



Designation: F1185 – 03(Reapproved 2009)

Standard Specification for Composition of Hydroxylapatite for Surgical Implants¹

This standard is issued under the fixed designation F1185; 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 [F1088](#).)

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards*:³

[F748](#) Practice for Selecting Generic Biological Test Methods for Materials and Devices

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.

Current edition approved June 15, 2009. Published July 2009. Originally approved in 1988. Last previous edition approved in 2003 as F1185 – 03. DOI: 10.1520/F1185-03R09.

² The boldface numbers in parentheses refer to the list of references at the end of this specification.

³ 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.

[F981](#) Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

[F1088](#) Specification for Beta-Tricalcium Phosphate for Surgical Implantation

[F2024](#) Practice for X-ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings

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 *Definitions of Terms Specific to This Standard*:

3.1.1 *hydroxylapatite*—the chemical substance having the empirical formula $\text{Ca}_5(\text{PO}_4)_3\text{OH}$.⁹

4. Chemical Requirements

4.1 Elemental analysis for calcium and phosphorus will be consistent with the expected stoichiometry of hydroxylapatite.

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, <http://www.asq.org>.

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