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Cloprostenol Injection

» Cloprostenol Injection is a sterile solution of Cloprostenol Sodium in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of cloprostenol ($C_{22}H_{29}ClO_6$).

Packaging and storage—Preserve in single-dose or multiple-dose containers protected from light. Store at controlled room temperature.

Labeling—Label it to indicate that it is for veterinary use only, and to indicate the strength as the equivalent amount of cloprostenol per dose.

USP Reference Standards ⟨11⟩—
USP Cloprostenol Sodium RS
USP Hydrocortisone Acetate RS

Identification—

A: The retention time of the cloprostenol peak in the chromatogram of the *Assay preparation* corresponds to that of the cloprostenol peak in the chromatogram of the *Standard preparation,* obtained as directed in the *Assay*.

B: It meets the requirements of the test for *Sodium* ⟨191⟩.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 2500 USP Endotoxin Units per mg of cloprostenol.

Sterility Tests ⟨71⟩—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

Related compounds—

Mobile phase and *System suitability solution*—Prepare as directed in the *Assay*.

Standard solution—Prepare as directed for *Standard preparation* under *Assay*.

Test solution—Prepare as directed for *Assay preparation*.

Chromatographic system (see *Chromatography ⟨621⟩*)—Prepare as directed in the *Assay*.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure all of the peak responses. Calculate the percentage of each impurity in the portion of Injection taken by the formula:

$$100(C_S/C_T)(r_i/r_S)$$

in which C_S is the concentration, in mg per mL, of USP Cloprostenol Sodium RS in the *Standard solution*; C_T is the concentration, in mg per mL, of cloprostenol in the *Test solution*; r_i is the peak response for each impurity obtained from the *Test solution;* and r_S is the peak response of cloprostenol obtained from the *Standard solution*: not more than 1.0% of any individual impurity is found, and not more than 2.5% of total impurities is found. Disregard any peak below 0.05%.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—

pH 2.5 Monobasic sodium phosphate solution—Prepare an aqueous solution containing 2.4 mg of monobasic sodium phosphate dihydrate per mL of solution. Adjust with phosphoric acid to a pH of 2.5.

Mobile phase—Prepare a filtered and degassed mixture of *pH 2.5 Monobasic sodium phosphate solution* and acetonitrile (73:27). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

System suitability solution—Dissolve an accurately weighed quantity of USP Cloprostenol Sodium RS and USP Hydrocortisone Acetate RS in dehydrated alcohol, and dilute with *Mobile phase* to obtain a solution containing about 0.25 mg of cloprostenol sodium and 0.5 mg of hydrocortisone acetate per mL of solution.

Standard preparation—Dissolve an accurately weighed quantity of USP Cloprostenol Sodium RS in dehydrated alcohol, and dilute quantitatively, and stepwise if necessary, with dehydrated alcohol to obtain a solution having a known concentration of about 0.1 mg per mL.

Assay preparation—Dilute a volume of Injection in dehydrated alcohol and dilute quantitatively, and stepwise if necessary, with dehydrated alcohol to obtain a solution containing 0.1 mg of cloprostenol per mL of solution, based on the label claim.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 220-nm detector and a 5-mm × 25-cm column that contains packing L1. The flow rate is about 1.8 mL per minute. Chromatograph the *System suitability solution,* and record the

peak responses as directed for *Procedure*: the resolution, *R,* between the hydrocortisone acetate peak and the cloprostenol peak is not less than 6. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure*: the tailing factor is not more than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the cloprostenol peak. Calculate the percentage label claim of cloprostenol ($C_{22}H_{29}ClO_6$) in the portion of Injection taken by the formula:

$$100(C_S/C_U)(r_U/r_S)(M_1/M_2)$$

in which C_S is the concentration, in mg per mL, of USP Cloprostenol Sodium RS in the *Standard preparation;* C_U is the concentration, in mg per mL, of cloprostenol in the *Assay preparation*; r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively, M_1 is the molecular weight of cloprostenol (424.92), and M_2 is the molecular weight of cloprostenol sodium (446.90).

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CLOPROSTENOL INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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