

Certificate of Analysis

Magnesium Stearate

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	PT
NF – Identification B	Passes Test	PT
NF – Acidity or Alkalinity	Passes Test	PT
NF – Microbiological	Passes Test	PT
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	PT
NF – Escherichia Coli (negative)	Passes Test	PT
NF – Loss on Drying at 105°C	<= 6.0 %	3.4
Specific Surface Area, m ² /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	PT
EP/BP – Identification D	Passes Test	PT
EP/BP – Acidity or Alkalinity	Passes Test	PT
EP/ BP – Chloride (Cl)	<= 0.1 %	< 0.1

Test	Specification	Result
EP/BP – Sulfate (SO ₄)	<= 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	PT
EP/BP – Assay (as as Mg) (dried basis)	4.0 – 5.0 %	4.6
Salmonella (absent)	Passes Test	PT
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	PT
JP – Acidity or Alkalinity	Passes Test	PT
JP – Chloride (Cl)	<= 0.1 %	< 0.1
JP – Sulfate (SO ₄)	<= 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	PT
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	PT
JP – Escherichia Coli (negative)	Passes Test	PT
JP – Assay (as as Mg) (dried basis)	4.0 – 5.0 %	4.8
FCC – Identification A	Passes Test	PT
FCC – Identification B	Passes Test	PT
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/cm ³	0.13
Particle Size (50th percentile) (µm)	10.5 – 16.5	11.5
Particle Size (90th percentile) (µm)	<= 35	24