

Certificate of Analysis Reference Material

Lipomed Document QC-CA-156FB
Version: 006-24.Jan.2014

Supersedes: 005-05.Jun.2012

Chemical name: **Cocaine**
Methyl (1R,2R,3S,5S)-3-benzoyloxy-8-methyl-8-azabicyclo[3.2.1]octane-2-carboxylate

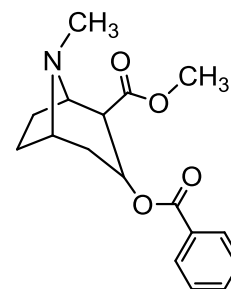
Lot Nr: 156.1B12.3
Art. Nr: COC-156-FB

Retested: January 24, 2014
Retest date: **January 2019**

Chemical formula: C₁₇H₂₁NO₄

Molwt: 303.36

CAS Registry Nr: 50-36-2



TEST	SPECIFICATIONS	RESULTS
1. Appearance	white to off-white crystalline powder	conforms
2. Purity	HPLC > 98.5 % The purity is calculated from the distribution of 6 HPLC analyses with a 95% level of confidence.	99.580 ± 0.016 %
3. Optical rotation	$[\alpha]_D^{25} = -26 \pm 2^\circ$ (c = 1.0 in acetonitrile)	$[\alpha]_D^{25} = -25.9^\circ$ (c = 1.0 in acetonitrile)
4. Water content	Karl Fischer < 1 %	0.2 %
5. Identity	IR	IR corresponds

Following on next page

FOR ANALYTICAL PURPOSES ONLY: NOT FOR HUMAN OR ANIMAL USE!

Storage conditions: For maximum stability store air-tight at 2 - 8 °C in a dark location.

Lipomed certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the retest date when stored unopened as recommended.

QC - Officer: Deputy: Dr. L. Prévot

Date sign: Arlesheim,



January 24, 2014



Lipomed AG is **ISO 9001:2008** certified and **ISO/IEC 17025:2005, ISO Guide 34:2009** accredited.

SWITZERLAND: LIPOMED AG, FABRIKMATTENWEG 4, CH-4144 ARLESHEIM · ☎ +41 61 702 02 00 · FAX +41 61 702 02 20

GERMANY: LIPOMED GmbH, HEGENHEIMER STRASSE 2, D-79576 WEIL AM RHEIN ☎ +49 7621 1693 473 FAX +49 7621 1693 474

USA: LIPOMED INC., ONE BROADWAY, CAMBRIDGE, MA 02142 · ☎ (617) 577 7222 · FAX (617) 577 1776

INTERNET: <http://www.lipomed.com> e-mail: lipomed@lipomed.com

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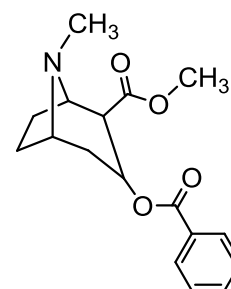
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TEST

SPECIFICATIONS

RESULTS

UV: in acetonitrile
 $\lambda_{\max,1} = 228.0 \pm 1.0 \text{ nm}$
 $\epsilon_{\text{mol},1} = 13500 \pm 1500$

 $\lambda_{\max,2} = 273.0 \pm 1.0 \text{ nm}$
 $\epsilon_{\text{mol},2} = 950 \pm 100$

UV: in acetonitrile
 $\lambda_{\max,1} = 228.3 \text{ nm}$
 $\epsilon_{\text{mol},1} = 14070$

 $\lambda_{\max,2} = 272.4 \text{ nm}$
 $\epsilon_{\text{mol},2} = 1042$

Melting point: 97.0 ± 3 °C

94.0 - 96.0 °C



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GENERAL INFORMATION

Quality Documentation:

This certificate is designed in accordance with ISO Guide 31 (Reference Materials – Contents of Certificates and Labels) and ISO Guide 35 (Reference Materials – General and Statistical Principles for Certification).

Quality Standards:

- ISO 9001:2008** Quality Management System. Manufacturing, analysis, packaging and distribution of Analytical Reference Materials and Pharmaceuticals. IQNet/SQS Certification: 37199
- ISO/IEC 17025:2005** General requirements for the competence of Testing Analytical Reference Standards. ACLASS Certificate number: AT-1760
- ISO Guide 34:2009** General requirements for the competence of Reference Material Producer. ACLASS Certificate number: AR-1761

Quality Control Assessment:

The product quality is controlled by regularly performed quality control tests (retests).

Intended Use:

The product covered by this certificate is designed for calibration or for use in quality control procedures for the specified chemical compound listed page 1. This product can be used for quantification and/or identification. If dilution is required use only diluent compatible with all certified analyses in this preparation. All solutions should be thoroughly mixed prior to use.

Expiration/Retest dates:

Expiration date/Retest date of the unopened flask stored at the recommended storage condition is the last day of the month listed page 1.

A retest is performed 6 months prior to the stated retest date. Upon successful retesting, a new retest date or expiration date is set for the product. The certificate of analysis is then updated and made available on our web-site.

Uncertainty and Expiration/Retest dates of the Reference Material are based on the unopened flask being stored according to the recommended condition found in the storage field.

Gravimetric preparation:

All balances are calibrated annually by an ISO/IEC 17025 accredited calibration service. Calibration verification is performed weekly with certified traceable weights. Each balance has been assigned a minimum weighing.

Purity:

- Purity and/or chemical identity are determined by one or more of the following techniques: HPLC, GC/FID, LC/MS, IR, UV, NMR, Karl Fischer, melting point and optical rotation if applicable
- Purity of isomeric compounds is reported as the sum of the isomers
- Purity values are rounded up to the third decimal place

Uncertainty Statistics and Confidence limits:

The uncertainties are determined in accordance with ISO Guide 34 and 17025. The certified combined stressed uncertainty value (includes gravimetric uncertainty, homogeneity uncertainty, storage stability uncertainty and shipping stability uncertainty) were combined using the following formula:

$$Uc(y) = k \sqrt{U_{characterization}^2 + U_{homogeneity}^2 + U_{storage\ stability}^2 + U_{shipping\ stability}^2}$$

K is a coverage factor of 2, which gives the level of confidence of approximately 95%.

The packaged amount is the minimum sample size for which uncertainty is valid.

Stability:

The manufacturer guarantees the stability of this Reference Material through the date stated on page 1 of the certificate when handled and stored accordingly to the conditions stated page 1.

Legal Notice and Limit of Liability:

This product is for routine laboratory analysis and research proposal only. Due to the hazardous nature, only trained personnel should handle this product. The company's liability will be limited to replacement of product or refund or purchase price. Notice of claims must be made within thirty (30) days from date of delivery.



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