

SPECIFICATION

Product	Tribasic Calcium Phosphate [BP, EP, and E341 (iii)]	
Grade	Granular/Directly Compressible	Powder/Milled
Product Code	T/B/01	T/B/02

Document No.	Effective Date	Next review date	Amendment History
SPE/T/BP	18/02/2010	18/01/2012	NIL

General Characteristics			
Formula	Ca ₅ (OH)(PO ₄) ₃ or Ca ₃ (PO ₄) ₂	Appearance	Free flowing white granules/powder
Molecular weight	502.31 g/mol or 310 g/mol	Taste	Tasteless
CAS Number	7758-23-8	Odor	Odorless
EINECS Number	Granular: 215-145-7 Powder: 231-840-8	Solubility	In ethanol & water - Insoluble In dilute hydrochloric acid - soluble In dilute nitric acid – soluble
HS Code	2835 2500		

Pharmacopoeia and additional Monograph

The product is primarily intended to be used as raw material in foods and pharmaceuticals and corresponds to the latest editions of the following pharmacopoeial monograph: **BP, EP, E341(iii)**

Physical Analysis			
Particle size/Sieve analysis	Method	Granular/ Directly compressible	Powder/Milled
Retained on 40# BSS (390 micron) Retained on 100# BSS (150 micron) Retained on 300# BSS (53 micron)	In house	15.0% Maxi. 80.0% Mini. 95.0% Mini.	Mini. 95.0% passing through 200# BSS (75 micron)
Bulk Density (Tapped)	In house	Mini. 0.80 g/ml	Mini. 0.55 g/ml

Chemical Analysis				
Properties	Method	Specification Values		
		Unit	Mini.	Maxi.
Identification	BP	---	Complies	
Acid insoluble substances	BP	%	---	0.2
Chloride	BP	%	---	0.15
Sulphate	BP	%	---	0.5
Fluoride	E341 (iii)	ppm	---	50
Arsenic	E341 (iii)	ppm	---	3.0
Heavy metals (as Pb)	BP	ppm	---	30
Iron	BP	ppm	---	400
Lead*	ICP-MS	ppm	---	0.3
Cadmium*	ICP-MS	ppm	---	1.0
Mercury*	ICP-MS	ppm	---	0.1
Assay as Ca	BP	%	35.0	40.0
P ₂ O ₅	E341 (iii)	%	38.5	48.0
Loss on ignition (800 °C)	BP	%	---	8.0

*test done at regular interval.

Microbiological Specification				
Properties	Method	Unit	Mini.	Maxi.
Total aerobic count	In house	cfu/gm	----	1,000
Total yeast and mold count		cfu/gm	----	100
E.coli		Negative/gm	----	Negative/gm
Salmonella		Negative/gm	----	Negative/gm
Nutritional Values				
Calcium (w/w)	Mini. 35.0%			
Phosphorous (w/w)	Mini. 18%			
Calcium/Phosphorous (w/w)	1.9/1			
Shelf Life				
Expiry/Re-test period	Granular/Directly Compressible		Powder/Milled	
	2 years		5 years	
Quality Assurance/ Certificate				
<p>GMP : Sudeep Pharma Ltd is GMP certified. (Issued by Food & Drug Control Administration. Certificate No.S-GMP/1001064).</p> <p>ISO : Sudeep Pharma Ltd is ISO 9001 : 2000 certified (Issued by M/s Benchmark. Certificate No.3032).</p> <p>HACCP : Sudeep Pharma Ltd is HACCP Certified (Issued by M/s Benchmark. Certificate No.3032H).</p> <p>Halal : Our product is strictly Halal (Registration no. 0550).</p> <p>Kosher : Our product is strictly Kosher.</p> <p>Note : All certificates are available upon request.</p>				
Certificate of Compliance				
<p>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.</p> <p>Non-Irradiation: The product was never subjected to any kind of ionized irradiation and contains no radioactivity not even in minor amounts.</p> <p>Allergens: The product does not contain any of the below mentioned allergens: Cereals containing Gluten, Crustaceans, Eggs, Fish, Peanuts, Treenuts, Soybeans, Milk, Sesame seeds, Sulphur Dioxide and sulphites (concentrations >10 mg/kg), Lupin, Molluscs. Directly compressible grade contains minimum 1.5% HPMC as binder.</p> <p>TSE/BSE: The Product is not derived from animal/plant origin & hence this product is free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE). It is synthetically derived.</p> <p>Residual Solvent: Class 1, Class 2, Class 3 & Table 4 solvents are not used in the production of our product.</p> <p>Vegetarians / Vegans: Our product is suitable for consumption by vegetarians and vegans.</p>				
Storage Recommendations				
Store in a cool, dry place				
Packaging				
25 kg net weight packed in white paper lined HDPE bag with inner liner.				