

Datasheet Dienestrol-D₂

Reference number : CEC/MAT : 02

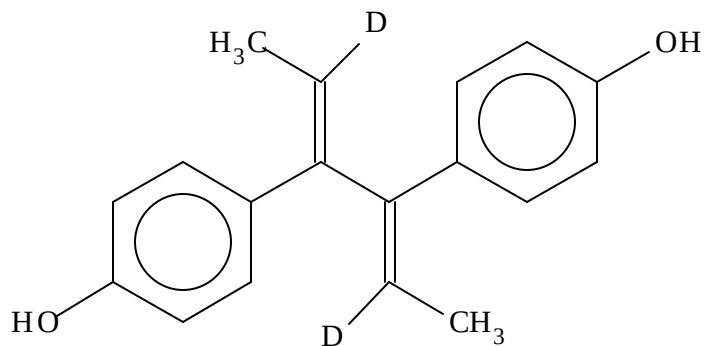
Date of preparation: 1993.01.29

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source : RIVM

“Bank of Reference Standards”

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DIENESTROL-D2

Name : 4,4'-(1,2-Di(deutero)ethylidene-1,2-ethanediyl)diphenol
 Synonym : dienestrol-D₂
 Molecular formula : C₁₈H₁₆O₂D₂
 Cas # : not available
 Molecular weight : 268.35

Long term stability tested on 1997.09.08 : 87.6 ± 2.0 %
 (storage 4°C, analysis HPLC-UV, 6 tests on 2 ampoules)

Date : 1998.01.06

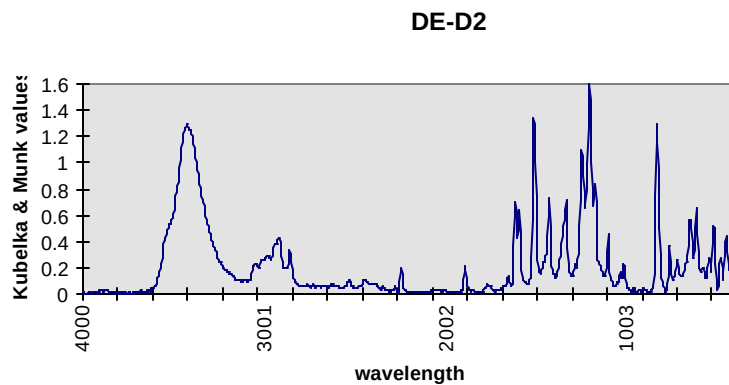
Methods used for characterization

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

I IR-SPECTROSCOPY

Instrument: Bruker IFS-55 FTIR; detector DTGS

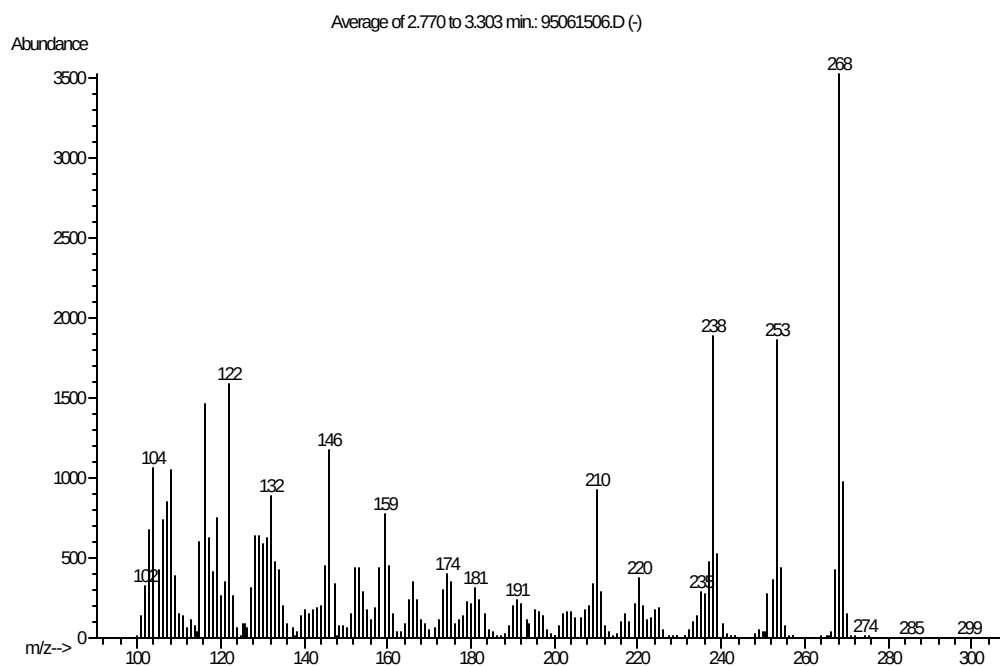
Sampling technique: KBr-tablet.



II MASS SPECTROMETRY

Instrument: Hewlett Packard 5989 A MS

MS-spectrum, DIP = direct inlet probe

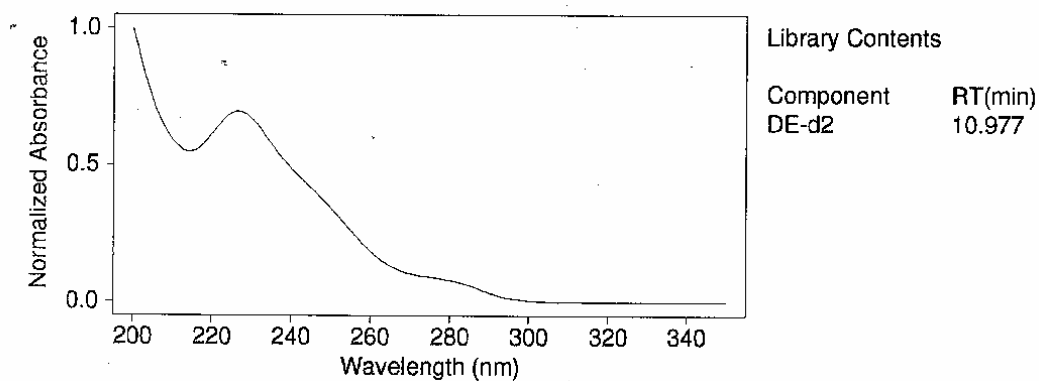


III HPLC-UV spectrum

Instrument: TSP spectrasystem UV2000; resolution 2nm.

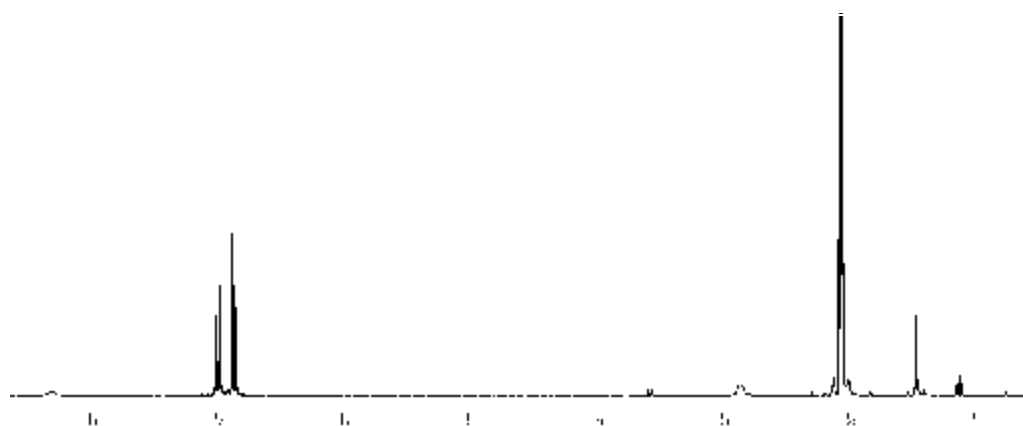
HPLC eluents: methanol/water (70:30 %v/v)

HPLC column: Lichrocart 125-4 hplc cartridge



IV ¹H-NMR SPECTROMETRY

Instrument: FT-NMR Jeol GSX; 270 MHz, 5 mm probe, solvent Aceton-D₆



Chemical shifts (ppm)	Amount of protons (multiplicity)	Designation
1.45	6 (s)	CH ₃ (2x)
6.93	8 (m)	arom.

V HOMOGENEITY AND STABILITY

Stability and homogeneity test of DE- D₂

CEC/ MAT: 02

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)	t= 24 months (n = 2) µg (m ± SD)
4 °C	(98 ± 2)	(99 ± 1)	(98 ± 1)	(97 ± 2)	(106 ± 3)	(110 ± 1)
20 °C		(98 ± 1)	(98 ± 1)	(95 ± 4)	(104 ± 1)	(108 ± 1)
37 °C		(100 ± 1)	(99 ± 1)	(96 ± 1)	(105 ± 1)	(108 ± 1)

