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Hydrocortisone Acetate and Neomycin Ear Drops

[General Notices](#)

Hydrocortisone and Neomycin Ear Drops

Action and use

Corticosteroid + Aminoglycoside antibacterial.

DEFINITION

Hydrocortisone Acetate and Neomycin Ear Drops are a suspension of Hydrocortisone Acetate in a solution of Neomycin Sulfate in Purified Water.

The ear drops comply with the requirements stated under Ear Preparations and with the following requirements.

Content of [hydrocortisone acetate](#), $C_{23}H_{32}O_6$

90.0 to 110.0% w/v of the stated amount.

IDENTIFICATION

- A. Comply with test A for Identification described under [Hydrocortisone and Neomycin Cream](#) using the following solutions. For solution (1) add 10 mL of [chloroform](#) to a quantity of the ear drops containing 5 mg of [Hydrocortisone Acetate](#) in a separating funnel, shake for 2 to 3 minutes and allow the layers to separate. Filter if necessary and use the chloroform layer. Solution (2) contains 0.05% w/v of [hydrocortisone acetate](#) BPCRS in [chloroform](#).
- B. In the Assay for [hydrocortisone acetate](#) the chromatogram obtained with solution (3) shows a peak with the same retention time as the peak due to [hydrocortisone acetate](#) in the chromatogram obtained with solution (1).
- C. Comply with test C for Identification described under [Hydrocortisone and Neomycin Cream](#). For solution (1) dilute a volume containing 3500 IU of Neomycin Sulfate with [water](#) to 2.5 mL, shake with 3 mL of [chloroform](#), centrifuge and use the clear, upper layer.

TESTS

Acidity or alkalinity

pH, 6.5 to 8.0, [Appendix V L](#).

Neamine

Comply with the test described under [Hydrocortisone and Neomycin Cream](#). For solution (1) dilute a volume containing 3500 IU of Neomycin Sulfate with 2.5 mL of [water](#), shake gently with 3 mL of [chloroform](#), centrifuge and use the aqueous layer.

Neomycin C

Comply with the test described under [Hydrocortisone and Neomycin Cream](#) but using as solution (2) a solution prepared in the following manner. Dilute the ear drops with 0.02M [sodium tetraborate](#) to contain 700 IU per mL. To 0.5 mL of the resulting solution add 1.5 mL of a freshly prepared 2% w/v solution of [1-fluoro-2,4-dinitrobenzene](#) in [methanol](#), heat in a water bath at 60° for 1 hour, cool and dilute the solution to 25 mL with the mobile phase; allow to stand and use the clear, lower layer.

ASSAY

For [hydrocortisone acetate](#)

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions. Solution (1) contains 0.020% w/v of [hydrocortisone acetate](#) BPCRS and 0.016% w/v of [fluoxymesterone](#) BPCRS (internal standard) in [chloroform](#). For solution (2) shake a quantity of the ear drops containing 10 mg of [Hydrocortisone Acetate](#) with 25 mL of a 0.032% w/v solution of [fluoxymesterone](#) BPCRS in [chloroform](#), add 25 mL of [chloroform](#), mix and filter through [anhydrous sodium sulfate](#).

The chromatographic procedure may be carried out using (a) a stainless steel column (30 cm × 3.9 mm) packed with [silica gel for chromatography](#) (10 µm) (µPorasil is suitable), (b) a mixture of 425 volumes of [butyl chloride](#), 425 volumes of [butyl chloride](#) saturated with [water](#), 70 volumes of [tetrahydrofuran](#), 35 volumes of [methanol](#) and 30 volumes of [glacial acetic acid](#) as the mobile phase with a flow rate of 1 mL per minute and (c) a detection wavelength of 254 nm.

Calculate the content of $C_{23}H_{32}O_6$ in the ear drops using the declared content of $C_{23}H_{32}O_6$ in [hydrocortisone acetate](#) BPCRS.

For neomycin sulfate

Dilute a volume containing 3500 IU to 50 mL with sterile [phosphate buffer pH 8.0](#), dilute 10 mL of the resulting solution to 100 mL with the same solvent and carry out the [microbiological assay of antibiotics, Appendix XIV A](#). The precision of the assay is such that the fiducial limits of error are not less than 95% and not more than 105% of the estimated potency. The upper fiducial limit of error is not less than 90.0% and the lower fiducial limit of error is not more than 115.0% of the stated number of IU per mL.

LABELLING

The strength with respect to Neomycin Sulfate is stated as the number of IU (Units) per mL.