Claims

1. A pharmaceutical formulation comprising
(a). insulin aspart in a concentration from 10 U/mL to 1000 U/mL; and
(b). Zn(II), wherein Zn(II) is present in a concentration from 0.0100 to 0.0600 mg / 100 U of insulin aspart; and
wherein the pharmaceutical formulation contains less than 0.17 mg/mL sodium chloride; wherein the pharmaceutical formulation is an aqueous solution having a pH value in the range from 7.0 to 7.8; and
wherein the pharmaceutical formulation is chemically and physically stable when stored at 5°C ± 3°C for 1 month.

2. The pharmaceutical formulation as claimed in claim 1, wherein the pharmaceutical formulation is free of sodium chloride.

3. The pharmaceutical formulation as claimed in one or more of claims 1 to 2, wherein protamine is present in a concentration from 0.1 to 0.5 mg/mL.

4. The pharmaceutical formulation as claimed in one or more of claims 1 to 3, wherein the pharmaceutical formulation further contains a buffering agent.

5. The pharmaceutical formulation as claimed in one or more of claims 1 to 4, wherein the pharmaceutical formulation comprises one or more further active pharmaceutical ingredients.

6. The pharmaceutical formulation according to claim 5, wherein the further active pharmaceutical ingredient is an antidiabetic agent.

7. The pharmaceutical formulation according to claim 5 or 6, 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.

8. The pharmaceutical formulation as claimed in one or more of claims 1 to 7, wherein the pharmaceutical formulation further comprises a fast acting analogue and/or derivative of insulin or a long acting analogue and/or derivative of insulin.

9. The pharmaceutical formulation according to claim 8, wherein the fast acting insulin is one or more insulin selected from the group consisting of insulin lispro and insulin glulisine and wherein the long acting insulin is one or more insulin selected from the group consisting of insulin detemir, insulin glargin and insulin degludec.

10. The pharmaceutical formulation as claimed in claim 1, wherein the pharmaceutical formulation consists of:
(a). 3.5 mg/mL insulin aspart;
(b). 0.0196 mg/mL Zn(II);
(c). 1.88 mg/mL Na_2HPO_4 x 7 H_2O;
(d). 1.72 mg/mL m-cresol;
(e). 1.5 mg/mL phenol;
(f). 17.88 mg/mL glycerol;
(g). sodium hydroxide and/or hydrochloric acid to adjust the pH to 7.4; and
(h). water.

11. The pharmaceutical formulation as claimed in claim 1, wherein the pharmaceutical formulation consists of:
(a). 3.5 mg/mL insulin aspart;
(b). 0.0196 mg/mL Zn(II);
(c). 1.88 mg/mL Na_2HPO_4 x 7 H_2O;
(d). 1.72 mg/mL m-cresol;
(e). 1.5 mg/mL phenol;
(f). 17.88 mg/mL glycerol;
(g). from 0.1 mg/mL to 0.5 mg/mL protamine sulfate;
(h). sodium hydroxide and/or hydrochloric acid to adjust the pH to 7.4; and
(i). water.

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

13. A kit comprising one or more separate packages of
(a). the pharmaceutical formulation as claimed in one or more of claims 1 to 11; and
(b). a medical device.

14. A kit comprising one or more separate packages of
(a). the pharmaceutical formulation as claimed in one or more of claims 1 to 9; and
(b). at least one further active pharmaceutical ingredient;
(c). and optionally a medical device.

15. The kit according to claim 14, wherein the further active pharmaceutical ingredient is an antidiabetic agent.

16. The kit as claimed in one or more of claims 14 to 15, 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.

17. The kit as claimed in one or more of claims 14 to 16, wherein the further active pharmaceutical ingredient is an analogue or derivative of insulin selected from the group consisting of fast acting insulin and long acting insulin.

18. The kit according to claim 17, 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 insulin degludec.

19. Use of the pharmaceutical formulation as claimed in one or more of claims 1 to 11 for the preparation of a medicament for the treatment of diabetes mellitus.

20. Use of the pharmaceutical formulation as claimed in one or more of claims 1 to 11 for the preparation of a medicament for the treatment of hyperglycemia.

21. Use of the pharmaceutical formulation of any one of claims 1 to 11 for the preparation of a medicament for the treatment of diabetes mellitus.

22. Use of the pharmaceutical formulation of any one of claims 1 to 11 for the preparation of a medicament for the treatment of hyperglycemia.

23. Medical device for administering the pharmaceutical formulation as claimed in one or more of claims 1 to 11 to an animal and/or human, wherein said medical device comprises said pharmaceutical formulation.