Designation: F 1185 – 03

Standard Specification for Composition of Hydroxylapatite for Surgical Implants[1]

This standard is issued under the fixed designation F 1185; 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 chemical and crystallographic requirements for hydroxylapatite intended for surgical implants. For a material to be called hydroxylapatite, it must conform to this specification. (See Appendix X1.)

1.2 The biological response to hydroxylapatite in soft tissue and bone has been characterized by a history of clinical use **(1-3)**[2] and by laboratory studies **(4-6)**.

1.3 This specification includes powder, particulate, and forms intended for use as surgical implants, components of surgical implants, or as raw materials for manufacturing processes such as thermal spray coating, electrophoretic deposition, physical vapor deposition, and so forth.

1.4 This specification specifically excludes hydroxylapatite coatings, amorphous calcium phosphate, ceramic-glasses, tribasic calcium phosphate, whitlockite, and alpha- and beta-tricalcium phosphate. (See Specification F 1088.)

2. Referenced Documents

2.1 *ASTM Standards:*

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[3]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[3]

F 1088 Specification for Beta-Tricalcium Phosphate for Surgical Implantation[3]

F 2024 Practice for X-Ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings[3]

2.2 *Code of Federal Regulations:*[4]

Title 21, Part 820.

2.3 *National Formulary:*[5]

Tribasic Calcium Phosphate

2.4 *United States Pharmacopeia:*[6]

Identification Tests for Calcium and Phosphate <191>

Lead < 251>

Mercury <261>

Arsenic <211>

Heavy Metals <231> Method 1

2.5 *U. S. Geological Survey Method:*[7]

Cadmium

2.6 *American Society for Quality:*[8]

C1 Specification of General Requirements for a Quality Program

3. Terminology

3.1 *Descriptions of Terms Specific to This Standard:*

3.1.1 *hydroxylapatite*—the chemical substance having the empirical formula $Ca_5(PO_4)_3OH$.[9]

4. Chemical Requirements

4.1 Elemental analysis for calcium and phosphorus will be consistent with the expected stoichiometry of hydroxylapatite. The calcium and phosphorus contents shall be determined using a suitable method such as ion chromatography.

4.2 A quantitative X-ray diffraction analysis shall indicate a minimum hydroxylapatite content of 95 % as determined in accordance with Practice F 2024. Analysis of relative peak intensities shall be consistent with published data.[10]

[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] The boldface numbers in parentheses refer to the list of references at the end of this specification.

[3] *Annual Book of ASTM Standards*, Vol 13.01.

[4] Available from U.S. Government Printing Office, N. Capitol and H St., NW, Washington, DC 20402.

[5] National Formulary XVI. Available from U.S. Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

[6] United States Pharmacopeia XXI. Available from U.S. Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

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

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

[9] Chemical Abstracts Service Registry Number [1306-06-5].

[10] The Joint Committee on Powdered Diffraction Standards has established a Powder Diffraction File. The Committee operates on an international basis and cooperates closely with the Data Commission of the International Union of Crystallography and ASTM (American Society for Testing and Materials). Hydroxylapatite data can be found on file card number 9-432 and is available from the Joint Committee on Powder Diffraction Standards, 1600 Park Lane, Swarthmore, PA 19081.