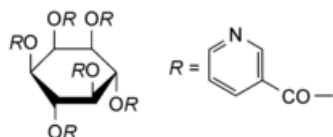




Edition: BP 2025 (Ph. Eur. 11.6 update)

## Inositol Nicotinate

### [General Notices](#)



$C_{42}H_{30}N_6O_{12}$  810.7 6556-11-2

### Action and use

Vasodilator.

### Preparation

#### [Inositol Nicotinate Tablets](#)

## DEFINITION

Inositol Nicotinate is *myo*-inositol hexanicotinate. It contains not less than 98.0% and not more than 101.0% of  $C_{42}H_{30}N_6O_{12}$ , calculated with reference to the dried substance.

## CHARACTERISTICS

A white or almost white powder.

Practically insoluble in [water](#); practically insoluble in [acetone](#), in [ethanol \(96%\)](#) and in [ether](#). It dissolves in dilute mineral acids.

## IDENTIFICATION

The [infrared absorption spectrum](#), [Appendix II A](#), is concordant with the *reference spectrum* of inositol nicotinate ([RS 190](#)).

## TESTS

### Clarity and colour of solution

A 5.0% w/v solution in 0.5M [sulfuric acid](#) is *clear*, [Appendix IV A](#), and not more intensely coloured than *reference solution* BY<sub>6</sub>, [Appendix IV B](#), Method II.

## Chloride

Dissolve 0.14 g in a sufficient quantity of 2M [nitric acid](#) and dilute to 16 mL with [water](#). The resulting solution complies with the [limit test for chlorides, Appendix VII](#), beginning at the words 'pour the mixture as a single addition...' (350 ppm).

## Free nicotinic acid

To 1 g 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 0.8 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 a plate 200 mm × 200 mm in size and [silica gel GF<sub>254</sub>](#) as the coating substance. For the first development use a mixture of 90 volumes of [chloroform](#) and 10 volumes of [methanol](#) as the mobile phase. Apply to the bottom right-hand corner of the plate 5 µL of solution (1) containing 5.0% w/v of the substance being examined in a mixture of 9 volumes of [chloroform](#) and 1 volume of [methanol](#) and develop over a path of 12 cm. After removal of the plate, allow it to dry in air and turn the plate through 90° in a clockwise direction. Apply separately to the bottom right-hand corner of the plate, and to the right of the solvent front, 5 µL of each of two solutions of the substance being examined in a mixture of 9 volumes of [chloroform](#) and 1 volume of [methanol](#) containing (2) 0.075% w/v and (3) 0.050% w/v. For the second development use a mixture of 50 volumes of [ethyl acetate](#) and 5 volumes each of [glacial acetic acid](#), [ethanol \(96%\)](#) and [water](#) as the mobile phase. After removal of the plate, allow it to dry in air and examine under [ultraviolet light \(254 nm\)](#). In the chromatogram obtained with solution (1) any [secondary spot](#) 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%).

## Acetone

Prepare a 0.020% v/v solution of [butan-2-one](#) (internal standard) in [dimethylformamide](#) (solution A). Carry out the method for [gas chromatography, Appendix III B](#), using the following solutions. Solution (1) contains 0.020% v/v of [acetone](#) in solution A. For solution (2) add 5 mL of [dimethylformamide](#) to 0.20 g of the substance being examined contained in a suitable vessel, stopper securely, suspend in a water bath until solution is complete and allow to cool. Prepare solution (3) in the same manner as solution (2) but using 5 mL of solution A in place of the dimethylformamide.

The chromatographic procedure may be carried out using a glass column (1.5 m × 4 mm) packed with [acid-washed, silanised diatomaceous support](#) coated with 10% w/w of polyethylene glycol 1000 and maintained at 60°.

In the chromatogram obtained with solution (3) the ratio of the area of any peak corresponding to acetone to the area of the peak due to the internal standard is not greater than the corresponding ratio in the chromatogram obtained with solution (1).

## Loss on drying

When dried to constant weight at 105°, loses not more than 0.5% of its weight. Use 1 g.

## Sulfated ash

Not more than 0.1%, [Appendix IX A](#).

## ASSAY

Carry out Method I for [non-aqueous titration, Appendix VIII A](#), using 0.2 g and [1-naphtholbenzein solution](#) as indicator. Each mL of [0.1M perchloric acid VS](#) is equivalent to 13.51 mg of C<sub>42</sub>H<sub>30</sub>N<sub>6</sub>O<sub>12</sub>.

