

## Certificate of Analysis Certified Reference Material

Lipomed Document QC-CA-1840L1  
Version: 003-22.Sep.2022

Supersedes: 002-02.Feb.2021

Product Name: **1 ml Propofol solution**  
(1 mg/1 ml methanol)  
2,6-Diisopropylphenol

Lot No: 1840.1B1.1L1  
Art. No: PPF-1840-1LM

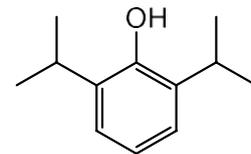
Release Date: July 19, 2019  
Last Testing Date: September 22, 2022  
Retest Date: **September 2025**

### Bulk Product Information: 1840.1B1.1

Chemical Formula: C<sub>12</sub>H<sub>18</sub>O

Molwt: 178.27

CAS Registry No: 2078-54-8



PARAMETER	SPECIFICATION	RESULT
<b>Certified Concentration</b>	<b>0.9500 – 1.0500 mg/ml</b>	<b>1.0036 mg/ml</b>
<b>Combined Uncertainty</b>	<b>≤ 5.0 %</b>	<b>1.3 %</b>

Certified concentration is verified through duplicate analysis of multiple ampoules representative from the lot compared with 2 independently prepared solutions.  
Uncertainty of the certified concentration is an uncertainty determined in accordance with ISO/IEC 17025 and ISO 17034. The calculation was based on the analytical methods applicable to reference standards in solution and incorporates the analytical method uncertainty and the ampoule to ampoule homogeneity (within bottles and between bottles) according to U(y) equation on the last page of this certificate.

**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,

**September 22, 2022**

### Used Standard Solutions for Calibration:

Solution	Concentration	Position of Samples	Concentration
Reference 1	1.1032 mg/ml	Start	1.0010 mg/ml
Reference 2	1.0286 mg/ml	Middle	1.0063 mg/ml
		End	1.0034 mg/ml

### Homogeneity:

Lot	Specification	Result
Current	1840.1B1.1L1	RSD ≤ 5.0 %
Comparative	1840.1B1.1L2	RSD ≤ 5.0 %

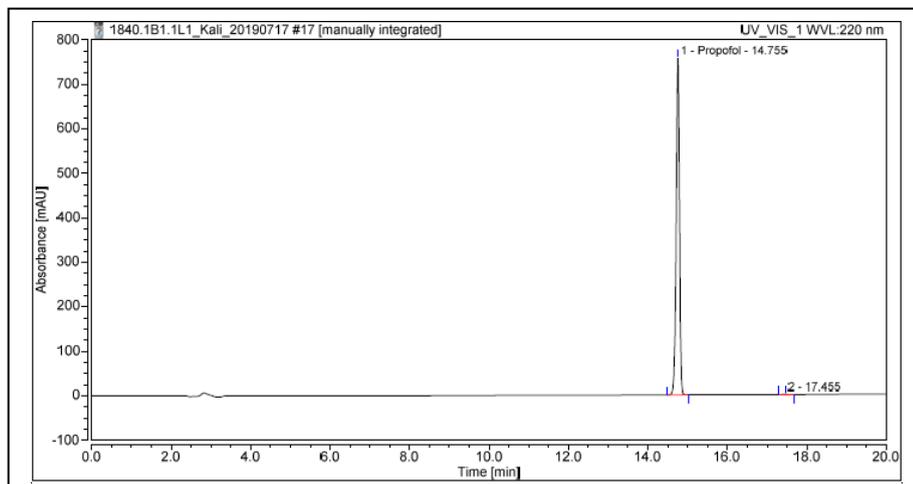
### Lot to Lot Consistency:

Lot	Concentration
Current	1840.1B1.1L1
Previous	1840.1B1.1L2

### Supportive Data:

Parameter	Specification	Result
Appearance	clear colorless solution	conforms
Identity	HPLC $R_t$ corresponds to $R_t$ of reference standard ( $\pm 0.5$ min)	$R_t$ standard = 14.8 min $R_t$ test = 14.8 min
Solution Purity	HPLC > 98.5 %	99.8034 $\pm$ 0.0055 %
Solvent Purity (GC)	methanol > 99.9 %	> 99.9 %
Extractable Volume	> 1 ml	conforms

## 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.) 60% A/40% B  
1 min 60% A/40% B  
15 min 10% A/90% B  
19 min 10% A/90% B  
Flow rate: 1 ml/min  
Wavelength: 220 nm  
Injection volume: 2 ul

Integration Results					
No.	Peak Name	Retention Time min	Area mAU*min	Height mAU	Relative Area %
1	Propofol	14.75	71.678	756.9	99.89797
2		17.45	0.073	0.8	0.10203
Total:			71.751	757.691	100.00

## 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. These data support the transport conditions of this product to be at ambient temperature.

**Long Term Stability:** Long term stability studies have been performed in refrigerator (+2°C to +8°C). A stability of 62 months has been established. No decrease in purity has been observed during this period.

Based on these stability values, shipping uncertainty has been considered insignificant to the overall uncertainty.

## Document History:

Version	Change	Date
Version 1	New version	August 30, 2019
Version 2	Long term stability has been updated to 42 months after release date.	February 2, 2021
Version 3	Long term stability has been updated to 62 months after release date.	September 22, 2022

## 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:

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

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.