Certificate of Analysis
Reference Material

Lipomed Document QC-CA-1475L1
Version: 002-21.Jul.2014 Supersedes: 001-04.Sep.2012

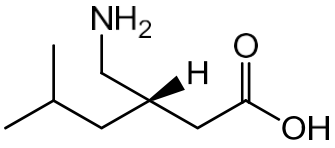
Product name: **1 ml Pregabalin solution** (1 mg/1 ml methanol)
(*S*)-3-(Aminomethyl)-5-methylhexanoic acid

Lot Nr: 1475.1B0.1L1 Retested: September 17, 2020
Art. Nr: PRE-1475-1LM Retest date: **September 2025**

Bulk Product Information: 1475.1B0.1

Chemical formula: $C_8H_{17}NO_2$ Molwt: 159.23

CAS Registry Nr: 148553-50-8



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 = 10.7 min R_t test = 10.7 min
3. Purity	HPLC > 98.5 %	99.486 ± 0.068 %
4. Concentration of calibrated ampoule	1.000 ± 0.050 mg/ml	0.999 ± 0.003 mg/ml (mean value)
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.

QC - Officer: Deputy: Dr. L. Prévot Date sign: Arlesheim,

September 17, 2020

Standard Solution Calibration:

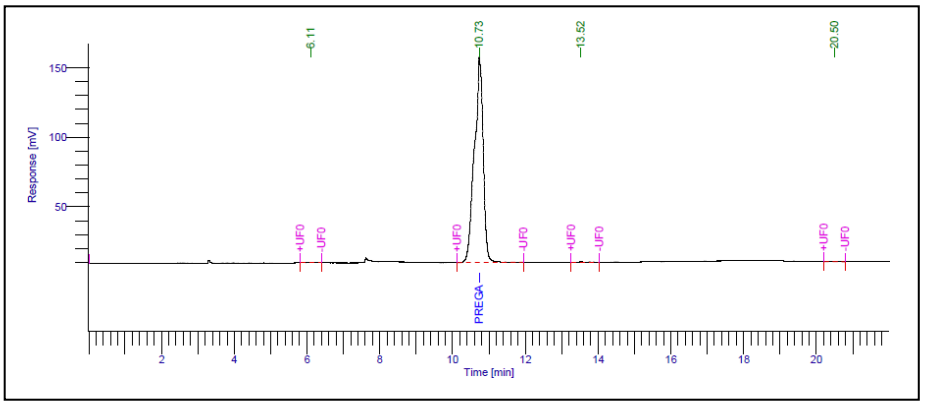
Bulk Reference Solutions	Prepared concentration in mg/ml
Reference 1	1.020 mg/ml
Reference 2	1.016 mg/ml

Ampoules	Analyzed concentration in mg/ml
First sample	1.001 mg/ml
Second sample	0.995 mg/ml
Third sample	1.000 mg/ml

Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	1475.1B0.1L1	0.999 ± 0.003 mg/ml
Previous Lot	N/A	N/A

HPLC Data:



Analytical conditions:

column:
Supelcosil LC-ABZ 5um (250*4.6)mm
mobile phase:
A: water
B: acetonitrile
Gradient:
1 min 100%A / 0%B
15 min 90%A / 10%B
5 min 90%A / 10%B
flow rate: 1.0 ml/min
wavelength: 210 nm
injection volume: 100 ul

Peak #	Component Name	Time [min]	Area [uV*sec]	Area [%]
1		6.11	3269.6	0.131
2	Pregabalin	10.73	2479892.4	99.528
3		13.52	4119.2	0.165
4		20.50	4379.3	0.176

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 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.

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 3 ampoules. These samples are representative of the batch from which they are taken.

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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