Ibuprofen tablets (Ibuprofeni compressi)

Category. Non-steroidal anti-inflammatory drug.

Additional information. Strengths in the current WHO Model list of essential medicines: 200 mg, 400 mg and 600 mg. Strengths in the current WHO Model list of essential medicines for children: 200 mg, 400 mg and 600 mg.

Requirements

Comply with the monograph for *Tablets*.

Ibuprofen tablets contain not less than 90.0% and not more than 110.0% of the amount of $C_{13}H_{18}O_2$ stated on the label.

Identity tests

-Either tests A and C or tests B and C may be applied.

To a quantity of the powdered tablets equivalent to about 0.8 g of Ibuprofen add 20 mL of acetone R, filter and allow the filtrate to evaporate without heating. To the residue add 10 mL of acetone R, allow to crystallize, separate the crystals, dry in air and use the dried crystals for the following tests.

A. Carry out the examination with the dried crystals as described under *1.7 Spectrophotometry in the infrared region*. The infrared absorption spectrum is concordant with the spectrum obtained from ibuprofen RS or with the *reference spectrum* of ibuprofen.

B. Dissolve 25 mg of the dried crystals in sufficient sodium hydroxide (0.1 mol/l) VS to produce 100 mL. The absorption spectrum of the resulting solution, when observed between 230 nm and 350 nm, exhibits maxima at about 265 nm and 273 nm, minima at about 245 nm and 271 nm, and a shoulder at about 259 nm.

C. Melting temperature of the dried crystals, about 76 °C.

Related substances

Carry out the test as described under *1.14.1 Chromatography*, Thin-layer chromatography using silica gel R3 as the coating substance and a mixture of 15 volumes of hexane R, 5 volumes of ethyl acetate R and 1 volume of glacial acetic acid R as the mobile phase. Apply separately to the plate 5 µl of each of the following 3 solutions. For solution (A) shake a quantity of the powdered tablets equivalent to about 0.2 g of Ibuprofen with three 10 mL quantities of chloroform R, filter, evaporate the combined filtrates to a volume of about 1 mL and add sufficient chloroform R to produce 2 mL. For solution (B) dilute 1 volume of solution A to 100 volumes with chloroform R. After removing the plate from the chromatographic chamber allow it to dry in air and spray very lightly with a solution of 10 mg of potassium permanganate R per mL of sulfuric acid (~100 g/l) TS. Heat again at 120 °C for 20 minutes and examine the chromatogram in ultraviolet light (365 nm).

Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution B.

Assay

Weigh and powder 20 tablets. To a quantity of the powder equivalent to about 0.5 g of Ibuprofen add 60 mL of chloroform R and shake for 15 minutes. Filter through a fine glass microfibre paper (e.g. Whatman GF/F) under reduced pressure. Wash the residue with 2 quantities, each of 20 mL of chloroform R and evaporate the combined filtrates in a current of air until just dry. Dissolve the residue in 100 mL of neutralized ethanol TS and titrate with sodium hydroxide (0.1 mol/l) VS, determining the end-point potentiometrically.

Each mL of sodium hydroxide (0.1 mol/l) VS is equivalent to 20.63 mg of $C_{13}H_{18}O_2$.

Dissolution

Carry out the test as described under *5.5 Dissolution test for solid oral dosage forms*.