



Designation: F 1580 – 95

Standard Specification for Titanium and Titanium-6 % Aluminum-4 % Vanadium Alloy Powders for Coatings of Surgical Implants¹

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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 Powders²

B 215 Methods of Sampling Finished Lots of Metal Powders²

B 299 Specification for Titanium Sponge³

E 11 Specification for Wire-Cloth Sieves for Testing Purposes⁴

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys⁵

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications³

F 1472 Specification for Wrought Ti-6Al-4V Alloy for Surgical Implant Applications⁶

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.

TABLE 1 Chemical Requirements

Element	Unalloyed Ti powder weight per cent		Ti-6Al-4V powder weight per cent	
	min.	max.	min.	max.
Al			5.50	6.75
V			3.50	4.50
O		0.40		0.20
Fe		0.50		0.30
C		0.10		0.08
H		0.05		0.015
N		0.05		0.05
Cu				0.10
Sn				0.10
Si		0.04		
Cl		0.20 ^A		
Na		0.19 ^A		
Ti	balance ^B		balance ^B	

^A Lower maximum chlorine and sodium contents may be agreed upon between buyer and seller.

^B The percentage of titanium is determined by difference and need not be measured.

TABLE 2 Product Analysis Tolerances^A

Element	Variation Under Min. or Over Max.
Aluminum	0.04
Vanadium	0.015
Oxygen	0.03 ^B
Oxygen	0.02 ^C
Iron	0.10
Hydrogen	0.002
Carbon	0.02
Nitrogen	0.02
Copper	0.05
Tin	0.15
Silicon	0.02

^A Refer to AMS 2249.

^B For unalloyed Ti powder.

^C For Ti-6Al-4V alloy powder.

7. Cleanliness

7.1 Powder shall be handled at all times so as to ensure freedom from contamination with non-metallic materials or other metal alloy powders, or both.

7.2 Powder cleanliness shall be determined by examining a representative sample, per Methods B 215 or as agreed upon between buyer and seller, comprising at least 1 in.² (6.45 cm²) of a closely packed mono-layer of powder per lot at 20×

magnification. No foreign material shall be visible under these conditions. Powder cleanliness shall be determined prior to the addition of any processing aids.

8. Special Requirements

8.1 Various materials known as processing aids may be added to the powder to provide enhanced processibility. The powder supplier shall identify the chemical composition and weight percentage of any added processing aids on the material certification.

8.2 Processing aids shall have no detrimental effect on the corrosion resistance or biocompatibility of the final coating.

NOTE 1—Finely divided titanium powder may be considered pyrophoric and should be handled in accordance with the appropriate guidelines in the Material Safety Data Sheet.

9. Certification

9.1 Powder shipped under this specification shall be accompanied by certification that includes:

- 9.1.1 ASTM designation.
- 9.1.2 Quantity (weight).
- 9.1.3 Method of manufacture.
- 9.1.4 Chemical analysis per 5.1.
- 9.1.5 Sieve analysis per 6.1.
- 9.1.6 Powder cleanliness per 7.2.
- 9.1.7 Special requirement per 8.2.
- 9.1.8 Other requirements.

10. Quality Program Requirements

10.1 The producer shall maintain a quality program, such as that defined in the ASQC C1, for example.

10.2 The manufacturer of surgical implants shall be ensured of the producer's quality program for conformance to the intent of ASQC C1 or other recognized programs.

11. Keywords

11.1 coatings; metallic; metals (for surgical implants titanium alloys); orthopaedic medical devices (titanium/titanium alloys); powder; porous coatings; titanium/titanium alloys (for surgical implants)

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Coatings formed from metallic powders have become widely used as a means of improving tissue attachment to uncemented orthopedic joint prosthesis. Such coatings have also been demonstrated to improve bonding of acrylic cement to prostheses.

X1.2 The biocompatibility of metallic implants is a direct function of their composition. The compositions of titanium and titanium alloy powders allowed by this specification have been used in wrought form for surgical implants and are in

widespread commercial use for fabrication of porous coatings.

X1.3 Chemical composition limits for O, Fe, C, and N in the unalloyed grade are taken from Specification F 67, grade 4. Limits for Si, Cl, H, and Na are taken from Specification B 299, grade SL.

X1.4 Chemical composition limits for Al, V, O, Fe, C, H, and N in the Ti-6Al-4V grade are taken from Specification F 1472. Limits for Cu and Sn are taken from AMS 4998.