Certificate of Analysis
Certified Reference Material

Lipomed Document QC-CA-1752L1
Version: 003-28.Oct.2019 Supersedes: 002-07.Sep.2018

Product name: **1 ml Chlorpromazine.HCl solution** (1 mg free base/1 ml methanol)
2-Chloro-10-(3-dimethylaminopropyl)phenothiazine.hydrochloride

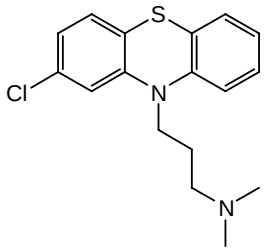
Lot No: 1752.1B1.1L1
Art. No: CPZ-1752-HC-1LM

Release date: February 06, 2017
Last testing date: October 16, 2020
Retest date: **October 2025**

Bulk Product Information: 1752.1B1.1

Chemical formula: $C_{17}H_{19}ClN_2S$ Hydrochloride
Molwt: 318.86 355.32

CAS Registry No: 69-09-0



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 = 8.5 min
3. Solution Purity	HPLC > 98.5 %	99.475 ± 0.005 %
4. Certified Concentration	0.9500 – 1.0500 mg/ml free base	0.9898 ± 0.0199 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,

October 28, 2020

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Standard Solution Calibration:

Bulk Reference Solutions	Prepared concentration in mg/ml
Reference 1	0.9916 mg/ml
Reference 2	1.0019 mg/ml

Fill position	Analyzed concentration in mg/ml
Early	0.9899 mg/ml
Middle	0.9892 mg/ml
Late	0.9901 mg/ml

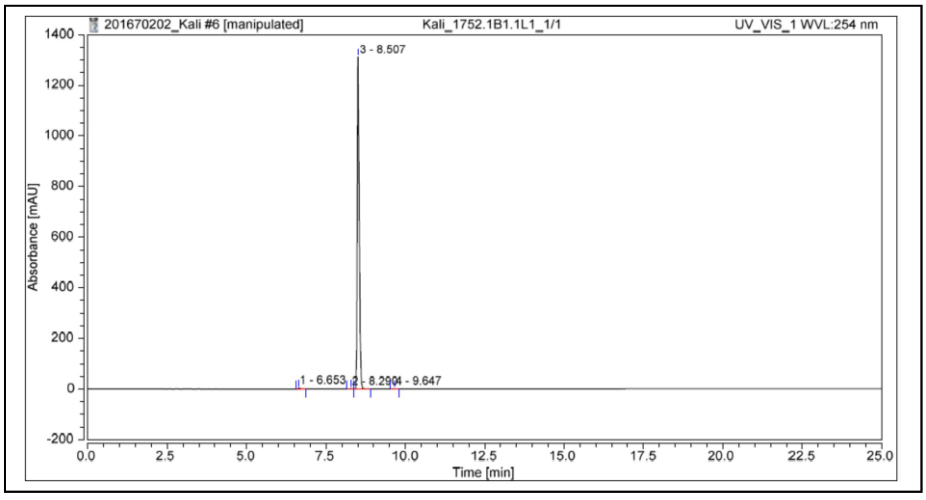
Homogeneity:

	Specification	Result
% RSD	< 5.0 %	1.0 %

Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	1752.1B1.1L1	0.9898 ± 0.0199 mg/ml free base
Previous Lot	N/A	N/A

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.) 70% A/30% B
1 min 70% A/30% B
21 min 30% A/70% B
24 min 30% A/70% B
Flow rate: 1 ml/min
Wavelength: 254 nm
Injection volume: 1 ul

Integration Results

No.	Peak Name	Retention Time min	Area mAU*min	Height mAU	Relative Area %
1		6.65	0.265	4.4	0.27540
2		8.29	0.122	2.2	0.12668
3		8.51	95.957	1311.9	99.53753
4		9.65	0.058	1.0	0.06039
Total:			**96.403**	**1319.374**	**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. 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 56 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	February 28, 2017
Version 2	Long term stability updated to 43 months after release.	September 7, 2018
Version 3	Long term stability updated to 56 months after release date.	October 28, 2019

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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 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, 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 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:

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

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 12 ampoules. 4 ampoules are taken at start, middle and end of the filling process. 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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