

Magnesium Sulfate, 7-Hydrate, Crystal, U.S.P.  
Multi-Compendial



Material No.: 2504-08  
Batch No.: 0000065873  
Manufactured Date: 2013/08/09  
Retest Date: 2018/08/08

## Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets U.S.P Requirements,  
GMP Manufactured Product

Test	Specification	Result
USP – Identification	Passes Test	PT
USP – pH (1 in 20)	5.0 – 9.2	7.0
USP – Loss on Ignition	40.0 – 52.0 %	50.8
USP – Chloride (Cl)	<= 0.014 %	< 0.014
USP – Heavy Metals (as Pb)	<= 0.001 %	< 0.001
USP – Iron (Fe)	<= 0.5 ppm	< 0.5
USP – Selenium (Se)	<= 0.003 %	< 0.003
USP – Assay (MgSO <sub>4</sub> ) (anhydrous basis)	99.0 – 100.5 %	99.7
USP – Endotoxin Concentration (EU/g)	<= 2.5	< 2.0
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Acidity or Alkalinity	Passes Test	PT
EP/BP – Chloride (Cl)	<= 300 ppm	< 300
EP/BP – Arsenic (As)	<= 2 ppm	< 2
EP/BP – Heavy Metals (as Pb)	<= 10 ppm	10
EP/BP – Iron (Fe)	<= 20 ppm	< 20
EP/BP – Loss on Drying	48.0 – 52.0 %	50.6
EP/BP – Assay (MgSO <sub>4</sub> ) (anhydrous basis)	99.0 – 100.5 %	99.8
Solution Test	Passes Test	PT

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging  
No Class 1,2,3 or other solvents are used or produced in the  
manufacturing or purification of the product.

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Metallic Residues: No metal catalysts or metal reagents, as defined by  
EMA Guideline EMEA/CHMP/SWP/4446/2000 , are used in the production of  
this material.

This product is intended for use in preparing parenteral and  
nonparenteral dosage forms.

Storage Conditions: Preserve in well-closed containers.

Country of Origin: US

Packaging Site: Phillipsburg Mfg Ctr & DC

Manufacturer: P0032001

Manufacturer source batch: U130809

ISO

Phillipsburg, NJ 9001:2008, 14001:2004  
Paris, KY 9001:2008  
Mexico City, Mexico 9001:2008  
Deventer, The Netherlands 9001:2008, 14001:2004, 13485:2003  
Gliwice, Poland 9001:2008, 17025:2005  
Selangor, Malaysia 9001:2008  
Dehradun, India, 9001:2008, 14001:2004, 13485:2003  
Mumbai, India, 9001:2008, 17025:2005  
Panoli, India 9001:2008



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