


Typical COA form: calibrated.HCl solution

Lipomed's calibrated standard solutions are certified for purity, identity and strength. Ampoules are over-filled to ensure target volume of 1 ml can be quantitatively transferred.



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Specifications and Certificate of Analysis

Lipomed Document QC-CA-1252L1
Version: 001-00.May.2010 Supersedes: new


Product name: 1 ml 4-Methylmethacathinone.HCl; Mephedrone.HCl solution
(1 mg free base/1 ml methanol)
(4)-1-(4-methylphenyl)-2-methylaminopropan-1-one Hydrochloride

Lot No: 1252-1B1-1L1 Release date: 20.05.2010
Art. Nr.: MMC-1252-HC-1LM Retest date: May 2012

Bulk Product Information: 1252-1B1-1

Chemical formula: $C_{11}H_{16}NO$ Molwt: 177.24
Hydrochloride 213.70

CAS Registry Nr: 1189726-22-4



TEST	SPECIFICATIONS	RESULTS
1. Appearance	clear colorless solution	conforms
2. Identity	HPLC R_f corresponds to R_f of reference standard (\pm 0.5 min)	R_f standard = 9.7 min R_f test = 9.7 min
3. Purity	HPLC > 98.5 %	99.732 \pm 0.027 % *
4. Concentration of calibrated ampoule	1.000 \pm 0.050 mg/ml free base	0.993 \pm 0.009 mg/ml * (mean value) free base
5. Solvent purity (GC)	methanol > 99.9 %	> 99.9 %

* The purity and the concentration of the ampoules are calculated from the distribution of 8 HPLC analysis (calibrated analysis of 3 ampoules) compared with 2 independent, freshly-prepared reference solutions, with a 95% level of confidence. The free base content is easily converted from the salt form, the purity and residual water.

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.
Note: To ensure the accuracy of stock solutions, we advise laboratories to measure precise volume of standard solution from ampoules before diluting to the desired volume.

QC - Officer: Deputy: Dr. L. Prévot Date sign: Arlesheim,
May 20, 2010

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Batch validity expressed as retest date

Batch number of bulk material used to prepare the solution

Measured concentration based on the free drug form and determined by comparison to two independently and freshly prepared solutions

Random samples are analyzed to verify the consistency within the lot


Newly manufactured products are compared to a sample from the previous lot to verify consistency between lots

Lot no. & product no.

Storage recommendations

Fresh solutions prepared from bulk to ensure the content in ampoule

Chromatographic data including analytical conditions, spectra and peak picking of the newly released lot



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Standard Solution Calibration:

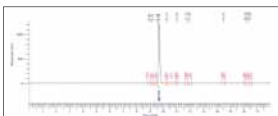
Bulk Reference Solutions ^a	Prepared concentration in mg/ml	Ampoules	Analyzed concentration in mg/ml ^b
Reference 1	0.977 mg/ml	First sample	0.991 mg/ml
Reference 2	1.002 mg/ml	Second sample	0.987 mg/ml
		Third sample	1.001 mg/ml

^a Gravimetric preparation of each bulk reference solution is ensured by using balances calibrated with Iso-NPA traceable weights. The bulk reference solutions and the ampoules are prepared from the same lot.
^b 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.

Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	1252-1B1-1L1	0.993 \pm 0.009 mg/ml free base
Previous Lot	N/A	N/A

HPLC Data:



Analytical conditions:

Mobile phase: 0.1% formic acid in water / 0.1% formic acid in acetonitrile

Flow rate: 1.0 ml/min

Column: C18, 150 x 4.6 mm

Temperature: 30 °C

Detection: 210 nm

Injection volume: 10 µl

Injection concentration: 1.0 mg/ml

Injection solvent: MeOH

Retention Time (min)	Area	Height	Width	Asymmetry	Resolution
9.700	1000000	100000	0.100	1.000	-

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