

SPECIFICATION

Product	Dibasic Calcium Phosphate Dihydrate [BP, EP, and E 341(ii)]		
Grade	Directly Compressible	Unmilled	Powder/Milled
Product Code	DD/B/01	DD/B/02	DD/B/03

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

General Characteristics			
Formula	CaHPO ₄ . 2H ₂ O	Appearance	Free flowing white granules/powder
Molecular weight	172.1 g/mol	Taste	Tasteless
CAS Number	7789-77-7	Odor	Odorless
EINECS Number	231-826-1	Solubility	In alcohol & water - Insoluble
HS Code	2835 2500		In dilute hydrochloric acid - soluble In dilute nitric acid - soluble

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(ii)**

Physical Analysis				
Particle size/Sieve analysis	Method	Directly Compressible	Unmilled	Powder/Milled
Retained on 30# BSS (500 micron) Retained on 100# BSS (150 micron) Retained on 200# BSS (75 micron) Retained on 300# BSS (53 micron)	In house	0.5% Maxi. 60.0% Mini. 90.0% Mini. 98.0% Mini.	0.5% Maxi. 55.0% Mini. ---- 95.0% Mini.	Mini. 95.0% passing through 200 # BSS (75 micron)
Bulk Density	Loose Tapped	In house	Mini. 0.70 g/ml Mini. 0.85 g/ml	

Chemical Analysis				
Properties	Method	Specification Values		
		Unit	Mini.	Maxi.
Identification	EP	---	Complies	
Acid insoluble substances	EP	%	---	0.2
Carbonates	EP	---	Complies	
Chloride	BP	ppm	---	330
Fluoride	E-341(ii)	ppm	---	50
Sulphate	EP	%	---	0.5
Arsenic	E-341(ii)	ppm	---	3.0
Barium	EP	---	Complies	
Heavy metals (as Pb)	EP	ppm	---	40
Iron	BP	ppm	---	400
Lead*	ICP-MS	ppm	---	3.0
Cadmium*	ICP-MS	ppm	---	1.0
Mercury*	ICP-MS	ppm	---	0.1
Assay CaHPO ₄ . 2H ₂ O	E-341(ii)	%	98.0	102.0
Monocalcium & Tri Calcium Phosphate	BP	ml	11.0	12.5
P ₂ O ₅ (anhydrous basis)	E-341(ii)	%	50.0	52.5
Loss on ignition (800°C to 825°C)	EP	%	24.5	26.5

*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. 23.3%			
Phosphorous (w/w)	Mini. 18.0%			
Calcium/Phosphorous (w/w)	1.28/1			
Shelf Life				
Expiry/Re-test period: 5 years after date of manufacture				
Quality Assurance/ Certificate				
<p>GMP : Sudeep Pharma Ltd is GMP certified. (Issued by Indian 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.</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.				