CLAIMS:

1. A pharmaceutical formulation comprising
(a). at least one analogue and/or derivative of insulin, wherein said analogue of insulin is selected from the group consisting of insulin aspart, insulin lispro, insulin glulisine, and insulin glargine; and wherein said derivative of insulin is insulin detemir and/or insulin degludec;
(b). Zn(II); and
(c). sodium chloride in a concentration from 0.01 mg/ml to 8.3 mg/ml; and
(d). optionally protamine;
wherein the pharmaceutical formulation has a pH value in the range from 6.0 to 9.0 and is free of any additional buffering agent.

2. The pharmaceutical formulation according to claim 1, wherein the pharmaceutical formulation is an aqueous pharmaceutical formulation.

3. The pharmaceutical formulation according to claim 1 or 2, wherein the pharmaceutical formulation has a pH value in the range from 7.0 to 7.8.

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 sodium chloride is present in a concentration from 6.8 to 8.3 mg/ml.

7. The pharmaceutical formulation as claimed in one or more of claims 1 to 6, wherein protamine is protamine sulfate which is present in a concentration from 0.1 to 0.5 mg/ml.

8. The pharmaceutical formulation as claimed in one or more of claims 1 to 7, wherein the pharmaceutical formulation is free of any additional buffering agent selected from the group consisting of 2-amino-2-hydroxymethyl-propane-1 ,3-diol (TRIS), phosphate, citric acid, citrate, acetic acid, acetate, glycylglycine and methionine.

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). an FGF-21 analogue;
(e). an 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). 1.72 mg/ml metacresol;
(c). 1.50 mg/ml phenol;
(d). 0.04087 mg/ml zinc chloride;
(e). 6.8 mg/ml sodium chloride;
(f). 0.02 mg/ml polysorbate 20;
(g). sodium hydroxide and/or hydrochloric acid to adjust the pH to 7.4, and
(h). 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). 1.72 mg/ml metacresol;
(c). 1.50 mg/ml phenol;
(d). 0.04087 mg/ml zinc chloride;
(e). from 6.8 mg/ml to 8.3 mg/ml sodium chloride;
(f). 0.02 mg/ml polysorbate 20;
(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 a pH in the range from
7.1 to 7.6; and
(i). 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 or suspension, 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 17 or 18, wherein the further active pharmaceutical ingredient is an antidiabetic agent.

20. The kit as claimed in one or more of claims 17 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). human FGF-21;
(d). an FGF-21 analogue;
(e). an 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 insulin degludec.

23. 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 use in the treatment of diabetes mellitus.

24. 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 use in the treatment of hyperglycemia.

25. 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 use in lowering blood glucose level.

26. A method of treating diabetes mellitus in a subject in need thereof comprising administering the pharmaceutical formulation of any one of claims 1 to 15.

27. A method of treating hyperglycemia in a subject in need thereof comprising administering the pharmaceutical formulation of any one of claims 1 to 15.

28. A method of lowering blood glucose levels in a subject in need thereof comprising administering the pharmaceutical formulation of any one of claims 1 to 15.

29. Medical device when used to administer the pharmaceutical formulation as claimed in one or more of claims 1 to 15 to an animal and/or human; wherein said medical device comprises said pharmaceutical formulation.