TESTS

Solution S. Dissolve the residue obtained in the test for non-volatile matter in 1 ml of 1 M hydrochloric acid and dilute to 50.0 ml with water R.

Appearance. The substance to be examined is clear (2.2.1) and colourless (2.2.2, Method II). Dilute 2 ml to 10 ml with water R. After 5 min, the solution is clear (2.2.1).

Acidity or alkalinity. To 10.0 ml of carbon dioxide-free water R add 0.1 ml of phenolphthalein solution R and 0.01 M sodium hydroxide until the solution becomes pale pink. After addition of 5.0 ml of the substance to be examined the colour of the solution does not become more intense. If the colour fades, add 0.2 ml of 0.01 M sodium hydroxide. The solution is pink.

Absorbance (2.2.25). Measure the absorbance between 230 nm and 310 nm using water R as the compensation liquid. The absorbance $A$ is not greater than the following values.

<table>
<thead>
<tr>
<th>Wavelength (nm)</th>
<th>Absorbance $A$</th>
</tr>
</thead>
<tbody>
<tr>
<td>230</td>
<td>0.300</td>
</tr>
<tr>
<td>250</td>
<td>0.100</td>
</tr>
<tr>
<td>270</td>
<td>0.030</td>
</tr>
<tr>
<td>290</td>
<td>0.020</td>
</tr>
<tr>
<td>310</td>
<td>0.010</td>
</tr>
</tbody>
</table>

The absorption curve does not show any peaks.

Reducing substances. Place 10.0 ml in a test tube of about 20 mm in diameter in a water bath at 20 °C. Keep protected from actinic light and add 1.0 ml of a freshly prepared 0.16 g/l solution of potassium permanganate R. The mixture, maintained at 20 °C, slowly changes its colour from violet to red. After 30 min, the test solution is not less intensely coloured (2.2.2, Method II) than 10.0 ml of a reference solution prepared as follows: to 5.5 ml of primary solution yellow, add 13.0 ml of primary solution red and dilute to 100.0 ml with water R.

Related substances. Gas chromatography (2.2.28). Test solution. The substance to be examined.

Reference solution (a). Dilute 1.0 ml of the test solution to 100.0 ml with heptane R. Dilute 1.0 ml of the solution to 10.0 ml with heptane R.

Reference solution (b). Mix 0.1 ml of acetone R with 0.1 ml of 2-propanol and dilute to 100 ml with the test solution.

Column:
- material: fused silica,
- size: $l = 30 \text{ m}, \phi = 0.25 \text{ mm},$
- stationary phase: poly[(cyanopropyl)(phenyl)]dimethylsiloxane R (film thickness 1.4 µm).

Carrier gas: helium for chromatography R.

Linear velocity: 25 cm/s.

Split ratio: 1:200.

Temperature:

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Temperature (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Column</td>
<td></td>
</tr>
<tr>
<td>0 - 12</td>
<td>40</td>
</tr>
<tr>
<td>12 - 28</td>
<td>40 → 200</td>
</tr>
<tr>
<td>28 - 38</td>
<td>200</td>
</tr>
<tr>
<td>Injection port</td>
<td></td>
</tr>
<tr>
<td>240</td>
<td></td>
</tr>
<tr>
<td>Detector</td>
<td></td>
</tr>
<tr>
<td>240</td>
<td></td>
</tr>
</tbody>
</table>

Detection: flame ionisation.

Non-volatile matter: maximum 0.004 per cent.

Water (2.5.12): maximum 0.2 per cent, determined on 10 g.

STORAGE

Protected from light.

IMPURITIES

A. CH$_3$-OH: methanol,
B. ethanol,
C. CH$_3$-CH$_2$-CHO: propanal,
D. acetone,
E. isopropyl alcohol (2-propanol),
F. butan-2-ol (sec-butanol),
G. 2-methylpropan-1-ol (isobutanol),
H. CH$_3$[CH$_2$]$_3$-OH: butan-1-ol (n-butanol),
I. CH$_3$[CH$_2$]$_4$-OH: pentan-1-ol (n-pentanol),
J. CH$_3$[CH$_2$]$_5$-OH: hexan-1-ol (n-hexanol).

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PROPANTHELINE BROMIDE

Propanthelini bromidum

$C_{23}H_{30}BrNO_3$ $M$, 448.4
DEFINITION
Propofol contains not less than 98.0 per cent and not more than the equivalent of 102.0 per cent of C_{12}H_{18}O_3, as determined on 1.000 g by drying in an oven at 100 °C to 105 °C.

ASSAY
Dissolve 0.400 g in 50 ml of acetic anhydride R. Titrate with 0.1 M perchloric acid, determining the end-point potentiometrically (2.2.20). 1 ml of 0.1 M perchloric acid corresponds to 44.84 mg of C_{12}H_{18}O_3.

STORAGE
Store in an airtight container.

PROPOFOL
Propofolum

C_{12}H_{18}O_3, M, 178.3

DEFINITION
Propofol contains not less than 98.0 per cent and not more than the equivalent of 102.0 per cent of 2,6-bis(1-methylethyl)phenol.