Designation: F 1580 – 95

Standard Specification for Titanium and Titanium-6 % Aluminum-4 % Vanadium Alloy Powders for Coatings of Surgical Implants[1]

This standard is issued under the fixed designation F 1580; 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 the requirements for unalloyed titanium and Ti-6Al-4V alloy powders for use in fabricating coatings on titanium alloy implants.

1.2 Powders covered under this specification may be used to form coatings by sintering or thermal spraying techniques.

1.3 This specification covers powder requirements only. It does not address properties of the coatings formed from them.

2. Referenced Documents

2.1 *ASTM Standards:*

B 214 Test Method Sieve Analysis of Granular Metal Powders[2]

B 215 Methods of Sampling Finished Lots of Metal Powders[2]

B 299 Specification for Titanium Sponge[3]

E 11 Specification for Wire-Cloth Sieves for Testing Purposes[4]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[5]

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications[3]

F 1472 Specification for Wrought Ti-6Al-4V Alloy for Surgical Implant Applications[6]

2.2 *American Society for Quality Control (ASQC) Standards:*[7]

ASQC C1 General Requirements for a Quality Control Program

2.3 *Aerospace Material Specifications:*[8]

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 4998A Powder, 6Al-4V, Premium Quality (noncurrent)

3. Significance and Use

3.1 Coatings formed from metallic powders have become widely used as a means of improving tissue attachment to implants. Such coatings have also been demonstrated to improve bonding of acrylic cement to prostheses. This specification addresses the special requirements of the metal powders used to form these coatings.

4. Methods of Manufacture

4.1 Powders may be manufactured by the plasma rotating electrode process, inert gas atomization, hydride-dehydride, or other method capable of producing powder meeting the requirements of this specification.

5. Chemical Requirements

5.1 The chemical analysis of the powder shall conform to the requirements set forth in Table 1. Analysis shall be performed prior to the addition of any processing aids.

5.1.1 Requirements for the major and minor elemental constituents for unalloyed titanium and Ti-6Al-4V alloy powders are listed in Table 1. Also listed are all important residual elements. Analysis for elements not listed in Table 1 is not required to verify compliance with this specification.

5.2 The product analysis tolerance shall conform to the requirements set forth in Table 2.

5.3 For referee purposes, Test Methods E 120 shall be used.

5.4 Intentional elemental additions other than those specified in Table 1 are not permitted.

5.5 For powder that includes particle size fractions finer than 200 mesh (74 microns), the oxygen content limits shall be agreed upon between buyer and seller.

6. Particle Size

6.1 Powder shall be sieved to the customer's requirements with stainless steel screens conforming to Specification E 11. Analysis of sieved powder for conformance to the customer's particle size range requirements shall be in accordance with Test Method B 214.

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Devices and is under the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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[2] *Annual Book of ASTM Standards*, Vol 02.05.

[3] *Annual Book of ASTM Standards*, Vol 02.04.

[4] *Annual Book of ASTM Standards*, Vol 14.02.

[5] *Annual Book of ASTM Standards*, Vol 03.05.

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

[7] Available from the American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

[8] Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096.