

SBF PHRMA

Mfg. Bulk Drug

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CERTIFICATE OF ANALYSIS

Product	Dibasic Calcium Phosphate Dihydrate
Grade	IP.

Report No.	Batch No.	Batch Qty.	Mfg.: Date	Exp: Date	Quantity	Drug lic no.
#08/23-24	#08/23-24	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

		CHEIVIICALANACISIS		
Properties	Unit	Mini	Maxi	Result
Identification A, B & C				Complies
Acid insoluble substances	%		0.1	0.074
Carbonates		No effervescence	With hcl	Complies
		should be produced		
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
portentous 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	100.92

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
O V I (ORGANIC VOLATILE		Meets the		Meets	Complies
IMPURITES)		requirement			
B S E / TSE		Absent		Absent	Complies

Shelf Life				
Expiry/Re-Test Period:	5 Years after Date of Manufacture			
Quality Assurance/Cer	tificate			
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 Complian	nce			
GMO The Product Does Not Contain any genetically Modified Organisms (GMO) or Raw Materials 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 Store in a room temperature avoid direct sunlight. Recommendations				

Analyzed By	Approved By
Kalpesh Nadiya	Kiran Mistry
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