

**SBF PHARMA**

Mfg. Bulk Drug

Block - 263/03, Santej
Ta-Kalol, Dis.-Gandhinagar,
Gujarat - 382721.

Phone-+91 79460 48549

Web: www.sbfpharma.comMail: info@sbpharma.com**Certificate of Analysis**

Product	Dibasic Calcium Phosphate Dihydrate
Grade	IP/BP/USP

Report No.	Batch No.	Batch Qty.	Mfg.: Date	Exp: Date	Quantity	Drug lic no.
#02/23-24	#02/23-24	3000 kg	June-2023	5 Years	100 gm	G- 1498

General Characteristics

Appearance	White or almost white, crystalline granules	Complies
Taste	Tasteless	Complies
Odor	Odorless	Complies
Solubility	Practically insoluble in water and in ethanol (96 percent)	Complies
	It Dissolve in dilute hydrochloric acid and in dilute nitric acid	Complies

CHEMICAL ANALYSIS

Properties	Unit	Mini	Maxi	Result
Identification A, B & C	--	--	--	Complies
Acid insoluble substances	%	--	0.1	0.074
Carbonates	--	No effervescence should be produced	With hcl	Complies
Chlorides	%	--	0.25	<0.125
Fluorides	Ppm	--	50	21
Sulphates	%	--	0.5	<0.5
Arsenic	Ppm	--	3.0	<3.0
Barium	--	No turbidity should	Be produced	Complies
Heavy metals (as Pb)	Ppm	--	40	<40
Iron	Ppm	--	400	<400
Loss on ignition (800°C to 825°)	%	24.5	26.5	25.94
Nitrate	--	To Pass Test	To Pass Test	Complies
Reducing Substances	--	To Pass Test	To Pass Test	Complies
Protein Impurities	--	To Pass Test	To Pass Test	Complies
Mono Calcium and Tri Calcium Phosphate	ml	11.0	12.5	11.6
Assay (Dihydrate)	%	98.0	105	100.71
Calcium Ca	%	28.9	30.0	29.6
Phosphorus	%	50.0	52.5	51.7
Particle size	Mesh	80		99.9 Passing

Microbiological Analysis

Total Aerobic microbial count	In House	Cfu/gm	--	1,000	Complies
Total yeast and mold count		Cfu/gm	--	100	Complies
Escherichia Coli		Absent/g	--	Absent/g	Complies
Salmonella		Absent/g	--	Absent/g	Complies
Pathogens		Absent	--	Absent	Complies

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
	