

Stearic Acid, Powder
NF – GenAR®
Vegetable Grade, 50



Material No.: 2236-24
Batch No.: 0000095008
Manufactured Date: 2015/01/11
Expiration Date: 2017/01/10

Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets J.P. Chemical Specifications, Meets N.F. Requirements,
GMP Manufactured Product

Test	Specification	Result
NF – Identification A	Passes Test	PT
NF – Identification B (Acid Value)	194 – 212	208
NF – Identification C	Passes Test	PT
NF – Residue on Ignition	<= 0.1 %	< 0.1
NF – Heavy Metals (as Pb)	<= 10 ppm	< 10
NF – Acidity	Passes Test	PT
NF – Color of Solution	Passes Test	PT
NF – Iodine Value	<= 4.0	< 4.0
NF – Freezing Point	53 – 59 °C	55
NF – Assay (C ₁₈ H ₃₆ O ₂) (stearic acid)	40.0 – 60.0 %	45.3
NF – Assay (Total of Stearic & Palmitic)	>= 90.0 %	99.5
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Identification C	Passes Test	PT
EP/BP – Appearance	Passes Test	PT
EP/BP – Acidity	Passes Test	PT
EP/BP – Iodine Value	<= 4.0	< 4.0
EP/BP – Freezing Point	53 – 59 °C	55
EP/BP – Nickel (Ni)	<= 1 ppm	< 1
EP/BP – Stearic Acid	40.0 – 60.0 %	45.3
EP/BP – Stearic and Palmitic Acids	>= 90.0 %	99.5
JP – Acid Value	194 – 210	208
JP – Iodine Value	<= 4.0	< 4.0

Test	Specification	Result
JP - Mineral Acids	Passes Test	PT
JP - Heavy Metals (as Pb)	<= 20 ppm	< 20
JP - Fat and Paraffin	Passes Test	PT
JP - Residue on Ignition	<= 0.10 %	< 0.01
Thru U.S. No. 30 Sieve	99.5 - 100.0 %	99.9
Thru U.S. No. 60 Sieve, For Information Only	%	100
Thru U.S. No. 100 Sieve	95.0 - 100.0 %	99.7
Thru U.S. No. 200 Sieve, For Information Only	%	91

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Appearance (fine, white or yellowish-white powder)

No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.

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.

Storage Conditions: Preserve in well-closed containers.

Country of Origin: US

Manufacturer: P0092001

Manufacturer source batch: MEM-419780



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, 17025:2005
Selangor, Malaysia 9001:2008
Dehradun, India, 9001:2008, 14001:2004, 13485:2003
Mumbai, India, 9001:2008, 17025:2005
Panoli, India 9001:2008

Richard M Siberski
Vice President Global Quality

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600
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