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Nitrofurantoin Oral Suspension

General Notices

Action and use

Antibacterial.

DEFINITION

Nitrofurantoin Oral Suspension is a suspension of Nitrofurantoin in a suitable flavoured vehicle.

Nitrofurantoin Oral Suspension should not be diluted.

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

Content of nitrofurantoin, $C_8H_6N_4O_5$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. The *light absorption*, Appendix II B, in the range 300 to 400 nm, of the final solution obtained in the Assay exhibits a maximum at 367 nm.
B. Dissolve 5 mg of the residue obtained by centrifuging a quantity of the oral suspension containing 50 mg of Nitrofurantoin in 5 mL of 0.1M *sodium hydroxide*. A deep yellow solution is produced, which changes to deep orange-red.

ASSAY

Carry out the following procedure in subdued light. To a weighed quantity containing 30 mg of Nitrofurantoin add, in successive small volumes, 50 mL of *dimethylformamide*, stirring well between each addition. Continue stirring until the sample is completely dissolved and dilute to 500 mL with an aqueous solution containing 1.8% w/v of *sodium acetate* and 0.14% v/v of *glacial acetic acid*. Dilute 10 mL of this solution to 100 mL with the sodium acetate-acetic acid solution and measure the *absorbance* of the resulting solution at the maximum at 367 nm, Appendix II B, using in the reference cell a 1% v/v solution of *dimethylformamide* in the sodium acetate-acetic acid solution. Calculate the content of $C_8H_6N_4O_5$ taking 765 as the value of A(1%, 1 cm) at the maximum at 367 nm. Determine the *weight per mL* of the oral suspension, Appendix V G, and calculate the content of $C_8H_6N_4O_5$, weight in volume.

STORAGE

Nitrofurantoin Oral Suspension should be protected from light.