



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	Dibasic Calcium Phosphate Dihydrate Unmilled				
Grade	BP/USP				
Report No.	Batch No.	Mfg.: Date	Exp: Date	Quantity	Drug lic no.
#02/23-24	#02/23-24	June-2023	3 Years	100 gm	G- 1498

General Characteristics

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

CHEMICAL ANALYSIS

Properties	Unit	Mini	Maxi	Result
Identification A, B & C	--	--	--	Complies
Acid insoluble substances	%	--	0.05%	0.04%
Carbonates	--	To Confirm Test	To Confirm Test	Complies
Organic volatile impurities	--		Meet USP standards	Complies
Chlorides	Ppm	00	No effervescence occurs	Complies
Calcium	%	22.80	24.43	23.3
Fluorides	Ppm	--	50	<50 ppm
Arsenic	Ppm	--	2	<2 ppm
Barium	--	To Confirm Test	To Confirm Test	Complies
Heavy metals (as Pb)	Ppm	--	30	<10 ppm
Iron	%	--	0.04	0.03
Loss on ignition	%	24.5%	26.5%	26.3%
Assay (USP)	%	98%	105%	99.7%
Lead (ICP/MS)	ppm	--	0.25	<25 ppm
Cadmium (ICP/MS)	ppm	--	2	<1 ppm
Mercury (ICP/MS)	Ppm	--	1	0.03 ppm
Sulphate	%	--	0.48	<0.16%
Ph (20%)	%	7%	8%	7.5%
On USS 20 Mesh Sieve Pass	%	--	100%	100%
On USS 100 Mesh Sieve Pass	%	--	32%	27%
Through USS 325 Mesh Sieve Pass	%	--	1%	0.9%

Microbiological Analysis

Total Plate count	In House	Cfu/gm	--	1,000	100
Total yeast and Mold count		Cfu/gm	--	100	20
E. coli		Negative			Negative
Salmonella species		Negative			Negative
Staphylococcus aureus		Negative			Negative
Pseudomonas aeruginosa		Negative			Negative

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.

Analysed By	Approved By
Kalpesh Nadiya	Kiran Mistry
	