

Standard Reference Material[®] 3289

Multivitamin Tablets

CERTIFICATE OF ANALYSIS

Purpose: The certified values delivered by this Standard Reference Material (SRM) are intended for use in evaluating methods for measurement of vitamins in dietary supplement tablets and similar matrices and for assigning values to in-house control materials.

Description: A unit of SRM 3289 consists of five bottles which are individually sealed. Each bottle contains 30 tablets weighing approximately 1.8 g per tablet. The SRM is provided as whole, coated tablets to provide stability and grinding would compromise this coating.

Certified Values: Certified values are provided in Table 1. A NIST certified value is a value for which NIST has the highest confidence in its accuracy in that all known or suspected sources of bias and variability have been taken into account [1]. The values are reported on an as-received basis. Metrological traceability is to the International System of Units (SI) unit for mass, expressed as mass fraction in milligrams analyte per gram material and micrograms analyte per gram material [2]. These values are metrologically traceable to the SI through the purity evaluations and gravimetric procedures used to prepare the calibration solutions used in assigning the values.

Table 1. Certified Mass Fraction Values for Water-Soluble Vitamin-Related Analytes in SRM 3289

Measurand	Mass Fraction ^(a)	Units
Vitamin B ₁ (Thiamine) ^(b)	1.17 ± 0.09	mg/g
Vitamin B ₂ (Riboflavin) ^(b)	1.40 ± 0.15	mg/g
Vitamin B ₃ (Niacin) ^(b)	12.33 ± 0.13	mg/g
Vitamin B ₅ (Pantothenic Acid) ^(b)	6.96 ± 0.10	mg/g
Vitamin B ₆ (Pyridoxine) ^(b)	1.39 ± 0.10	mg/g
Vitamin B ₇ (Biotin) ^(b)	22.58 ± 2.00	µg/g
Vitamin B ₁₂ (Cyanocobalamin) ^(c)	5.19 ± 1.19	µg/g

^(a) Values are expressed as $x \pm U_{95\%}(x)$, where x is the certified value and $U_{95\%}(x)$ is the expanded uncertainty of the certified value. The true value of the analyte is believed to lie within the interval $x \pm U_{95\%}(x)$ with 95 % confidence. To propagate this uncertainty, treat the certified value as a normally distributed random variable with mean x and standard deviation $U_{95\%}(x)/2$ [2–4].

^(b) Results reported by the weighted means of the results provided by NIST, manufacturer, and collaborating laboratories.

^(c) Results reported by the weighted means of the results provided by NIST and manufacturer.

Non-Certified Values: Non-certified values are provided in Appendix A.

Period of Validity: The certified values delivered by **SRM 3289** are valid within the measurement uncertainty specified until **01 January 2032**. The certified values are nullified if the material is stored or used improperly, damaged, contaminated, or otherwise modified.

Maintenance of Certified Values: NIST will monitor this SRM over the period of its validity. If substantive technical changes occur that affect the certification, NIST will issue an amended certificate through the NIST SRM website (<https://www.nist.gov/srm>) and notify registered users. SRM users can register online from a link available on the NIST SRM website or fill out the user registration form that is supplied with the SRM at the time of purchase. Before making use of any of the values delivered by this material, users should verify they have the most recent version of this documentation, available free of charge through the NIST SRM website.

Analysis: Measurements used to certify SRM 3289 values were performed at NIST using a variety of analytical techniques and by participants of interlaboratory comparison studies using their routine methods [5].

Safety: SRM 3289 IS INTENDED FOR RESEARCH USE; NOT FOR HUMAN CONSUMPTION. Consult the Safety Data Sheet (SDS) for hazard information.

Storage: The original unopened bottles of SRM 3289 should be stored in the dark at controlled room temperature (20 °C to 25 °C) until needed. The unground tablets can be used for one week after opening provided that the 15 whole tablets are stored in the original packaging in a refrigerator (approximately 5 °C).

Use: Prior to removal of a test portion for analysis, 15 tablets (1/2 the bottle) should be ground and mixed thoroughly to achieve homogeneity. To relate analytical determinations to the certified values in this Certificate of Analysis, it is recommended that test portions for analysis be 0.3 g to 2 g for water-soluble vitamins. Test portions should be analyzed as-received.

Source: The SRM 3289 bottles of multivitamin tablets were obtained from a commercial source.

Additional Information: The development of SRM 3289 was spurred by requests from the food industry and federal regulators for food-matrix reference materials to support nutrition labelling. The development of SRM 3289 was a collaboration between the National Institute of Standards and Technology (NIST) and the National Institutes of Health (NIH), Office of Dietary Supplements (ODS). Full details on the production and evaluation of SRM 3289 are provided free of charge in [5].

REFERENCES

- [1] Beauchamp, C.R.; Camara, J.E.; Carney, J.; Choquette, S.J.; Cole, K.D.; DeRose, P.C.; Duewer, D.L.; Epstein, M.S.; Kline, M.C.; Lippa, K.A.; Lucon, E.; Molloy, J.; Nelson, M.A.; Phinney, K.W.; Polakoski, M.; Possolo, A.; Sander, L.C.; Schiel, J.E.; Sharpless, K.E.; Toman, B.; Winchester, M.R.; Windover, D.; *Metrological Tools for the Reference Materials and Reference Instruments of the NIST Material Measurement Laboratory*; NIST Special Publication (NIST SP) 260-136, 2021 edition; U.S. Government Printing Office: Washington, DC (2021); available at <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.260-136-2021.pdf> (accessed Mar 2022).
- [2] Thompson, A.; Taylor, B.N.; *Guide for the Use of the International System of Units (SI)*; NIST Special Publication 811; U.S. Government Printing Office: Washington, DC (2008); available at <https://www.nist.gov/pml/special-publication-811> (accessed Mar 2022).
- [3] JCGM 100:2008; *Evaluation of Measurement Data — Guide to the Expression of Uncertainty in Measurement (GUM 1995 with Minor Corrections)*; Joint Committee for Guides in Metrology (JCGM) (2008); available at <https://www.bipm.org/en/publications/guides> (accessed Mar 2022); see also Taylor, B.N.; Kuyatt, C.E.; *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*; NIST Technical Note 1297; U.S. Government Printing Office: Washington, DC (1994); available at <https://www.nist.gov/pml/nist-technical-note-1297> (accessed Mar 2022).
- [4] JCGM 101:2008; *Evaluation of Measurement Data — Supplement 1 to the “Guide to the Expression of Uncertainty in Measurement” — Propagation of Distributions using a Monte Carlo Method*; JCGM (2008); available at <https://www.bipm.org/en/publications/guides> (accessed Mar 2022).
- [5] Hayes, H.V.; Mulloor, J.; Nelson, M.A.; Rimmer, C.A.; Regalado, L.; Yen J.H.; Yu, L.L.; *Certification of Standard Reference Material® 3289 Multivitamin Tablets*; NIST Special Publication 260-220 (2021); U.S. Government Printing Office: Washington, DC (2021); available at <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.260-220-2021.pdf> (accessed Mar 2022).

If you use this SRM in published work, please reference:

Hayes HV, Mulloor J, Nelson MA, Rimmer CA, Regalado L, Yen JH, Yu LL (2021) Certification of Standard Reference Material® 3289 Multivitamin Tablets. (National Institute of Standards and Technology, Gaithersburg, MD), NIST Special Publication (SP) 260-220. <https://doi.org/10.6028/NIST.SP.260-220>

Certain commercial equipment, instruments, or materials may be identified in this Certificate of Analysis to adequately specify the experimental procedure. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology, nor does it imply that the materials or equipment identified are necessarily the best available for the purpose.

Users of this SRM should ensure that the Certificate of Analysis in their possession is current. This can be accomplished by contacting the Office of Reference Materials 100 Bureau Drive, Stop 2300, Gaithersburg, MD 20899-2300; telephone (301) 975-2200; e-mail srminfo@nist.gov; or the Internet at <https://www.nist.gov/srm>.

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APPENDIX A

Non-Certified Values: Non-certified values are suitable for use in method development, method harmonization, and process control but do not meet the NIST criteria for certification [1] and are the best estimates of the true values based on available data. The values are provided with an uncertainty that may reflect only measurement reproducibility, may not include all sources of uncertainty, and/or may reflect a lack of sufficient statistical agreement among multiple analytical methods.

Non-Certified Values Provided by Manufacturer and Interlaboratory Studies: Non-certified mass fraction values for carotenoids and fat-soluble vitamins in SRM 3289, reported on an as-received basis, are provided in Table A1; and are the weighted means of results provided by the manufacturer and collaborating laboratories. These values are metrologically traceable to the materials and procedures used by the manufacturer and participants of interlaboratory comparison studies using their routine methods.

Table A1. Non-Certified Mass Fraction Values for SRM 3289

Measurand	Mass Fraction ^(a)	Units
Vitamin A (beta-Carotene) ^(b)	623 ± 119	µg/g
Vitamin A (Retinyl Acetate) ^(c)	891 ± 21	µg/g
Vitamin C (Ascorbic Acid) ^(b)	45.29 ± 2.70	mg/g
Vitamin D ₂ (Ergocalciferol) ^(b)	9.1 ± 3.3	µg/g
Vitamin D ₃ (Cholecalciferol) ^(b)	9.7 ± 2.2	µg/g
Vitamin E (α-Tocopherol Acetate) ^(b)	19.54 ± 0.30	mg/g
Folic Acid ^(b)	439 ± 52	µg/g
Vitamin K ₁ (Phytonadione) ^(b)	15.0 ± 2.8	µg/g
Lutein ^(b)	198 ± 9	mg/kg

^(a) Values are expressed as $x \pm 2u(x)$, where x is the non-certified value and $u(x)$ is the standard uncertainty of the non-certified value. To propagate this uncertainty, the non-certified value should be treated as a normally distributed random variable with mean x and standard deviation $u(x)$ [2–4].

^(b) Results reported by the weighted means of the results provided by the manufacturer and collaborating laboratories [5].

^(c) Results reported by the weighted means of the results provided by manufacturer.

Maintenance of Non-Certified Values: NIST will monitor this material to the end of its period of validity. If substantive technical changes occur that affect the non-certified values during this period, NIST will update this Appendix. Before making use of any of the values delivered by this material, users should obtain the most recent version of this documentation, available free of charge through the <https://www.nist.gov/srm> website.

***** End of Appendix A *****