

calc-i-pur β -TCP (Beta Tricalcium Phosphate) for Implantable Medical Applications

Product Description

calc-i-pur β tricalcium phosphate [$\text{Ca}_3(\text{PO}_4)_2$] is a biocompatible mineral powder comprised of calcium and orthophosphate ions.

General Requirements

calc-i-pur β tricalcium phosphate meets the general requirements of ASTM F1088 “Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation”.

Where Used

calc-i-pur β tricalcium phosphate is commonly used in manufacturing orthopedic, spinal and dental implants including osteoconductive and bioresorbable composites. Composites are custom manufactured using bioresorbable polymers (PLA, PGA) as well as hydroxyapatite additives (HA) for biphasic formulations.

Chemical Requirements

Quantitative X-Ray diffraction analysis shall be $\geq 95\%$ β tricalcium phosphate as defined by PDF 09 0169.

The maximum allowable metals having adverse biological reactions (heavy metals as lead) shall be a total of 50 ppm.

The concentration of trace elements shall be limited as follows:

Element	ppm, max
As	3
Cd	3
Hg	5
Pb	30
Total heavy metals (as lead)	50

Particle Size

The nominal mean particle size for β tricalcium phosphate is 7 μm .

Physical Characteristics

Bulk density shall be determined per USP <616>.

The color of β tricalcium phosphate shall be white to off white.

Additional physical characteristics will be further defined by specific customer application and requirements.

Shelf Life

The shelf life for this product is 36 months from Date of Manufacture.

About Foster Polymer Distribution

Foster Polymer Distribution specializes in the strategic sourcing of specialty performance polymers and additives for implantable medical applications. Foster caters to the unique demands of the medical device community by providing custom distribution services including product development, material sampling, lot selection, GMP batches and regulatory submission. calc-i-pur β tricalcium phosphate can be purchased from Foster Polymer Distribution in an unmodified form or as custom formulated biopolymer composite.

* Calc-i-pur is a product of Degradable Solutions AG

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