Specifications and Certificate of Analysis

Lipomed Document QC-CA-1094L1
Version: 002-25.May.2010 Supersedes: 001-21.Oct.2008

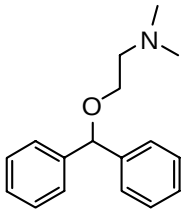
Product name: **1 ml Diphenhydramine.HCl solution**
(1 mg free base/1 ml methanol)
2-benzhydryloxy-N,N-dimethylethanamine hydrochloride

Lot Nr: 1094.1B0.1L1 Retested: 25.05.2020
Art. Nr.: DPH-1094-HC-1LM Retest date: **May 2025**

Bulk Product Information: 1094.1B0.1

Chemical formula: $C_{17}H_{21}NO$ Molwt: 255.35
Hydrochloride 291.81

CAS Registry Nr: 147-24-0



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 = 5.8 min R_t test = 5.9 min
3. Purity	HPLC > 98.5 %	99.790 ± 0.005 % [a]
4. Concentration of calibrated ampoule	1.000 ± 0.050 mg/ml free base	1.000 ± 0.003 mg/ml [a] (mean value) free base
5. Solvent purity (GC)	methanol > 99.9 %	> 99.9 %

a : The purity and the concentration of the ampoules are calculated from the distribution of 6 HPLC analyses (duplicated analysis of 3 ampoules) compared with 2 independent, freshly-prepared reference solutions, with a 95% level of confidence. The free base content is already corrected 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 25, 2020

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Standard Solution Calibration:

Bulk Reference Solutions [b]	Prepared concentration in mg/ml
Reference 1	1.009 mg/ml
Reference 2	1.014 mg/ml

Ampoules	Analyzed concentration in mg/ml [c]
First sample	0.998 mg/ml
Second sample	1.001 mg/ml
Third sample	1.000 mg/ml

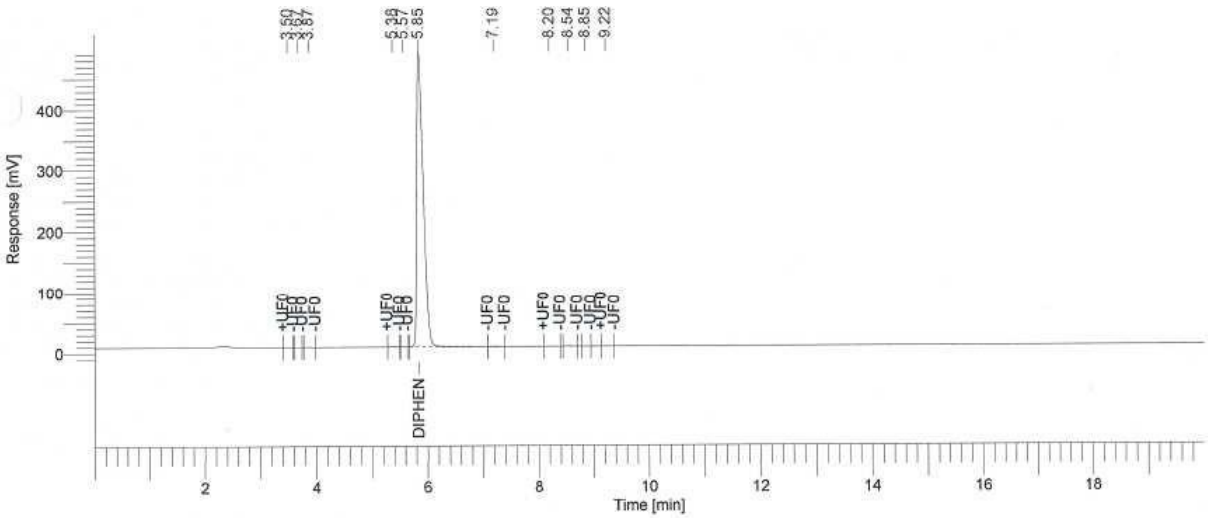
b: Gravimetric preparation of each bulk reference solution is ensured by using balances calibrated with ilac-MRA traceable weights. The bulk reference solutions and the ampoules are prepared from the same lot.

c: 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	1094.1B0.1L1	1.000 ± 0.003 mg/ml free base
Previous Lot	N/A	N/A

HPLC Chromatogram:



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