

SPECIFICATION

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

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

General Characteristics			
Formula	CaHPO ₄	Appearance	Free flowing white granules/powder
Molecular weight	136.1 g/mol	Taste	Tasteless
CAS Number	7757-93-9	Odor	Odorless
EINECS Number	231-826-1	Solubility	In ethanol & 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** pharmacopeial 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. 85.0% Mini. 95.0% Mini.	0.5% Maxi. 50.0% Mini. ---- 92.0% 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	IP	%	98.0	105.0
Loss on ignition (500 °C)	IP	%	6.5	8.5
Reducing substances	IP	---	Complies	
Proteinous impurities	IP	---	Complies	
Mono Calcium & Tri Calcium phosphate	IP	ml	14.0	15.5

Nutritional Values	
Calcium (w/w)	Mini. 29.0%
Phosphorous (w/w)	Mini. 22.2%
Calcium/Phosphorous (w/w)	1.3/1
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.	