



Block - 263/03, Santej
Ta-Kalol, Dis.-Gandhinagar,
Gujarat - 382721.
Phone-+91 79460 48549
Web: www.sbfpharma.com
Mail: info@sbfpharma.com

Certificate of Analysis

Product	Magnesium Stearate
Grade	BP

Report No.	Batch No.	Mfg.: Date	Exp: Date	Quantity	Drug lic no.
#01/23-24	#01/23-24	June-2023	5 Years	100 gm	G- 1498

General Characteristics

Appearance	White or almost white very fine, light powder Greasy to the Touch.	Complies
Solubility	Practically insoluble in water and in Anhydrous ethanol	Complies

CHEMICAL ANALYSIS

Properties	Unit	Specification	Result
Identification	--	Test A- Freezing Point – NLT 53°C Test B- Acid value is 195-210 Test C-passes Test D-passes	A-58°C B-Acid Value – 204 Complies Complies
Acidity or Alkalinity		NMT 0.05 ml of 0.1 M NaOH req. for the Change of Indicator Color	0.03
Acid Value of the Fatty Acid	--	195-210	204
Chloride	%	0.1 Max	<0.1
Sulphates	%	1.0 Max	<1.0
Cadmium	Ppm	3.0 Max	1.08
Lead	Ppm	10 Max	3.7
Nickel	Ppm	5 Max	2.0
Loss on Drying	%	Not More Than 6.0	3.82
Microbial Contamination	CFU/g	TAMC-NMT 10 ³ TYMC-NMT 10 ² Salmonella & Escherichia Coli- Absent	Complies With BP
Assay (mg on Dried Basis)	%	4.0 – 5.0	4.74
Fatty Acid Composition	%	For 1. NLT 40.0	Complies With BP
1. Stearic Acid	%	For 2 NLT 90.0	
2. Sum of palmitic Acid+st. Acid		NLT = Not Less Than	
Particle Size – Particle 50 (Laser)	%	NMT 2.0	Complies With BP
Specific Surface Area	M ²	3M ² /gm – 14M ² gm	9.90
Thermogravimetry	-	Passes	Complies With BP

OPINION: The above product is declared as standard quality.

Shelf Life	
Expiry/Re-Test Period: 5 Years after Date of Manufacture	
Quality Assurance/Certificate	
ISO	SBF Pharma Is ISO 9001:2015 Certified. Certificate No: 21DQHR27
Halal	Our Product is Strictly Halal. Certificate No: 20ZKCM5040HL
Kosher	Our Product is Strictly Kosher. Certificate No: UQ-1102101
Note	All Certificates are Available on Request
Certificate of Compliance	
GMO	The Product Does Not Contain any genetically Modified Organisms (GMO) or Raw Materials Used in Manufacturing of the same are also not Genetically Modified.
Non – Irradiation	The Product was Never Subjected to any kind of Ionized Irradiation and Contains no Radioactivity not even in Monir Amounts.
Allergens	The Product Does Not Contain any of the Below mentioned Allergens: Cereals Containing Gluten, Crustaceans, Eggs, Fish, Peanuts, Tree nuts, Soybeans, Milk, sesame, Seeds, Sulphur Dioxide and Sulphate (Concentrations > 10mg/kg)
TSE/BSE	The Product is not Derived from animal/plant origin & hence this Product I free From Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE). It is Synthetically Derived
Residual Solvent	Class 1, Class 2, Class 3 & Table 4 Solvents are not used in the Production of Product.
Vegetarians/Vegans	Our Product is Suitable for Consumption by Vegetarians and vegans
Storage Recommendations	Store in a room temperature avoid direct sunlight.

Analyzed By	Approved By
Kalpesh Nadiya	Kiran Mistry
	