

SBF PHARMA

Mfg. Bulk Drug

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

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Certificate of Analysis

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Product	Dibasic Calcium Phosphate Anhydrous Granules (DC Grade)						
Grade	IP/BP/USP						
Report No.	Batch No.	Batch Quantity	Mfg.: Date	Exp: Date	Quantity	Drug licno.	
#03/23-24	#03/23-24	3000 kg	June-2023	5 Years	100 gm	G- 1498	

GENERAL CHARACTERISTICS

Appearance	Free Flowing White Granules	Complies
Taste	Tasteless	Complies
Odor	Odorless	Complies
Solubility	In Ethanol& Water – Insoluble	Complies
	In Dilute Hydrochloride Acid — Soluble in	Complies
	Dilute Nitric Acid — Soluble	Complies

CHEMICAL ANALYSIS

Properties			Method	Unit	Mini Maxi			Result		
Identification				USP		To Comply with the Test				Complies
Acid insoluble substances				USP	%	0.2				0.074
Carbonates				USP		To Comply with the Test				Complies
Chloride			USP	%	0.25				< 0.25	
Fluoride			USP	ppm	50				18	
Sulphate			USP	%	0.5				<0.5	
Arsenic			USP	ppm	3				< 3	
Barium				USP		To Comply with the Test				Complies
Heavy metals			IH	ppm	30				< 30	
Lead*				ICP-MS	ppm	1.0			Complies	
Cadmium*				ICP-MS	ppm	1.0				Complies
Mercury*			ICP-MS	ppm	0.1				Complies	
Assay CaHPO ₄				USP	%	98.0 103.0				100.14
Loss on ignition (800°C to 825°)				USP	%	6.6		8.5		8.04
Test Done at Regular I	Interval									
				MICROB	IOLOGICA	L ANALYSIS				
Total Aerobic count				Cfu/gm		1,000		1,000	C	omplies
Total yeast and mold count		In		Cfu/gm				100		omplies
Escherichia Coli		House		Absent/g				Absent/g		omplies
Salmonella		1	Absent/10g				Absent/10g		omplies	
				PHY	SICAL AN	ALYSIS				
·		0% Maxi. Retained on 20# BSS (841 micron)						0.0		
			2.0% Maxi. Retained on 40#BBS (400 micron)							0.2
			40.0	% Mini. Retai	ned on 10	00#BBS (149 m	icron)25.0% maxi.		60.4
			thru	on 200#BBS	(74 micror	1)				10
			5.0%	maxithru or	325# BBS	(44 micron)				2.5

PARTICLE SIZE CAN BE ADJUSTED AND UPDATED AS PER THE CUSTOMER REQUIREMENT

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 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.	Kisun