



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 Name	Magnesium Stearate				
Grade	USP				
Report No.	Batch No.	Mfg.: Date	Exp: Date	Quantity	Drug lic no.
#05/23-24	#05/23-24	June-2023	5 Years	100 gm	G- 1498
Tests	Results		Specification		
Description	Complies		A Very Fine, Light, White Powder, Odorless or with a faint odor of stearic acid; unctuous and free from grittiness		
Solubility	Complies		Practically insoluble in water, in ethanol & in ether		
Identification:					
(A) Freezing Point	56° C		Not Less Than 53° C		
(B) Acid Value	Complies		The Acid Value of the fatty acid is 195 to 210		
(C) Fatty Acid Composition	Complies		As Per IP		
(D) Reaction on Magnesium	Complies		Solution A gives the reaction of magnesium		
Appearance of solution	Complies		Solution A is not more intensely colored than reference solution YS6		
Appearance of solution of the fatty acids.	Complies		The solution is clear, and not more intensely colored than reference solution YS5		
Acidity of Alkalinity	0.004 ml of 0.1 M HCl is Required		NMT 0.05 ml of 0.1M HCl or 0.1 M NaOH is required to change the color of the solution		
Acid value of the fatty acids	208.2		195 to 210		
Free Stearic acid	1.41%		NMT 3 %		
Zinc Stearate	Complies		No violet Precipitate is formed		
Lead	Complies		Max 10 ppm		
Chlorides	Complies		<0.1%		
Sulphates	0.7%		Not more than 1.0%		
Loss on Drying at 105°C, 1.0 g	2.86%		NMT 6.0%		
Cadium	Complies		NMT 3ppm		
Assay	4.75%		4.0% -5.0% Mg on the Dried Basis		
The relative contain of stearate	Complies		NLT 40.0%		
Sum of stearic acid and palmitic acid	Complies		NLT 90.0%		
TAMC	<1000 Cfug		Acceptance criterion 20 ³ Cfug		
TYMC	<500 Cfug		Acceptance criterion 500 Cfug		
Escherichia coli	Absent		Absent		
Salmonella	Absent		Absent		
Particle size	95%		< 100um		
Nickel	2ppm		NMT 5ppm		
Mercury	Complies		NMT 3ppm		
Arsenic	Complies		NMT 1.5%		
Specific surface area	<90%		NLT 90% (6.0 – 12.0) m ² /g		

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
	