Designation: F1580 – 12

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 F1580; 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.

1.5 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

B214 Test Method for Sieve Analysis of Metal Powders

B215 Practices for Sampling Metal Powders

B299 Specification for Titanium Sponge

E11 Specification for Woven Wire Test Sieve Cloth and Test Sieves

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

F1472 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 *Aerospace Material Specifications:*[4]

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 4998 Powder, 6Al-4V

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 specified in Table 1.

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 Method E2371 shall be used.

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

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

[4] 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**

TABLE 1 Chemical Requirements

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

[A] Chemistry per Specification F67 except hydrogen.
[B] Chemistry per Specification B299, general purpose grade.
[C] Chemistry per Specification F1472.
[D] Oxygen per Specification B299 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
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.

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 µm), 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 E11. Analysis of sieved powder for conformance to the customer's particle size range requirements shall be in accordance with Test Method B214.

7. Cleanliness

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.

7.2 Powder cleanliness shall be determined by examining a representative sample, per Practices B215 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.

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 E29.

9. Certification

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

9.1.1 ASTM designation and date of issue.
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 Other requirements.

10. Quality Program Requirements

10.1 The supplier shall maintain a quality program, such as that defined in ISO 9001 or similar quality program.

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)

APPENDIXES

(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 oxygen, iron, carbon, and nitrogen in the unalloyed grade are taken from Specification F67, Grade 4. Limits for silicon, chlorine, hydrogen, and sodium are taken from Specification B299, Grade SL.

X1.4 Chemical composition limits for aluminum, vanadium, oxygen, iron, carbon, hydrogen, and nitrogen in the Ti-6Al-4V grade are taken from Specification F1472. Limits for copper and tin are taken from AMS 4998.

X1.5 Product analysis tolerances are taken directly from AMS 2249. No recognized product analysis tolerances currently exist specifically for chlorine or sodium in titanium alloys.

X1.6 Processing aids are frequently used to facilitate powder processing and application of porous coatings to implant surfaces. It is beyond the scope of this specification to identify suitable processing aids or define their use. It is the responsibility of the implant manufacturer to ensure that any processing aid or residue of a processing aid has no detrimental effect on biocompatibility or coating properties.

X1.7 It should be recognized that the heat treatments used to form porous coatings can create microstructures that are substantially different from wrought titanium alloys. Porous coated implants also exhibit much greater surface area than monolithic implants. For these reasons, the biocompatibility and corrosion behavior must be characterized on finished coatings.

X1.8 Likewise, these heat treatments can create microstructures that give substantially different corrosion fatigue behavior from that of typical wrought titanium alloys. Corrosion fatigue behavior must be evaluated on finished coated substrates.

X1.9 Pore size and morphology are important factors influencing tissue ingrowth and acrylic penetration of porous coatings. Particle size, size distribution, and shape are critical to controlling the pore size and morphology in the final coating. Particle size and size distribution are conventionally controlled by screening. The referenced ASTM International standards allow comparison of powder to a manufacturer's specifications for a given coating process. A number of methods to characterize particle shape exists. The coating manufacturer should select a means of particle shape characterization suitable for this process.

X1.10 This specification requires sampling for particle size and powder cleanliness on each powder lot. In some cases, sampling on each shipping container of powder may be appropriate.

X1.11 Other process parameters are also critical to determining final pore size and morphology in the final coating. Because these parameters are not directly related to the chemical and physical characteristics of the starting powder, they are not addressed in this specification.

X1.12 The requirements for powder cleanliness ensure freedom from contaminants that might adversely affect either the biocompatibility or the finished coatings or the ability to bond the coating properly during manufacturing. The method in 7.2 (Practices B215) is commonly used for relatively coarse spherical powders used to fabricate sintered porous coatings. Other types of powders may require different methods for cleanliness characterization. The development and implementation of such methods are the responsibility of the implant manufacturer.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification has a long history of successful clinical application in soft tissue and bone implants in humans, with a well-characterized level of biological response.

X2.2 No known surgical implant material has ever been shown to be completely free from adverse reactions in the human body. Long-term clinical experience of the use of the material referred to in this specification, however, has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F1580 – 07) that may impact the use of this standard. (Approved March 1, 2012.)

The document was revised according to the template language: *(1)* Section 10, revised to eliminate reference to ASQ C1. *(2)* Section 2. revised to remove ASQ C1 and corresponding footnote.