

## **Datasheet Melengestrolacetate-D<sub>3</sub>**

**Reference number : CEC/MAT : 15**

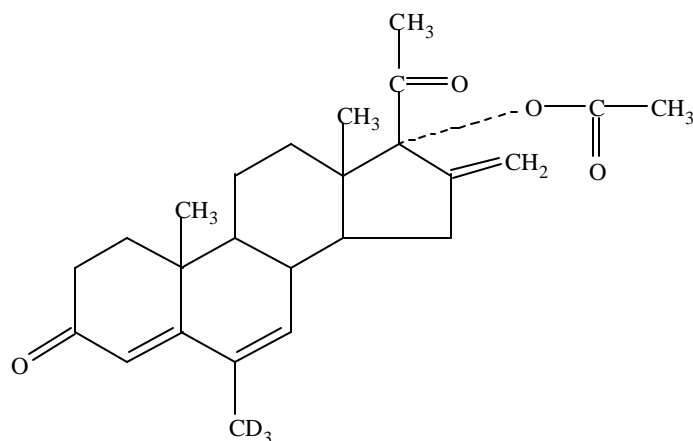
**Date of preparation : 1994.05.31**

date : 17 January 2003

source : MAT - RIVM

**“Bank of Reference Standards”**

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Contract MAT 1 - CT92 - 0020**



MELENGESTROLACETATE-D3

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

Synonym : melengestrolacetate-D<sub>3</sub>

Molecular formula : C<sub>25</sub>H<sub>29</sub>O<sub>4</sub>D<sub>3</sub>

Cas # : not available

Molecular weight : 399.54

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

Last update : 1998.01.06

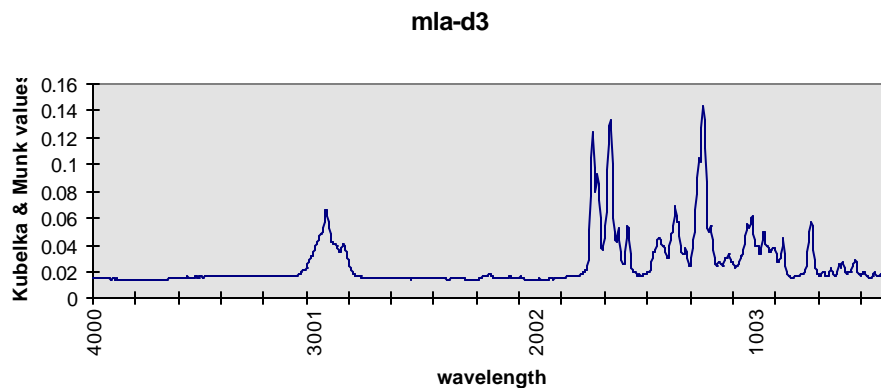
**Methods used for characterization:**

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

## I IR-SPECTROSCOPY

Instrument: Bruker IFS-55 FTIR; detector DTGS

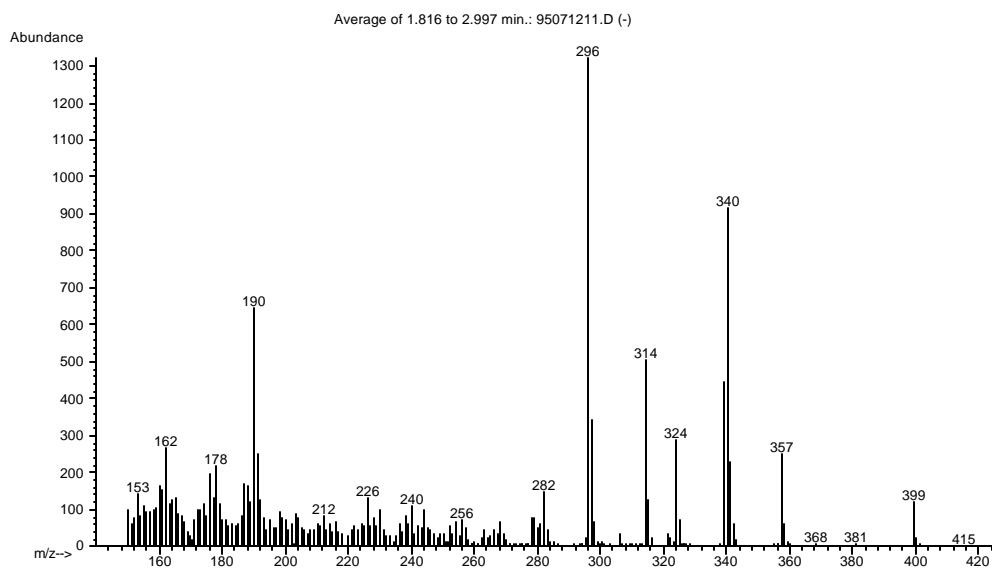
Sampling technique: KBr-tablet.



## II MASS-SPECTROMETRY

Instrument: Hewlett Packard 5989 A MS

MS-spectrum, DIP = direct inlet probe

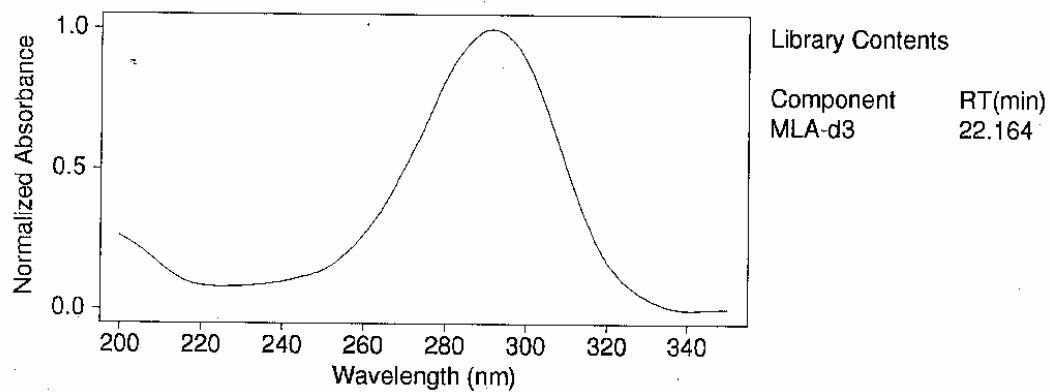


## III HPLC-UV spectrum

Instrument: TSP spectrasystem UV2000; resolution 2nm.

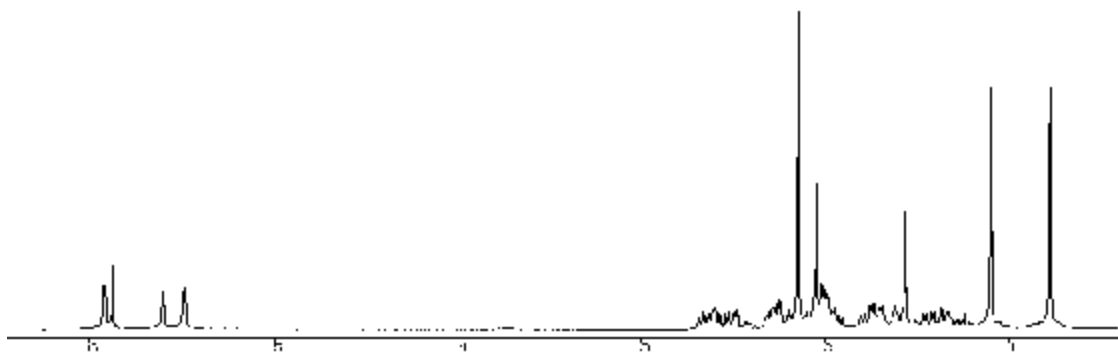
HPLC eluens: methanol/water (70:30 v/v)

HPLC column: Lichrocart 125-4 hplc cartridge



#### IV <sup>1</sup>H-NMR SPECTROMETRY

Instrmnt: FT-NMR Jeol GSX; 270 MHz, 5 mm probe, solvent CDCl<sub>3</sub>



Chemical shifts (ppm)	Amount of protons (multiplicity)	Designation
0.78	3 (s)	18-CH <sub>3</sub>
1.12	3 (s)	19-CH <sub>3</sub>
2.05	3 (s)	21-CH <sub>3</sub>
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<sub>3</sub>

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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 mont hs (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)

