

Datasheet Megestrol-D₃

Reference number : CEC/MAT : 12

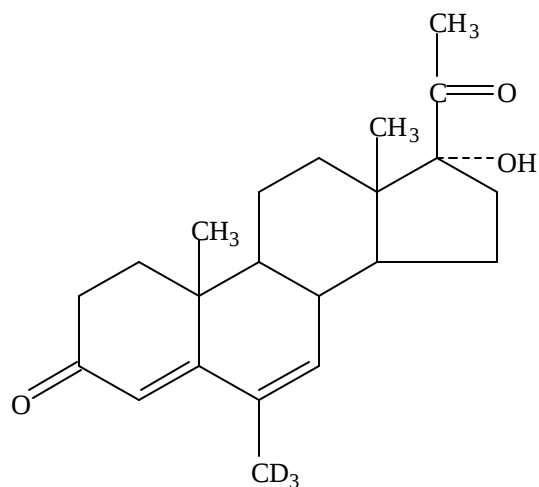
Date of preparation: 1994.05.16

date : 17 January 2003

source : MAT - RIVM

“Bank of Reference Standards”

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MEGESTROL-D3

Name : 17 α -Hydroxy-6-trideuteromethylpregna-4,6-diene-3,20-dione
 Synonym : megestrol-D₃
 Molecular formula : C₂₂H₂₇O₃D₃
 Cas # : not available
 Molecular weight : 345.49

Long term stability tested on 1997.09.22 : 98.6 $\pm$ 1.3 %
 (storage 4°C, analysis HPLC-UV, 6 tests on 2 ampoules)

Date : 1998.01.06

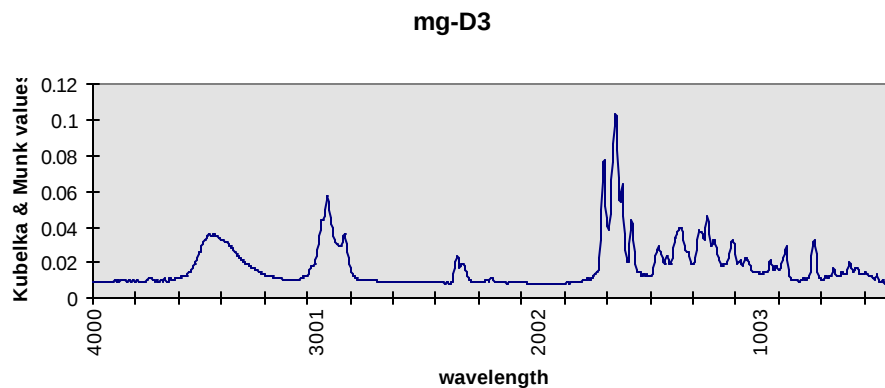
Methods used for characterization:

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

I IR-SPECTROSCOPY

Instrument: Bruker IFS-55 FTIR; dectector DTGS

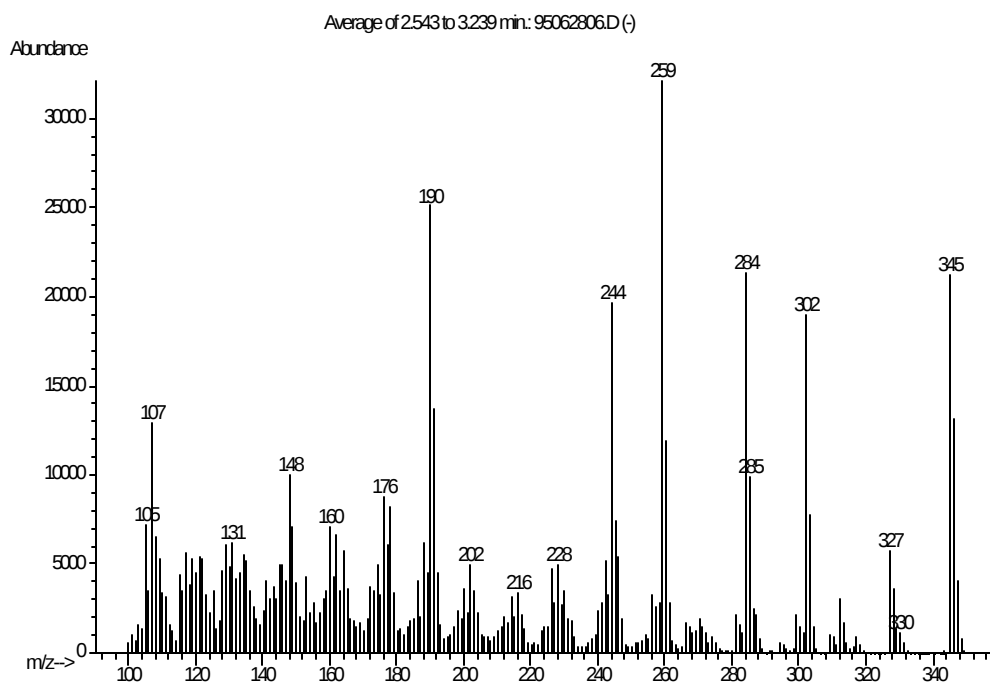
Sampling technique: KBr-tablet.



II MASS-SPECTROSCOPY

Instrument: Hewlett Packard 5989 A MS

MS-spectrum, DIP = direct inlet probe

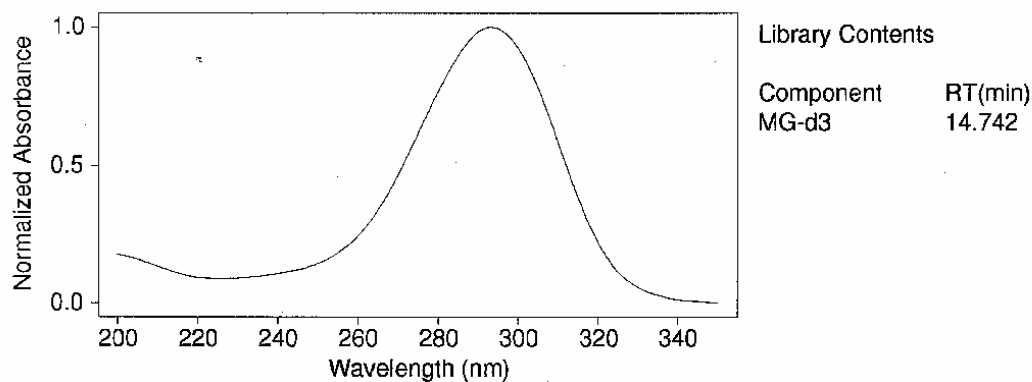


III HPLC-UV SPECTROSCOPY

Instrument: TSP spectrasystem UV2000; resolution 2nm.

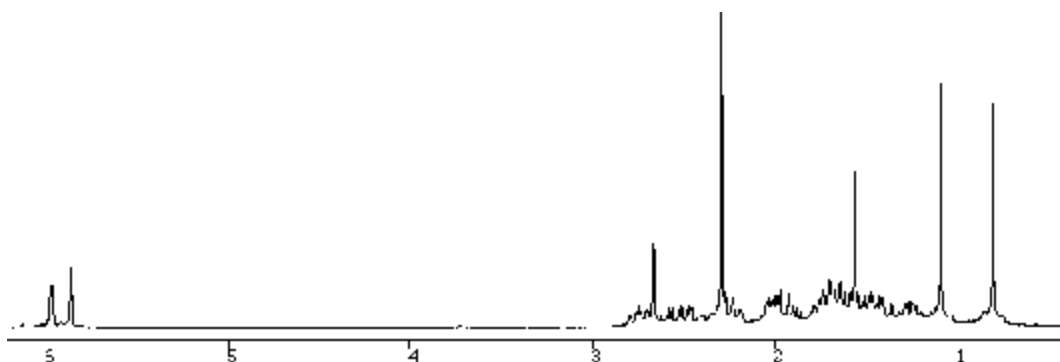
HPLC eluens: methanol/water (70:30 %_v)

HPLC column: Lichrocart 125-4 hplc cartridge



IV ¹H-NMR SPECTROMETRY

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



Chemical shifts (ppm)	Amount of protons (multiplicity)	Designation
0.81	3 (s)	18-CH ₃
1.10	3 (s)	19-CH ₃
2.30	3 (s)	21-CH ₃
5.92	2 (2s)	4-H en 7-H

V HOMOGENEITY AND STABILITY

Stability and homogeneity test of Megestrol - D₃

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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 ± 7)	(103 ± 1)	(108 ± 1)	(107 ± 1)	(101 ± 1)
20°C		(112 ± 1)	(101 ± 4)	(107 ± 1)	(103 ± 2)
37°C		(108 ± 1)	(111 ± 3)	(114 ± 1)	(102 ± 1)

