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

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1. Scope

1.1 This specification covers chemical and crystallographic requirements for 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).

1.2 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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 Insertion into Bone

2.2 *American Society for Quality (ASQ) Document:*[3]

C1 Specification of General Requirements for a Quality Program

2.3 *International Organization for Standardization Document:*[4]

ISO 10993-1 Biological Evaluation of Medical Devices — Part 1: Evaluation Within a Risk Management System

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

USP <191> Identification Tests for Calcium and Phosphate

USP <232> United States Pharmacopeia: Elemental Impurities – Limits

USP <233> United States Pharmacopeia: Elemental Impurities – Procedure

2.5 *ICH Document:*[6]

ICH Q3D International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guideline for Elemental Impurities

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 #550898[7] and a method equivalent to Forman[8] or Rietveld.[9,10]

3.3 *Elemental Impurities:*

3.3.1 The significance of elemental impurities within an absorbable material is ultimately dependent on the dimensional characteristics of the final product and the rate of release of those initially interstitial elements into the surrounding tissue and extracelluar fluid. Thus, any risk assessment of such impurities will be dependent on the final product design and intended application. Consequently, this raw material (not final device) standard provides for appropriate reporting of elemental impurities values, but does not mandate any specific performance requirements. More detailed and pharmaceutical-oriented guidance regarding the appropriate means for both

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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, http://www.asq.org.

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

[5] Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.

[6] Available from ICH Secretariat, c/o IFPMA, 30 rue de St-Jean, P.O. Box 758, 1211 Geneva 13, Switzerland. Available online at http://www.ich.org/LOB/media/MEDIA423.pdf.

[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.