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

Inositol Nicotinate Tablets

General Notices

Action and use

Vasodilator.

DEFINITION

Inositol Nicotinate Tablets contain Inositol Nicotinate.

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

Content of inositol nicotinate, $C_{42}H_{30}N_6O_{12}$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Shake a quantity of the powdered tablets containing 1 g of Inositol Nicotinate with 30 mL of a mixture of 9 volumes of *chloroform* and 1 volume of *methanol*, filter and evaporate to dryness. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of inositol nicotinate *(RS 190)*. Retain the remainder of the residue for use in the Related substances test.

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 1M *hydrochloric acid*, at a temperature of 37°, as the medium.

PROCEDURE

(1) After 45 minutes withdraw a 20 mL sample of the medium and filter.
(2) Measure the *absorbance* of the filtrate, Appendix II B, diluted with 1M *hydrochloric acid* if necessary, at the maximum at 262 nm using 1M *hydrochloric acid* in the reference cell.

DETERMINATION OF CONTENT

Calculate the total content of inositol nicotinate, $C_{42}H_{30}N_6O_{12}$, in the medium taking 398 as the value of A(1%, 1 cm) at the maximum at 262 nm.

Free nicotinic acid

To a quantity of the powdered tablets containing 1 g of Inositol Nicotinate add 75 mL of *water*, shake for 15 minutes and titrate with *0.02M sodium hydroxide VS* using *phenolphthalein solution R1* as indicator. Not more than 1.0 mL of *0.02M sodium hydroxide VS* is required to produce the first pink colour.

Related substances

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

(1) 5.0% w/v of the residue obtained in test A for Identification in a mixture of 1 volume of *methanol* and 9 volumes of *chloroform*.
(2) 0.075% w/v of the residue obtained in test A for Identification in a mixture of 1 volume of *methanol* and 9 volumes of *chloroform*.
(3) 0.050% w/v of the residue obtained in test A for Identification in a mixture of 1 volume of *methanol* and 9 volumes of *chloroform*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as a plate 200 mm × 200 mm in size and *silica gel* GF_{254} as the coating substance.
(b) Use the mobile phase as described below for the first development.
(c) Apply to the bottom right-hand corner of the plate 5 µL of solution (1).
(d) Develop the plate to 12 cm.
(e) After removal of the plate, allow it to dry in air and turn the plate through 90° in a clockwise direction.
(f) Use the mobile phase as described below for the second development.
(g) Apply separately to the bottom right-hand corner of the plate, and to the right of the solvent front, 5 µL of solutions (2) and (3).
(h) After removal of the plate, allow it to dry in air and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

For the first development: 10 volumes of *methanol* and 90 volumes of *chloroform*.

For the second development: 5 volumes each of *glacial acetic acid*, *ethanol (96%)* and *water* and 50 volumes of *ethyl acetate*.

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) (1.5%) and not more than one such spot is more intense than the spot in the chromatogram obtained with solution (3) (1%).

ASSAY

Weigh and powder 20 tablets. To a quantity of the powdered tablets containing 0.25 g of Inositol Nicotinate add 50 mL of *anhydrous acetic acid*, heat to boiling and allow to cool. Carry out Method I for *non-aqueous titration*, Appendix VIII A, using *1-naphtholbenzein solution* as indicator. Each mL of *0.1M perchloric acid VS* is equivalent to 13.51 mg of $C_{42}H_{30}N_6O_{12}$.