Datasheet Nortestosterone-D$_3$

Reference number : CEC/MAT : 04

Date of preparation: 1993.11.23

date : 17 January 2003

source : RIVM

“Bank of Reference Standards”

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Contract MAT 1 - CT92 - 0020
17β-NORTESTOSTERONE-D3

Name : 17β-Hydroxy-17α-deutero-18-dideuteroestr-4-en-3-one
Synonym : 17β-nortestosterone-D3
Molecular formula : C₁₈H₂₃O₂D₃
Cas # : not available
Molecular weight : 277.42

Long term stability tested on 1997.09.17 : 94.4 ± 0.6 %
(storage < -15°C, analysis HPLC-UV, 6 tests on 2 ampoules)

Date : 1998.01.06

Ampoule is not stable enough for long term storage at room temperature or +37°C. Ampoule should be stored at a temperature < -15°C (see page 4).

**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 SPECTROSCOPY

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

Instrument: FT-NMR Jeol GSX; 270 MHz, 5 mm probe, solvent CDCl$_3$

<table>
<thead>
<tr>
<th>Chemical shifts (ppm)</th>
<th>Amount of protons (multiplicity)</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.91</td>
<td>3 (s)</td>
<td>18-CH$_3$</td>
</tr>
<tr>
<td>5.85</td>
<td>1 (s)</td>
<td>4-H</td>
</tr>
</tbody>
</table>
### V HOMOGENEITY AND STABILITY

#### Stability and homogeneity test of NT-D3

**CEC/MAT: 04**

<table>
<thead>
<tr>
<th>temp.</th>
<th>t= 0 months homogeneity (n = 10) µg (m ± SD)</th>
<th>t=1,5 months (n =2) µg (m ± SD)</th>
<th>t = 3 months (n = 2) µg (m ± SD)</th>
<th>t = 6 months (n = 2) µg (m ± SD)</th>
<th>t= 12 months (n = 2) µg (m ± SD)</th>
<th>t= 24 months (n = 2) µg (m ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4°C</td>
<td>(107 ± 7)</td>
<td>(102 ± 3)</td>
<td>(106 ± 4)</td>
<td>(99 ± 1)</td>
<td>(95 ± 9)</td>
<td>(105 ± 1)</td>
</tr>
<tr>
<td>20°C</td>
<td>(103 ± 1)</td>
<td>(93 ± 1)</td>
<td>(96 ± 3)</td>
<td>(92 ± 5)</td>
<td>(82 ± 3)</td>
<td></td>
</tr>
<tr>
<td>37°C</td>
<td>(86 ± 1)</td>
<td>(65 ± 3)</td>
<td>(57 ± 1)</td>
<td>(43 ± 7)</td>
<td>(39 ± 1)</td>
<td></td>
</tr>
</tbody>
</table>

#### Stability test Nortestosterone-d3

![Graph showing stability test](image)

- 4°C
- 20°C
- 37°C

---> months

\(--\rightarrow\text{amount (µg/ampoule)}\)

\(\rightarrow\text{months}\)