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Hydrocortisone Acetate and Neomycin Eye Ointment

General Notices

Action and use

Corticosteroid + Aminoglycoside antibacterial.

DEFINITION

Hydrocortisone Acetate and Neomycin Eye Ointment is a sterile preparation containing Hydrocortisone Acetate and Neomycin Sulfate in a suitable basis.

The eye ointment complies with the requirements stated under Eye Preparations and with the following requirements.

Content of hydrocortisone acetate, $C_{23}H_{32}O_6$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

A. Complies with test A for Identification described under Hydrocortisone and Neomycin Cream using the following solutions. For solution (1) add 10 mL of *hexane* saturated with *acetonitrile* to a quantity of the ointment containing 5 mg of Hydrocortisone Acetate and shake for 2 to 3 minutes. Add 10 mL of *acetonitrile* saturated with *hexane*, shake for 10 minutes and allow the layers to separate. Centrifuge, filter the acetonitrile layer if necessary, evaporate 5 mL to dryness and dissolve the residue in 5 mL of a mixture of equal volumes of *chloroform* and *ethanol (96%)*. Solution (2) contains 0.05% w/v of *hydrocortisone acetate BPCRS* in a mixture of equal volumes of *chloroform* and *ethanol (96%)*.
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. Complies with test C for Identification described under Hydrocortisone and Neomycin Cream. For solution (1) shake a quantity containing 7000 IU of Neomycin Sulfate with 10 mL of *chloroform*, add 5 mL of *water*, shake, centrifuge and use the clear, upper layer.

TESTS

Neamine

Complies with the test described under Hydrocortisone and Neomycin Cream. For solution (1) disperse a quantity containing 7000 IU of Neomycin Sulfate in 10 mL of *chloroform*, shake gently with 5 mL of *water*, centrifuge and use the aqueous layer.

Neomycin C

Complies with the test described under Hydrocortisone and Neomycin Cream.

ASSAY

For hydrocortisone acetate

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. Solution (1) contains 0.025% w/v of *hydrocortisone acetate BPCRS* and 0.050% w/v of *fluoxymesterone BPCRS* (internal standard) in *chloroform*. For solution (2) shake a quantity of the ointment containing 25 mg of Hydrocortisone Acetate with 20 mL of a 0.25% w/v solution of *fluoxymesterone BPCRS* in *chloroform* and several glass beads for 30 minutes. Centrifuge; to 10 mL of the clear, supernatant layer add sufficient *chloroform* to produce 50 mL.

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 ointment using the declared content of $C_{23}H_{32}O_6$ in *hydrocortisone acetate BPCRS*.

For neomycin sulfate

Dissolve a quantity containing 3500 IU in 50 mL of *ether*, extract the solution with three 30-mL quantities of sterile *phosphate buffer pH 8.0* and discard the ether phase. Pass *nitrogen* through the combined aqueous extracts to remove dissolved ether, dilute to 100 mL with sterile *phosphate buffer pH 8.0* 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 g.

LABELLING

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