Certificate of Analysis
Reference Material

Lipomed Document QC-CA-1249L1
Version: 003-24.Apr.2020 Supersedes: 002-25.Jul.2014

Product Name: **1 ml Methandienone solution**
(1 mg/1 ml methanol)
(8R,9S,10R,13S,14S,17S)-17-Hydroxy-10,13,17-trimethyl-7,8,9,11,12,14,15,16-octahydro-6H-cyclopenta[a]phenanthren-3-one

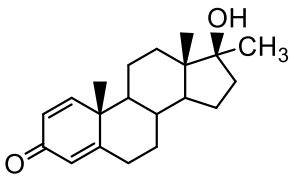
Lot No: 1249.1B1.1L2
Art. No: TES-1249-1LM

Release Date: May 07, 2015
Last Testing Date: March 01, 2022
Expiry Date: **May 2025**

Bulk Product Information: 1249.1B1.1

Chemical Formula: $C_{20}H_{28}O_2$ Molwt: 300.44

CAS Registry No: 72-63-9



TEST	SPECIFICATION	RESULT
1. Appearance	clear colorless solution	conforms
2. Identity	HPLC R_t corresponds to R_t of reference standard (± 0.5 min)	R_t standard = 17.3 min R_t test = 17.3 min
3. Purity	HPLC > 98.5 %	99.827 ± 0.041 %
4. Concentration of Calibrated Ampoule	0.9500 – 1.0500 mg/ml	0.9924 ± 0.0344 mg/ml (mean value)
5. Solvent Purity (GC)	methanol > 99.9 %	> 99.9 %
6. Extractable Volume	> 1 ml	conforms

Storage Conditions: For maximum stability store airtight 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 throughout the retest/expiry date when stored unopened and compliant to the above stated storage conditions. The product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.

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

Issued by Dr. L. Prévot

Date sign: Arlesheim,

March 02, 2022

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Standard Solution Calibration:

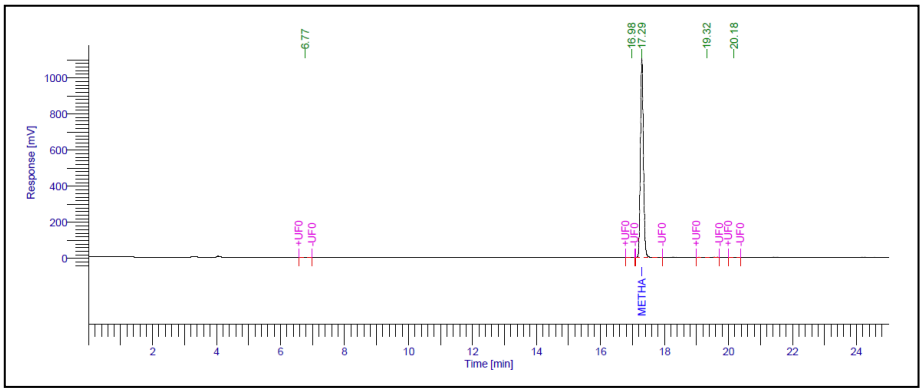
Bulk Reference Solutions	Prepared Concentration in mg/ml
Reference 1	1.0165 mg/ml
Reference 2	1.0020 mg/ml

Ampoules	Analyzed Concentration in mg/ml
First sample	0.9924 mg/ml
Second sample	0.9918 mg/ml
Third sample	0.9929 mg/ml

Lot to Lot Consistency:

Standard Solution	Lot Number	Concentration
Actual Lot	1249.1B1.1L2	0.9246 ± 0.0344 mg/ml
Previous Lot	1249.1B1.1L1	0.9946 ± 0.0101 mg/ml

HPLC Data:



Analytical Conditions:

column:
YMC Pack Pro C18 (250*4.6)mm
mobile phase:
A: 0.1% phosphoric acid in nanopure H2O
B: 0.1% phosphoric acid in Acetonitrile
Gradient:
1 min 70%A / 30%B
20 min 10%A / 90%B
3 min 10%A / 90%B
flow rate: 1.0 ml/min
wavelength: 245 nm
injection volume: 2 ul

Peak #	Component Name	Time [min]	Area [uV*sec]	Area [%]
1		6.77	1205.4	0.017
2		16.98	844.6	0.012
3	Methandienone	17.29	7059174.2	99.851
4		19.32	6319.7	0.089
5		20.18	2143.4	0.030

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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 for Arlesheim Production Site:

ISO 9001 Quality Management System. Manufacturing, analysis, packaging and distribution of Analytical Reference Materials and Pharmaceuticals. IQNet/SQS Certification: 37199

ISO/IEC 17025 General requirements for the competence of Testing Analytical Reference Standards. ANAB Certificate number: AT-1760

ISO 17034 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 analytical 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 on the first page. This product can be used for quantification and/or identification. All solutions should be thoroughly mixed prior to use. If dilution is required, use only diluent compatible with the substance and solvent in this preparation.

Expiration/Retest Date:

Expiration/retest date of the unopened ampoule stored at the recommended storage conditions is the last day of the month.

A retest will be 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 website. For our products, the extension of the shelf life is capped to 10 years after release as the maximum period.

Gravimetric Preparation:

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

Purity:

- Purity and/or chemical identity are determined by one or more of the following techniques: HPLC/UV, GC/FID, LC/MS, IR, UV, 1H 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 to the last decimal place given
- The salt form, purity, residual water, and residual solvents are already taken into account for the given content value.

Uncertainty Statistics:

The uncertainties are determined in accordance with ISO 17034 and ISO/IEC 17025. Uncertainty is given for a minimum injection volume of 1 µl. The certified uncertainty value (including characterization uncertainty, homogeneity between ampoules uncertainty, storage stability uncertainty and shipping stability uncertainty) is combined using the following formula:

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

For expanded uncertainty with confidence interval of 95% multiply combined uncertainty, here above, by coverage factor k=2. The filling volume is the minimum sample size for which the uncertainty is valid. The ampoules are over-filled to ensure that the minimum filling volume can be sufficiently transferred.

Homogeneity:

Homogeneity of the lot is confirmed by a duplicate analysis of at least 12 ampoules. At least 4 ampoules are taken at start, middle and end of the filling process. The number of ampoules to be analyzed depends on the lot size. The analyzed concentration at each position is the average value obtained from duplicate analysis of 4 ampoules.

Stability:

The manufacturer guarantees the stability of this product throughout its intended shelf life, when handled and stored accordingly to the given storage conditions.

Legal and Safety Notice:

This product is for routine laboratory analysis and research purposes only. Due to the hazardous nature, only trained personnel should handle this product. The General Terms and Conditions of Lipomed apply.

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