

Specifications and Certificate of Analysis

Lipomed Document QC-CA-34L1
Version: 003-28.Oct.2009

Supersedes: 002-08.Sep.2006

Product name: **1 ml Normorphine.HCl solution** (1 mg free base/1 ml methanol)
(5 α ,6 α)-7,8-Didehydro-4,5-epoxymorphinan-3,6-diol hydrochloride

Lot Nr: 34.1B12.1L3
Art. Nr.: M-34-HC-1LM

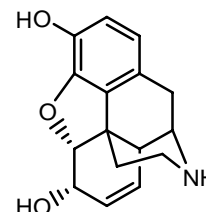
Release date: 28.10.2023
Expiry date: **October 2026**

Bulk Product Information: 34.1B12.1

Chemical formula: C₁₆H₁₇NO₃
Hydrochloride-0.15 hydrate

Molwt: 271.32
310.60

CAS Registry Nr: 3372-02-9



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 = 14.4 min R _t test = 14.4 min
3. Purity	HPLC > 97.0 %	98.005 \pm 0.255 % ^a
4. Concentration of calibrated ampoule	1.000 \pm 0.050 mg/ml free base	0.985 \pm 0.019 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.

QC - Officer: Deputy: Dr. L. Prévot

Date sign: Arlesheim,

October 28, 2023

Standard Solution Calibration:

Bulk Reference Solutions ^b	Prepared concentration in mg/ml
Reference 1	0.996 mg/ml
Reference 2	1.006 mg/ml

Ampoules	Analyzed concentration in mg/ml ^c
First sample	0.983 mg/ml
Second sample	0.986 mg/ml
Third sample	0.987 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.

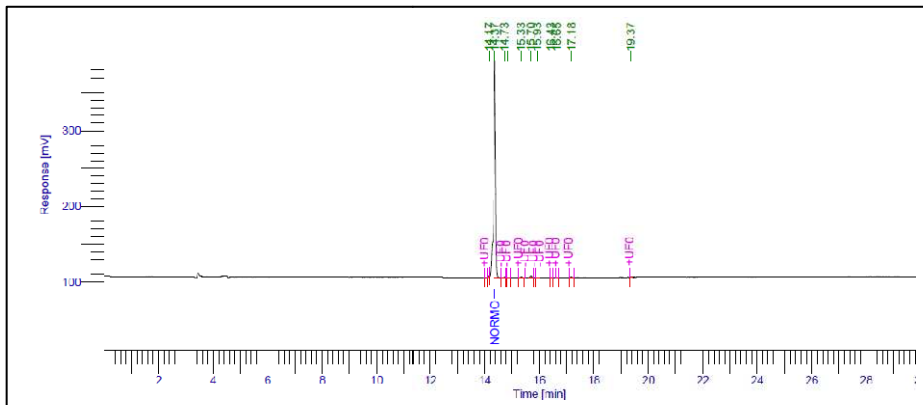
c: Homogeneity of the lot is confirmed by a duplicate analysis of 3 ampoules. These samples are representative of the batch from which they are taken.

Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	34.1B12.1L3	0.985 ± 0.019 mg/ml free base
Previous Lot	34.1B12.1L2	1.010 ± 0.023 mg/ml free base

HPLC Data:

Analytical conditions:



column:
YMC Pack Pro C18 5 µm (250 x 4.6) mm
mobile phase:
A: 0.05% TFA in water
B: 0.05% TFA in acetonitrile
gradient:
5 min 90% A / 10% B
15 min 50% A / 50% B
10 min 50% A / 50% B
flow rate: 1 ml/min
wavelength: 280 nm
injection volume: 5 µl

Peak #	Component Name	Time [min]	Area [uV*sec]	Area [%]
1		14.17	2929.76	0.220
2	Normorphine	14.37	1310989.90	98.261
3		14.73	3251.35	0.244
4		14.85	522.32	0.039
5		15.33	4094.10	0.307
6		15.70	8023.78	0.601
7		15.93	387.74	0.029
8		16.43	413.15	0.031
9		16.65	311.22	0.023
10		17.18	2691.37	0.202
11		19.37	574.43	0.043