Certificate of Analysis
Certified Reference Material

Lipomed Document QC-CA-156HCL1
Version: 001-27.Jan.2016 Supersedes: new

Product name: **1 ml Cocaine.HCl solution** (1 mg free base/1 ml methanol)
Methyl (1R,2R,3S,5S)-3-benzoyloxy-8-methyl-8-azabicyclo[3.2.1] octane-2-carboxylate.hydrochloride

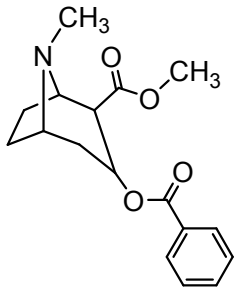
Lot Nr: 156.1B26.1L1
Art. Nr: COC-156-HC-1LM

Release date: July 20, 2017
Last testing date: N/A
Expiry date: **July 2021**

Bulk Product Information: 156.1B26.1

Chemical formula: $C_{17}H_{21}NO_4$ Hydrochloride
Molwt: 303.36 / 339.82

CAS Registry Nr: 53-21-4



TEST	SPECIFICATIONS	RESULTS
1. Appearance	clear colorless solution	conforms
2. Identity	HPLC R_t corresponds to R_t of reference standard (± 0.5 min)	R_t standard = 8.3 min R_t test = 8.3 min
3. Solution Purity	HPLC > 98.5 %	99.647 ± 0.059 %
4. Certified Concentration	0.9500 – 1.0500 mg/ml free base	1.0198 ± 0.0144 mg/ml (mean value) free base
5. Solvent purity (GC)	methanol > 99.9 %	> 99.9 %
6. Extractable volume	> 1 ml	conforms

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. The product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.

Issued by Dr. L. Prévot

Date sign: Arlesheim,

July 25, 2017

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Standard Solution Calibration:

Bulk Reference Solutions	Prepared concentration in mg/ml
Reference 1	1.0195 mg/ml
Reference 2	1.0096 mg/ml

Fill position	Analyzed concentration in mg/ml
Early	1.0212 mg/ml
Middle	1.0172 mg/ml
Late	1.0211 mg/ml

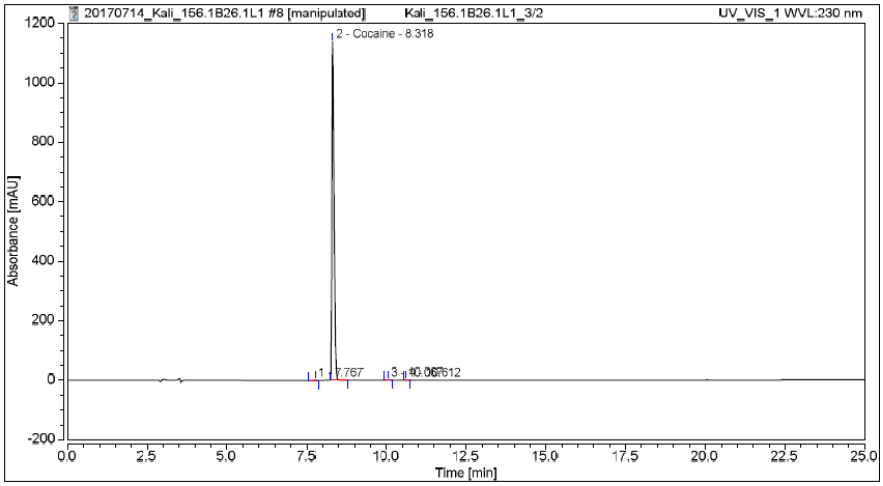
Homogeneity:

	Specification	Result
% RSD	< 5 %	4.3 %

Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	156.1B26.1L1	1.0198 ± 0.0144 mg/ml free base
Previous Lot	156.1B18.1L3	0.9863 ± 0.0005 mg/ml free base

HPLC Data:



Analytical conditions:

Column
YMC Pack Pro C18, (250*4.6) mm, 5 um
Mobile Phase
A: 0.1% H3PO4 in water
B: 0.1% H3PO4 in acetonitrile
Gradient:
10 min (equilib.) 85% A/15% B
1 min 85% A/15% B
20 min 35% A/65% B
3 min 35% A/65% B
Flow rate: 1 ml/min
Wavelength: 230 nm
Injection volume: 3 ul

Integration Results

No.	Peak Name	Retention Time min	Area mAU*min	Height mAU	Relative Area %
1		7.77	0.054	0.8	0.06498
2	Cocaine	8.32	83.060	1140.0	99.67829
3		10.07	0.151	2.5	0.18068
4		10.61	0.063	1.1	0.07605
Total:			**83.328**	**1144.441**	**100.00**

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Stability:

Short term stability: Short term stability studies have been performed at -18°C and +40°C during a period of 2 weeks. No decrease in purity was observed at -18°C. A decrease of 0.5 % has been observed at +40°C.These data support transport of this product at ambient temperature.

Long term stability: Long term stability studies have been performed in refrigerator (+2°C to +8°C). A stability of a maximum of 48 months has been established and a decrease of 1 % in purity has been observed during this period.

Document history:

Version	Change	Date
Version 1	New version	January 27, 2016

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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. ANAB Certificate number: AT-1760
ISO Guide 34:2009	General requirements for the competence of Reference Material Producer. ANAB 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 ampoule 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. A maximum of 5 years after the release date is given. Upon successful retesting after these 5 years, an expiry date of 2 years is stated.

Uncertainty, concentration and Expiration/Retest dates of the Reference Material are based on the unopened ampoule 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
- The content is already corrected from the salt form, the purity, residual water and residual solvents.

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 between ampoules uncertainty, storage stability uncertainty and shipping stability uncertainty) were combined using the following formula:

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

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. The ampoules are over-filled to ensure that the minimum packaged amount can be sufficiently transferred.

Homogeneity:

Homogeneity of the lot is confirmed by a duplicate analysis of 12 ampoules. 4 ampoules are taken in each early, middle and late fill position. The analyzed concentration in each early, middle and late fill position is the average value obtained from duplicate analysis of 4 ampoules

Stability:

The manufacturer guarantees the stability of this solution 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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