



SBF PHARMA

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 NAME			CALCIUM STEARATE			
GRADE			BP			
Report No.	Batch No.	Batch Qty.	Mfg.: Date	Exp: Date	Quantity	Drug lic no.
#01/23-24	#01/23-24	3000 kg	June-2023	5 Years	100 gm	G- 1498
PROPERTY	UNIT	SPECIFICATIONS			TEST VALUE	
Color & Appearance	-	White Free Flowing Powder			White Free Flowing Powder	
Solubility	-	Practically insoluble in water and in ethanol (96 percent).			Complies with BP	
Acidity Or Alkalinity	-	NMT 0.5 ml of 0.01 M Hcl or 0.01 M NaOH Required for Change thecolor.			Complies with BP	
Identification	-	Test A – Freezing Point-53°CMin Test B- Acid Value between195-210 Test C – Passes Test D -Passes			A - 59 °C B - 205 Complies with BP Complies with BP	
Acidity Or Alkalinity	-	NMT 0.5 ml of 0.01 M Hcl or0.01 M NaOH Required for Change the color.			Complies with BP	
Chloride	% Max	0.1 %			Complies with BP	
Sulphates	%Max	0.3 %			Complies with BP	
Cadmium	Ppm max	3.0			2.6	
Lead	Ppm max	10.0			8.4	
Nickel	Ppm max	5.0			3.5	
Loss on Drying	% Max.	6.0 %			2.60	
Microbial Contamination	CFU/g	TAMC-NMT 10 ³ , TYMC-NMT 10 ² , Salmonella & Escherichia ColiAbsent			Complies with BP	
Assay As Ca	%	6.4 -7.4			7.39	
Fatty Acid Composition 1. Stearic Acid Sum of Palmiticacid +St.Acid	%	For 1. NLT 40% For 2. NLT 90% NLT=Not Less Than			41.4% 94.2%	
Particle Size Distribution	-	Passes			Complies with BP	
Specific Surface Area	-	0.05 – 0.15			Complies with BP	



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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
	