

SPECIFICATION

Product	Dibasic Calcium Phosphate Dihydrate [IP]		
Grade	Directly Compressible	Unmilled	Powder/Milled
Product Code	DD/I/01	DD/I/02	DD/I/03

Document No.	Effective Date	Next review date	Amendment History
SPE/D/IP	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 2690		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 Indian pharmacopoeial monograph.

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 100 # BSS (150 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	IP	---	Complies	
Acid insoluble substances	IP	%	---	0.1
Carbonates	IP	---	Complies	
Chloride	IP	%	---	0.125
Sulphate	IP	%	---	0.5
Arsenic	IP	ppm	---	10
Barium	IP	---	Complies	
Heavy metals (as Pb)	IP	ppm	---	40
Iron	IP	ppm	---	400
Nitrate	IP	---	Complies	
Assay CaHPO ₄ . 2H ₂ O	IP	%	98.0	105.0
Loss on ignition (500 °C)	IP	%	24.5	26.5
Reducing substances	IP	---	Complies	
Proteinous impurities	IP	---	Complies	
Mono Calcium & Tri Calcium phosphate	IP	ml	11.0	12.5

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 HDPE bag with inner liner.	