Prednisolone phosphate injection (Prednisoloni phosphatis injectio)  

**Description.** A colourless solution.

**Category.** Adrenal hormone.

**Storage.** Prednisolone phosphate injection should be kept in a well-closed container.

**Labelling.** The designation on the container should state the amount of active ingredient as the equivalent quantity of prednisolone in a suitable dose volume. It should also state whether any buffering agent is added.

**Additional information.** Available strengths: 20 mg, 25 mg in vials.

Prednisolone phosphate injection contains a suitable stabilizing agent, and may contain a suitable buffering agent. The solution is sterilized by "Filtration" or by another suitable method (see 5.8 Methods of sterilisation).

**Requirements**

Complies with the monograph for *Parenteral preparations*.

**Definition.** Prednisolone phosphate injection is a sterile solution of prednisolone sodium phosphate in water for injections.

Prednisolone phosphate injection contains not less than 90.0% and not more than 110.0% of the equivalent amount of prednisolone C$_{21}$H$_{28}$O$_{5}$ stated on the label.

**Identity tests**

A. Carry out the test as described under 1.14.1 Thin-layer chromatography using silica gel R4 as the coating substance and 6 volumes of 1-butanol R, 2 volumes of acetic anhydride R and 2 volumes of water as the mobile phase, prepared immediately before use. Apply separately to the plate 5 μL of each of the following four solutions. For solution (A) dilute a volume of the injection to obtain a concentration of the equivalent of 2 mg of prednisolone per mL. For solution (B) dissolve 27 mg of prednisolone sodium phosphate RS in 10 mL of water. For solution (C) prepare a mixture of equal volumes of solutions A and B. For solution (D) mix 2 mL of solution B with 2 mL of a solution containing 29 mg of betamethasone sodium phosphate RS in 10 mL of water. After removing the plate from the chromatographic chamber allow it to dry in air until the odour of solvent is no longer perceptible, heat to 110 °C for 10 minutes and examine the chromatogram in ultraviolet light (254 nm).

The principal spot obtained with solution A corresponds in position, appearance and intensity with that obtained with solution B. The chromatogram obtained with solution D shows two principal spots with almost the same $R_f$ values. Additional spots due to pharmaceutical aids may be observed in the chromatograms obtained with solutions A and C.

B. Evaporate a volume of the injection equivalent to 2 mg of prednisolone to dryness on a water-bath. Dissolve the residue in 2 mL of sulfuric acid (~1760 g/L) TS and allow to stand for 2 minutes; a red colour is produced.

**pH value.** pH of the injection, 7.0–9.0.

**Assay**

Dilute an accurately measured volume of the injection equivalent to about 20 mg of prednisolone with sufficient water to produce 200 mL. To 25 mL of this solution add 2.5 g of sodium chloride R and 1 mL of hydrochloric acid (0.1 mol/L) VS, mix and shake with three quantities, each of 25 mL, of chloroform R. Wash each chloroform extract with 1 mL of hydrochloric acid (0.1 mol/L) VS, add the washings to the aqueous solution and discard the chloroform layers. Extract the aqueous solution with two quantities, each of 10 mL, of tributyl phosphate R and dilute the combined extracts to 25 mL with methanol R. Transfer 2 mL to a stoppered tube and add 10 mL of isoniazid TS, heat to 50 °C for 3 hours, protecting the solution from light, and cool.

Measure the absorbance in a 1 cm layer at the maximum at about 405 nm. Similarly prepare a blank solution, omitting the injection to be examined. Repeat the procedure using 25 mL of a solution of prednisolone sodium phosphate RS containing the equivalent of 0.10 mg/mL of prednisolone. Determine the latter by diluting an aliquot with water, measuring the absorbance of the dilution at the maximum at about 247 nm. Calculate the content of C$_{21}$H$_{28}$O$_{5}$ in the injection being examined by comparison with the absorbances obtained and the exact strength of the solution of prednisolone sodium phosphate RS, using 419 as the absorbance at the maximum at 247 nm.

**Bacterial endotoxins.** Carry out the test as described under 3.4 Test for bacterial endotoxins; contains less than 4.09 IU of endotoxin per mg Prednisolone.