Specifications and Certificate of Analysis

Lipomed Document QC-CA-780L1
Version: 002-28.Jan.2010 Supersedes: 001-15.Aug.2008

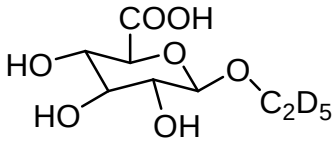
Product name: **1 ml Ethyl-β-D-glucuronide-D_5.solution**
(1 mg /1 ml methanol)
(2S,3S,4S,5R)-6-pentadeuteroethoxy-3,4,5-trihydroxy-oxane-2-carboxylic acid

Lot Nr: 780.1B4.1L3 Release date: 17.05.2010
Art. Nr.: EGL-780-1LM Retest date: **May 2013**

Bulk Product Information: 780.1B4.1

Chemical formula: $C_8H_9D_5O_7$ Molwt: 227.22

CAS Registry Nr: N/A



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 = 6.7 min R_t test = 6.7 min
3. Purity	HPLC > 98.5 %	99.950 ± 0.050 % [a]
4. Concentration of calibrated ampoule	1.000 ± 0.050 mg/ml	0.983 ± 0.012 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 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 ℃ 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 17, 2010

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Standard Solution Calibration:

Bulk Reference Solutions [b]	Prepared concentration in mg/ml
Reference 1	1.021 mg/ml
Reference 2	1.018 mg/ml

Ampoules	Analyzed concentration in mg/ml [c]
First sample	0.979 mg/ml
Second sample	0.985 mg/ml
Third sample	0.985 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.

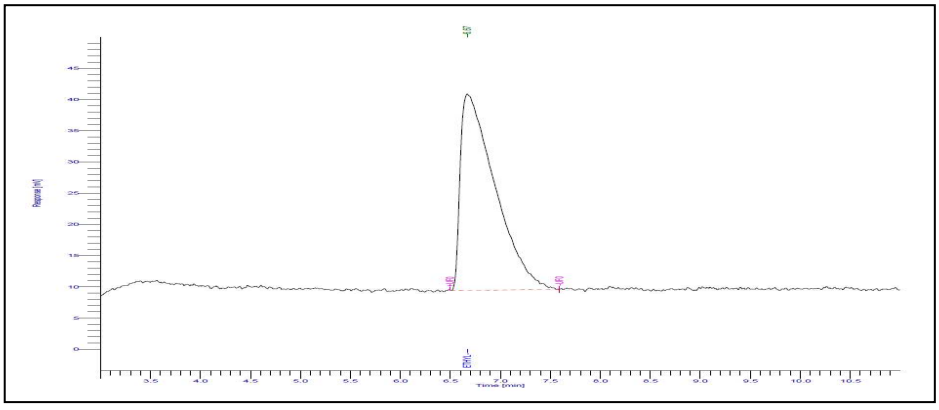
Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	780.1B4.1L3	0.983 ± 0.012 mg/ml
Previous Lot	780.1B4.1L2	0.997 ± 0.017 mg/ml

HPLC Data:

Analytical conditions:

column:
Primesep D 5 um, (150 x 4.6) mm
mobile phase:
0.2% formic acid in water / acetonitrile 90/10
run time: 11 min isocratic
flow rate: 1 ml/min
wavelength: 210 nm
injection volume: 150 ul



Peak #	Component Name	Time [min]	Area [uV*sec]	Area [%]
1	Ethyl-glucuronide-D5	6.67	757109.8	1e+02

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