

Standard Reference Material® 3383

Yohimbe-Containing Solid Oral Dosage Form

CERTIFICATE OF ANALYSIS

Purpose: The certified values delivered by this Standard Reference Material (SRM) are intended for validating methods for determining yohimbine and rauhimbine in yohimbe-containing solid oral dosage form and similar materials for quality assurance when assigning values to in-house control materials.

Description: A unit of SRM 3383 consists of 5 packets, each containing approximately 1.1 g of material.

Certified Value: The NIST certified value is traceable to the International System of Units (SI) derived unit of mass fraction, expressed as milligrams per gram. The value is reported on an as-received basis [1].

Table 1. Certified Mass Fraction Value for Yohimbine in SRM 3383

Material	Mass Fraction ^(a) (mg/g)
Yohimbine	3.20 ± 0.24

^(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 lies within the interval as $x \pm U_{95\%}(x)$ with 95 % confidence. To propagate this uncertainty, treat the certified value as a normally distributed random variable with mean x and standard deviation $U_{95\%}(x)/2$ [2–6].

Non-Certified Values: A non-certified mass fraction value is provided in Appendix A.

Period of Validity: The certified value delivered by **SRM 3383** is valid within the measurement uncertainty specified until **31 December 2030**. The certified value is 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. Registration will facilitate notification. 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 through the NIST SRM website (<https://www.nist.gov/srm>).

Carlos A. Gonzalez, Chief
Chemical Sciences Division

Steven J. Choquette, Director
Office of Reference Materials

Safety: SRM 3383 is intended for research use only; not for human consumption.

Storage and Handling: The original unopened packages of SRM 3383 should be stored at room temperature ($20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$). An open packet can be reused until the material reaches its expiration date, provided that the open packet is resealed and stored at room temperature ($20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$).

Use: Before use, the contents of the unopened packet should be mixed thoroughly by inverting and shaking. Homogeneity of the material has not been evaluated for sample sizes smaller than those used by NIST methods [7]. Therefore, the certified value may not be valid for test portions smaller than 5 mg for determination of yohimbine.

Source and Analysis: Material preparation and measurements used to value assign SRM 3383 were performed at NIST using multiple analytical techniques [7].

Additional Information: Support for the development of SRM 3383 was provided in part by the National Institutes of Health Office of Dietary Supplements.

REFERENCES

- [1] Beauchamp, C.R.; Camara, J.E.; Carney, J.; Choquette, S.J.; Cole, K.D.; DeRose, P.C.; Diewer, 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 260-136, 2021 edition; National Institute of Standards and Technology, Gaithersburg, MD (2021); available at <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.260-136-2021.pdf> (accessed Mar 2024).
- [2] 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 (2008); available at <https://www.bipm.org/en/committees/jc/jcgm/publications> (accessed Mar 2024); 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 2024).
- [3] 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*; Joint Committee for Guides in Metrology (JCGM) (2008); available at <https://www.bipm.org/en/committees/jc/jcgm/publications> (accessed Mar 2024).
- [4] Efron, B.; Tibshirani, R.J.; *An Introduction to the Bootstrap*; Chapman & Hall: London, UK (1993).
- [5] Searle, S.; Casella, G.; McCulloch, C.; *Variance Components*; John Wiley: Hoboken, NJ (1992).
- [6] Rukhin, A.L.; Possolo, A.; *Laplace Random Effects Models for Interlaboratory Studies*; Comput. Stat. Data Anal.; Vol. 55, pp. 1815–1827 (2011).
- [7] Wilson, W.B.; Hosbas Coskun, S.; Mulloor, J.; Nelson, M.A.; Yen, J.H.; *Certification of Standard Reference Material[®] 3383*; NIST Special Publication 260-240; National Institute of Standards and Technology, Gaithersburg, MD (2023); available at <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.260-240.pdf> (accessed Mar 2024).

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

Wilson WB, Coskun SH, Mulloor J, Nelson MA, Yen J (2023) Certification of Standard Reference Materials[®] 3383 Yohimbe-Containing Solid Oral Dosage Form. (National Institute of Standards and Technology, Gaithersburg, MD), NIST Special Publication (SP) 260-240. <https://doi.org/10.6028/NIST.SP.260-240>.

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>.

***** End of Certificate of Analysis *****

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] nor provide metrological traceability to the International System of Units (SI) or other higher-order reference system. A non-certified mass fraction value is provided below.

Table A1. Non-Certified Mass Fraction Value for Rauhimbine in SRM 3383

Material	Mass Fraction ^(a) (mg/g)
Rauhimbine	0.971 ± 0.060

^(a) These values are expressed as $x \pm 2u(x)$, where x is a mean value and $u(x)$ is its associated standard uncertainty. While the best estimate of measurand mass fraction lies within the interval $x \pm 2u(x)$, neither the purity nor the identity of the calibrants used have been determined by NIST. For purposes of harmonization and process control, the imprecision and homogeneity components of uncertainty can be propagated as $u(x)/x$ relative standard deviations.

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 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. Registration will facilitate notification. 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 through the NIST SRM website (<https://www.nist.gov/srm>).

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