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# Hydrocortisone Acetate Oral Suspension

General Notices

*NOTE: This monograph has been developed to cover unlicensed formulations.*

**Action and use**

Corticosteroid.

## DEFINITION

Hydrocortisone Acetate Oral Suspension is a suspension of Hydrocortisone Acetate in a suitable flavoured aqueous vehicle.

*The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements. Where appropriate, the oral suspension also complies with the requirements stated under Unlicensed Medicines.*

**Content of hydrocortisone, $C_{21}H_{30}O_5$**

95.0 to 105.0% of the stated amount.

*The oral suspension should be shaken vigorously before carrying out the following tests.*

## IDENTIFICATION

A. Filter a volume of the oral suspension containing the equivalent of 50 mg of hydrocortisone through a sintered-glass filter, wash the residue with four 5-mL quantities of *water*, dissolve in 20 mL of *dichloromethane*, wash the dichloromethane solution with four 10-mL quantities of *water*, discard the washings, filter the dichloromethane solution through absorbent cotton and evaporate the filtrate to dryness. The residue complies with the test for *identification of steroids*, Appendix III A, using *impregnating solvent I* and *mobile phase B*.
B. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) corresponds to that of the principal peak in the chromatogram obtained with solution (2).
C. The residue obtained in test A yields the reaction characteristic of *acetyl groups*, Appendix VI.

## TESTS

**Dissolution**

Complies with the requirements stated under Unlicensed Medicines, Oral Suspensions. Use a volume of the oral suspension containing one dose.

## ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) To a weighed quantity of the oral suspension containing the equivalent of 10 mg of hydrocortisone add 50 mL of *methanol*, mix with the aid of ultrasound, dilute to 100 mL with *methanol* and filter (Whatman No. 1 paper is suitable).

(2) 0.01% w/v of *hydrocortisone BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Nucleosil C18 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 240 nm.
(f) Inject 10 µL of each solution.

MOBILE PHASE

4 volumes of a 1% w/v solution of *acetic acid* in *water* and 6 volumes of *methanol*.

DETERMINATION OF CONTENT

Determine the *weight per mL* of the oral suspension, Appendix V G, and calculate the content of $C_{21}H_{30}O_5$, weight in volume, using the declared content of $C_{21}H_{30}O_5$ in *hydrocortisone BPCRS*.

## LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of hydrocortisone.