CLAIMS

1. A method for producing a polypeptide composition comprising: combining a polypeptide with a volatile additive to form a liquid mixture and lyophilizing the liquid mixture to obtain a lyophilized polypeptide composition, wherein the liquid mixture comprises about 2% by volume of volatile additive, and the volatile additive is t-butanol.

2. The method of claim 1 wherein the polypeptide is an antigen binding polypeptide.

3. The method of claim 1 wherein the polypeptide comprises at least two GLP-1 polypeptides genetically fused to the N-terminus of human serum albumin.

4. The method of claim 1 wherein the antigen binding polypeptide is selected from the group consisting of soluble receptor, antibody, antibody fragment, immunoglobulin single variable domain, Fab, $F(ab')_2$, Fv, disulphide linked Fv, scFv, closed conformation multispecific antibody, disulphide-linked scFv, and diabody.

5. A dry polypeptide composition produced by the method of claim 1.

6. The polypeptide composition of claim 5 that comprises at least two GLP-1 polypeptides genetically fused to the N-terminus of human serum albumin.

7. A method for producing a liquid polypeptide composition comprising: obtaining a lyophilized polypeptide produced by the method of claim 1, and reconstituting the lyophilized polypeptide with a sufficient amount of a pharmaceutically acceptable dispersing agent to yield a liquid polypeptide composition.

8. The method of claim 7 wherein the polypeptide is an antigen binding polypeptide.

9. The method of claim 7 wherein the polypeptide comprises at least two GLP-1 polypeptides genetically fused to the N-terminus of human serum albumin.

10. The method of claim 8 wherein the antigen binding polypeptide is selected from the group consisting of soluble receptor, antibody, antibody fragment, immunoglobulin single variable domain, Fab, $F(ab')_2$, Fv, disulphide linked Fv, scFv, closed conformation multispecific antibody, disulphide-linked scFv, and diabody.

11. A liquid polypeptide composition produced by the method of claim 7.

12. A method for reducing the reconstitution time of a lyophilized polypeptide composition comprising:
a) lyophilizing a liquid mixture comprising the polypeptide, wherein the liquid mixture comprises about 2% by volume of volatile additive, wherein the volatile additive is t-butanol and
b) reconstituting the lyophilized polypeptide with a sufficient amount of a pharmaceutically acceptable dispersing agent to the lyophilized polypeptide composition to yield a liquid polypeptide composition,
wherein time for reconstituting the polypeptide lyophilized in the presence of the volatile additive is less than the time for reconstituting the same polypeptide lyophilized in the absence of the volatile additive.

13. The method of claim 12 wherein the polypeptide is an antigen binding polypeptide.

14. The method of claim 12 wherein the polypeptide comprises at least two GLP-1 polypeptides genetically fused to the N-terminus of human serum albumin.

15. The method of claim 12 wherein the antigen binding polypeptide is selected from the group consisting of soluble receptor, antibody, antibody fragment, immunoglobulin single variable domain, Fab, $F(ab')_2$, Fv, disulphide linked Fv, scFv, closed conformation multispecific antibody, disulphide-linked scFv, and diabody.

16. A composition comprising: a therapeutic polypeptide, a buffer, a surfactant, at least one excipient, and at least one volatile additive wherein the volatile additive is t-butanol and the t-butanol is present at about 2% by volume.

17. The composition of claim 16 wherein the therapeutic polypeptide comprises GLP-1 or a fragment and/or variant thereof.

18. The composition of claim 16 wherein the therapeutic polypeptide comprises at least two GLP-1(7-36(A8G)) polypeptides genetically fused to the N-terminus of human serum albumin.

19. The composition of any one of claims 16 to 18 wherein the therapeutic polypeptide comprises SEQ ID NO:1.

20. The composition of either one of 16 or 19 wherein the buffer is sodium phosphate.

21. The composition of any one of claims 16 to 20 wherein the surfactant is polysorbate-80.

22. The composition of any one of claims 16 to 21 wherein the at least one excipient is selected from: trehalose, maltose, sucrose, mannose, lactose, mannitol, sorbitol, glycerol and dextrose.

23. The composition of any one of claims 16 to 22 wherein the excipient comprises: trehalose and mannitol.

24. A composition comprising: a polypeptide comprising SEQ ID NO:1, sodium phosphate, trehalose, mannitol, polysorbate-80 and t-butanol wherein the t-butanol is present at about 2% by volume.

CLAIMS

1. A method for producing a polypeptide composition comprising: combining a polypeptide with a volatile additive to form a liquid mixture and lyophilizing the liquid mixture to obtain a lyophilized polypeptide composition, wherein the liquid mixture comprises about 0.25% to about 5% by volume of volatile additive, and the volatile additive is t-butanol.

2. The method of claim 1 wherein the polypeptide is an antigen binding polypeptide.

3. The method of claim 1 wherein the polypeptide comprises at least two GLP-1 polypeptides genetically fused to the N-terminus of human serum albumin.

4. The method of claim 2 wherein the antigen binding polypeptide is selected from the group consisting of soluble receptor, antibody, antibody fragment, immunoglobulin single variable domain, Fab, $F(ab')_2$, Fv, disulphide linked Fv, scFv, closed conformation multispecific antibody, disulphide-linked scFv, and diabody.

5. A dry polypeptide composition produced by the method of claim 1.

6. The polypeptide composition of claim 5 that comprises at least two GLP-1 polypeptides genetically fused to the N-terminus of human serum albumin.

7. A method for producing a liquid polypeptide composition comprising: obtaining a lyophilized polypeptide produced by the method of claim 1, and reconstituting the lyophilized polypeptide with a sufficient amount of a pharmaceutically acceptable dispersing agent to yield a liquid polypeptide composition.

8. The method of claim 7 wherein the polypeptide is an antigen binding polypeptide.

9. The method of claim 7 wherein the polypeptide comprises at least two GLP-1 polypeptides genetically fused to the N-terminus of human serum albumin.

10. The method of claim 8 wherein the antigen binding polypeptide is selected from the group consisting of soluble receptor, antibody, antibody fragment, immunoglobulin single variable

domain, Fab, $F(ab')_2$, Fv, disulphide linked Fv, scFv, closed conformation multispecific antibody, disulphide-linked scFv, and diabody.

11. A liquid polypeptide composition produced by the method of any one of claims 7 to 10.

12. A method for reducing the reconstitution time of a lyophilized polypeptide composition comprising:

a) lyophilizing a liquid mixture comprising the polypeptide, wherein the liquid mixture comprises about 0.25 to about 5% by volume of volatile additive, wherein the volatile additive is t-butanol and

b) reconstituting the lyophilized polypeptide with a sufficient amount of a pharmaceutically acceptable dispersing agent to the lyophilized polypeptide composition to yield a liquid polypeptide composition,

wherein time for reconstituting the polypeptide lyophilized in the presence of the volatile additive is less than the time for reconstituting the same polypeptide lyophilized in the absence of the volatile additive.

13. The method of claim 12 wherein the polypeptide is an antigen binding polypeptide.

14. The method of claim 12 wherein the polypeptide comprises at least two GLP-1 polypeptides genetically fused to the N-terminus of human serum albumin.

15. The method of claim 13 wherein the antigen binding polypeptide is selected from the group consisting of soluble receptor, antibody, antibody fragment, immunoglobulin single variable domain, Fab, $F(ab')_2$, Fv, disulphide linked Fv, scFv, closed conformation multispecific antibody, disulphide-linked scFv, and diabody.

16. A composition comprising: a therapeutic polypeptide, a buffer, a surfactant, at least one excipient, and at least one volatile additive, wherein the volatile additive is t-butanol and the t-butanol is present at about 0.25% to about 5% by volume.

17. The composition of claim 16 wherein the therapeutic polypeptide comprises GLP-1 or a fragment and/or variant thereof.

18. The composition of claim 16 wherein the therapeutic polypeptide comprises at least two GLP-1(7-36(A8G)) polypeptides genetically fused to the N-terminus of human serum albumin.

19. The composition of any one of claims 16 to 18 wherein the therapeutic polypeptide comprises SEQ ID NO:1.

20. The composition of any one of claims 16 or 19 wherein the buffer is sodium phosphate.

21. The composition of any one of claims 16 to 20 wherein the surfactant is polysorbate-80.

22. The composition of any one of claims 16 to 21 wherein the at least one excipient is selected from: trehalose, maltose, sucrose, mannose, lactose, mannitol, sorbitol, glycerol and dextrose.

23. The composition of any one of claims 16 to 22 wherein the excipient comprises: trehalose and mannitol.

24. A composition comprising: a polypeptide comprising SEQ ID NO:1, sodium phosphate, trehalose, mannitol, polysorbate-80 and t-butanol, wherein the t-butanol is present at about 0.25% to about 5% by volume.