Stearic Acid

 Portions of this monograph that are national USP text, and are not part of the harmonized text, are marked with symbols (∗•) to specify this fact.

 Octadecanoic acid;
 Stearic acid [57-11-4].

 DEFINITION

 Change to read:

 Mixture consisting of stearic (octadecanoic) acid (C₁₈H₃₆O₂; M₀, 284.5) and palmitic (hexadecanoic) acid (C₁₆H₃₂O₂; M₀, 256.4) obtained from fats or oils of vegetable or animal origin.

 Content:

 \[
 \text{Stearic acid: 40.0\%–60.0\%. Sum of the contents of stearic acid and palmitic acids: NLT 90.0\%.}
 \]

 [NOTE—Stearic Acid labeled solely for external use is exempt from the requirement that it be prepared from edible sources.]

 IDENTIFICATION

 • A. It meets the requirements of the test for Freezing Point.

 Change to read:

 • B. ACID VALUE

 Light petroleum: Use a sample that has the following properties: a clear, colorless, liquid without fluorescence; practically insoluble in water; miscible with alcohol; density at 20° about 0.720; distillation range 100°– 120°; water content NMT 0.03%.

 Sample solution: Dissolve 0.5 g of Stearic Acid in 50 mL of a mixture of equal volumes of alcohol and Light petroleum previously neutralized with 0.1 N potassium hydroxide or 0.1 N sodium hydroxide, using 0.5 mL of phenolphthalein TS as indicator. If necessary, heat to about 90° to dissolve the substance to be examined.

 Analysis: Titrate the Sample solution with 0.1 N potassium hydroxide or 0.1 N sodium hydroxide until the pink color persists for at least 15 s. When heating has been applied to aid dissolution, maintain the temperature at about 90° during the titration.

 Calculate the acid value (IA) of the portion of Stearic Acid taken:

 \[
 \text{\textit{Result}} = \frac{(n/m)}{N} \times M_{\text{AO}}\text{NFS4}
 \]

 \[n = \text{amount of titrant used (mL)}
 \]

 \[m = \text{amount of Stearic Acid taken to prepare the Sample solution (g)}
 \]

 \[N = \text{normality of the potassium hydroxide solution}
 \]

 \[= \text{molecular weight of potassium hydroxide,} \]

 \[M_{\text{AO}}\text{NFS4} = 56.1\text{NFS4}
 \]

 Acceptance criteria: 194–212

 • C. The retention times of the major peaks of the Sample solution correspond to those of the Standard solution, as obtained in the Assay.

 ASSAY

 • PROCEDURE

 Boron trifluoride–methanol solution: 140 g/L of boron trifluoride in methanol

 Sample solution: Dissolve 100 mg of Stearic Acid in a small conical flask fitted with a suitable reflux attachment with 5 mL of Boron trifluoride–methanol solution.

 Boil under reflux for 10 min. Add 4.0 mL of heptane through the condenser, and boil again under reflux for 10 min. Allow to cool. Add 20 mL of a saturated solution of sodium chloride. Shake, and allow the layers to separate. Remove about 2 mL of the organic layer, and dry it over 0.2 g of anhydrous sodium sulfate. Dilute 1.0 mL of this solution with heptane to 10.0 mL.

 Standard solution: Prepare as directed in the Sample solution using 50 mg of USP Stearic Acid RS and 50 mg of USP Palmitic Acid RS.

 Chromatographic system

 (See Chromatography (621), System Suitability.)

 Mode: GC

 Detector: Flame ionization

 Column: 30-m × 0.32-mm fused silica coated with a 0.5-µm layer of stationary phase G16

 Temperatures

 Injection port: 220°

 Detector: 260°

 Column: See Table 1.

<table>
<thead>
<tr>
<th>Initial Temperature (°C)</th>
<th>Temperature Ramp (°C/min)</th>
<th>Final Temperature (°C)</th>
<th>Hold Time at Final Temperature (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>70</td>
<td>—</td>
<td>70</td>
<td>2</td>
</tr>
<tr>
<td>70</td>
<td>5</td>
<td>240</td>
<td>5</td>
</tr>
</tbody>
</table>

 Carrier gas: Helium, passed through a bed of molecular sieve for drying, if necessary

 Flow rate: 2.4 mL/min

 Injection volume: 1 µL

 System suitability

 Sample: Standard solution

 Suitability requirements

 Resolution: NLT 5.0 between the methyl palmitate and methyl stearate peaks determined on six injections

 Relative standard deviation: NMT 3.0% for the methyl stearate and methyl palmitate peaks (from six replicate injections of Sample solution); NMT 1.0% for the ratio of the peak areas of methyl palmitate to the peak areas of methyl stearate, from six replicate injections

 Analysis

 Sample: Sample solution

 Calculate the percentage of stearic acid (C₁₈H₃₆O₂) in the portion of Stearic Acid taken:

 \[
 \text{Result} = \frac{(A_t/A_i) \times 100}{100}
 \]

 \[A_i = \text{peak area due to methyl stearate}
 \]

 \[A_t = \text{sum of the peak areas of all the fatty acid esters}
 \]

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Calculate the percentage of palmitic acid \((\text{C}_{16}\text{H}_{32}\text{O}_2)\) in the portion of Palmitic Acid taken:

\[
\text{Result} = \left( \frac{A_p}{A_T} \right) \times 100
\]

\(A_p\) = peak area due to methyl palmitate

\(A_T\) = sum of the peak areas of all the fatty acid esters

**Acceptance criteria**

For Stearic acid 50: 40.0–60.0% of stearic (octadecanoic) acid \((\text{C}_{18}\text{H}_{36}\text{O}_2)\), and the sum of the stearic acid and palmitic acid is NLT 90.0%

For Stearic acid 70: 60.0–80.0% of stearic (octadecanoic) acid \((\text{C}_{18}\text{H}_{36}\text{O}_2)\), and the sum of the stearic acid and palmitic acid is NLT 90.0%

For Stearic acid 95: NLT 90.0% of stearic (octadecanoic) acid \((\text{C}_{18}\text{H}_{36}\text{O}_2)\), and the sum of the stearic acid and palmitic acid is NLT 96.0%

**IMPURITIES**

- **Residue on Ignition (281)**: NMT 4 mg, determined on a 4-g portion (0.1%).

*Delete the following:*

- **Heavy Metals, Method II (231)**: NMT 10 ppm (Official 1-Dec-2015)

**SPECIFIC TESTS**

- **Fats and Fixed Oils, Iodine Value (401)**
  
  **Sample:** 1 g
  
  **Analysis:** Proceed as directed in Method I, except use 15 mL of chloroform.
  
  **Acceptance criteria:** See Table 2.

<table>
<thead>
<tr>
<th>Type</th>
<th>Iodine Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stearic acid 50</td>
<td>NMT 4.0</td>
</tr>
<tr>
<td>Stearic acid 70</td>
<td>NMT 4.0</td>
</tr>
<tr>
<td>Stearic acid 95</td>
<td>NMT 1.5</td>
</tr>
</tbody>
</table>

**Change to read:**

- **Color of Solution**
  
  **Standard stock solution Y** (yellow): 2.4 mL of ferric chloride CS, 0.6 mL of cobaltous chloride CS, and 7.0 mL of hydrochloric acid solution (10 g/L)
  
  **Standard stock solution BY (brownish-yellow):**
  
  2.4 mL of ferric chloride CS, 1.0 mL of cobaltous chloride CS, 0.4 mL of cupric sulfate CS, and 6.2 mL of hydrochloric acid solution (10 g/L)
  
  **Standard solution Y:** 2.5 mL of Standard stock solution Y and 97.5 mL of hydrochloric acid solution (10 g/L)
  
  **Standard solution BY:** 2.5 mL of Standard stock solution BY and 97.5 mL of hydrochloric acid solution (10 g/L)
  
  **Analysis:** Heat Stearic Acid to 75°C.
  
  **Acceptance criteria:** The resulting liquid is not more intensely colored than Standard solution Y or Standard solution BY.

**ADDITonal REQUIREMENTS**

- **Packaging and Storage:** Preserve in well-closed containers.

**Change to read:**

- **Labeling:** If it is for external use only, the labeling so indicates. The label states the type of stearic acid (50, 70, or 95).

**USP Reference Standards** (11)

- USP Palmitic Acid RS
- USP Stearic Acid RS

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