



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

Nicotinamide Tablets

[General Notices](#)

Action and use

Component of vitamin B.

DEFINITION

Nicotinamide Tablets contain Nicotinamide.

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

Content of nicotinamide, $C_6H_6N_2O$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

- A. Shake a quantity of the powdered tablets containing 0.1 g of Nicotinamide with 25 mL of [absolute ethanol](#) for 15 minutes, filter and evaporate the filtrate to dryness on a water bath. The [infrared absorption spectrum](#) of the residue, [Appendix II A](#), is concordant with the *reference spectrum* of nicotinamide ([RS 246](#)).
- B. The [light absorption](#) of the solution obtained in the Assay, [Appendix II B](#), in the range 230 to 350 nm exhibits a maximum only at 262 nm and two shoulders, at 258 nm and 269 nm.
- C. Shake a quantity of the powdered tablets containing 50 mg of Nicotinamide with 50 mL of [water](#) and filter. To 2 mL of the filtrate add 2 mL of [cyanogen bromide solution](#) and 3 mL of a 2.5% v/v solution of [aniline](#) and shake. A yellow colour is produced.

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 0.1 g of Nicotinamide with 15 mL of [absolute ethanol](#), filter, evaporate to dryness on a water bath and dissolve the residue as completely as possible in 1 mL of [absolute ethanol](#).
- (2) Dilute 1 volume of solution (1) to 400 volumes with [absolute ethanol](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a silica gel F₂₅₄ precoated plate (Merck [silica gel 60 F₂₅₄](#) plates are suitable).
- (b) Use the mobile phase as described below.
- (c) Apply 5 µL of each solution.
- (d) Develop the plate to 10 cm.
- (e) After removal of the plate, dry in air and examine under [ultraviolet light \(254 nm\)](#).

MOBILE PHASE

10 volumes of [water](#), 45 volumes of [ethanol \(96%\)](#) and 48 volumes of [chloroform](#).

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) (0.25%).

ASSAY

Weigh and powder 20 tablets. Shake a quantity of the powder containing 50 mg of Nicotinamide with 50 mL of [ethanol \(96%\)](#), dilute to 100 mL with [ethanol \(96%\)](#) and filter. Dilute 5 mL of the filtrate to 100 mL with [ethanol \(96%\)](#) and measure the [absorbance](#) of the resulting solution at the maximum at 262 nm, [Appendix II B](#). Calculate the content of $C_6H_6N_2O$ taking 241 as the value of A(1%, 1 cm) at the maximum at 262 nm.

STORAGE

Nicotinamide Tablets should be protected from light.