

SPECIFICATION

| | | |
|---------------------|---|----------------------|
| Product | Tribasic Calcium Phosphate [USP] | |
| Grade | Granular/Directly Compressible | Powder/Milled |
| Product Code | T/U/01 | T/U/02 |

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

| General Characteristics | | | |
|--------------------------------|---|-------------------|--|
| Formula | Ca ₅ (OH)(PO ₄) ₃ | Appearance | Free flowing white granules/powder |
| Molecular weight | 502.31 g/mol | Taste | Tasteless |
| CAS Number | 7758-23-8 | Odor | Odorless |
| EINECS No.: | 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 **U.S** pharmacopeial monograph.

| 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 | USP | --- | Complies |
| Acid insoluble substances | USP | % | --- 0.2 |
| Carbonates | USP | --- | Complies |
| Chloride | USP | % | --- 0.14 |
| Sulphate | USP | % | --- 0.8 |
| Fluoride | USP | % | --- 0.0075 |
| Arsenic | USP | ppm | --- 3.0 |
| Barium | USP | --- | Complies |
| Heavy metals (as Pb) | USP | % | --- 0.003 |
| Lead* | ICP-MS | ppm | --- 0.3 |
| Cadmium* | ICP-MS | ppm | --- 1.0 |
| Mercury* | ICP-MS | ppm | --- 0.1 |
| Nitrate | USP | --- | Complies |
| Assay as Ca | USP | % | 34.0 40.0 |
| Water soluble substance | USP | % | --- 0.5 |
| Dibasic salt and calcium oxide | USP | ml | 13.0 14.3 |
| Loss on ignition (800 °C) | USP | % | --- 8.0 |

*test done at regular interval.



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Page 2 of 2

| 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 | | | | |
| GMP : Sudeep Pharma Ltd is GMP certified. (Issued by Indian Food & Drug Control Administration. Certificate No.S-GMP/1001064). | | | | |
| ISO : Sudeep Pharma Ltd is ISO 9001 : 2000 certified (Issued by M/s Benchmark. Certificate No.3032). | | | | |
| HACCP : Sudeep Pharma Ltd is HACCP Certified (Issued by M/s Benchmark. Certificate No.3032H). | | | | |
| Halal : Our product is strictly Halal (Registration no. 0550). | | | | |
| Kosher : Our product is strictly Kosher. | | | | |
| Note : All certificates are available upon request. | | | | |
| Certificate of Compliance | | | | |
| 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. | | | | |
| Non-Irradiation: The product was never subjected to any kind of ionized irradiation and contains no radioactivity not even in minor amounts. | | | | |
| 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. | | | | |
| 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. | | | | |
| Residual Solvent: Class 1, Class 2, Class 3 & Table 4 solvents are not used in the production of our product. | | | | |
| Vegetarians / Vegans: Our product is suitable for consumption by vegetarians and vegans. | | | | |
| Storage Recommendations | | | | |
| Store in a cool, dry place | | | | |
| Packaging | | | | |
| 25 kg net weight packed in white paper lined HDPE bag with inner liner. | | | | |