
1711 Tiles Court
Grand Haven, MI 49417
USA
PH: 616-935-6900

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E.coli test method	Negative
Salmonella Test Method	Negative
Staphylococcus aureus test method	Negative

This product meets the Residual Solvents specification as described in USP <467>.
As per EDQM instructions, TLC and Specific Rotation are 2nd ID tests and are only intended for use in Pharmacies.

Small particle size mannitol powder products may become compacted during shipment and storage.
Store in tightly closed original container. Protect from extreme heat and humidity.

Company Name:

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Signature Manifest

Document Number: SPI-SPEC-159

Revision: 00

Title: 112-1211 Mannogem® Emerald Powder Mannitol USP/EP

All dates and times are in Eastern Time.

GH-19-163_112-1211_ProdSpec

QC Approval

Name/Signature	Title	Date	Meaning/Reason
Michael Todd (MTODD)	R&D Senior Scientist	10 Feb 2020, 03:47:10 PM	Approved
Christopher Golden (CGOLDEN)	Site Head of Quality	10 Feb 2020, 04:56:32 PM	Approved

QA Approval

Name/Signature	Title	Date	Meaning/Reason
Jacob Wendling (JWENDLIN)	QA Supervisor	11 Feb 2020, 02:04:10 PM	Approved