

SBF PHARMA

Mfg. Bulk Drug

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

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CERTIFICATE OF ANALYSIS

Product Tri basic Calcium Phosphate (IP)

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

Properties	Standard	Result
Description	White amorphous almost odorless powder comparable to control	Complies
Solubility	Practically insoluble in water	
Identification		
Test A	Gives reaction(a) of calcium salts (2.3.1)	
Test B	Dissolve 0.1 gm in mixture of 5 ml of 2 M nitric acid and 5 ml of	
	water; the solution gives reaction C of phosphates (2.3.1)	Complies
Acid insoluble substance	Not more than 0.30% w/w	0.23% w/w
pH of 1% solution in purified water	Between 6.5 to 7.5	7.2
Sieve analysis	Not less than 100% should pass through 300 mesh on slurry. (10% w/v in purified water)	Complies
Water soluble substance	Not more than 0.5% w/w	<0.5% w/w
Arsenic	Not more than 5.0% ppm	4.3 ppm
Heavy metals (Cumulative	Not more than 40 ppm	29 ppm
value of lead, mercury,		
arsenic, cadmium, and		
lithium)		
Iron	Not more than 200 ppm	Complies
Carbonate	No effervescence is produced	Complies
Chloride	Not more than 0.1%	Complies
Calcium	Between 35.0%w/w and 40.0% w/w	38.5 %
Phosphorus	Between 17% - 18%	17.3%
Sulphate	Not more than 0.6%	Complies
Protein impurities	No changed in color is observed and no unpleasant odor is emitted	Complies
Loss on ignition at 800°C	Not more than 8.0% w/w	7.2 % w/w
Water	Not more than 2.5 % w/w	1.9 % w/w
Assay	90.0% to 100.5%	98%

OPINION: The above product is declared as standard quality.

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 no 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	
Kalpesh.	Lisury	