Magnesium Stearate, Hyqual®, Vegetable Source NF - GenAR®



Material No.: 2257-06 Batch No.: 0000179125 Manufactured Date: 2016/12/01 Retest Date: 2021/11/30

## Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets F.C.C. Requirements, Meets J.P. Chemical Specifications, Meets N.F. Requirements,

GMP Manufactured Product, Food GMP Manufactured Product

Test	Specification	Result
NF – Assay (as as Mg) (dried basis)	4.0 - 5.0 %	4.8
NF – Stearic Acid	>= 40 %	67
NF – Stearic and Palmitic Acids	>= 90 %	98
NF – Identification A	Passes Test	РТ
NF – Identification B	Passes Test	РТ
NF – Acidity or Alkalinity	Passes Test	РТ
NF – Microbiological	Passes Test	РТ
NF – Total Aerobic Microbial Count (cfu/g)	<= 1000	< 10
NF – Total Mold and Yeast Count (cfu/g)	<= 500	< 10
NF – Salmonella Species (negative)	Passes Test	РТ
NF – Escherichia Coli (negative)	Passes Test	РТ
NF – Loss on Drying at 105°C	<= 6.0 %	3.4
Specific Surface Area, m²/g	5.0 - 10.0	7.0
NF – Limit of Chloride	<= 0.1 %	< 0.1
NF – Limit of Sulfate	<= 1.0 %	< 1.0
NF – Cadmium (Cd)	<= 3 ppm	< 3
NF – Lead (Pb)	<= 10 ppm	< 10
NF – Nickel (Ni)	<= 5 ppm	< 5
EP/BP - Identification C	Passes Test	РТ
EP/BP - Identification D	Passes Test	РТ
EP/BP - Acidity or Alkalinity	Passes Test	РТ
EP/ BP – Chloride (Cl)	<= 0.1 %	< 0.1

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600 Avantor Performance Materials, LLC.

3477 Corporate Parkway. Center Valley, PA 18034. U.S.A. Phone: 610.573.2600 . Fax: 610.573.2610

Test	Specification	Result
EP/BP – Sulfate (SO4)	<= 1.0 %	< 1.0
EP/BP – Cadmium (Cd)	<= 3 ppm	< 3
EP/BP – Lead (Pb)	<= 10 ppm	< 10
EP/BP – Nickel (Ni)	<= 5 ppm	< 5
EP/BP – Loss on Drying at 105°C	<= 6.0 %	3.4
Total Aerobic Microbial Count (cfu/g)	<= 1000	< 10
Escherichia Coli (negative)	Passes Test	РТ
EP/BP – Assay (as as Mg) (dried basis)	4.0 - 5.0 %	4.6
Salmonella (absent)	Passes Test	РТ
EP/BP - Stearic Acid	>= 40.0 %	66.6
EP/BP - Stearic and Palmitic Acids	>= 90.0 %	97.8
Total Mold and Yeast Count (cfu/g)	<= 100	< 10
JP - Identification	Passes Test	РТ
JP – Acidity or Alkalinity	Passes Test	РТ
JP – Chloride (Cl)	<= 0.1 %	< 0.1
JP – Sulfate (SO4)	<= 1.0 %	< 1.0
JP – Heavy Metals (as Pb)	<= 20 ppm	< 20
JP - Stearic Acid	>= 40 %	67
JP – Stearic and Palmitic Acids	>= 90 %	98
JP – Loss on Drying at 105°C	<= 6.0 %	3.4
JP – Microbiological	Passes Test	РТ
JP – Total Aerobic Microbial Count (cfu/g)	<= 1000	< 10
JP - Total Mold and Yeast Count (cfu/g)	<= 500	< 10
JP – Salmonella Species (negative)	Passes Test	РТ
JP – Escherichia Coli (negative)	Passes Test	РТ
JP – Assay (as as Mg) (dried basis)	4.0 - 5.0 %	4.8
FCC - Identification A	Passes Test	РТ
FCC - Identification B	Passes Test	РТ
FCC – Assay (as MgO)	6.8 - 8.3 %	7.8
FCC – Lead (Pb)	<= 5 mg/kg	< 5
FCC – Loss on Drying at 105°C	<= 4.0 %	3.4
Thru U.S. No. 325 Sieve, For Information Only	%	100
Tapped Density (g/cc)	0.21 - 0.33	0.25
Apparent (Bulk) Density	0.07 – 0.17 g/cm3	0.13
Particle Size (50th percentile) (µm)	10.5 - 16.5	11.5
Particle Size (90th percentile) (µm)	<= 35	24

Bulk Food Chemical Bulk Pharmaceutical Chemical

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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.

Country of Origin:	US
Packaging Site:	Paris Mfg Ctr & DC
Manufacturer:	P0110001
Manufacturer source batch:	1612000002



Phillipsburg, NJ 9001:2008, 14001:2004, FSSC 22000 Paris, KY 9001:2008 Mexico City, Mexico 9001:2008 Deventer, The Netherlands 9001:2008, 14001:2004, 13485:2003 Gliwice, Poland 9001:2008, 13485:2012 Selangor, Malaysia 9001:2008 Dehradun, India, 9001:2008, 14001:2004, 13485:2003 Mumbai, India, 9001:2008 Panoli, India 9001:2008

James Techie

Jamie Ethier Vice President Global Quality

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