Sulphur for external use

EUROPEAN PHARMACOPOEIA 5.0

IMPURITIES

A. (E)-[5-fluoro-2-methyl-1-[4-(methylsulphinyl)benzylidene]-1H-inden-3-yl]acetic acid,

B. X = SO₂ : (Z)-[5-fluoro-2-methyl-1-[4-(methylsulphonyl)benzylidene]-1H-inden-3-yl]acetic acid,

C. X = S: (Z)-[5-fluoro-2-methyl-1-[4-methylsulphanyl)benzylidene]-1H-inden-3-yl]acetic acid.

DEFINITION

Sulphur contains not less than 99.0 per cent and not more than the equivalent of 101.0 per cent of S.

CHARACTERS

A yellow powder, practically insoluble in water, soluble in carbon disulphide, slightly soluble in vegetable oils. The size of most of the particles is not greater than 20 µm and that of almost all the particles is not greater than 40 µm.

It melts at about 120 °C.

IDENTIFICATION

A. Heated in the presence of air, it burns with a blue flame, emitting sulphur dioxide which changes the colour of moistened blue litmus paper R to red.

B. Heat 0.1 g with 0.5 ml of bromine water R until decolourised. Add 5 ml of water R and filter. The solution gives reaction (a) of sulphates (2.3.1).

TESTS

Solution S. To 5 g add 50 ml of carbon dioxide-free water R prepared from distilled water R. Allow to stand for 30 min with frequent shaking and filter.

Appearance of solution. Solution S is colourless (2.2.2, Method II).

Odour (2.3.4). The substance to be examined has no perceptible odour of hydrogen sulphide.

Acidity or alkalinity. To 5 ml of solution S add 0.1 ml of phenolphthalein solution R1. The solution is colourless. Add 0.2 ml of 0.01 M sodium hydroxide. The solution is red. Add 0.3 ml of 0.01 M hydrochloric acid. The solution is colourless. Add 0.15 ml of methyl red solution R. The solution is orange-red.

Chlorides (2.4.4). Dilute 5 ml of solution S to 15 ml with water R. The solution complies with the limit test for chlorides (100 ppm).

Sulphates (2.4.13). 15 ml of solution S complies with the limit test for sulphates (100 ppm).

ASSAY

Carry out the oxygen-flask method (2.5.10), using 60.0 mg of the substance to be examined in a 1000 ml combustion flask. Absorb the combustion products in a mixture of 5 ml of dilute hydrogen peroxide solution R and 10 ml of water R. Heat to boiling, boil gently for 2 min and cool. Using 0.2 ml of phenolphthalein solution R as indicator, titrate with 0.1 M sodium hydroxide until the colour changes from colourless to red. Carry out a blank titration under the same conditions.

1 ml of 0.1 M sodium hydroxide is equivalent to 1.603 mg of S.

STORAGE

Store protected from light.

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SULPHURIC ACID

Acidum sulfuricum

DEFINITION

Sulphuric acid contains not less than 95.0 per cent m/m and not more than 100.5 per cent m/m of H₂SO₄.

CHARACTERS

A colourless, oily liquid, very hygroscopic, miscible with water and with alcohol producing intense heat.

The relative density is about 1.84.

IDENTIFICATION

A. Carefully add 1 ml to 100 ml of water R. The solution is strongly acid (2.2.4).

B. The solution obtained in identification test A gives reaction (a) of sulphates (2.3.1).

TESTS

Appearance of solution. Carefully pour, while cooling, 5 ml into 30 ml of water R and dilute to 50 ml with the same solvent. The solution is clear (2.2.1) and colourless (2.2.2, Method II).