



Designation: F1580 – 18

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

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 *Units*—The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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

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.

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 Direct Current Plasma and Inductively Coupled Plasma Atomic Emission Spectrometry (Performance-Based Test Methodology)

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 Insertion into Bone

F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)

IEEE/ASTM SI 10 American National Standard for Metric Practice

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. Ordering Information

4.1 Include with inquiries and orders for material under this specification the following information:

- 4.1.1 Quantity (weight),
- 4.1.2 ASTM specification and date of issue,

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

- 4.1.3 *Method of Manufacture*—Type of powder (un-alloyed, sponge or Ti-6Al-4V),
- 4.1.4 *Units to be Certified*—SI or inch-pound,
- 4.1.5 Sieve analysis per 7.1,
- 4.1.6 Powder cleanliness per 8.2,
- 4.1.7 Special tests, if any, and
- 4.1.8 Other requirements.

5. Methods of Manufacture

5.1 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.

6. Chemical Requirements

6.1 The chemical analysis of the powder shall conform to the requirements specified in Table 1.

6.1.1 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.

6.1.2 All commercial metals contain small amounts of elements other than those which are specified. It is neither practical nor necessary to specify limits for unspecified elements, whether residual elements or trace elements. The producer is permitted to analyze for unspecified elements and is permitted to report such analyses. The presence of an unspecified element and the reporting of an analysis for that element shall not be a basis for rejection.

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

6.2 *Product Analysis:*

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

6.3 For referee purposes, Test Method E2371 shall be used.

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

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

7. Particle Size

7.1 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.

8. Cleanliness

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

8.2 Powder cleanliness shall be determined by examining a representative sample, per Practices B215 or as agreed upon between buyer and seller, comprising at least 6.45 cm² (1 in.²) of a closely packed mono-layer of powder per lot at 20x magnification. No foreign material shall be visible under these conditions.

9. Dimensions and Permissible Variation

9.1 *Units of Measure:*

9.1.1 *Selection*—This specification requires that the purchaser selects the units (SI or inch-pound) to be used for product certification. In the absence of a stated selection of units on the purchase order, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

9.1.2 If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

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	

^AChemistry per Specification F67 except hydrogen.
^BChemistry per Specification B299, general purpose grade.
^CChemistry per Specification F1472.
^DOxygen 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.
^ELower maximum chlorine content may be agreed upon between buyer purchaser and seller supplier.
^FSodium or magnesium, 0.50 maximum.
^GApproximately equal to the difference of 100 % and the sum percentage of the other specified elements. The percentage of the titanium difference is not required to be reported.

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

^ARefer to AMS 2249.
^BFor unalloyed Ti powder.
^CFor Ti-6Al-4V alloy powder.