



Lipomed Document QC-CA-921L1
Version: 003-12.Jan.2009

Supersedes: 002-02.Jul.2007

Product name: **1 ml Zopiclone solution** (1 mg free base /1 ml acetonitrile)
[8-(5-chloropyridin-2-yl)-7-oxo-2,5,8-triazabicyclo[4.3.0]nona-1,3,5-trien-9-yl] 4-methylpiperazine-1-carboxylate

Lot Nr: 921.1B0.1L1
Art. Nr.: ZOP-921-FB-1LA

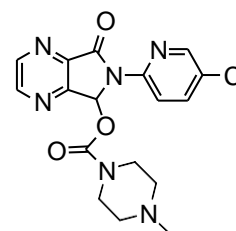
Retested: 04.11.2020
Expiry date: **November 2025**

Bulk Product Information: 921.1B0.1

Chemical formula: C₁₇H₁₇ClN₆O₃

Molwt: 388.81

CAS Registry Nr: 43200-80-2



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 %	99.754 ± 0.005 % ^a
4. Concentration of calibrated ampoule	1.000 ± 0.050 mg/ml free base	1.008 ± 0.009 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 04, 2020

Standard Solution Calibration:

Bulk Reference Solutions ^b	Prepared concentration in mg/ml	Ampoules	Analyzed concentration in mg/ml ^c
Reference 1	1.026 mg/ml	First sample	1.013 mg/ml
Reference 2	1.058 mg/ml	Second sample	1.013 mg/ml
		Third sample	0.998 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	921.1B0.1L1	1.008 ± 0.009 mg/ml free base
Previous Lot	N/A	N/A

HPLC Spectrum:

