



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

Nitrofurantoin Tablets

[General Notices](#)

Action and use

Antibacterial.

DEFINITION

Nitrofurantoin Tablets contain Nitrofurantoin.

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

Content of nitrofurantoin, $C_8H_6N_4O_5$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

The [light absorption](#), [Appendix II B](#), in the range 220 to 400 nm of the final solution obtained in the Assay exhibits two maxima, at 266 nm and 367 nm.

Related substances

Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using [silica gel](#) HF_{254} as the coating substance and a mixture of 10 volumes of [methanol](#) and 90 volumes of [nitromethane](#) as the mobile phase. Apply separately to the plate 10 µL of each of the following solutions. For solution (1) shake a quantity of the powdered tablets containing 0.1 g of Nitrofurantoin with 10 mL of a mixture of 1 volume of [dimethylformamide](#) and 9 volumes of [acetone](#) and filter. For solution (2) dilute 1 volume of solution (1) to 100 volumes with [acetone](#). After removal of the plate, allow it to dry in air, heat at 100° to 105° for 5 minutes and examine under [ultraviolet light \(254 nm\)](#). Spray the plate with [phenylhydrazine hydrochloride solution](#) and heat it at 100° to 105° for a further 10 minutes. By each method of visualisation, 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%).

ASSAY

Carry out the following procedure in subdued light. Weigh and powder 20 tablets. To a quantity of the powder containing 0.12 g of Nitrofurantoin add 50 mL of [dimethylformamide](#), shake for 5 minutes, add sufficient [water](#) to produce 1000 mL and mix. Dilute 5 mL to 100 mL with a solution containing 1.8% w/v of [sodium acetate](#) and 0.14% v/v of [glacial acetic acid](#) and filter. Measure the [absorbance](#) of the filtrate at the maximum at 367 nm, [Appendix II B](#), using the sodium acetate-acetic acid solution in the reference cell. Calculate the content of $C_8H_6N_4O_5$ taking 765 as the value of $A(1\%, 1\text{ cm})$ at 367 nm.

STORAGE

Nitrofurantoin Tablets should be protected from light.