Claims

1. A parenteral dosage form comprising a ready-to-inject, sterile and stable aqueous solution comprising:

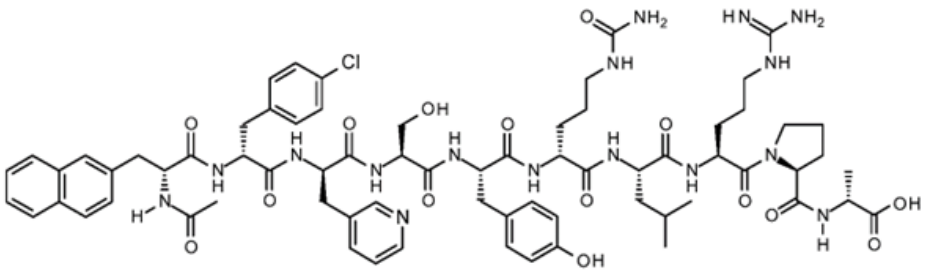
(i) cetrorelix or a pharmaceutically acceptable salt thereof in a concentration equivalent to 0.25 mg/ml of cetrorelix base;

(ii) lactic acid in an amount sufficient to adjust the pH of the solution in the range of 4.00 to 5.00;

(iii) an osmotic agent, and

(iv) water for injection,

wherein after 6 months of storage at 25°C and 60% relative humidity, the solution contains an amount of Impurity A, a decapeptide of Formula I,



Formula I

which is 1 % w /v of cetrorelix base or less.

2. The parenteral dosage form as claimed in claim 1, wherein after 6 months of storage at 25°C and 60% relative humidity, the solution contains an amount of Impurity A which is 0.5% w/v of cetrorelix base or less.

3. The parenteral dosage form as claimed in claim 1, wherein after 6 months of storage at 25°C and 60% relative humidity, the solution contains a single maximum unknown impurity of less than 0.5% by weight of cetrorelix base.

4. The parenteral dosage form as claimed in claim 1, wherein the osmotic agent is mannitol.

5. The parenteral dosage form as claimed in claim 4, wherein the aqueous solution has a mannitol concentration ranging from 50.0 mg/ml to 58.0 mg/ml.

6. The parenteral dosage form according to claim 1, wherein the pharmaceutically acceptable salt of cetrorelix is cetrorelix acetate.

7. The parenteral dosage form according to claim 1, wherein the osmotic agent is present in an amount sufficient for osmolality of the solution in the range of 250 to 375 mOsm/Kg.

8. The parenteral dosage form according to claim 1, wherein the parenteral dosage form is present in the reservoir of an injection device.

9. The parenteral dosage form according to claim 8, wherein the injection device is a prefilled syringe.

10. The parenteral dosage form according to claim 8, wherein the injection device is an auto-injector.

11. The parenteral dosage form according to claim 8, wherein the injection device is a pen auto-injector.

12. The parenteral dosage form according to claim 1, wherein the pH of the solution prior to storage is 4.

13. The parenteral dosage form according to claim 1, wherein the pH of the solution prior to storage is 4.5.

14. The parenteral dosage form according to claim 1, wherein the pH of the solution prior to storage is 5.

15. The parenteral dosage form according to claim 1, wherein the parenteral dosage form is suitable for subcutaneous use.

16. The parenteral dosage form according to claim 1, wherein the parenteral dosage form is suitable for intramuscular use.

17. The parenteral dosage form according to claim 1, wherein the solution has a turbidity of less than 2 NTU after 6 months of storage at 25°C and 60% relative humidity.

18. The parenteral dosage form according to claim 1, wherein the solution is free of co-solvents, preservatives and antioxidants.

19. The parenteral dosage form of claim 1, wherein after 6 months of storage at 25°C and 60% relative humidity, the solution contains an amount of Impurity A which is from 0.001% to 0.5% by weight of cetrorelix base.

20. The parenteral dosage form according to claim 8, wherein the aqueous solution has been aseptically filtered.

21. A parenteral dosage form according to any one of claims 1-21 for use in the treatment of premature luteinizing hormone surges in women undergoing controlled ovarian stimulation.