Designation: F 1088 – 04

Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation[1]

This standard is issued under the fixed designation F 1088; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers material requirements for biocompatible beta tricalcium phosphate (β-TCP) for surgical implant applications. For a material to be called beta-tricalcium phosphate, it must conform to this specification (see Appendix X1).

1.2 Beta-tricalcium phosphate is used in medical devices which have been cleared for marketing by the U.S. Food and Drug Administration.

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.13 on Ceramic Materials.

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2. Referenced Documents

2.1 *ASTM Standards:* [2]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F 981 Practice for Assessment of Compatibility of Biomaterials (Non-porous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

2.2 *American Society for Quality (ASQ) Document:*

C1 Specification of General Requirements for a Quality Program[3]

2.3 *International Organization for Standardization Document:*

ISO 10993 Biological Evaluation of Medical Devices[4]

2.4 *United States Phamacopaeia (USP) Documents:*[5]

Identification Tests for Calcium and Phosphate <191>

Lead <252>

Mercury <261>

Arsenic <211>

Heavy Metals <231> Method 1

2.5 *Other Reference:*

U.S. Geological Survey Method[6]

3. Chemical Requirements

3.1 Elemental analysis for calcium and phosphorus will be consistent with the expected stoichiometry of β-tricalcium phosphate ($Ca_3(PO_4)_2$. The calcium and phosphorus content shall be determined using a suitable method such as USP <191> (see 2.4) or ion chromatography.

3.2 A quantitative X-ray diffraction analysis shall indicate a minimum β-tricalcium phosphate content of 95 % as determined using Powder Diffraction File #0901695[7] and a method equivalent to Balmain[8] and Forman.[9]

3.3 For β-tricalcium phosphate derived from natural sources, the concentration of trace elements shall be limited as follows:

Element Other Metals	ppm
Pb	≤30
Hg	≤5
As	≤3
Cd	≤5
Total Heavy Metals (as Pb)	≤50

Either inductively coupled plasm/mass spectroscopy (ICP/MS), atomic absorption (AAS), or the methods listed in 2.4 and 2.5 shall be used.

3.3.1 The analysis of other trace elements may be required, based on the conditions, apparatus, or environments specific to the manufacturing techniques and raw materials.

3.4 The maximum allowable limit of all heavy metals determined as lead will be 50 ppm as described in 2.4 or equivalent. Sample preparation will be identical to that for tribasic calcium phosphate as specified in the National Formulatory (see 2.4).

3.5 It is recommended that all metals or oxides not detected as lead present in concentrations equal or greater than 0.1 % be noted in material descriptions.

4. Quality Program Requirements

4.1 The producer shall maintain a quality program, such as the program defined in ASQ C1.

5. Keywords

5.1 advanced ceramics; β-TCP; β-tricalcium phosphate; calcium phosphate material; ceramic; surgical implant

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203-3005.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[5] Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852.

[6] Crock, J. G., Felichte, F. E., and Briggs, P. H., "Determination of Elements in National Bureaus of Standards Geological Reference Materials SRM 278 Obsidian and SRM 688 Basalt by Inductively Coupled Plasma—Atomic Emission Spectrometry," *Geostandards Newsletter*, Vol 7, 1983, pp. 335-340.

[7] International Centre for Diffraction Data, 12 Campus Blvd, Newtown Square, PA 19073-3273.

[8] Balmain, N., et al, "X-Ray Diffraction of Calcined Bone Tissue: A Reliable Method for the Determination of Bone Ca/P Molar Ratio," *Calcified Tissue International*, Vol 34, Supplement 2, 1982, pp. S93-98.

[9] Forman, D. W. and Metsger, D. S., "The Determination of Phase Composition of Calcium Phosphate Ceramics by X-Ray Diffraction," *Transactions of the Seventh Annual Meeting of the American Society for Bone and Mineral Research*, Kelseyville, CA, 1985 p. 391.

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 This specification is needed to ensure a high quality material for use in medical device applications. The chemical, crystallographic, and phase requirements serve as criteria for a high-purity, consistent product that can be implanted in the body. These requirements provide specifications for biocompatible grades of β-tricalcium phosphate for use in the physiological environments.

X1.2 It is recognized that a separate performance standard may be necessary for each end-use product. For this reason, physical and mechanical properties were not specified. A source of general test methods for ceramics may be found in Vol 15.02 of the *Annual Book of ASTM Standards*.

X2. BIOCOMPATIBILITY

X2.1 This specification is needed to ensure a high quality material for use in biological applications. β-tricalcium phosphate has been demonstrated to exhibit a well characterized biological response equivalent or better than that exhibited by reference materials cited and tested in Practices F 981 and F 748 or equivalent. The chemical, crystallographic, and phase requirements contained in this specification serve as criteria for a high purity, consistent product that can be implanted in the body. The suitability of the material from a human implant perspective is dependent on the specific application. The biological test appropriate for the specific site, such as recommended in Practice F 748 or ISO 10993 should be used as a guideline. Further testing of specific properties may be required for specific applications.