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

Nalidixic Acid Tablets

General Notices

Action and use

Quinolone antibacterial.

DEFINITION

Nalidixic Acid Tablets contain Nalidixic Acid.

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

Content of nalidixic acid, $C_{12}H_{12}N_2O_3$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

To a quantity of the powdered tablets containing 1 g of Nalidixic Acid add 50 mL of *chloroform*, shake for 15 minutes, filter and evaporate the filtrate to dryness. The residue, after drying at 105°, complies with the following tests.

A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of nalidixic acid *(RS 241)*.
B. The *light absorption*, Appendix II B, in the range 230 to 350 nm of a 0.0008% w/v solution in 0.1M *sodium hydroxide* exhibits maxima at 258 nm and 334 nm.
C. *Melting point*, about 228°, Appendix V A.

TESTS

Dissolution

Comply with the requirements for Monographs of the British Pharmacopoeia in the *dissolution test for tablets and capsules*, Appendix XII B1, using Apparatus 2. Rotate the paddle at 60 revolutions per minute and use as the medium 900 mL of a methanolic phosphate buffer prepared in the following manner: mix 2.3 volumes of 0.2M *sodium hydroxide* with 2.5 volumes of 0.2M *potassium dihydrogen orthophosphate* and 2.0 volumes of *methanol*, dilute to 10 volumes with *water* and, if necessary, adjust the pH to 8.6 using 1M *sodium hydroxide*. Withdraw a sample of 10 mL of the medium, filter and measure the *absorbance* of the solution, suitably diluted if necessary, at the maximum at 334 nm, Appendix II B. Calculate the total content of nalidixic acid, $C_{12}H_{12}N_2O_3$, in the medium taking 494 as the value of A(1%, 1 cm) at the maximum at 334 nm.

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using *silica gel* GF_{254} as the coating substance and a mixture of 10 volumes of 5M *ammonia*, 20 volumes of *dichloromethane* and 70 volumes of *ethanol (96%)* 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 0.10 g of Nalidixic Acid with 50 mL of *dichloromethane* for 15 minutes, filter, evaporate to dryness and dissolve the residue in 5 mL of *dichloromethane*. For solution (2) dilute 1 volume of solution (1) to 200 volumes with *dichloromethane* and further dilute 1 volume of the resulting solution to 2 volumes with *dichloromethane*. For solution (3) dilute 1 volume of solution (2) to 2.5 volumes with *dichloromethane*. After removal of the plate, allow it to dry in air and examine under *ultraviolet light (254 nm)*. 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%) and not more than one such spot is more intense than the spot in the chromatogram obtained with solution (3) (0.1%).

ASSAY

Weigh and powder 20 tablets. To a quantity of the powdered tablets containing 0.1 g of Nalidixic Acid add 150 mL of 1M *sodium hydroxide*, shake for 3 minutes, dilute to 200 mL with 1M *sodium hydroxide*, mix and allow to stand for 15 minutes. Dilute 2 mL to 200 mL with *water* and measure the *absorbance* of the resulting solution at the maximum at 334 nm, Appendix II B, using 0.01M *sodium hydroxide* in the reference cell. Calculate the content of $C_{12}H_{12}N_2O_3$ taking 494 as the value of A(1%, 1 cm) at the maximum at 334 nm.

STORAGE

Nalidixic Acid Tablets should be protected from light.