

## SPECIFICATION

<b>Product</b>	<b>Dibasic Calcium Phosphate Dihydrate [USP]</b>		
<b>Grade</b>	<b>Directly Compressible</b>	<b>Unmilled</b>	<b>Powder/Milled</b>
<b>Product Code</b>	DD/U/01	DD/U/02	DD/U/03

<b>Document No.</b>	<b>Effective Date</b>	<b>Next review date</b>	<b>Amendment History</b>
SPE/D/USP	18/02/2010	18/01/2012	NIL

General Characteristics			
<b>Formula</b>	CaHPO <sub>4</sub> . 2H <sub>2</sub> O	<b>Appearance</b>	Free flowing white granules/powder
<b>Molecular weight</b>	172.1 g/mol	<b>Taste</b>	Tasteless
<b>CAS Number</b>	7789-77-7	<b>Odor</b>	Odorless
<b>EINECS Number</b>	231-826-1	<b>Solubility</b>	In alcohol & water - Insoluble
<b>HS Code</b>	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 <b>U.S</b> 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. 90.0% Mini. 98.0% Mini.	0.5% Maxi. 55.0% Mini. ---- 95.0% Mini.	Mini. 95.0% passing through 200 # BSS (75 micron)
<b>Bulk Density</b>	Loose Tapped	In house	Mini. 0.70 g/ml Mini. 0.85 g/ml	

Chemical Analysis				
Properties	Method	Specification Values		
		Unit	Mini.	Maxi.
Identification	USP	---	Complies	
Acid insoluble substances	USP	%	---	0.2
Carbonates	USP	---	Complies	
Chloride	USP	%	---	0.25
Fluoride	USP	%	---	0.005
Sulphate	USP	%	---	0.5
Arsenic	USP	ppm	---	3.0
Barium	USP	---	Complies	
Heavy metals	USP	%	---	0.003
Lead*	ICP-MS	ppm	---	0.3
Cadmium*	ICP-MS	ppm	---	1.0
Mercury*	ICP-MS	ppm	---	0.1
Assay CaHPO <sub>4</sub> 2H <sub>2</sub> O	USP	%	98.0	105.0
Loss on ignition (800 °C to 825 °C)	USP	%	24.5	26.5
Organic Volatile Impurities	USP	---	Meets the requirement	

\*test done at regular interval.

<b>Microbiological Specification</b>				
<b>Properties</b>	<b>Method</b>	<b>Unit</b>	<b>Mini.</b>	<b>Maxi.</b>
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
<b>Nutritional Values</b>				
Calcium (w/w)	Mini. 23.3%			
Phosphorous (w/w)		Mini. 18.0%		
Calcium/Phosphorous (w/w)		1.28/1		
<b>Shelf Life</b>				
<b>Expiry/Re-test period:</b> 5 years after date of manufacture				
<b>Quality Assurance/ Certificate</b>				
<p><b>GMP</b> : Sudeep Pharma Ltd is GMP certified. (Issued by Indian Food &amp; Drug Control Administration. Certificate No.S-GMP/1001064).</p> <p><b>ISO</b> : Sudeep Pharma Ltd is ISO 9001 : 2000 certified (Issued by M/s Benchmark. Certificate No.3032).</p> <p><b>HACCP</b> : Sudeep Pharma Ltd is HACCP Certified (Issued by M/s Benchmark. Certificate No.3032H).</p> <p><b>Halal</b> : Our product is strictly Halal (Registration no. 0550).</p> <p><b>Kosher</b> : Our product is strictly Kosher.</p> <p><b>Note</b> : <b>All certificates are available upon request.</b></p>				
<b>Certificate of Compliance</b>				
<p><b>GMO:</b> 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><b>Non-Irradiation:</b> The product was never subjected to any kind of ionized irradiation and contains no radioactivity not even in minor amounts.</p> <p><b>Allergens:</b> 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 &gt;10 mg/kg), Lupin, Molluscs.</p> <p><b>TSE/BSE:</b> The Product is not derived from animal/plant origin &amp; hence this product is free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE). It is synthetically derived.</p> <p><b>Residual Solvent:</b> Class 1, Class 2, Class 3 &amp; Table 4 solvents are not used in the production of our product.</p> <p><b>Vegetarians / Vegans:</b> Our product is suitable for consumption by vegetarians and vegans.</p>				
<b>Storage Recommendations</b>				
Store in a cool, dry place				
<b>Packaging</b>				
25 kg net weight packed in white paper lined HDPE bag with inner liner.				