



Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants¹

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1. Scope

1.1 This specification covers material requirements for unfabricated and fabricated forms of hydrated calcium sulfate intended for surgical implants. Fabricated forms may include pressed and cast surgical implants in various geometric shapes. The calcium sulfate hemihydrate in the unfabricated form can be converted with the addition of water or other water-containing solutions to a fabricated calcium sulfate dihydrate form.

1.2 The requirements of this specification apply to calcium sulfate combined with two molecules of water or two calcium sulfate molecules sharing one water molecule.

Approximate chemical formulae:

Calcium Sulfate Dihydrate
 $\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$

Calcium Sulfate Hemihydrate
 $\text{CaSO}_4 \cdot 1/2\text{H}_2\text{O}$ or $\text{CaSO}_4 \cdot \text{H}_2\text{O} \cdot \text{CaSO}_4$

1.3 This specification specifically excludes calcium sulfate anhydrite and calcium sulfate forms that contain additives such as reinforcing phases, medicaments, biological agents, and so forth.

1.4 The presence of processing aids does not exclude a product from the physical and mechanical requirements of this specification.

1.5 Some provisions of Specification C 59/C 59M and Test Methods C 472 apply. Special requirements that are detailed in this specification are included to characterize the material which will be used in surgical implants.

1.6 The biological response to calcium sulfate in bone tissue has been well characterized by a history of clinical use **(1-14)**² and by laboratory studies **(15-18)**.

1.7 The following precautionary caveat pertains only to the test method portion, Sections 4, 5, and 6, of this specification. *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 requirements prior to use.

2. Referenced Documents

2.1 ASTM Standards:

C 59/C 59M Specification for Gypsum Casting Plaster and Gypsum Molding Plaster³

C 472 Test Methods for Physical Testing of Gypsum, Gypsum Plasters and Gypsum Concrete³

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants⁴

F 756 Practice for Assessment of Hemolytic Properties of Materials⁴

F 763 Practice for Short-Term Screening of Implant Materials⁴

F 813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices⁴

F 895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity⁴

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone⁴

F 1088 Specification for Beta-Tricalcium Phosphate for Surgical Implantation⁴

F 1635 Test Method for In Vitro Degradation Testing of Poly(L-lactic acid) Resin and Fabricated Form for Surgical Implants⁴

2.2 Other Documents:

BS 6463-102: 2001 Quicklime, Hydrated Lime and Natural Calcium Carbonate—Part 102: Methods for Chemical Analysis⁵

US Pharmacopeia XXIV (USP 24) NF-19⁶

³ Annual Book of ASTM Standards, Vol 04.01.

⁴ Annual Book of ASTM Standards, Vol 13.01.

⁵ Available from the British Standards Institution, c/o IHS Engineering/IHS International, 15 Inverness Way East, Englewood, CO 80112.

⁶ Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852.

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 standard.