

Datasheet Chlormadinoneacetate-³⁷Cl

Reference number : CEC/MAT : 19

Date of preparation: 1994.12.09

date : 17 January 2003

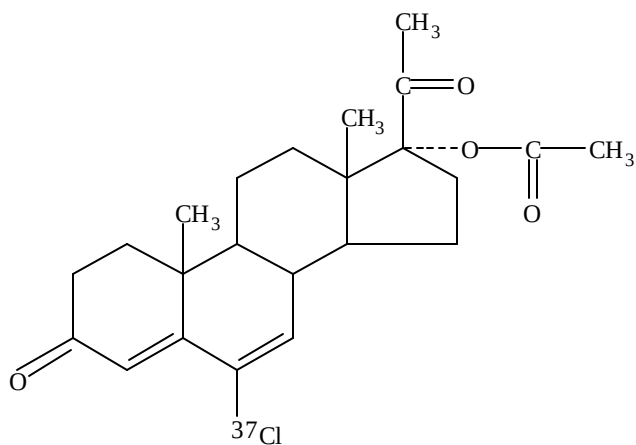
source : MAT - RIVM

“Bank of Reference Standards”

The Bank of Reference Standards was financially supported by the European Commission

Directorate General “Science, Research and Development DG XII”

Contract MAT 1 - CT92 - 0020



CHLORMADINONEACETATE- ^{37}Cl

Name : 6- ^{37}Cl Chloro-17-hydroxy-pregna -4,6-diene-3,20-dione acetate
 Synonym : chlormadinoneacetate- ^{37}Cl
 Molecular formula : $\text{C}_{23}\text{H}_{29}\text{O}_4^{37}\text{Cl}$
 Cas # : not available
 Molecular Weight : 406.45

Long term stability tested on 1997.10.02 : $101.9 \pm 0.9 \%$
 (storage 4°C , analysis HPLC-UV, 6 tests on 2 ampoules)

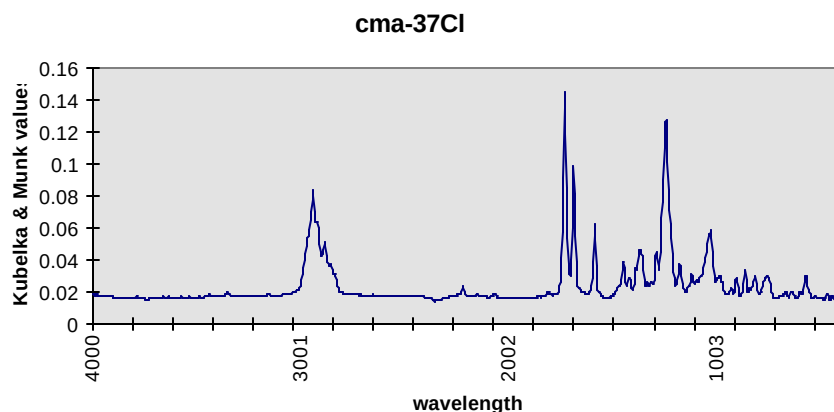
Date : 1998.01.06

Methods used for characterization

- I IR spectroscopy
- II Mass spectrometry
- III HPLC-UV spectroscopy
- IV ^1H -NMR spectroscopy
- V Homogeneity and stability obtained with HPLC

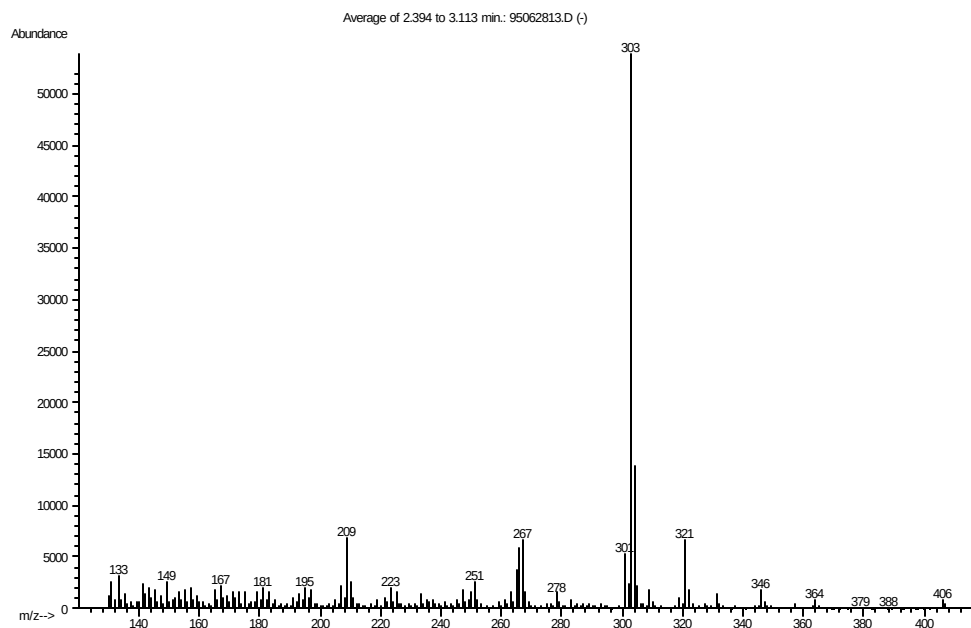
I IR-SPECTROSCOPY

Instrument: Bruker IFS-55 FTIR; detector DTGS
Sampling technique: KBr-tablet.



II MASS-SPECTROMETRY

Instrument: Hewlett Packard 5989 A MS
MS-spectrum, DIP = direct inlet probe

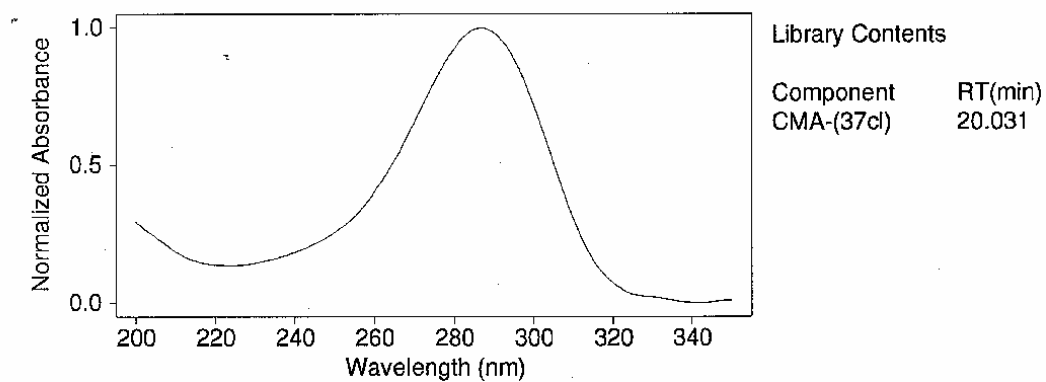


III HPLC-UV SPECTROSCOPY

Instrument: TSP spectrasystem UV2000; resolution 2nm.

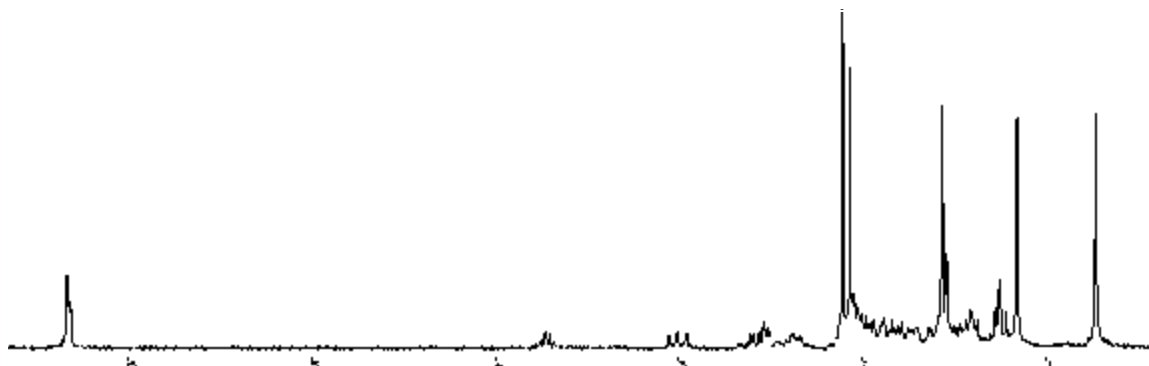
HPLC eluents: methanol/water (70:30 %v/v)

HPLC column: Lichrocart 125-4 hplc cartridge



IV ¹H-NMR SPECTROMETRY

Instrument: FT-NMR Jeol GSX; 270 MHz, 5 mm probe, solvent CDCl₃



Chemical shifts (ppm)	Amount of protons (multipliciteit)	Designation
0.73	3 (s)	18-CH ₃
1.15	3 (s)	19-CH ₃
2.05	3 (s)	21-CH ₃
2.10	3 (s)	17-acetyl
6.30	2 (m)	H4 en H7

*ethanol was found (1.1 en 3.6 ppm), used as solvent during ampouling.

V HOMOGENEITY AND STABILITY

Stability and homogeneity test of Chlormadinone acetate-³⁷Cl

CEC/ MAT: 19

temp.	t= 0 months homogeneity (n = 10) µg (m ± SD)	t=1,5 months (n = 2) µg (m ± SD)	t = 3 months (n = 2) µg (m ± SD)	t = 6 months (n = 2) µg (m ± SD)	t= 12 months (n = 2) µg (m ± SD)
4°C	(104 ± 2)	(104 ± 1)	(109 ± 1)	(106 ± 1)	
20°C		(105 ± 1)	(107 ± 1)	(105 ± 1)	
37°C		(105 ± 1)	(109 ± 1)	(107 ± 1)	

