Claims

1. A pharmaceutical formulation comprising
(a). at least one analogue and/or derivative of insulin; and
(b). Zn(II); and
(c). sorbitol; and
(d). optionally protamine;
wherein the pharmaceutical formulation is an aqueous solution having a pH value in the range from 7.0 to 7.8; and wherein the formulation is chemically and physically stable when stored at 5°C ± 3°C for 3 months.

2. The pharmaceutical formulation as claimed in claim 1, wherein the analogue of insulin is selected from the group consisting of insulin aspart, insulin lispro and insulin glulisine.

3. The pharmaceutical formulation as claimed in claim 1, wherein the derivative of insulin is insulin detemir and/or insulin degludec.

4. The pharmaceutical formulation as claimed in one or more of claims 1 to 3, wherein the analogue and/or derivative of insulin is present in a concentration from 10 U/mL to 1000 U/mL.

5. The pharmaceutical formulation as claimed in one or more of claims 1 to 4, wherein Zn(II) is present in a concentration from 0.0100 to 0.0600 mg / 100 U of the analogue and/or derivative of insulin.

6. The pharmaceutical formulation as claimed in one or more of claims 1 to 5, wherein the pharmaceutical formulation further contains sodium chloride.

7. The pharmaceutical formulation as claimed in claim 6, wherein sodium chloride is present in a concentration from 0.01 to 6.0 mg/mL.

8. The pharmaceutical formulation as claimed in one or more of claims 1 to 7, wherein protamine is present in a concentration from 0.1 to 0.5 mg/mL.

9. The pharmaceutical formulation as claimed in one or more of claims 1 to 8, wherein the pharmaceutical formulation comprises one or more further active pharmaceutical ingredients.

10. The pharmaceutical formulation according to claim 9, wherein the further active pharmaceutical ingredient is an antidiabetic agent.

11. The pharmaceutical formulation according to claim 9 or 10, wherein the further active pharmaceutical ingredient is an antidiabetic agent selected from the group consisting of:
(a). a GLP-1 receptor agonist;
(b). a dual GLP-1 receptor/glucagon receptor agonist;
(c). human FGF-21;
(d). a FGF-21 analogue;
(e). a FGF-21 derivative;
(f). insulin;
(g). human insulin;
(h). an analogue of insulin; and
(i). a derivative of insulin.

12. The pharmaceutical formulation as claimed in one or more of claims 1 to 11, wherein the pharmaceutical formulation comprises more than one analogue and/or derivative of insulin, wherein one analogue and/or derivative of insulin is a fast acting insulin and one analogue and/or derivative of insulin is a long acting insulin.

13. The pharmaceutical formulation according to claim 12, wherein the fast acting insulin is one or more insulin selected from the group consisting of insulin aspart, insulin lispro and insulin glulisine and wherein the long acting insulin is one or more insulin selected from the group consisting of insulin detemir and insulin degludec.

14. The pharmaceutical formulation as claimed in one or more of claims 1 to 13, wherein the pharmaceutical formulation consists of:
(a). 3.5 mg/mL insulin aspart;
(b). 31.62 mg/mL sorbitol;
(c). 1.72 mg/mL metacresol;
(d). 1.50 mg/mL phenol;
(e). 0.0196 mg/mL Zn(II);

(f). 0.58 mg/mL sodium chloride;
(g). 1.88 mg/mL Na_2HPO_4 x 7 H_2O;
(h). sodium hydroxide and/or hydrochloric acid to adjust the pH to 7.4; and
(i). water.

15. The pharmaceutical formulation as claimed in one or more of claims 1 to 13, wherein the pharmaceutical formulation consists of:
(a). 3.5 mg/mL insulin aspart;
(b). 31.62 mg/mL sorbitol;
(c). 1.72 mg/mL metacresol;
(d). 1.50 mg/mL phenol;
(e). 0.0196 mg/mL Zn(II);
(f). 0.58 mg/mL sodium chloride;
(g). 1.88 mg/mL Na_2HPO_4 x 7 H_2O; a
(h). from 0.1 mg/mL to 0.5 mg/ml protamine;
(i). sodium hydroxide and/or hydrochloric acid to adjust the pH to a pH in the range from 7.1 to 7.6;
(j). and water.

16. A process for preparing the pharmaceutical formulation according to claim 1, wherein the components are mixed together in the form of a solution, the pH is adjusted to reach the desired pH and water is added to reach the final volume.

17. A kit comprising one or more separate packages of
(a). the pharmaceutical formulation as claimed in one or more of claims 1 to 15; and
(b). a medical device.

18. A kit comprising one or more separate packages of
(a). the pharmaceutical formulation as claimed in one or more of claims 1 to 15; and
(b). at least one further active pharmaceutical ingredient;
(c). and optionally a medical device.

19. The kit according to claim 18, wherein the further active pharmaceutical ingredient is an antidiabetic agent.

20. The kit as claimed in one or more of claims 18 to 19, wherein the further active pharmaceutical ingredient is an antidiabetic agent selected from the group consisting of:
(a). a GLP-1 receptor agonist;
(b). a dual GLP-1 receptor/glucagon receptor agonist;
(c). ahuman FGF-21;
(d). a FGF-21 analogue;
(e). a FGF-21 derivative;
(f). insulin;
(g). human insulin;
(h). an analogue of insulin; and
(i). a derivative of insulin.

21. The kit as claimed in one or more of claims 17 to 20, wherein the kit comprises more than one analogue and/or derivative of insulin, wherein one analogue and/or derivative of insulin is a fast acting insulin and one analogue and/or derivative of insulin is a long acting insulin.

22. The kit according to claim 21, wherein the fast acting insulin is selected from the group consisting of insulin aspart, insulin lispro and insulin glulisine and wherein the long acting insulin is selected from the group consisting of insulin glargin, insulin detemir and/or insulin degludec.

23. Use of the pharmaceutical formulation as claimed in one or more of claims 1 to 15 or the kit as claimed in one or more of claims 17 to 22 for the preparation of a medicament for the treatment of diabetes mellitus.

24. Use of the pharmaceutical formulation as claimed in one or more of claims 1 to 15 or the kit as claimed in one or more of claims 17 to 22 for the preparation of a medicament for the treatment of hyperglycemia.

25. Use of the pharmaceutical formulation as claimed in one or more of claims 1 to 15 or the kit as claimed in one or more of claims 17 to 22 for the preparation of a medicament for lowering blood glucose level.

26. Medical device comprising the pharmaceutical formulation as claimed in one or more of claims 1 to 15, wherein said medical device is suitable for administering said pharmaceutical formulation to an animal and/or human.