Datasheet Salbutamol-D6

Reference number: EU/CRL 09

Date of preparation: 2002.06.27

source: Rikilt

“Bank of Reference Standards”
Name: 4-Hydroxy-3-hydroxymethyl-[(hexadeutero-tert-butylamino)methyl]-benzyl alcohol
Synonym: salbutamol-D₆ (.HCl)
Molecular formula: C₁₃H₁₅NO₃D₆ (.HCl)
Cas #: not available
Molecular weight: 245.35

Last update: 2003.08.05

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 LC-MS
I IR-SPECTROSCOPY

Date of Measurement: 2003.04.02  Sample Name: Salbutamol-D<sub>6</sub>
Time of Measurement: 14:39:24  Sample Form: KBr
Resolution: 2  Instrument Type: IFS55

II MASS-SPECTROSCOPY

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

datasheet EU/CRL reference standard material SAL-D<sub>6</sub>, page 2 of 4
III HPLC-UV SPECTROSCOPY

NOT AVAILABLE

IV $^1$H-NMR SPECTROMETRY

Instrument: FT-NMR Jeol GSX; 270 MHz, 5 mm probe, solvent Aceton-D$_6$

<table>
<thead>
<tr>
<th>Chemical shifts (ppm)</th>
<th>Amount of protons (multiplicity)</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.21</td>
<td>3 (s)</td>
<td>CH$_3$</td>
</tr>
<tr>
<td>2.85</td>
<td>2 (m)</td>
<td>CH$_2$NH</td>
</tr>
<tr>
<td>4.75</td>
<td>3 (m)</td>
<td>CHOH en CH$_2$OH</td>
</tr>
<tr>
<td>7.00</td>
<td>3 (m)</td>
<td>arom</td>
</tr>
</tbody>
</table>

* An organical solvent was found (1.95 ppm)
V HOMOGENEITY AND STABILITY

The homogeneity of the ampoules was tested at random. All tested ampoules contained 100 g salbutamol-d6.

<table>
<thead>
<tr>
<th>time (weeks)</th>
<th>temp. 4 °C</th>
<th>temp. 20 °C</th>
<th>temp. 37 °C</th>
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<tr>
<td>0</td>
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<td>100</td>
<td>100</td>
</tr>
<tr>
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<td>88</td>
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<td>94</td>
<td>90</td>
<td>93</td>
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</tbody>
</table>

Stability of salbutamol-d6