

Specifications and Certificate of Analysis

Lipomed Document QC-CA-874L1
Version: 002-05.Nov.2009

Supersedes: 001-24.Aug.2006

Product name: **1 ml Atropine solution** (1 mg free base/1 ml acetonitrile)
[(1R,5S)-8-methyl-8-azabicyclo[3.2.1]octan-3-yl] 3-hydroxy-2-phenylpropanoate

Lot Nr: 874.1B0.1L1
Art. Nr.: ATR-874-FB-1LA

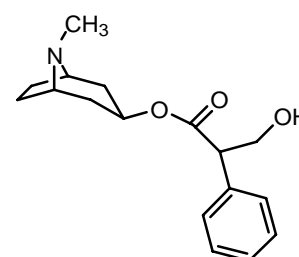
Retested: 05.11.2020
Retest date: **November 2025**

Bulk Product Information: 874.1B0.1

Chemical formula: C₁₇ H₂₃ NO₃
Free base

Molwt: 289.37

CAS Registry Nr: 51-55-8



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 = 11.4 min R _t test = 11.4 min
3. Purity	HPLC > 98.5 %	99.157 ± 0.012 % ^a
4. Concentration of calibrated ampoule	1.000 ± 0.050 mg/ml free base	1.000 ± 0.006 mg/ml ^a (mean value) free base
5. Solvent purity (GC)	acetonitrile > 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,

November 05, 2020

Standard Solution Calibration:

Bulk Reference Solutions ^b	Prepared concentration in mg/ml
Reference 1	1.025 mg/ml
Reference 2	0.962 mg/ml

Ampoules	Analyzed concentration in mg/ml ^c
First sample	1.003 mg/ml
Second sample	1.002 mg/ml
Third sample	0.997 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	874.1B0.1L1	1.000 ± 0.006 mg/ml free base
Previous Lot	N/A	N/A

HPLC Chromatogram:

