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

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ε^1 NOTE—Subsection 3.2 was editorially corrected in June 2006.

1. Scope

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

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F981 Practice for Assessment of Compatibility of Biomaterials 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 Pharmacopeia (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 beta-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 X-ray fluorescence.

3.2 A quantitative X-ray diffraction analysis shall indicate a minimum beta-tricalcium phosphate content of 95 % as determined using Powder Diffraction File #5508987[7] and a method equivalent to Forman[8] or Rietveld.[9,10]

3.3 For beta-tricalcium phosphate, the concentration of trace elements shall be limited as follows:

Element	ppm, max
Other Metals	
Pb	30
Hg	5
As	3
Cd	5

Inductively coupled plasma/mass spectroscopy (ICP/MS), atomic absorption spectroscopy (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

[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] 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] 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.

[9] Jackson, L. E., Barralet, J. E., and Wright, A. J., "Rietveld Analysis in Sintering Studies of Ca-Deficient Hydrxyapatite," *Bioceramics 16*, Key Engineering Materials, Vols 254-256, 2004, pp. 297-300.

[10] Rietveld, H. M., Acta Crystallogr., Vol 22, 1967, p. 151.