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Hydrocortisone Acetate and Neomycin Eye Drops

General Notices

Hydrocortisone and Neomycin Eye Drops

Action and use

Corticosteroid + Aminoglycoside antibacterial.

DEFINITION

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

The eye drops comply with the requirements stated under Eye 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 eye 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 (2) 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 eye 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 eye 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 eye 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.