Edition: BP 2025 (Ph. Eur. 11.6 update)

Zinc Stearate

General Notices

(Ph. Eur. monograph 0306)

557-05-1

Action and use

Excipient.

Ph Eur

DEFINITION

Zinc stearate [$(C_{17}H_{35}COO)_2Zn$; M_r 632] may contain varying proportions of zinc palmitate [$(C_{15}H_{31}COO)_2Zn$; M_r 576.2] and zinc oleate [$(C_{17}H_{33}COO)_2Zn$; M_r 628].

Content

10.0 per cent to 12.0 per cent of Zn.

CHARACTERS

Appearance

Light, white or almost white, amorphous powder, free from gritty particles.

Solubility

Practically insoluble in water and in anhydrous ethanol.

IDENTIFICATION

A. Freezing point (*2.2.18*): minimum 53 °C, determined on the residue obtained in the preparation of solution S (see Tests).
B. Neutralise 5 mL of solution S to *red litmus paper R* with *strong sodium hydroxide solution R*. The solution gives the reaction of zinc (*2.3.1*).

TESTS

Solution S

To 5.0 g add 50 mL of *ether R* and 40 mL of a 7.5 per cent *V/V* solution of *nitric acid R* in *distilled water R*. Heat under a reflux condenser until dissolution is complete. Allow to cool. In a separating funnel, separate the aqueous layer and shake the ether layer with 2 quantities, each of 4 mL, of *distilled water R*. Combine the aqueous layers, wash with 15 mL of *ether R* and heat on a water-bath until ether is completely eliminated. Allow to cool and dilute to 50.0 mL with *distilled water R* (solution S). Evaporate the ether layer to dryness and dry the residue at 105 °C.

Appearance of solution

Solution S is not more intensely coloured than reference solution Y_6 (*2.2.2, Method II*).

Appearance of solution of fatty acids

Dissolve 0.5 g of the residue obtained in the preparation of solution S in 10 mL of *chloroform R*. The solution is clear (*2.2.1*) and not more intensely coloured than reference solution Y_5 (*2.2.2, Method II*).

Acidity or alkalinity

Shake 1.0 g with 5 mL of *ethanol (96 per cent) R* and add 20 mL of *carbon dioxide-free water R* and 0.1 mL of *phenol red solution R*. Not more than 0.3 mL of *0.1 M hydrochloric acid* or 0.1 mL of *0.1 M sodium hydroxide* is required to change the colour of the indicator.

Acid value of the fatty acids (*2.5.1*)

195 to 210.

Dissolve 0.20 g of the residue obtained in the preparation of solution S in 25 mL of the prescribed mixture of solvents.

Chlorides (*2.4.4*)

Maximum 250 ppm.

Dilute 2 mL of solution S to 15 mL with *water R*.

Sulfates (*2.4.13*)

Maximum 0.6 per cent.

Dilute 1 mL of solution S to 50 mL with *distilled water R*. Dilute 12.5 mL of this solution to 15 mL with *distilled water R*.

ASSAY

To 1.000 g add 50 mL of *dilute acetic acid R* and boil for at least 10 min or until the layer of fatty acids is clear, adding more *water R* as necessary to maintain the original volume. Cool and filter. Wash the filter and the flask with *water R* until the washings are no longer acid to *blue litmus paper R*. Combine the filtrate and washings. Carry out the complexometric titration of zinc (*2.5.11*).

1 mL of *0.1 M sodium edetate* is equivalent to 6.54 mg of Zn.
