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

Indometacin Capsules

General Notices

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Indometacin Capsules contain Indometacin.

The capsules comply with the requirements stated under Capsules and with the following requirements.

Content of indometacin, $C_{19}H_{16}ClNO_4$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Shake a quantity of the contents of the capsules containing 0.1 g of Indometacin with 5 mL of *chloroform*, filter and evaporate the filtrate to dryness. Dry the residue at 60° at a pressure not exceeding 0.7 kPa for 1 hour. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of indometacin *(RS 187)*.
B. The *light absorption*, Appendix II B, in the range 300 to 350 nm of the solution obtained in the Assay exhibits a maximum only at 320 nm.
C. Mix a quantity of the contents of the capsules containing 25 mg of Indometacin with 2 mL of *water* and add 2 mL of 2M *sodium hydroxide*. A bright yellow colour is produced which fades rapidly.

TESTS

Dissolution

Comply with the requirements for Monographs of the British Pharmacopoeia in the *dissolution test for tablets and capsules*, Appendix XII B1.

TEST CONDITIONS

(a) Use Apparatus 2, rotating the paddle at 50 revolutions per minute.
(b) Use 900 mL of *phosphate buffer pH 7.2*, at a temperature of 37°, as the medium.

PROCEDURE

(1) Withdraw a 10 mL sample of the medium and measure the *absorbance* of the filtered sample, suitably diluted with the dissolution medium if necessary, at the maximum at 320 nm, Appendix II B using *phosphate buffer pH 7.2* in the reference cell.

DETERMINATION OF CONTENT

Calculate the total content of indometacin, $C_{19}H_{16}ClNO_4$, in the medium taking 196 as the value of A(1%, 1 cm) at the maximum at 320 nm.

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Shake a quantity of the contents of the capsules containing 0.10 g of Indometacin with 5 mL of *chloroform*, filter and use the filtrate.
(2) Dilute 1 volume of solution (1) to 200 volumes with *chloroform*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a suspension of *silica gel* HF_{254} in a 4.68% w/v solution of *sodium dihydrogen orthophosphate* to coat the plate.
(b) Use the mobile phase as described below.
(c) Apply 5 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

30 volumes of *petroleum spirit (boiling range, 60° to 80°)* and 70 volumes of *ether*.

LIMITS

Any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2).

ASSAY

To a quantity of the mixed contents of 20 capsules containing 50 mg of Indometacin add 10 mL of *water* and allow to stand for 10 minutes, swirling occasionally. Add 75 mL of *methanol*, shake well, add sufficient *methanol* to produce 100 mL and filter if necessary. To 5 mL of the filtrate add sufficient of a mixture of equal volumes of *methanol* and *phosphate buffer pH 7.2* to produce 100 mL. Measure the *absorbance* of the resulting solution at the maximum at 320 nm, Appendix II B. Calculate the content of $C_{19}H_{16}ClNO_4$ taking 193 as the value of A(1%, 1 cm) at the maximum at 320 nm.