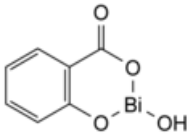
Edition: BP 2025 (Ph. Eur. 11.6 update)

Bismuth Subsalicylate

General Notices

(Ph. Eur. monograph 1495)



$C_7H_5BiO_4$ 362.1 *14882-18-9*

Ph Eur

DEFINITION

2-Hydroxy-2*H*,4*H*-1,3,2-benzodioxabismin-4-one. Complex of bismuth and salicylic acid.

Content

56.0 per cent to 59.4 per cent of Bi (A_r 209.0) (dried substance).

CHARACTERS

Appearance

White or almost white powder.

Solubility

Practically insoluble in water and in ethanol (96 per cent). It dissolves in mineral acids with decomposition.

IDENTIFICATION

A. To 0.5 g add 10 mL of *hydrochloric acid R1*. Heat on a water-bath for 5 min. Cool and filter. Retain the filtrate for identification test B. Wash the residue with *dilute hydrochloric acid R* and then with *water R*. Dissolve the residue in 0.5-1 mL of *dilute sodium hydroxide solution R*. Add 15 mL of *water R*. Neutralise with *dilute hydrochloric acid R*. The solution gives reaction (a) of salicylates (*2.3.1*).
B. The filtrate obtained in identification test A gives reaction (b) of bismuth (*2.3.1*).

TESTS

Acidity

Shake 2.0 g with 30 mL of *ether R* for 1 min and filter. To the filtrate add 30 mL of *ethanol (96 per cent) R* and 0.1 mL of *thymol blue solution R*. Not more than 0.35 mL of *0.1 M sodium hydroxide* is required to change the colour of the indicator to blue.

Chlorides (*2.4.4*)

Maximum 200 ppm.

Dissolve 0.250 g in a mixture of 2 mL of *nitric acid R*, 5 mL of *water R* and 8 mL of *methanol R*.

Nitrates

Maximum 0.4 per cent.

To 0.1 g add 10 mL of *water R* and, with caution, 20 mL of *sulfuric acid R* and stir. The solution is not more intensely yellow coloured than a reference solution prepared at the same time using 0.1 g of *salicylic acid R*, 6 mL of *water R*, 4 mL of *nitrate standard solution (100 ppm NO_3) R* and 20 mL of *sulfuric acid R*.

Soluble bismuth

Maximum 40 ppm.

Atomic absorption spectrometry (*2.2.23, Method I*).

Test solution Suspend 5.0 g in 100 mL of *water R*. Stir constantly for 2 h at 20-23 °C. Filter through filter paper (slow filtration) then through a cellulose micropore membrane filter (0.1 µm). To 10.0 mL of clear filtrate, add 0.1 mL of *nitric acid R*.

Reference solutions Prepare the reference solutions using *bismuth standard solution (100 ppm Bi) R* and diluting with a mixture of equal volumes of *dilute nitric acid R* and *water R*.

Source Bismuth hollow-cathode lamp.

Wavelength 223.06 nm.

Atomisation device Air-acetylene flame.

Loss on drying (*2.2.32*)

Maximum 1.0 per cent, determined on 1.000 g by drying in an oven at 105 °C.

ASSAY

Dissolve with heating 0.300 g in 10 mL of a mixture of 2 volumes of *perchloric acid R* and 5 volumes of *water R*. To the hot solution, add 200 mL of *water R* and 50 mg of *xylenol orange triturate R*. Titrate with *0.1 M sodium edetate* until a yellow colour is obtained.

1 mL of *0.1 M sodium edetate* is equivalent to 20.90 mg of Bi.

STORAGE

Protected from light.