

SBF PHRMA

Mfg. Bulk Drug

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CERTIFICATE OF ANALYSIS

PRODUCT NAME	MAGNESIUM STEARATE	
GRADE	IP	

Report No.:	Batch No.:	Quantity:	Mfg. Date:	Exp. Date:	Drug lic no.:
#04/23-24	#04/23-24	100 gm	June-2023	5 Years	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 ⁰ C	Not Less Than 53 ^o 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 thecolor 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
Heavy Metals	Complies	Max 20 ppm
Chlorides	Complies	Max 250 ppm
Sulphates	Complies	Max 0.6%
Loss on Drying at 105°C,1.0 g	2.86%	NMT 6.0%
Bulk Density (In House)	0.22 g/cc	0.15-0.3 g/cc
Assay	4.75%	3.8% -5.0% Mg on the Dried Basis
The Fatty acid Fraction Stearic Acid	Complies	NLT 40.0%
Sum of stearic acid and palmitic acid	Complies	NLT 90.0%
TAMC	<1000 Cfu/g	Acceptance criterion 10 ³ Cfu/g
ТҮМС	<100 Cfu/g	Acceptance criterion 10 ² Cfu/g
Escherichia coli	Absent	Absent
Salmonella	Absent	Absent

Shelf Life				
Expiry/Re-Test Period: 5 Years after Date of Manufacture Quality Assurance/Certificate				
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 Complia	ince			
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	
Kalpesh	Kistery	