

Datasheet Megestrolacetate-D₃

Reference number : CEC/MAT : 13

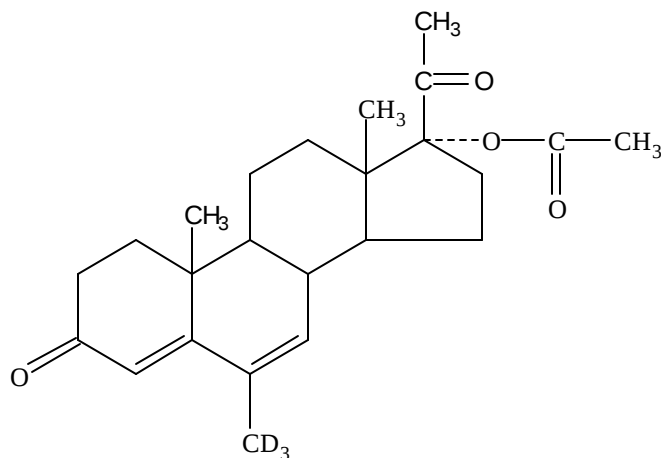
Date of preparation : 1994.05.16

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**



MEGESTROLACETATE- D₃

Name : 17 α -Hydroxy-6-trideuteromethylpregna-4,6-diene-3,20-dione acetate
 Synonym : megestrolacetate - D₃
 Molecular formula : C₂₄H₂₉O₄D₃
 Cas # : not available
 Molecular weight : 387.53

Long term stability tested on 1997.09.22 : 98.2 $\pm$ 2.3 %
 (storage 4°C, analysis HPLC-UV, 6 tests on 2 ampoules)

Last update : 1998.01.06

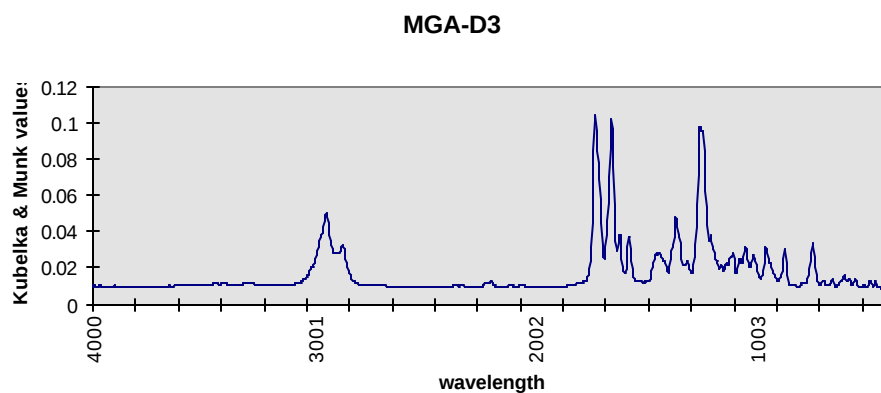
Method used for characterization

- 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; detector DTGS

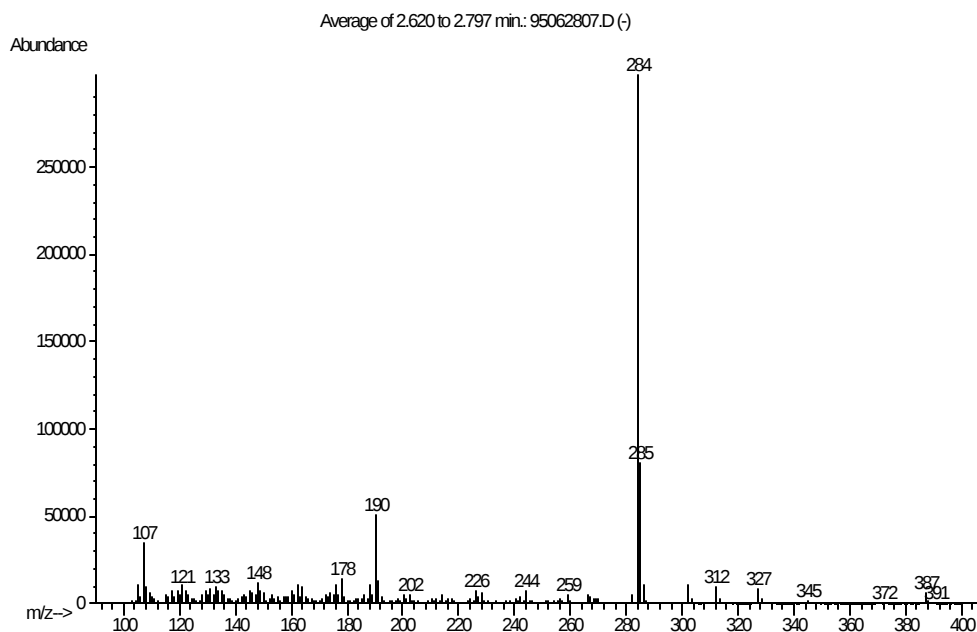
Sampling technique: KBr-tablet.



II MASS-SPECTROMETRY

Instrument: Hewlett Packard 5989 A MS

MS-spectrum, DIP = direct inlet probe



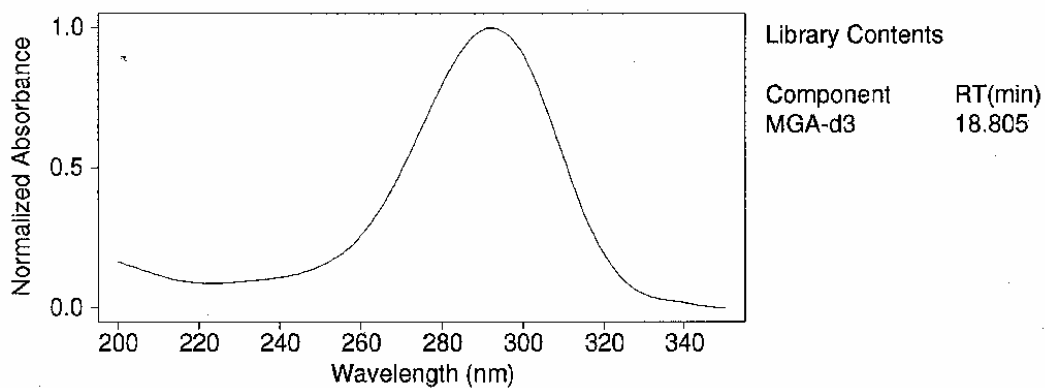
III HPLC-UV spectrum

Instrument: TSP spectrasystem UV2000; resolution 2nm.

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

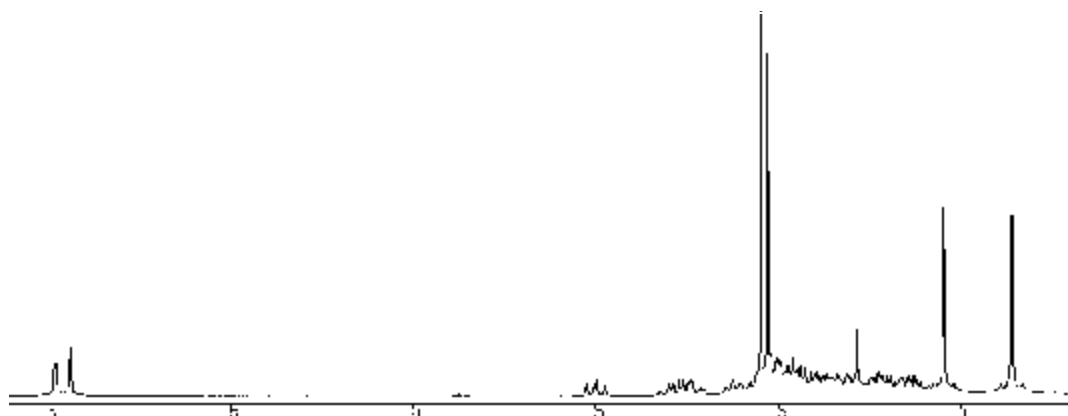
datasheet CEC-MAT reference standard material MGA-D₃, page 2 of 4

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
0.75	3 (s)	18-CH ₃
1.12	3 (s)	19-CH ₃
2.08	3 (s)	21-CH ₃
2.10	3 (s)	17-acetyl
5.92	2 (2s)	4-H en 7-H

V HOMOGENEITY AND STABILITY

Stability and homogeneity test of Megestrol-acetate-D₃

CEC/ MAT: 13

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	(94 ± 4)	(93 ± 1)	(91 ± 4)	(92 ± 1)	(102 ± 3)
20°C		(88 ± 1)	(87 ± 1)	(92 ± 4)	(102 ± 1)
37°C		(90 ± 1)	(94 ± 1)	(93 ± 1)	(99 ± 1)

