Claims:

1. An aqueous pharmaceutical formulation comprising 200 – 1000 U/mL [equimolar to 200 – 1000 IU human insulin] of insulin glargine, with the proviso that the concentration of said formulation is not 684 U/mL of insulin glargine.

2. The aqueous formulation of claim 1 comprising 200 U/ml to 650 U/mL of insulin glargine.

3. The aqueous formulation of claim 1 comprising 700 U/ml to 1000 U/mL of insulin glargine.

4. The aqueous formulation of claim 2 comprising 270 – 330 U/mL of insulin glargine [equimolar to 270 – 330 IU human insulin].

5. The aqueous formulation of claim 4 comprising 300 U/mL of insulin glargine [equimolar to 300 IU human insulin].

6. The aqueous pharmaceutical formulation of any of the foregoing claims comprising an analogue of exendin-4.

7. The aqueous formulation of claim 6, wherein the analogue of exendin-4 is selected from a group comprising lixisentatide, exenatide and liraglutide.

8. The aqueous formulation of claim 7 comprising 0.1 µg to 10 µg lixisenatide per U insulin glargine.

9. The aqueous formulation of claim 8 comprising 0.2 to 1 µg lixisenatide per U insulin glargine.

10. The aqueous formulation of claim 9 comprising 0.25 µg to 0.7 µg lixisenatide per U insulin glargine.

11. The aqueous formulation of any of the foregoing claims comprising one or more excipients selected from a group comprising zinc, m-cresol, glycerol, polysorbate 20 and sodium.

12. The aqueous formulation of claim 11 comprising 90 µg/mL zinc, 2.7 mg/mL m-cresol and 20 mg/ml glycerol 85%.

13. The aqueous formulation of claim 11 comprising 90 µg/mL zinc, 2.7 mg/mL m-cresol, 20µg/mL polysorbate 20 and 20 mg/mL glycerol 85%.

14. The aqueous formulation of any of the foregoing claims, wherein the pH is between 3.4 and 4.6.

15. The aqueous formulation of claim 15, wherein the pH is 4.

16. The aqueous formulation of claim 15, wherein the pH is 4.5.

17. Use of an aqueous pharmaceutical composition comprising insulin glargine in a concentration of 300 U/mL in the manufacture of a medicament for treating Type I and Type II Diabetes Mellitus.

18. The use of claim 17, wherein said pharmaceutical composition further comprises excipients selected from the group consisting of zinc, m-cresol, glycerol, polysorbate 20 and sodium.

19. The use of claim 17, wherein said pharmaceutical composition further comprises 0.1 µg to 10 µg lixisenatide per U insulin glargine.

20. Use of an aqueous pharmaceutical composition comprising insulin glargine in a concentration of 300 U/mL in the manufacture of a medicament for extending the duration of exposure of a long acting insulin in the treatment of Type I and Type II Diabetes Mellitus.

21. The use of claim 20, wherein said pharmaceutical composition further comprises excipients selected from the group consisting of zinc, m-cresol, glycerol, polysorbate 20 and sodium.

22. The use of claim 20, wherein said pharmaceutical composition further comprises 0.1 µg to 10 µg lixisenatide per U insulin glargine.

23. Use of an aqueous pharmaceutical composition comprising insulin glargine in a concentration of 300 U/mL in the manufacture of a medicament for reducing the incidence of hypoglycaemia in the treatment of Type I and Type II Diabetes Mellitus in a patient with a long acting insulin.

24. The use of claim 23, wherein said pharmaceutical composition further comprises excipients selected from the group consisting of zinc, m-cresol, glycerol, polysorbate 20 and sodium.

25. The use of claim 23, wherein said pharmaceutical composition further comprises 0.1 µg to 10 µg lixisenatide per U insulin glargine.

26. Use of an aqueous pharmaceutical composition comprising insulin glargine in a concentration of 300 U/mL in the manufacture of a medicament for providing a peakless long acting basal insulin in the treatment of Type I and Type II Diabetes Mellitus.

27. The use of claim 26, wherein said pharmaceutical composition further comprises excipients selected from the group consisting of zinc, m-cresol, glycerol, polysorbate 20 and sodium.

28. The use of claim 26, wherein said pharmaceutical composition further comprises 0.1 µg to 10 µg lixisenatide per U insulin glargine.

29. Use of an aqueous formulation according to any of the foregoing claims in the treatment of Type 1 Diabetes Mellitus and Type 2 Diabetes Mellitus.

Claims

1. An aqueous pharmaceutical formulation comprising 300 U/mL of insulin glargine being equimolar to 300 IU human insulin.

2. The aqueous pharmaceutical formulation of claim 1 further comprising an analogue of exendin-4.

3. The aqueous pharmaceutical formulation of claim 2, wherein the analogue of exendin-4 is selected from the group consisting of lixisentatide, exenatide, and liraglutide.

4. The aqueous pharmaceutical formulation of claim 3 comprising 0.1 µg to 10 µg lixisenatide per Unit insulin glargine.

5. The aqueous pharmaceutical formulation of claim 4 comprising 0.2 to 1 µg lixisenatide per Unit insulin glargine.

6. The aqueous pharmaceutical formulation of claim 5 comprising 0.25 µg to 0.7 µg lixisenatide per Unit insulin glargine.

7. The aqueous pharmaceutical formulation of any of the foregoing claims further comprising one or more excipients selected from the group consisting of zinc, m-cresol, glycerol, polysorbate 20, and sodium.

8. The aqueous pharmaceutical formulation of claim 7 comprising 90 µg/ml zinc, 2.7 mg/ml m-cresol, and 20 mg/ml glycerol 85%.

9. The aqueous pharmaceutical formulation of claim 7 comprising 90 µg/ml zinc, 2.7 mg/ml m-cresol, 20 µg/ml polysorbate 20, and 20 mg/ml glycerol 85%.

10. The aqueous pharmaceutical formulation of any of the foregoing claims, wherein the pH of the aqueous pharmaceutical formulation is between 3.4 and 4.6.

11. The aqueous pharmaceutical formulation of claim 10, wherein the pH of the aqueous pharmaceutical formulation is 4.

12. The aqueous pharmaceutical formulation of claim 10, wherein the pH of the aqueous pharmaceutical formulation is 4.5.

13. Use of an aqueous pharmaceutical composition comprising insulin glargine in a concentration of 300 U/ml in the manufacture of a medicament for treating Type I and Type II Diabetes Mellitus.

14. The use of claim 13 wherein the aqueous pharmaceutical composition further comprises one or more excipients selected from the group consisting of zinc, m-cresol, glycerol, polysorbate 20, and sodium.

15. The use of claim 13 wherein the aqueous pharmaceutical composition further comprises 0.1 µg to 10 µg lixisenatide per Unit insulin glargine.

16. Use of an aqueous pharmaceutical composition comprising insulin glargine in a concentration of 300 U/ml in the manufacture of a medicament for extending the duration of exposure of a long acting insulin in the treatment of Type I and Type II Diabetes Mellitus.

17. The use of claim 16 wherein the aqueous pharmaceutical composition further comprises one or more excipients selected from the group consisting of zinc, m-cresol, glycerol, polysorbate 20, and sodium.

18. The use of claim 16 wherein the aqueous pharmaceutical composition further comprises 0.1 µg to 10 µg lixisenatide per Unit insulin glargine.

19. Use of an aqueous pharmaceutical composition comprising insulin glargine in a concentration of 300 U/ml in the manufacture of a medicament for reducing the incidence of hypoglycaemia in the treatment of Type I and Type II Diabetes Mellitus in a patient with a long acting insulin.

20. The use of claim 19 wherein the aqueous pharmaceutical composition further comprises one or more excipients selected from the group consisting of zinc, m-cresol, glycerol, polysorbate 20, and sodium.

21. The use of claim 19 wherein the aqueous pharmaceutical composition further comprises 0.1 µg to 10 µg lixisenatide per Unit insulin glargine.

22. Use of an aqueous pharmaceutical composition comprising insulin glargine in a concentration of 300 U/ml in the manufacture of a medicament for providing a peakless long acting basal insulin in the treatment of Type I and Type II Diabetes Mellitus.

23. The use of claim 22 wherein the aqueous pharmaceutical composition further comprises one or more excipients selected from the group consisting of zinc, m-cresol, glycerol, polysorbate 20, and sodium.

24. The use of claim 22 wherein the aqueous pharmaceutical composition further comprises 0.1 µg to 10 µg lixisenatide per Unit insulin glargine.

25. Use of an aqueous pharmaceutical formulation according to any of claims 1 to 12 in the manufacture of a medicament for treating Type 1 Diabetes Mellitus or Type 2 Diabetes Mellitus.