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

Flavoxate Tablets

General Notices

Action and use

Anticholinergic.

DEFINITION

Flavoxate Tablets contain Flavoxate Hydrochloride. They are coated.

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

Content of flavoxate hydrochloride, $C_{24}H_{25}NO_4$,HCl

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Extract a quantity of the powdered tablets containing 0.2 g of Flavoxate Hydrochloride with 10 mL of *dichloromethane*, filter and evaporate the filtrate to dryness. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of flavoxate hydrochloride *(RS 143)*.
B. In the test for Related substances, the principal spot in the chromatogram obtained with solution (5) corresponds to that in the chromatogram obtained with solution (6).

TESTS

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Shake a quantity of the powdered tablets containing 0.2 g of Flavoxate Hydrochloride with 10 mL of *chloroform* and filter.
(2) 0.03% w/v of *flavoxate impurity A EPCRS* in *chloroform*.
(3) 0.015% w/v of *flavoxate impurity B EPCRS* in *chloroform*.
(4) Dilute 1 volume of solution (1) to 500 volumes with *chloroform*.
(5) Dilute 1 volume of solution (1) to 20 volumes with *chloroform*.
(6) 0.1% w/v of *flavoxate hydrochloride BPCRS* in *chloroform*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel* GF_{254}.
(b) Use the mobile phase as described below.
(c) Apply 50 µL of solution (1). Apply 10 µL of solutions (2), (3), (5), and (6). Apply 25 µL of solution (4).
(d) Develop the plate to 15 cm.
(e) After removal of the plate, allow it to dry in air and examine immediately under *ultraviolet light (254 nm)*.

MOBILE PHASE

1 volume of 18M *ammonia*, 80 volumes of *propan-2-ol* and 200 volumes of *ethyl acetate*.

LIMITS

Any spot corresponding to impurity B in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (3) (0.15%);

any other *secondary spot* in the chromatogram obtained with solution (1), other than the spot corresponding to impurity A, is not more intense than the spot in the chromatogram obtained with solution (4) (0.1%).

Impurity A

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Shake a quantity of the powdered tablets containing 0.2 g of Flavoxate Hydrochloride with 10 mL of *chloroform* and filter.
(2) 0.01% w/v solution of *flavoxate impurity A EPCRS* in *chloroform*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel GF$_{254}$* (Merck silica gel 60 F_{254} plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 50 µL of each solution (1).
(d) Develop the plate to 15 cm.
(e) After removal of the plate, allow it to dry in air and spray with *dilute potassium iodobismuthate solution*.

MOBILE PHASE

4 volumes of *glacial acetic acid*, 25 volumes of *ethyl acetate* and 70 volumes of *cyclohexane*.

LIMITS

Any spot corresponding to impurity A in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (0.5%).

ASSAY

Weigh and finely powder 20 tablets. To a quantity of the powdered tablets containing 1 g of Flavoxate Hydrochloride add 600 mL of 0.1M *hydrochloric acid* and disperse with the aid of ultrasound for 10 minutes. Place in a water bath at 70° for 90 minutes, cool, add sufficient 0.1M *hydrochloric acid* to produce 1 litre and filter. Dilute 5 mL to 250 mL with 0.1M *hydrochloric acid* and measure the *absorbance* of the resulting solution at 293 nm, Appendix II B. Calculate the content of $C_{24}H_{25}NO_4$,HCl from the absorbance obtained by repeating the measurement using a 0.002% w/v solution of *flavoxate hydrochloride BPCRS* in 0.1M *hydrochloric acid* *and* from the declared content of $C_{24}H_{25}NO_4$,HCl in *flavoxate hydrochloride BPCRS*.

STORAGE

Flavoxate Tablets should be protected from light.

IMPURITIES

The impurities limited by the requirements of this monograph include impurities A and B listed under Flavoxate Hydrochloride.