Certificate of Analysis
Reference Material

Lipomed Document QC-CA-690L1
Version: 005-25.Jan.2019

Supersedes: 004-13.May.2014

Product name: **1 ml Sufentanil solution** (1 mg free base/1 ml methanol)
N-[4-(Methoxymethyl)-1-(2-thiophen-2-ylethyl)-piperidin-4-yl]-N-phenylpropanamide

Lot Nr: 690.1B9.1L2
Art. Nr: SUF-690-FB-1LM

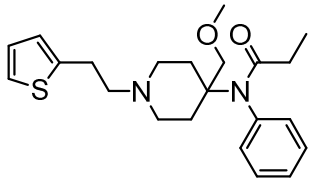
Release date: May 13, 2014
Last testing date: January 24, 2019
Retest date: **January 2021**

Bulk Product Information: 690.1B9.1

Chemical formula: $C_{22}H_{30}N_2O_2S$

Molwt: 386.56

CAS Registry Nr: 56030-54-7



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 = 10.8 min
3. Purity	HPLC > 98.5 %	99.880 ± 0.090 %
4. Concentration of calibrated ampoule	0.9500 – 1.0500 mg/ml free base	0.9858 ± 0.0077 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,

January 25, 2019

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Standard Solution Calibration:

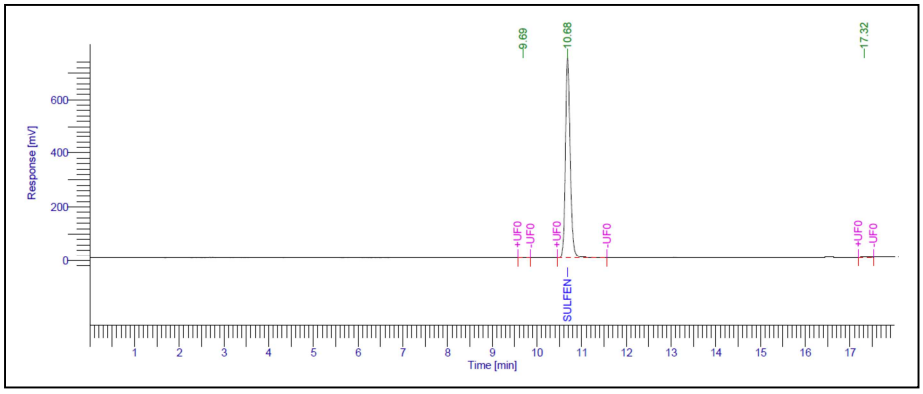
Bulk Reference Solutions	Prepared concentration in mg/ml
Reference 1	1.0015 mg/ml
Reference 2	1.0105 mg/ml

Ampoules	Analyzed concentration in mg/ml
First sample	0.9854 mg/ml
Second sample	0.9871 mg/ml
Third sample	0.9850 mg/ml

Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	690.1B9.1L2	0.9858 ± 0.0077 mg/ml free base
Previous Lot	690.1B9.1L1	0.9872 ± 0.0019 mg/ml free base

HPLC Data:



Analytical conditions:

column:
YMC Pack Pro C18 5um (250*4.6)mm
mobile phase:
A: 0.05% TFA in water
B: 0.05% TFA in Acetonitrile
1 min 80%A / 20%B
15 min 30%A / 70%B
1 min 30%A / 70%B
flow rate: 1.0 ml/min
wavelength: 230 nm
injection volume: 4 ul

Peak #	Component Name	Time [min]	Area [uV*sec]	Area [%]
1		9.69	748.0	0.014
2	Sulfentanyl	10.68	5529408.1	99.922
3		17.32	3543.1	0.064

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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	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 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. A maximum shelf-life of 10 years after the release date can be stated. 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 17034 and ISO/IEC 17025. Uncertainty is given for a minimum injection volume of 1 µl. 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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