

Specifications and Certificate of Analysis

Lipomed Document QC-CA-947L1
Version: 002-23.Apr.2009

Supersedes: 001-22.Feb.2007

Product name: **1 ml Desmethyldiazepam-D₅ (Nordazepam-D₅) solution**
(1 mg /1 ml methanol)
7-Chloro-5-pentadeuterophenyl-1,3-dihydro-2H-1,4-benzodiazepin-2-one

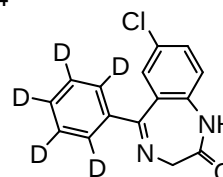
Lot Nr: 947.1B3.1L1
Art. Nr.: DIA-947-1LM

Release date: 30.09.2010
Retest date: **September 2012**

Bulk Product Information: 947.1B3.1

Chemical formula: C₁₅H₆D₅ClN₂O
CAS Registry Nr: 65891-80-7

Molwt: 275.74



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 = 9.8 min R _t test = 10.0 min
3. Purity	HPLC > 98.5 %	99.505 ± 0.005 % ^a
4. Concentration of calibrated ampoule	1.000 ± 0.050 mg/ml	0.959 ± 0.009 mg/ml ^a (mean value)
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,

September 30, 2010

Standard Solution Calibration:

Bulk Reference Solutions ^b	Prepared concentration in mg/ml	Ampoules	Analyzed concentration in mg/ml ^c
Reference 1	1.011 mg/ml	First sample	0.953 mg/ml
Reference 2	0.999 mg/ml	Second sample	0.963 mg/ml
		Third sample	0.961 mg/ml

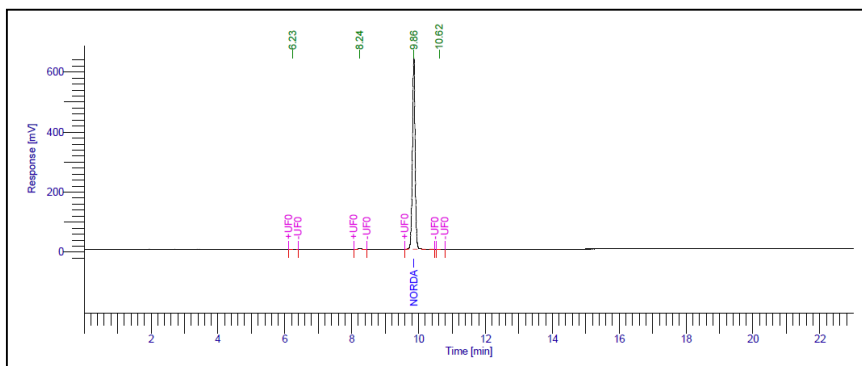
b: Gravimetric preparation of each bulk reference solution is ensured by using balances calibrated with ilac-MRA traceable weights. The bulk reference solutions and the ampoules are prepared from the same lot.

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	947.1B3.1L1	0.959 ± 0.009 mg/ml
Previous Lot	947.1B1.1L3	0.963 ± 0.008 mg/ml

HPLC Chromatogram:



Analytical conditions:

column:
YMC Pack Pro C18 5 um, (250 x 4.6) mm
mobile phase:
A: 0.1% phosphoric acid in water
B: 0.1% phosphoric acid in acetonitrile
gradient:
2 min 70% A / 30% B
15 min 20% A / 80% B
5 min 20% A / 80% B
flow rate: 1 ml/min
wavelength: 250 nm
injection volume: 1 ul

Peak #	Component Name	Time [min]	Area [uV*sec]	Area [%]
1		6.23	624.35	0.017
2		8.24	16180.86	0.449
3	Nordazepam-D5	9.86	3585499.62	99.508
4		10.62	932.53	0.026