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Nalidixic Acid Oral Suspension

General Notices

Action and use

Quinolone antibacterial.

DEFINITION

Nalidixic Acid Oral Suspension is a suspension of Nalidixic Acid in a suitable flavoured vehicle.

The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements.

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

92.5 to 107.5% of the stated amount.

IDENTIFICATION

To 5 mL add 30 mL of *water* and 20 mL of *dilute sodium carbonate solution*, mix and shake with two 30 mL quantities of *chloroform*; discard the chloroform layers. Acidify the aqueous solution with 5M *hydrochloric acid*, shake with 40 mL of *chloroform*, wash the chloroform layer with 10 mL of *water* to which has been added 0.5 mL of 5M *hydrochloric acid*, filter the chloroform layer through absorbent cotton and evaporate the filtrate to dryness. Dissolve the residue in sufficient 0.1M *sodium hydroxide* to produce a solution containing 0.0008% w/v of Nalidixic Acid. The *light absorption* of the solution, Appendix II B, in the range 230 to 350 nm exhibits two maxima, at 258 nm and 334 nm.

ASSAY

Dilute a weighed quantity containing 0.12 g of Nalidixic Acid to 100 mL with 0.01M *sodium hydroxide*, dilute 2 mL to 250 mL with 0.01M *sodium hydroxide* and measure the *absorbance* of the resulting solution at the maximum at 334 nm, Appendix II B. Determine the *weight per mL* of the oral suspension, Appendix V G, and calculate the content of $C_{12}H_{12}N_2O_3$, weight in volume, taking 494 as the value of A(1%, 1 cm) at the maximum at 334 nm.