

SBF PHRMA

Mfg. Bulk Drug

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 Tri Calcium Phosphate Micronized (IP/BP/USP)	
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Report No.	Batch No.	Batch qty.	Mfg. date.	Exp date.	Qty.	Drug lic no.
#03/23-24	#03/23-24	3000 kg	June-2023	5 years	100 gm	G-1498

Chemical analysis

Properties	Standard	Result
Description	White amorphous almost odourless powder comparable to control	Complies
Solubility	Practically insoluble in water	Complies
Identification		
Test A	A white precipitate is obtained that is only sparingly soluble in	Complies
	dilute acetic but is soluble in hydrochloric acid.	
Test B	A bright yellow precipitate is formed.	Complies
Acid insoluble substance	Not more than 0.30% w/w	0.23% w/w
pH of 1% solution in	Between 6.5 to 7.5	7.2
purified water		
Sieve analysis	100% Passing through 325 mesh	Complies
Bulk Density		
Untapped	Between 0.45 and 0.65 g/ml	0.58 g/ml
Tapped	Between 0.85 and 1.10 g/ml	0.98 g/ml
Water soluble substance	Not more than 3.0% w/w	2.6% w/w
Arsenic	Not more than 5.0 ppm	4.3 ppm
Heavy metals	Note more than 40 ppm	29 ppm
(Cumulative value of		
lead, mercury, arsenic,		
cadmium, and lithium)		
Iron	Not more than 200 ppm	167 ppm
Carbonate	No effervescence is produced	Complies
Chloride	Not more than 0.1000 ppm	0.892 ppm
Sulphate	Not more than 0.6000 ppm	0.5296 ppm
Protein impurities	No changed in colour is observed and no unpleasant odour is	Complies
	emitted	
Loss on ignition at 800"C	Not more than 8.0% w/w	7.2% w/w
Water	Note more than 2.5% w/w	1.9% w/w
Content of calcium	Between 35.0%w/w and 40.0% w/w	38.5% w/w

Shelf Life	
Expiry/Re-Test Period	: 5 Years after Date of Manufacture
Quality Assurance/Co	ertificate
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	ance
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		
kalpesh	Listery		