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

Urofollitropin Injection

General Notices

Action and use

Follicle-stimulating hormone.

DEFINITION

Urofollitropin Injection is a sterile solution of Urofollitropin in Sodium Chloride Infusion. It is prepared by dissolving Urofollitropin for Injection in the requisite amount of Sodium Chloride Infusion immediately before use.

The injection complies with the requirements stated under Parenteral Preparations.

STORAGE

Urofollitropin Injection should be used immediately after preparation.

UROFOLLITROPIN FOR INJECTION

DEFINITION

Urofollitropin for Injection is a sterile material consisting of Urofollitropin with or without excipients. It is supplied in a sealed container.

The contents of the sealed container comply with the requirements for Powders for Injections or Infusions stated under Parenteral Preparations and with the following requirements.

Potency

The estimated potency is not less than 80% and not more than 125% of the stated potency.

CHARACTERISTICS

An almost white or slightly yellow powder.

IDENTIFICATION

Causes enlargement of the ovaries of immature female rats when administered as directed in the Assay.

TESTS

Acidity or alkalinity

Dissolve the contents of the sealed container in 3 mL of *water* (solution A). The pH is 6.0 to 8.0, Appendix V L.

Clarity and colour of solution

Solution A is *clear*, Appendix IV A, and *colourless*, Appendix IV B, Method I.

Residual luteinising activity

Comply with the test described under Urofollitropin.

Water

Comply with the test described under Urofollitropin.

Bacterial endotoxins

Carry out the *test for bacterial endotoxins*, Appendix XIV C, using Method C. Dissolve the contents of the sealed container in *water BET* to give a solution containing 75 IU of urofollitropin per mL (solution A). The endotoxin limit concentration of solution A is 30 IU of endotoxin per mL. Carry out the test using a suitable dilution of solution A as described under Method C.

ASSAY

Carry out the Assay described under Urofollitropin. The fiducial limits of error are not less than 64% and not more than 156% of the stated potency.

STORAGE

The sealed container should be protected from light.

LABELLING

The label of the sealed container states the number of IU (Units) of follicle-stimulating hormone activity contained in it.