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

Cloprostenol Injection

General Notices

Action and use

Prostaglandin ($PGF_{2\alpha}$) analogue.

DEFINITION

Cloprostenol Injection is a sterile solution of Cloprostenol Sodium in Water for Injections.

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

Content of cloprostenol, $C_{22}H_{29}ClO_6$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the peak due to cloprostenol in the chromatogram obtained with solution (2).

Related substances

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

(1) Dilute the injection, if necessary, in *absolute ethanol* to contain the equivalent of 0.009% w/v of cloprostenol.
(2) 0.00018% w/v of *cloprostenol sodium BPCRS* in *absolute ethanol*.
(3) Dissolve 5 mg of *hydrocortisone acetate BPCRS* and 2.5 mg of *cloprostenol sodium BPCRS* in *absolute ethanol* and dilute to 10 mL with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 5 mm) packed with *base-deactivated octadecylsilyl silica gel for chromatography* (Waters Symmetry ODS is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.8 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 220 nm.
(f) Inject 20 µL of each solution.
(g) For solutions (1) and (2) allow the chromatography to proceed for 1.5 times the retention time of the principal peak.

MOBILE PHASE

270 volumes of *acetonitrile* and 730 volumes of a solution containing 0.24% w/v of *sodium dihydrogen orthophosphate* the pH of which has been adjusted to 2.5 with *orthophosphoric acid*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the peak due to hydrocortisone acetate (retention time about 25 minutes) and that of cloprostenol (retention time about 35 minutes) is at least 6.

LIMITS

In the chromatogram obtained with solution (1) the sum of the areas of any *secondary peaks* is not more than 1.25 times the area of the principal peak in the chromatogram obtained with solution (2) (2.5%).

ASSAY

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

(1) Dilute the injection, if necessary, in *absolute ethanol* to contain the equivalent of 0.009% w/v of cloprostenol.
(2) 0.009% w/v of *cloprostenol sodium BPCRS* in *absolute ethanol*.
(3) Dissolve 5 mg of *hydrocortisone acetate BPCRS* and 2.5 mg of *cloprostenol sodium BPCRS* in *absolute ethanol* and dilute to 10 mL with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the peak due to hydrocortisone acetate (retention time about 25 minutes) and that of cloprostenol (retention time about 35 minutes) is at least 6.

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{29}ClO_6$ in the injection using the declared content of $C_{22}H_{29}ClO_6$ in *cloprostenol sodium BPCRS*.

STORAGE

Cloprostenol Sodium Injection should be protected from light.

LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of cloprostenol in a suitable dose-volume.