Morphine sulfate tablets (Morphini sulfatis compressi)

Category. Opioid analgesic.

Additional information. Strength in the current WHO Model list of essential medicines: 10mg.

Requirements

Comply with the monograph for "Tablets".

Morphine sulfate tablets contain not less than 90.0% and not more than 110.0% of the amount of $(C_{17}H_{19}NO_3)_2, H_2SO_4, 5H_2O_3$ stated on the label.

Identity tests

• Either tests A and D or tests B, C, and D may be applied.

A. To a quantity of the powdered tablets equivalent to about 0.1g of Morphine sulfate add 10ml of ethanol (~750g/l) TS and shake for 15 minutes. Centrifuge and decant the supernatant liquid. Extract the remaining liquid with two further 10-mL quantities of ethanol (~750g/l) TS and evaporate the combined extracts to dryness. Carry out the examination with the residue as described under <u>1.7 Spectrophotometry in the infrared region</u>. The infrared absorption spectrum is concordant with the *reference spectrum* of morphine sulfate.

B. To a quantity of the powdered tablets equivalent to about 20mg of Morphine sulfate add 5ml of water, shake, and filter. To the filtrate add 0.05ml of ferric chloride (25g/l) TS; a blue colour is produced.

C. To a quantity of the powdered tablets equivalent to about 20mg of Morphine sulfate add 5ml of sulfuric acid (0.05mol/l) VS, shake, and filter. To the filtrate add 0.5ml of a saturated solution of potassium iodate R; an amber colour is produced which reaches maximum intensity after 5 minutes. Add 0.5ml of ammonia (~260g/l) TS; the colour darkens almost to black.

D. To a quantity of the powdered tablets equivalent to about 20mg of Morphine sulfate add 5ml of water, shake, and filter. The filtrate yields the reactions described under <u>2.1 General identification tests</u> as characteristic of sulfates.

Assay. Weigh and powder 20 tablets. To a quantity of the powdered tablets equivalent to about 0.4g of Morphine sulfate add 25ml of water, 5ml of sodium hydroxide (1mol/l) VS, and 1g of ammonium sulfate R, swirl to dissolve. Add 20ml of ethanol (~750g/l) TS and extract with successive quantities of 40ml, 20ml, 20ml, and 20ml of a mixture of 3 volumes of chloroform R and 1 volume of ethanol (~750g/l) TS. Wash each extract with the same 5ml of water, filter, and evaporate the solvent. Dissolve the residue in 10ml of hydrochloric acid (0.05mol/l) VS, boil, cool, add 15ml of water and a few drops of methyl red/ethanol TS. Titrate the excess acid with sodium hydroxide (0.05mol/l) VS.

Each mL of hydrochloric acid (0.05mol/l) VS is equivalent to 18.97mg of (C₁₇H₁₉NO₃)₂,H₂SO₄,5H₂O.