Designation: F 1088 – 87 (Reapproved 1992)ε1

# 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.

ε[1] NOTE—Section 7 was added editorially in December 1992.

## 1. Scope

1.1 The specification defines the chemical and crystallographic properties of beta-tricalcium phosphate intended for surgical implantation. It also informs the user that manufacturers and distributors are obligated to meet certain federal requirements.

1.2 It has been found that material meeting this specification engenders an acceptable biocompatible response as defined in Practice F 981 **(1)**.[2] Other properties of calcium phosphates such as grain size, density, strength, and resorption rates are dependent upon certain process parameters **(2-9)**.

1.3 This specification excludes tribasic calcium phosphate, whitlockite, alpha-tricalcium phosphate, and hydroxyapatite.

## 2. Referenced Documents

2.1 *ASTM Standards:*

C 674 Test Methods for Flexural Properties of Ceramic Whiteware Materials[3]

F 981 Practice for Assessment of Compatibility of Biomaterials (Non-porous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[4]

NOTE 1—Test Methods C 674 is referenced only to guide the future writers or users of performance standards that may yet be deemed necessary to promulgate. Test Methods C 674 does not contain any material specifications for beta-tricalcium phosphate.

2.2 *United States Code of Federal Regulations:*

Title 21 Part 820 Good Manufacturing Practices for Medical Devices[5]

## 3. Chemical Composition

3.1 Elemental analyses of calcium and phosphorus will be consistent with the expected stoichiometry of tricalcium phosphate.

NOTE 2—The precision of wet chemical methods for calcium and phosphorus are not sufficient to easily establish a 95 % purity of tricalcium phosphate. The theoretical calcium and phosphorus content of tricalcium phosphate is 38.76 and 19.97 %, respectively. The addition of 5 weight % hydroxyapatite results in calcium and phosphorous values of 38.82 and 19.90, respectively. To identify 5 weight % hydroxyapatite in tricalcium phosphate a maximum standard deviation for the calcium method must be 0.03; for phosphorus, 0.04 ($n$ = 10, alpha = 0.05, power (1-beta) = 0.90). Precision of this order of magnitude is not expected.

3.2 *Trace Metals*:

3.2.1 The maximum allowable limits of individual heavy metals are as shown:

| Metal | ppm, max |
|---|---|
| Lead | 30 |
| Mercury | 5 |
| Arsenic | 3 |
| Cadmium | 5 |

For referee purposes, Limit Tests 251, 261, 211, **(10)** and Ref **(11)** will be used.

NOTE 3—These maximum values are based upon historical levels found in commercial calcium phosphates manufactured in the United States intended for surgical implantation.

3.2.2 The maximum allowable limit of all heavy metals determined as lead will be 50 ppm as described in Heavy Metals (231) Method 1 **(10)** or equivalent. Sample preparation will be identical to that for tribasic calcium phosphate as specified in the National Formulary Official Monograph on Tribasic Calcium Phosphate **(12)** except that approximately 1 g of material will be dissolved in approximately 30 mL of 5 % hydrochloric acid and boiled.

3.2.3 It is recommended that all metals or oxides not detected as lead present in concentrations equal to or greater than 0.10 % be listed on the package insert.

[1] This specification is under the jurisdiction of ASTM Committee F-4 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 15.02.

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

[5] Available from U.S. Government Printing Office, North Capital and H Streets NW, Washington, DC 20401.