the expression:

\[
\text{percentage content of stearyl alcohol} = \frac{100 \times m_y}{S_{\text{H}, \text{corr}} \times m}
\]

Calculate the percentage content of stearyl alcohol using the expression:

\[
S_y = \text{area of the peak corresponding to stearyl alcohol in the chromatogram obtained with test solution (a)}.
\]

The percentage content of cetostearyl alcohol corresponds to the sum of the percentage content of cetyl alcohol and stearyl alcohol.

**Sodium cetostearyl sulphate.** Disperse 0.300 g in 25 ml of methylene chloride R. Add 50 ml of water R and 10 ml of dimidium bromide-sulphan blue mixed solution R. Titrate with 0.004 M benzethonium chloride, using sonication and heating and allowing the layers to separate before each addition, until the colour of the lower layer changes from pink to grey.

1 ml of 0.004 M benzethonium chloride is equivalent to 1.434 mg of sodium cetostearyl sulphate.

**LABELLING**

The label states, where applicable, the name and concentration of any added buffer.

**CETOSTEARYL ALCOHOL (TYPE B), EMULSIFYING**

Alcohol cetylicus et stearylicus emulsificans B

**DEFINITION**

Emulsifying cetostearyl alcohol (type B) is a mixture which contains not less than 80.0 per cent of cetostearyl alcohol and not less than 7.0 per cent of sodium laurilsulfate, both calculated with reference to the anhydrous substance. A suitable buffer may be added.

**CHARACTERS**

White or pale yellow, wax-like mass, plates, flakes or granules, soluble in hot water giving an opalescent solution, practically insoluble in cold water, slightly soluble in alcohol.

**IDENTIFICATION**

First identification: B, C, D.

Second identification: A, C.

A. Examine by thin-layer chromatography (2.2.27), using a TLC silanised silica gel plate R.

Test solution (a). Dissolve 0.1 g of the substance to be examined in 10 ml of trimethylpentane R, heating on a water-bath. Shake with 2 ml of alcohol (70 per cent V/V) R and allow to separate. Use the lower layer as test solution (b). Dilute 1 ml of the upper layer to 8 ml with trimethylpentane R.

Test solution (b). Use the lower layer obtained in the preparation of test solution (a).

Reference solution (a). Dissolve 40 mg of cetostearyl alcohol R in 10 ml of trimethylpentane R.

Reference solution (b). Dissolve 20 mg of sodium laurilsulfate R in 10 ml of alcohol (70 per cent V/V) R, heating on a water-bath.

Apply to the plate 2 µl of each solution. Develop over a path of 12 cm using a mixture of 20 volumes of water R, 40 volumes of acetone R and 40 volumes of methanol R. Allow the plate to dry in air and spray with a 50 g/l solution of phosphomolybdic acid R in alcohol R. Heat at 120 °C until spots appear (about 3 h). The 2 principal spots in the chromatogram obtained with test solution (a) are similar in position and colour to the principal spots in the chromatogram obtained with reference solution (a). 1 of the spots in the chromatogram obtained with test solution (b) is similar in position and colour to the principal spot in the chromatogram obtained with reference solution (b).

B. Examine the chromatograms obtained in the assay. The retention times of the 2 principal peaks in the chromatogram obtained with test solution (b) are similar to those of the 2 principal peaks in the chromatogram obtained with the reference solution.

C. It gives a yellow colour to a non-luminous flame.

D. To 0.3 g add 20 ml of ethanol R and heat to boiling on a water-bath with shaking. Filter the mixture immediately, evaporate to dryness and take up the residue in 7 ml of water R. To 1 ml of the solution add 0.1 ml of a 1 g/l solution of methylene blue R, 2 ml of dilute sulphuric acid R and 2 ml of methylene chloride R and shake. A blue colour develops in the lower layer.

**TESTS**

**Acid value (2.5.1).** Not more than 2.0.

**Iodine value (2.5.4).** Not more than 3.0, determined on 2.00 g dissolved in 25 ml of methylene chloride R.

**Saponification value (2.5.6).** Not more than 2.0.

**Water** (2.5.12). Not more than 3.0 per cent, determined on 2.50 g by the semi-micro determination of water.

**ASSAY**

**Cetostearyl alcohol.** Examine by gas chromatography (2.2.28).

Internal standard solution. Dissolve 0.60 g of heptadecanol CRS in ethanol R and dilute to 150 ml with the same solvent.

Test solution (a). Dissolve 0.300 g of the substance to be examined in 50 ml of the internal standard solution, add 50 ml of water R and shake with 4 quantities, each of 25 ml, of pentane R, adding sodium chloride R, if necessary, to facilitate the separation of the layers. Combine the organic layers. Wash with 2 quantities, each of 30 ml, of water R, dry over anhydrous sodium sulphate R and filter.

Test solution (b). Dissolve 0.300 g of the substance to be examined in 50 ml of ethanol R, add 50 ml of water R and shake with 4 quantities, each of 25 ml, of pentane R, adding sodium chloride R, if necessary, to facilitate the separation of the layers. Combine the organic layers. Wash with 2 quantities, each of 30 ml, of water R, dry over anhydrous sodium sulphate R and filter.
Cetostearyl isononanoate

**DEFINITION**
Cetostearyl isononanoate is a mixture of esters of cetostearyl alcohol with isononanoic acid, mainly 3,5,5-trimethylhexanoic acid.

**CHARACTERS**
A clear, colourless or slightly yellowish liquid, practically insoluble in water, soluble in alcohol and in light petroleum, miscible with fatty oils and with liquid paraffins. It has a viscosity of 15 mPas to 30 mPas, a relative density of 0.85 to 0.86 and a refractive index of 1.44 to 1.45.

**IDENTIFICATION**
A. On cooling, turbidity occurs below 15 °C.
B. It complies with the test for saponification value (see Tests).
C. Examine by infrared absorption spectrophotometry (2.2.24), comparing with the Ph. Eur. reference spectrum of cetostearyl isononanoate.

**TESTS**
**Appearance.** The substance to be examined is clear (2.2.1) and not more intensely coloured than reference solution Y6 (2.2.2, Method I).

**Acid value (2.5.1).** Not more than 1.0, determined on 5.0 g.

**Hydroxyl value (2.5.3, Method A).** Not more than 5.0.

**Iodine value (2.5.4).** Not more than 1.0.

---

**Reference solution.** Dissolve 50 mg of cetyl alcohol CRS and 50 mg of stearyl alcohol CRS in ethanol R and dilute to 10 ml with the same solvent. The chromatographic procedure may be carried out using:
- a fused-silica column 25 m long and 0.25 mm in internal diameter coated with poly(dimethyl)siloxane R,
- nitrogen for chromatography R as the carrier gas at a flow rate of 1 ml/min,
- a flame-ionisation detector,
- a split ratio of 1:100,

with the following temperature programme:

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Temperature (°C)</th>
<th>Rate (°C/min)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 20</td>
<td>150 → 250</td>
<td>5</td>
<td>linear gradient</td>
</tr>
<tr>
<td>Injection port</td>
<td>250</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detector</td>
<td>250</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The substances are eluted in the following order: cetyl alcohol, heptadecanol (internal standard) and stearyl alcohol. Inject 1 µl of test solution (a) and 1 µl of test solution (b). If the chromatogram obtained with test solution (a) shows a peak with the same retention time as the peak corresponding to the internal standard in the chromatogram obtained with test solution (a), calculate the ratio:

\[ r = \frac{S_{ci}}{S_{i}} \]

If \( r \) is less than 300, calculate the corrected area \( S_{Ha(corr)} \) of the peak corresponding to the internal standard in the chromatogram obtained with test solution (a):

\[ S_{Ha(corr)} = S_{Ha} - \frac{S_{i} \times S_{ci}}{S_{i}} \]

Then, calculate the percentage content of cetyl alcohol using the expression:

\[ S_{A} = \frac{100 \times m_{H}}{S_{Ha(corr)} \times m_{i}} \]

\( m_{A} \) = mass of the internal standard in test solution (a), in milligrams.

**Sodium laurilsulfate.** Disperse 0.300 g in 25 ml of methylene chloride R. Add 50 ml of water R and 10 ml of dimidium bromide-sulphan blue mixed solution R. Titrate with 0.004 M benzethonium chloride, using sonication and heating, and allowing the layers to separate before each addition, until the colour of the lower layer changes from pink to grey. 1 ml of 0.004 M benzethonium chloride is equivalent to 1.154 mg of sodium laurilsulfate.

**LABELLING**
The label states, where applicable, the name and concentration of any added buffer.

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