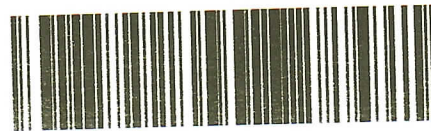


Item 300381

MAGNESIUM STEARATE VEGAN- KOSHER

Old Part Number 2000000784
 PO Number 2021-00-38382
 NutraStar Lot 21007397
 Received 03/31/2021
 Vendor Em Sergeant
 Vendor Lot 20L/MS/138
 Expires 10/01/2025

NET WT: 25.000 KG



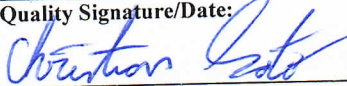
QUALITY:

SPECIFICATION VERSION: B

Review test results generated by a QC Technician, External Laboratory or stated on the supplier's CoA with the listed specification. Record the review by using the respective specification form.

REVIEW COMPLETED BY: Elizabeth Royst DATE: 04/01/2021

DISPOSITION:

<input checked="" type="checkbox"/> RELEASED – This lot (batch) is approved for use in production, further processing, or distribution.	Quality Signature/Date:  04/01/2021
<input type="checkbox"/> RELEASED WITH RESTRICTIONS – This lot (batch) is released for use in production, further processing, or distribution, subject to the following conditions.	Management Signature/Date:
<input type="checkbox"/> REJECTED – This lot (batch) is prohibited from use in production, further processing, or distribution due to the following reasons.	Quality Signature/Date:



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CERTIFICATE OF ANALYSIS

PRODUCT **MAGNESIUM STEARATE NF/EP (LUBRI-PREZ™)**
LOT No. 20L/MS/138
MFG DATE: NOVEMBER 2020
EXP DATE: OCTOBER 2025
COUNTRY OF ORIGIN INDIA

Description Very fine, light, white powder, slippery to touch with a slightly fatty odor; Insoluble in water, in alcohol, and in ether

<u>TEST ITEMS</u>	<u>SPECIFICATIONS</u>	<u>RESULTS</u>	<u>METHODS</u>
Identification			
Test A: Freezing Point	53°C min	56°C	EP
Test B: Acid Value	198 – 210	205.1	EP
Test C: GC	Pass	Complies	EP
Test D: Magnesium	White crystalline precipitate is formed	Complies	EP
Limit of Chlorine	0.1% max	< 0.1%	USP/EP
Limit of Sulfate	0.5% max	< 0.5%	EP/USP
Heavy Metals	10 ppm max	< 10 ppm	EP/USP
Lead	0.5 ppm max	< 0.5 ppm	ICP-MS
Arsenic	1 ppm max	< 1 ppm	ICP-MS
Cadmium	0.5 ppm	< 0.5 ppm	ICP-MS
Nickel	5 ppm max	< 5 ppm	ICP-MS
Mercury	0.1 ppm max	< 0.1 ppm	ICP-MS
ASSAY			
Magnesium (dried basis)	4.0 – 5.0%	4.89%	EP/USP
MgO content	6.65 – 8.3%	8.11%	EP/USP
Acidity or Alkalinity	Pass	Complies	USP/EP
Loss of Drying (105°C)	4.0% max	3.46%	EP/USP
Organic Volatile Impurities	Pass	Complies	EP/USP
Relative Content of Stearic and Palmitic Acid			
Stearic Acid Peak	40% min	46.60%	EP/USP
Sum of Stearic + Palmitic	90% min	95.95%	EP/USP
Specific Surface Area	6 – 12 m ² /g	6.95 m ² /g	USP
Particle Size	99% min thru 200 Mesh	Complies	In House
Bulk Density	140 – 200 g/L	193 g/L	In House
<u>MICROBIOLOGICAL</u>			
Total Plate Count	1,000 cfu/g max	Complies	USP
Yeast & Mold	100 cfu/g max	Complies	USP
E. coli, Staph aureus	Negative/g	Complies	USP
Salmonella	Negative/10g	Complies	USP

This material is vegetable grade.

This is a copy of the original Manufacturer's/Supplier's Certificate of Analysis

Ivaylo Balabanov, Quality Assurance



RAW MATERIAL SPECIFICATION AND ANALYSIS FORM

MATERIAL DESCRIPTION

SPECIFICATION VERSION: B

Storage Conditions: Ambient

Material Name: Magnesium Stearate Vegan

Item Number: 300381

Lot Number: 21007397

Primary Vendor: Em Sergeant

Category: Chemical Entity

REQUIRED TESTS AND EXAMINATION

1. APPEARANCE:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Color	VISUAL	White	CONFORMS
Texture	MACROSCOPIC	Fine Powder	CONFORMS

2. IDENTIFICATION:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Identity	IR SOP 03.013	Conforms	86%

3. STRENGTH (POTENCY):

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Assay	N/A	N/A	N/A

4. PHYSICAL CHARECTERISTIC:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Bulk Density	COA	>0.4 g/mL	N/A
Particle Size	COA	N/A	N/A

5. COMPOSITION (EXCIPIENT/CARRIER):

SPECIFICATION	Verified
N/A	N/A



RAW MATERIAL SPECIFICATION AND ANALYSIS FORM

6. CONTAMINANTS:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Microbiology	COA	TAMC <1,000 cfu/g TYMC <100 cfu/g E. Coli Absent/10g Salmonella Absent/10g	Conforms
Heavy Metals	COA	Arsenic < 15µg/g Cadmium < 5µg/g Lead < 5µg/g Mercury < 2µg/g	Conforms

7. QC NOTES:

Bulk Density	N/A
Particle Size	N/A
Strength	N/A
Micro	N/A
Metals	N/A

8. REVISION HISTORY:

Version	Effective Date	Reason for Change
A	06/21/2018	New Document
B	12/10/2020	Updated Template and Assay

9. DOCUMENT FORM HISTORY (See form history in SOP 03.011-F03.004)

Prepared by:	ORIGINAL SIGNATURES ON FILE
Approved by:	ORIGINAL SIGNATURES ON FILE