



Standard Test Method for Dissolution Testing of Calcium Phosphate Granules, Fabricated Forms, and Coatings¹

This standard is issued under the fixed designation F1926/F1926M; 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 test method covers calcium phosphate materials intended for use in surgical implant applications.

1.2 The material(s) shall be representative of that produced for sale. It shall have been produced and processed under standard manufacturing conditions.

1.3 The materials may be in the form of powders, granules, spall material, fabricated forms or coatings; and may be porous, nonporous, textured, and other implantable topographical substrate form representative of the end-use product.

1.4 The calcium phosphate material may constitute the only material in a substrate or it may be one of multiple materials so long as all other materials present do not dissolve under the test conditions described in this test method.

1.5 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance with the 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:*²

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

F1088 Specification for Beta-Tricalcium Phosphate for Surgical Implantation

¹ This test method 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 May 15, 2014. Published July 2014. Originally published in 1998. Last previous edition approved in 2010 as F1926/F1926M – 10. DOI: 10.1520/F1926_F1926M-14.

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.

F1185 Specification for Composition of Hydroxylapatite for Surgical Implants

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *calcium phosphate, n*—any one of a number of inorganic chemical compounds containing calcium and phosphate ions as its principal constituents.

3.1.2 *coating, n*—layer of material mechanically or chemically adhering to the surface of a substrate.

4. Significance and Use

4.1 Aspects of the biological response to calcium phosphate materials in soft tissue and bone have been reported from laboratory studies and clinical use (**1-11**).³

4.2 The requirements of this test method apply to calcium phosphate materials such as calcium hydroxyapatite (see Specification **F1185**), beta-tricalcium phosphate (see Specification **F1088**), and biphasic mixtures thereof with or without intentional addition of other minor components (<10 %).

4.3 This test method is limited to the laboratory evaluation of the dissolution rate of a calcium phosphate material. No correlation of the results to in vivo performance is implied. Therefore, it is recommended that a control material be included in the evaluation. The control material can be a standardized material such as NIST SRM 2910 or a historical control.

5. Dissolution Media

5.1 Water used for preparing reagents or dissolution media shall be degassed carbon dioxide free deionized or distilled water and have less than 0.1 ppm of residual Ca^{++} ion. Optionally, the water can be degassed *in situ*.

5.2 *Unbuffered Water Media*—Deionized or distilled water containing 8×10^{-5} M NaCl, 8×10^{-5} M CaCl_2 , and 5×10^{-5} M $\text{K}_3(\text{PO}_4)$.

³ The boldface numbers in parentheses refer to the list of references at the end of this standard.