



Edition: BP 2025 (Ph. Eur. 11.6 update)

## Hydrocortisone Acetate Injection

### [General Notices](#)

### Action and use

Corticosteroid.

### DEFINITION

Hydrocortisone Acetate Injection is a sterile suspension of Hydrocortisone Acetate in Water for Injections. It is prepared using aseptic technique.

*The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.*

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

95.0 to 105.0% of the stated amount.

### IDENTIFICATION

Filter a volume containing 50 mg of [Hydrocortisone Acetate](#) through a sintered-glass filter, wash the residue with four 5-mL quantities of [water](#), dissolve in 20 mL of [chloroform](#), wash the chloroform solution with four 10-mL quantities of [water](#), discard the washings, filter the chloroform solution through absorbent cotton and evaporate the filtrate to dryness. The residue complies with the following tests.

- The [infrared absorption spectrum](#), [Appendix II A](#), is concordant with the *reference spectrum* of [hydrocortisone acetate \(RS 179\)](#).
- Complies with the test for [identification of steroids](#), [Appendix III A](#), using [impregnating solvent I](#) and *mobile phase B*.
- Yields the reaction characteristic of [acetyl groups](#), [Appendix VI](#).

### ASSAY

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions.

- To a volume of the injection containing 50 mg of [Hydrocortisone Acetate](#), add 70 mL of [methanol](#). Shake to produce a clear solution and dilute to 100 mL with [methanol](#). Dilute 10 mL of the resulting solution to 20 mL with [water](#).
- Dissolve 25 mg of [hydrocortisone acetate BPCRS](#) in 50 mL of [methanol](#) and add sufficient [water](#) to produce 100 mL.

#### CHROMATOGRAPHIC CONDITIONS

- Use a stainless steel column (10 cm × 5 mm) packed with [octadecylsilyl silica gel for chromatography](#) (5 μm) (Spherisorb ODS 1 is suitable).
- Use isocratic elution and the mobile phase described below.
- Use a flow rate of 2 mL per minute.
- Use an ambient column temperature.
- Use a detection wavelength of 240 nm.
- Inject 20 μL of each solution.

MOBILE PHASE

50 volumes of [methanol](#) and 50 volumes of [water](#).

DETERMINATION OF CONTENT

Calculate the content of  $C_{23}H_{32}O_6$  in the injection from the chromatograms obtained using the declared content of  $C_{23}H_{32}O_6$  in [hydrocortisone acetate](#) *BPCRS*.

## STORAGE

Hydrocortisone Acetate Injection should be protected from light.

## LABELLING

The label states (1) that it is intended for local action; (2) that the container should be gently shaken before a dose is withdrawn.