Quality standards

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

Nicotinic Acid Tablets

General Notices

Action and use

Component of vitamin B.

DEFINITION

Nicotinic Acid Tablets contain Nicotinic Acid.

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

Content of nicotinic acid, C₆H₅NO₂

92.5 to 107.5% of the stated amount.

IDENTIFICATION

- A. Carry out the method for *thin-layer chromatography*, <u>Appendix III A</u>, using *silica gel GF*₂₅₄ as the coating substance and a mixture of 8 volumes of *water*, 45 volumes of *ethanol* (96%) and 48 volumes of *chloroform* as the mobile phase. Apply separately to the plate 5 µL of each of the following solutions. For solution (1) shake a quantity of the powdered tablets containing 50 mg of Nicotinic Acid with 50 mL of hot *ethanol* (96%), filter and allow the filtrate to cool. Solution (2) contains 0.1% w/v of *nicotinic acid* in *ethanol* (96%). After removal of the plate, allow it to dry in air and examine under *ultraviolet light* (254 nm). The spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).
- B. Shake a quantity of the powdered tablets containing 0.1 g of Nicotinic Acid with <u>ethanol (96%)</u>, filter and evaporate the filtrate to dryness. To the residue add 10 mg of <u>citric acid</u> and 0.15 mL of <u>acetic anhydride</u> and heat on a water bath. A reddish-violet colour is produced.
- C. Triturate a quantity of the powdered tablets containing 50 mg of Nicotinic Acid with 10 mL of <u>water</u> and filter. To 2 mL of the filtrate add 6 mL of <u>cyanogen bromide solution</u> and 1 mL of a 2.5% v/v solution of <u>aniline</u>. A golden yellow colour is produced.

ASSAY

Weigh and powder 20 tablets. To a quantity of the powder containing 0.3 g of Nicotinic Acid add 40 mL of hot <u>ethanol</u> (96%), previously neutralised to <u>phenolphthalein solution R1</u>, and shake. Allow to stand for 15 minutes, swirling occasionally, and then shake for 10 minutes. Filter through absorbent cotton and wash the filter with <u>ethanol</u> (96%). Add 50 mL of <u>carbon dioxide-free water</u> and titrate with <u>0.1M sodium hydroxide VS</u> using <u>phenol red solution</u> as indicator. Each mL of <u>0.1M sodium hydroxide VS</u> is equivalent to 12.31 mg of $C_6H_5NO_2$.

