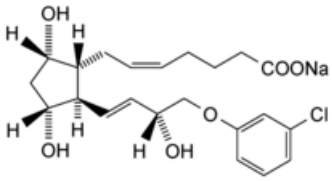
Edition: BP 2025 (Ph. Eur. 11.6 update)

Cloprostenol Sodium

General Notices



$C_{22}H_{28}ClNaO_6$ 446.9 *55028-72-3*

Action and use

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

Preparation

Cloprostenol Injection

DEFINITION

Cloprostenol Sodium is (±)-(5*Z*)-7-(1*R*,3*R*,5*S*)-2-[(1*E*,3*R*)-4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentylhept-5-enoate. It contains not less than 97.5% and not more than 102.5% of $C_{22}H_{28}ClNaO_6$, calculated with reference to the anhydrous substance.

CAUTION *Cloprostenol Sodium is extremely potent and extraordinary care should be taken in any procedure in which it is used*.

CHARACTERISTICS

A white or almost white, amorphous powder; hygroscopic.

Freely soluble in *water*, in *ethanol (96%)* and in *methanol*; practically insoluble in *acetone*.

IDENTIFICATION

A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of cloprostenol sodium *(RSV 11)*.
B. Yields reaction A characteristic of *sodium salts*, Appendix VI.

TESTS

Related substances

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

(1) 2.0% w/v of the substance being examined.
(2) 0.050% w/v of the substance being examined.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *silica gel for chromatography* (5 µm) (Partisil 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 5 µL of each solution.
(g) Allow the chromatography to proceed for twice the retention time of the peak due to Cloprostenol.

MOBILE PHASE

1 volume of *glacial acetic acid*, 70 volumes of *absolute ethanol* and 930 volumes of *hexane*.

LIMITS

In the chromatogram obtained with solution (1):

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

Water

Not more than 3.0% w/w, Appendix IX C. Use 50 mg dissolved in 1 mL of *absolute ethanol*.

ASSAY

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

(1) 0.08% w/v of the substance being examined.
(2) 0.08% w/v of *cloprostenol sodium BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *silica gel for chromatography* (5 µm) (Partisil 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 5 µL of each solution.

MOBILE PHASE

1 volume of *glacial acetic acid*, 100 volumes of *absolute ethanol* and 900 volumes of *hexane*.

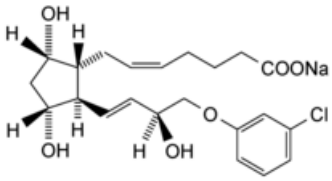
DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{28}ClNaO_6$ from the chromatograms obtained and using the declared content of $C_{22}H_{28}ClNaO_6$ in *cloprostenol sodium BPCRS*.

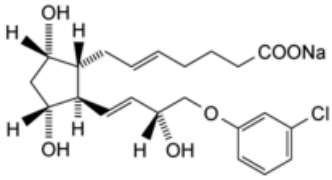
STORAGE

Cloprostenol Sodium should be protected from light and moisture.

IMPURITIES



A. (±)-(5*Z*)-7-(1*R*,3*R*,5*S*)-2-[(1*E*,3*S*)-4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentylhept-5-enoate *(epimer),*



B. (±)-(5*E*)-7-(1*R*,3*R*,5*S*)-2-[(1*E*,3 *R*)-4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentylhept-5-enoate *(*trans-*isomer)*.