

Specifications and Methods Manual

Page 1 of 2	Mallinckrodt Pharmaceuticals
Formula Wt. or Atomic Wt.	CODE: 2257 FORMULA: ITEM: MAGNESIUM STEARATE NF/EP/JP (POWDER) KOSHER PASSOVER HYQUAL®
SITE RESPONSIBLE: St. Louis	
INTENDED USE: Bulk Drug Component	

MEETS NATIONAL FORMULARY (NF) SPECIFICATIONS
MEETS EUROPEAN/BRITISH PHARMACOPEIA (EP/BP) SPECIFICATIONS
MEETS JAPANESE PHARMACOPEIA (JP) SPECIFICATIONS
MEETS CHINESE PHARMACOPEIA (ChP) SPECIFICATIONS
MEETS FOOD CHEMICALS CODEX (FCC) SPECIFICATIONS
MEETS MB (Mass Balance) RSPO CERTIFICATION. Member Number: 4-1048-18-000-00.
Certificate Number: BMT-RSPO-001149

NO CLASS I, II, III OR OTHER ORGANIC SOLVENTS ARE USED IN
THE MANUFACTURING PROCESS. MEETS USP <467> RESIDUAL
SOLVENT OPTION 1 GUIDELINES.

SAFETY PRECAUTIONS

- Use appropriate laboratory safety procedures. Consult your supervisor and the appropriate SDS (Safety Data Sheet).
- **WARNING! MAY FORM COMBUSTIBLE DUST CONCENTRATIONS IN AIR.** Store in a tightly closed container. Avoid dust cloud in presence of an ignition source. Maintain adequate ventilation.

TEST AND SPECIFICATION LIMITS

Appearance	Fine, white powder
Edible Vegetable Source	Certified
Chick Edema Factor	Certified
Identification (Magnesium) (NF/EP/BP/JP/ ChP /FCC)	Meets requirements
Identification (Major Peak) (NF/EP/BP/JP/ChP)	Peak retentions match
Identification (Solidification Point of Fatty Acids) (FCC)	54°C min
<u>Microbial Limits (NF/EP/BP/JP/ChP)</u>	
Total Aerobic Count	1000 cfu/g max
Total Mold And Yeast	100 cfu/g max
Salmonella	Negative
E. Coli	Negative
Acidity or Alkalinity (NF/EP/BP/JP/ChP)	Meets requirements

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Loss on Drying (NF/EP/BP/JP/FCC)	4.0% max
Loss on Drying (ChP)	5.0% max
Specific Surface Area (NF<846>Method II)(EP<2.9.26>Method II)	5.0-10.0 m ² /g
Limit of Chloride (NF/EP/BP/JP)	0.025% max
Limit of Chloride (ChP)	0.10% max
Limit of Sulfate (NF/EP/BP/JP)	0.5% max
Limit of Sulfate (ChP)	0.6% max
Iron (ChP)	0.01% max
Lead (NF/EP/BP) (VR#622)	10.0 ppm max
Lead (FCC)	5 ppm max
Cadmium (NF/EP/BP)	3.0 ppm max
Nickel (NF/EP/BP)	5.0 ppm max
Residual Solvents (USP<467>Method IV)	Certified free
Relative Content of Stearic Acid and Palmitic Acid (NF/JP/ChP)	
Fatty Acid Composition (EP/BP)	
Stearic Acid	40.0% min
Stearic Acid and Palmitic Acid	90.0% min
Assay (Mg) (Dried Basis) (NF/EP/BP/JP/ChP)	4.0-5.0%
Assay (MgO) (FCC)	6.8-8.3%
Heavy Metals (JP)	20 ppm max
Heavy Metals (ChP)	0.0015% max
Sieve Test US Standard No. 325	Report % through
Apparent Density	0.08-0.17 g/cc
Tapped Density	0.21-0.33 g/cc
Particle Size 90th Percentile	35 µm max
Particle Size 50th Percentile	10.5 - 16.5 µm
Acid Value	195-210