SBF PHRMA
Mfg. Bulk Drug
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	Calcium Stearate
Grade	IP

Report No.	Batch No.	Batch Qty.	Mfg.: Date	Exp: Date	Quantity	Drug lic no.
#07/23-24	#07/23-24	3000 kg	June-2023	5 Years	100 gm	G- 1498

General Characteristics

CHEMICAL ANALYSIS

Properties	Specification	Result
Description	A fine, white to yellowish white, bulky powder having a slight, characteristic odor. It should be unctuous and free from grittiness	Complies
Solubility	Insoluble in water, in alcohol and in ether	Complies
Identification (A) Test of calcium	White precipitates should be formed. The precipitate should be insoluble in 6N acetic but should dissolve in hydrochloric acid.	Complies
(B) HPCL	The retention times of the major peaks of the sample solution should correspond to those of the standard solution, as obtained in the assay	Complies
Loss on Drying (at 105^{O}C)	Not more than 4.0%	2.8%
Content of static acid and Palmitic acid (By GC)	The content of stearic acid in the fatty acid fraction should not be less than 40.0% of the total content. The sum of stearic acid and palmitic acid in the fatty acid fraction should not be less than 90.0% of the total content	Complies
Assay (By Titrimetric)	It should contain not less than 6.4% w/w and not more than 7.4% w/w of calcium (Ca), calculated on the dried basis	6.85% w/w
Residual solvents (By GC)	Chloroform: Not more than 60 ppm 1,4-dioxane: Not more than 380 ppm Methylene chloride: Not more than 600 ppm Trichloroethylene: Not more than 80 ppm	40 ppm 285 ppm 463 ppm 53 ppm
Visible foreign and black particles	The material should be free from visible foreign/ black particles	Complies
Heavy metals	Not more than 10 ppm	4.3 ppm

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