~~Designation:F1580–01~~ Designation: F 1580 – 07

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.

1.4 Finely divided titanium powder may be considered pyrophoric and should be handled in accordance with the appropriate guidelines.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

B 214 Test Method for Sieve Analysis of ~~Granular~~ Metal Powders

B 215~~Practices for Sampling Finished Lots of Metal Powders~~[2] Practices for Sampling Metal Powders

B 299 Specification for Titanium Sponge

E 11~~Specification for Wire-Cloth Sieves for Testing Purposes~~ Specification for Wire Cloth and Sieves for Testing Purposes

E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E120~~Test Methods for Chemical Analysis of Titanium and Titanium Alloys~~ 2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry

F 67~~Specification for Unalloyed Titanium for Surgical Implant Applications~~ Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

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

F 1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)

2.2 *ISO Standards:*[3]

ISO 9001 Quality Management System Requirements

2.3 *American Society for Quality (ASQ) Standards:*[4]

ASQ C1 General Requirements for a Quality Program

~~2.3~~

2.4 *Aerospace Material Specifications:*[5]

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

~~AMS4998APowder, 6Al-4V, Premium Quality (noncurrent)~~ AMS 4998 Powder, 6Al-4V

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

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

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[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* ~~, Vol 02.05.~~volume information, refer to the standard's Document Summary page on the ASTM website.

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

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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

[4] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

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

[5] Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

***A Summary of Changes section appears at the end of this standard.**

3. Methods of Manufacture

3.1Powders 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.

4.*Chemical Requirements* Chemical Requirements

4.1The chemical analysis of the powder shall conform to the requirements set forth in 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 specified in Table 1. Analysis shall be performed before the addition of any processing aids.

4.1.1Requirements for the major and minor elemental constituents for unalloyed titanium and Ti-6Al-4V alloy powders are listed in .

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.

4.2The5.2 The product analysis tolerance shall conform to the requirements set forth in Table 2.

TABLE 1 Chemical Requirements

Element	Unalloyed Ti Powder WeTight Powderecent[A] % (mass/mass)		Ti-6Al-4V P Spowdnger WPowder[B] % (mass/mass)		Tight-6Al-4V Powderecent[C] % (mass/mass)	
	Min	Max	Min	Max	Min	Max
Al			5.50	0.05	5.50	6.75
Al				0.05	5.50	6.75
V			3.50		3.50	4.50
V					3.50	4.50
O		0.40				0.20
O		0.40		0.40[D]		0.20
Fe		0.50				0.30
Fe		0.50		0.15		0.30
C		0.10				0.08
C		0.08		0.03		0.08
H		0.05				0.015
H		0.05		0.03		0.015
N		0.05				0.05
N		0.05		0.02		0.05
Cu						0.10
Sn						0.10
Si		0.04				
Si				0.04		
Cl		–		0.20[A]		
Cl				0.20[E]		
Na		0.19		[A]		
Na				[F] –		
Y						0.005[C]
Ti	balance[B]		balance[B]		balance[G]	
Ti	balance[G]		balance[G]		balance[G]	

[A] Lower maximum chlorine and sodium contents may be agreed upon between buyer and seller. except hydrogen.

[B] Chemistry per Specification B 299, general purpose grade.

[C] Chemistry per Specification F 1472.

[D] Oxygen per Specification B 299 is 0.15 %. This level is reasonable for sponge product but not for powder because of the increased surface area of small particle powder product.

[E] Lower maximum chlorine content may be agreed upon between buyer purchaser and seller supplier.

[F] Sodium or magnesium, 0.50 maximum.

[G] The percentage of titanium is determined by difference and need not be measured.

TABLE 2 Product Analysis Tolerances[A]

Element	Element Variation Under Min or Over Max
Aluminum	0.04
Vanadium	0.015
Oxygen	0.03[B]
Oxygen	0.02[C]
Hydrogen	0.002
Iron	0.10
~~Hydrogen~~	~~0.002~~
Carbon	0.02
Nitrogen	0.02
Copper	0.05
Tin	0.15
Silicon	0.02
Yttrium	0.0005[C]

[A] Refer to AMS 2249.
[B] For unalloyed Ti powder.
[C] For Ti-6Al-4V alloy powder.

~~4.3For referee purposes, Test Methods E120~~

5.3 For referee purposes, Test Method E 2371 shall be used.

~~4~~5.4 Intentional elemental additions other than those specified in Table 1 are not permitted.

~~4.5For~~5.5 For powder that includes particle size fractions finer than 200 mesh (74 μm), the oxygen content limits shall be agreed upon between buyer and seller.

~~5.~~6. Particle Size ~~and Shape~~

~~5.1~~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.

~~5.2Powder made from the plasma rotating electrode process and inert gas atomization tends to be spherical in shape, powder made from the hydride-dehydride process tends to be angular in shape and sponge powder tends to be irregular in shape.~~

~~6.~~

7. Cleanliness

~~6~~7.1 Powder shall be handled at all times so as to ensure freedom from contamination with nonmetallic materials or other metal alloy powders or both.

~~6.2~~7.2 Powder cleanliness shall be determined by examining a representative sample, per Practices B 215 or as agreed upon between buyer and seller, comprising at least 1 in.^{2} (6.45 cm^2) ~~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 before the addition of any processing aids.~~

~~**7.Special Requirements**~~

~~7.1Various 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.~~

~~7.2Processing aids shall have no detrimental effect on the corrosion resistance or biocomptability of the final coating.~~

~~NOTE1—Finely divided titanium powder may be considered pyrophoric and should be handled in accordance with the appropriate guidelines in the Material Safety Data Sheet.~~

~~**8.Certification**~~

~~8.1Powder shipped under this specification shall be accompanied by certification that includes:~~

~~8.1.1ASTM designation and date of issue.~~

~~8.1.2Quantity (weight).~~

~~8.1.3Method of manufacture.~~

~~8.1.4Chemical analysis per 4.1~~) of a closely packed mono-layer of powder per lot at 20× magnification. No foreign material shall be visible under these conditions.

8. Significance of Numerical Limits

8.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right hand digit used in expressing the specification limit, in accordance with the rounding method of Practice E 29.