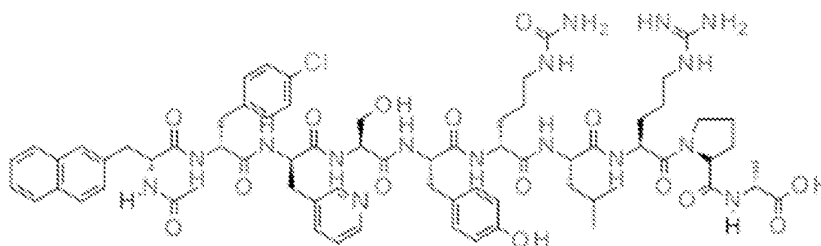


We claim:

- 1 1. A parenteral dosage form comprising a stable aqueous solution comprising:
- 2 (i) cetorelix or a pharmaceutically acceptable salt thereof; and
- 3 (ii) an impurity of Formula I in an amount less than 1% w/v of cetorelix base.



Formula I.

- 1 2. The parenteral dosage form as claimed in claim 1, wherein the dosage form is a
2 sterile, stable, aqueous solution.
- 1 3. The parenteral dosage form as claimed in claim 1, wherein the dosage form is a
2 sterile, ready-to-infuse dosage form.
- 1 4. The parenteral dosage form as claimed in claim 1, wherein the stable, aqueous
2 solution further comprises an organic acid to adjust the pH in the range of 3 to 5.
- 1 5. The parenteral dosage form as claimed in claim 4, wherein the stable, aqueous
2 solution further comprises an osmotic agent.
- 1 6 A parenteral dosage form according to claim 1, wherein the amount of cetorelix or
2 a pharmaceutically acceptable salt thereof is 0.25 mg/ml.
- 1 7. A parenteral dosage form according to claim 5, wherein the osmotic agent is
2 present in an amount sufficient for osmolality of the solution in the range of 250 to 375
3 mOsm/Kg.
- 1 8. The parenteral dosage form according to claim 1, wherein the parenteral dosage
2 form is a ready-to-inject, sterile, stable aqueous solution present in the reservoir of an
3 injection device.
- 1 9. The parenteral dosage form according to claim 8, wherein the injection device is a
2 prefilled syringe.
- 1 10. The parenteral dosage form according to claim 8, wherein the injection device is an

2 auto-injector.

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

1 12. The parenteral dosage form according to claim 1, wherein the stable, aqueous
2 solution is stable for at least 1 month at 25°C temperature and 60 % relative humidity.

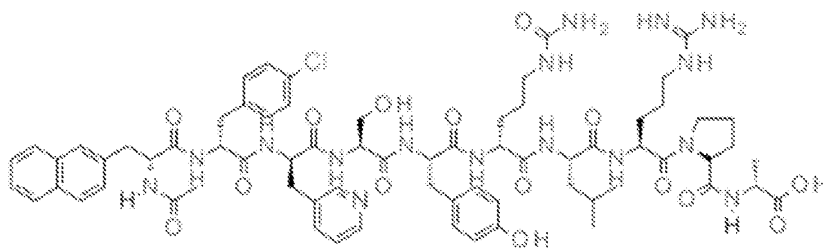
1 13. The parenteral dosage form according to claims 1, wherein the stable, aqueous
2 solution is stable for at least 3 months at 25°C temperature and 60 % relative humidity.

1 14. The parenteral dosage form according to claim 1, wherein the stable, aqueous
2 solution is stable for at least 6 months at 25°C temperature and 60 % relative humidity

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

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

1 17. A pharmaceutical composition of cetrorelix or a pharmaceutically acceptable salt
2 thereof, comprising a decapeptide of formula I:



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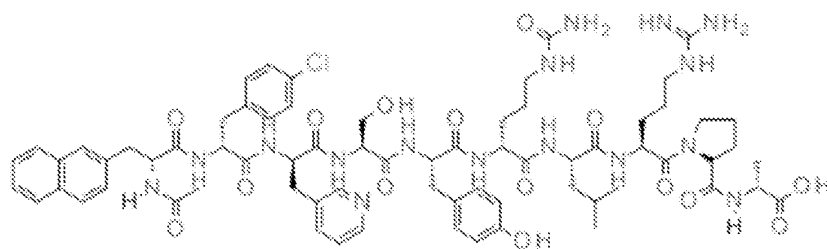
Formula I.

1 18. A method of inhibiting premature luteinizing hormone surges in women
2 undergoing controlled ovarian stimulation comprising:

3 a parenteral dosage form comprising: a ready-to-inject, sterile, stable, aqueous
4 solution comprising:

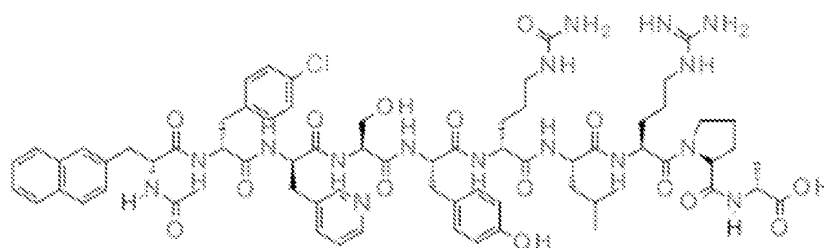
5 (i) cetrorelix or a pharmaceutically acceptable salt thereof,

6 (ii) Impurity A, a decapeptide of formula I, in an amount less than 1% w/v of
7 cetrorelix base,



Formula I

19. A decapeptide of formula I



Formula I.

20. The decapeptide of claim 19, wherein the decapeptide is identified by HPLC analysis, the process comprising:

- a) injecting a diluent comprising water, acetonitrile and formic acid into the chromatographic system,
- b) injecting a system suitability solution comprising cetorelix acetate, diluent and impurity stock solution and recording the chromatogram,
- c) injecting a standard solution comprising cetorelix acetate and diluent into the chromatographic system,
- d) injecting a sample comprising aqueous solution of cetorelix acetate and placebo preparation into the chromatographic system, and
- e) determining the relative retention time and relative response factor of impurities and cetorelix acetate with respect to cetorelix acetate.

21. A process to identify the decapeptide of claim 19 by HPLC analysis, the process comprising:

- a) injecting a diluent comprising water, acetonitrile and formic acid into the chromatographic system,

- 5 b) injecting a system suitability solution comprising cetorelix acetate, diluent
6 and impurity stock solution and recording the chromatogram,
- 7 c) injecting a standard solution comprising cetorelix acetate and diluent into
8 the chromatographic system,
- 9 d) injecting a sample comprising aqueous solution of cetorelix
10 acetate and placebo preparation into the chromatographic system, and
- 11 e) determining the relative retention time and relative response factor of
12 impurities and cetorelix acetate with respect to cetorelix acetate.
- 1 22. The process of claim 20 or 21, wherein the mobile phase A and B in the HPLC
2 analysis comprises a buffer, acetonitrile and tetrahydrofuran, and
- 3 wherein the relative retention time and relative response factor for the decapeptide is
4 determined to be 0.57 and 1.0, respectively.