

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 NAME			CALCIU	CALCIUM STEARATE					
GRADE			BP	BP					
Report No.	Batch	No.	Batch Qty.	Mfg.: Date	Exp: Date	Qu	Quantity Drug lic		
#01/23-24	#01/23	3-24	3000 kg	June-2023	5 Years	100	00 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 (NMT 0.5 ml of 0.01 M Hcl or 0.01 M NaOH Required for Change thecolor.			Complies with BP		
Identification		-	r	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 or 0.01 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	X	10.0			8.4		
Nickel		Ppm max	X	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		Fo	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/Ce	rtificate			
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 Complia	nce			
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