

SPECIFICATION

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

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

| General Characteristics | | | |
|--------------------------------|---|-------------------|--|
| Formula | Ca ₃ (PO ₄) ₂ | Appearance | Free flowing white granules/powder |
| Molecular weight | 310 g/mol | Taste | Tasteless |
| CAS Number | 7758-23-8 | Odor | Odorless |
| EINECS Number | 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 2690 | | |

| 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 | 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 100# BSS (150 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 | IP | --- | Complies | |
| Acid insoluble substances | IP | % | --- | 0.3 |
| Carbonates | IP | --- | Complies | |
| Chloride | IP | % | --- | 0.1 |
| Sulphate | IP | % | --- | 0.6 |
| Arsenic | IP | ppm | --- | 5.0 |
| Heavy metals (as Pb) | IP | ppm | --- | 40 |
| Iron | IP | ppm | --- | 200 |
| Assay Ca ₃ (PO ₄) ₂ | IP | % | 90.0 | 100.5 |
| Loss on ignition (800°C) | IP | % | --- | 8.0 |
| Water | IP | % | --- | 2.5 |
| Proteinous impurities | IP | --- | Complies | |
| Water soluble substance | IP | % | --- | 0.5 |

| 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 HDPE bag with inner liner. | | |