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

Mefenamic Acid Tablets

General Notices

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Mefenamic Acid Tablets contain Mefenamic Acid.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of mefenamic acid, $C_{15}H_{15}NO_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Extract a quantity of the powdered tablets containing 0.25 g of Mefenamic Acid with two 30-mL quantities of *ether*. Wash the combined extracts with *water*, evaporate to dryness on a water bath and dry the residue at 105°. Dissolve a sufficient quantity in the minimum volume of *absolute ethanol* and evaporate to dryness on a water bath. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of mefenamic acid *(RS 210)*.

TESTS

2,3-Dimethylaniline

Carry out the method for *thin-layer chromatography*, Appendix III A, using a *TLC silica gel G plate* and a mixture of 1 volume of 18M *ammonia*, 25 volumes of *1,4-dioxan* and 90 volumes of *toluene* as the mobile phase. Apply separately to the plate 40 µL of each of the following solutions. For solution (1) shake a quantity of the powdered tablets containing 0.25 g of Mefenamic Acid with a mixture of 7.5 mL of *dichloromethane* and 2.5 mL of *methanol* for 10 minutes, centrifuge and use the supernatant liquid. Solution (2) contains 0.00025% w/v of *2,3-dimethyl-aniline* in a mixture of 3 volumes of *dichloromethane* and 1 volume of *methanol*. After removal of the plate, dry it in a current of warm air and visualise by *Method I*. Any spot corresponding to 2,3-dimethylaniline in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (100 ppm).

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using a *TLC silica gel GF_{254} plate* and a mixture of 1 volume of *glacial acetic acid*, 25 volumes of *1,4-dioxan* and 90 volumes of *toluene* as the mobile phase. Apply separately to the plate 20 µL of each of the following solutions. For solution (1) use the supernatant liquid obtained in the test for 2,3-Dimethylaniline. For solution (2) dilute 1 volume of solution (1) to 500 volumes with a mixture of 3 volumes of *dichloromethane* and 1 volume of *methanol*. After removal of the plate, allow it to dry in air, expose to iodine vapour for 5 minutes and examine under *ultraviolet light (254 nm)*. Any *secondary spot* in the chromatogram obtained with solution (1)

is not more intense than the spot in the chromatogram obtained with solution (2) (0.2%). Disregard any spot with an Rf value of 0.04 or less.

ASSAY

Weigh and powder 20 tablets. Dissolve a quantity of the powdered tablets containing 0.5 g of Mefenamic Acid in about 80 mL of warm *absolute ethanol* previously neutralised to *phenol red solution* alternating between heating and ultrasound to aid dissolution. Cool, add sufficient of the neutralised absolute ethanol to produce 100 mL, mix well and titrate with *0.1M sodium hydroxide VS* using *phenol red solution* as indicator. Each mL of *0.1M sodium hydroxide VS* is equivalent to 24.13 mg of $C_{15}H_{15}NO_2$.