rivm
National Institute
for Public Health and
the Environment

Datasheet Melengestrolacetate-D_3

Reference number : CEC/MAT : 15

Date of preparation : 1994.05.31

date : 17 January 2003

source : MAT - RIVM

"Bank of Reference Standards"

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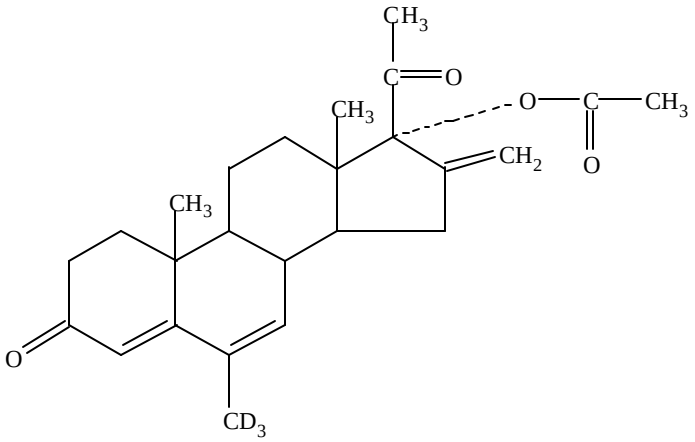


MELENGESTROLACETATE-D3

Name : 17α-Hydroxy-6-trideuteromethyl-16-methylenepregna-4,6-diene-3,20 dione acetate

Synonym : melengestrolacetate-D_3
Molecular formula : $C_{25}H_{29}O_4D_3$
Cas # : not available
Molecular weight : 399.54

Long term stability tested on 1997.09.24 : 95.1 ± 3.0 %
(storage 4°C, analysis HPLC-UV, 6 tests on 2 ampoules)

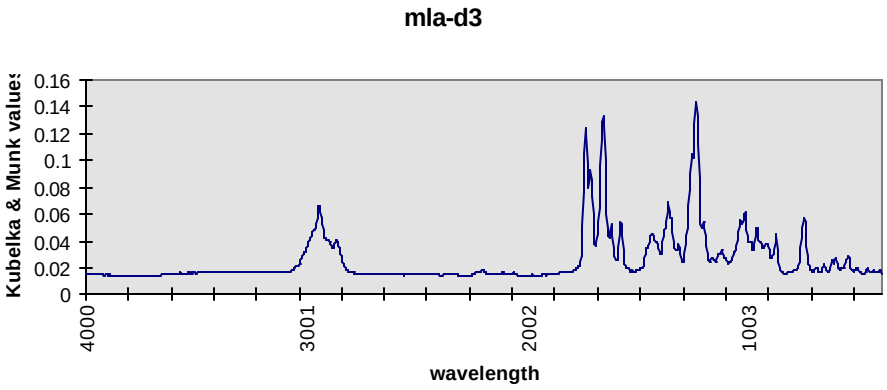
Last update : 1998.01.06

Methods used for characterization:

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

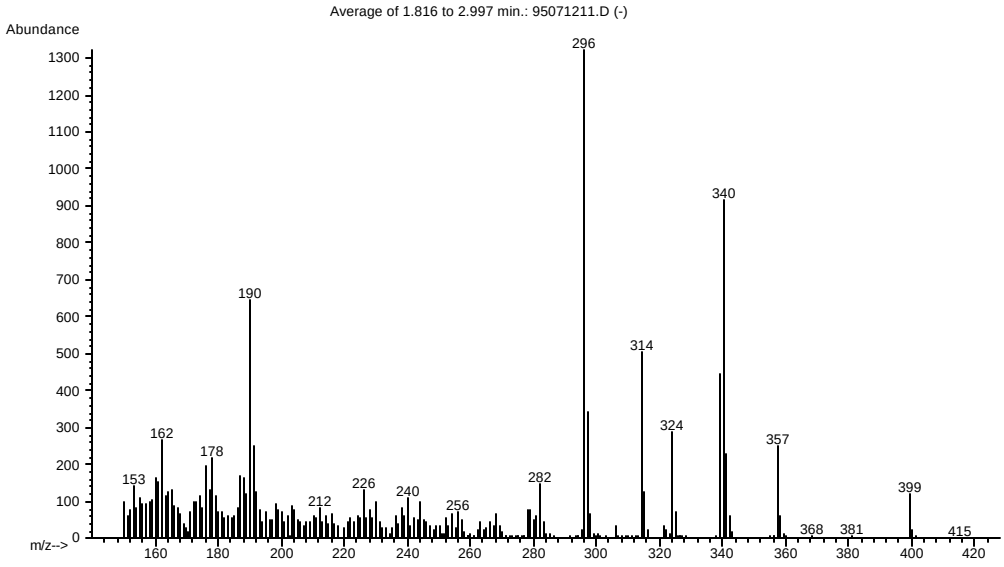
I IR-SPECTROSCOPY

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



II MASS-SPECTROMETRY

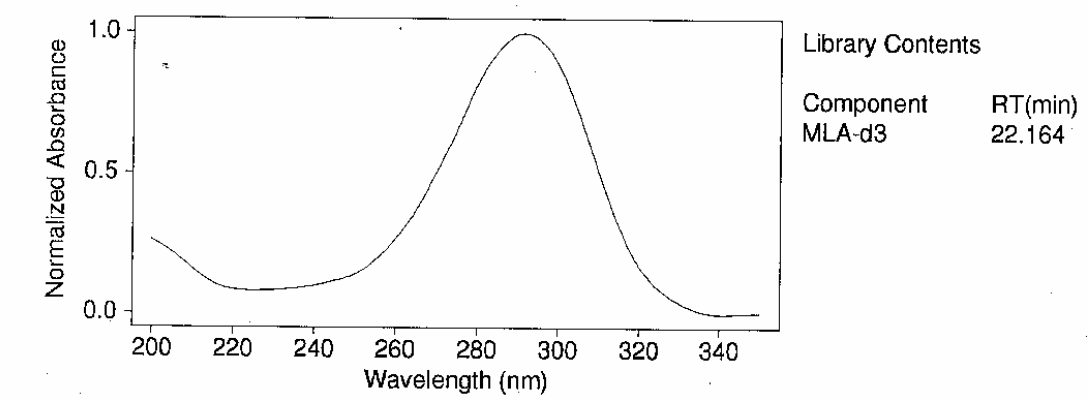
Instrument: Hewlett Packard 5989 A MS
MS-spectrum, DIP = direct inlet probe



III HPLC-UV spectrum

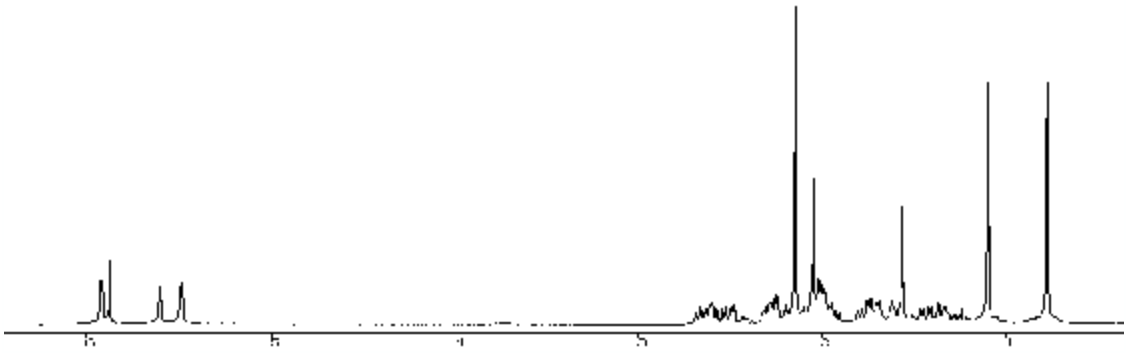
Instrument:TSP spectrasystem UV2000; resolution 2nm.
HPLC eluens: methanol/water (70:30 $^{v}/_{v}$)

HPLC column: Lichrocart 125-4 hplc cartridge



IV ^{1}H-NMR SPECTROMETRY

Instrment: FT-NMR Jeol GSX; 270 MHz, 5 mm probe, solvent $CDCl_3$



Chemical shifts (ppm)	Amount of protons (multiplicity)	Designation
0.78	3 (s)	18-CH_3
1.12	3 (s)	19-CH_3
2.05	3 (s)	21-CH_3
2.15	3 (s)	17-acetyl
5.57	2 (d)	16-methylene
5.92	2 (2s)	4-H en 7-H

V HOMOGENEITY AND STABILITY

Stability and homogeneity test of Melengestrol-acetate-D_3

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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	(102 ± 5)	(109 ± 2)	(100 ± 2)	(106 ± 1)	(92 ± 1)
20°C		(102 ± 4)	(107 ± 2)	(109 ± 1)	(94 ± 3)
37°C		(106 ± 1)	(104 ± 1)	(108 ± 2)	(102 ± 5)