

**Indometacin tablets (Indometacini compressi)**

**Category.** Non-steroidal anti-inflammatory drug.

**Requirements**

Comply with the monograph for "[Tablets](#)".

Indometacin tablets contain not less than **90.0%** and not more than **110.0%** of the amount of  $C_{19}H_{16}ClNO_4$  stated on the label.

**Identity tests**

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

A. To a quantity of the powdered tablets equivalent to about 0.1g of Indometacin add 5ml of chloroform R and shake. Filter and evaporate the filtrate to dryness. Dry the residue at 70°C under reduced pressure (not exceeding 0.6kPa or 5mm of mercury). Carry out the examination with the residue as described under [1.7 Spectrophotometry in the infrared region](#). The infrared absorption spectrum is concordant with the spectrum obtained from indometacin RS or with the *reference spectrum* of indometacin.

B. To a quantity of the powdered tablets equivalent to about 0.05g of Indometacin add 60ml of ethanol (~750g/l) TS and shake. Allow to stand for 10 minutes, shake again, and dilute with sufficient ethanol (~750g/l) TS to produce 100ml. Filter, discard the first 10ml of filtrate, then dilute 5ml of the filtrate to 100ml with the same solvent. The absorption spectrum of the resulting solution, when observed between 300nm and 350nm, exhibits a maximum at about 318nm.

C. To a quantity of the powdered tablets equivalent to about 25mg add 10ml of water, 2 drops of sodium hydroxide (~200g/l) TS, shake, and filter. To the filtrate add 1.0ml of sodium nitrite (10g/l) TS, allow to stand for 5 minutes, and carefully add about 0.5ml of hydrochloric acid (~250g/l) TS; a green colour is produced.

**Related substances.** Carry out the test as described under [1.14.1 Thin-layer chromatography](#), using silica gel R2 as the coating substance and preparing a slurry in sodium dihydrogen phosphate (45g/l) TS. As the mobile phase, use a mixture of 7 volumes of ether R and 3 volumes of light petroleum R1. Apply separately to the plate 5 µl of each of the following 2 solutions. For solution (A) shake a quantity of the powdered tablets equivalent to about 0.1g of Indometacin with 5ml of chloroform R, filter, and use the filtrate. For solution (B) dilute 1 volume of solution A to 20 volumes with chloroform R, further dilute 1 volume of this solution to 10 volumes with the same solvent. After removing the plate from the chromatographic chamber, allow it to dry in air, and examine the chromatogram in ultraviolet light (254nm).

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 of about 0.05g of Indometacin add 10ml of water and allow to stand for 15 minutes, swirling occasionally. Add 75ml of methanol R, shake well, add sufficient methanol R to produce 100ml, and filter. To 5ml of the filtrate add a mixture of equal volumes of methanol R and phosphate buffer pH 7.2, TS to produce 100ml. Measure the absorbance of a 1-cm layer at the maximum at about 318nm against a solvent cell containing the above solvent mixture.

Calculate the percentage content of  $C_{19}H_{16}ClNO_4$  using the absorptivity value of 19.3 ( $A_{1\%}^{1\text{cm}} = 193$ ).

**Dissolution.** Carry out the test as described under [5.5 Dissolution test for solid oral dosage forms](#).