

SBF PHARMA

Mfg. Bulk Drug

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

Gujarat - 382721.

Phone-+91 79460 48549 Web: www.sbfpharma.com

Certificate of Analysis

Mail: info@sbfpharma.com

Product	Dibasic Calcium Phosphate Anhydrous	
Grade	BP/USP	

Report No.	Report No. Batch No.		Exp: Date	Quantity	Drug lic no.
#12/23-24	#12/23-24	July-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	%		0.2%	0.01%
Carbonates		To Confirm Test	To Confirm Test	Complies
Chlorides	%	00	0.25%	<0.25%
Fluorides	Ppm		50	<50 ppm
Arsenic			3 Micro g/g	Complies
Barium		To Confirm Test	To Confirm Test	Complies
Heavy metals (as Pb)	Ppm		30	<30 ppm
Iron	Ppm		400	302 ppm
Loss on ignition (800°C to 825°)	%	6.6%	8.7%	7.5%
Mono Calcium & Tri Calcium Phosphate	ml	14.0	15.5	14.6
Assay	%	97.5	102.5	98.5%
Lead (ICP/MS)	ppm		0.25	<25 ppm
Cadmium (ICP/MS)	ppm		1	<1 ppm
Mercury (ICP/MS)	Ppm		1	<1 ppm
Sulphate	%		0.5	<0.2%

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

Remark: The above specifications complies with the BP & USP pharmacopeia.

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
Kolpesh.	Kistery