

Specifications and Certificate of Analysis

Lipomed Document QC-CA-945L1
Version: 002-27.Apr.2009

Supersedes: 001-12.Sep.2007

Product name: **1 ml Benzocaine solution** (1 mg free base/1 ml methanol)
4-Aminobenzoic acid ethyl ester

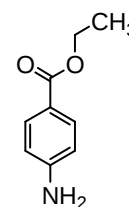
Lot Nr: 945.1B0.1L1
Art. Nr.: BZC-945-FB-1LM

Retested: 01.11.2010
Retest date: **November 2012**

Bulk Product Information: 945.1B0.1

Chemical formula: $C_9H_{11}NO_2$ Molwt: 165.19

CAS Registry Nr: 94-09-7



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 = 20.0 min R_t test = 20.0 min
3. Purity	HPLC > 98.5 %	99.882 ± 0.008 % ^a
4. Concentration of calibrated ampoule	1.000 ± 0.050 mg/ml free base	1.014 ± 0.012 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.
Lipomed disclaims any liability with respect to mistakes due to inadvertence (e.g. slips of the pen) readily identifiable for an expert or a practitioner.

QC - Officer: Deputy: Dr. L. Prévot

Date sign: Arlesheim,

November 01, 2010

Standard Solution Calibration:

Bulk Reference Solutions ^b	Prepared concentration in mg/ml	Ampoules	Analyzed concentration in mg/ml ^c
Reference 1	1.033 mg/ml	First sample	1.011 mg/ml
Reference 2	1.001 mg/ml	Second sample	1.004 mg/ml
		Third sample	1.028 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	945.1B0.1L1	1.014 ± 0.012 mg/ml free base
Previous Lot	N/A	N/A

HPLC Chromatogram:

