CLAIMS

1. A salt-free anti-TFPI antibody formulation, comprising:

a. 10 mM to 30 mM histidine,

b. 50 ppm to 200 ppm of a non-ionic surfactant,

c. 88 mM to 292 mM of a sugar or sugar alcohol selected from mannitol, dextrose, glucose, trehalose and sucrose,

d. 0 mM to 50 mM arginine,

e. 0 mM to 50 mM lysine,

f. 0 mM to 133 mM glycine or alanine

g. 0 mM to 10 mM methionine, and

h. 20 mg/ml to 150 mg/ml of anti-TFPI antibody;

wherein said anti-TFPI antibody formulation has a pH of pH 4.0 to pH 6.0 and wherein said anti-TFPI antibody formulation contains substantially no inorganic salt; and

wherein said anti-TFPI antibody is a human IgG2 monoclonal antibody and comprises a light chain comprising the amino acid sequence of SEQ ID NO: 1 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 2.

2. The salt-free anti-TFPI antibody formulation of claim 1 wherein said formulation has a viscosity ranging from 1 to 8 mPa-S at 22° C.

3. The salt-free anti-TFPI antibody formulation of claim 1 wherein said formulation has and osmolality ranging from 240 to 380 mmol/kg.

4. The salt-free anti-TFPI antibody formulation of claims 1 wherein said non-ionic surfactant is a polysorbate selected from polysorbate 20 and polysorbate 80.

5. The salt-free anti-TFPI antibody formulation of claim 1 wherein said sugar is sucrose.

6. The salt-free anti-TFPI antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 75 ppm Tween 80,

c. 234 mM sucrose,

d. 30 mM arginine, and

e. 10 mM methionine, and

f. 100 mg/ml anti-TFPI antibody;

wherein said anti-TFPI antibody formulation has a pH of 5.5.

7. A salt-free protein or antibody formulation, comprising:

a. 10 mM to 30 mM histidine;

b. 50 ppm to 200 ppm of a non-ionic surfactant;

c. 88 mM to 292 mM of a sugar or sugar alcohol selected from mannitol, dextrose, glucose, trehalose, and sucrose;

d. 0 mM to 50 mM arginine;

e. 0 mM to 50 mM lysine;

f. 0 mM to 133 mM glycine or alanine;

g. 0 mM to 10 mM methionine; and

h. 1 mg/ml to 150 mg/ml of a protein or an antibody;

wherein said protein or antibody formulation has a pH ranging from pH 4.0 to pH 6.0 and wherein said protein formulation contains substantially no inorganic salt.

8. The salt-free protein or antibody formulation of claim 7 wherein said formulation has a viscosity ranging from 1 to 8 mPa-S at 22°C.

9. The salt-free protein or antibody formulation of claim 7 wherein said formulation has and osmolality ranging from 240 to 380 mmol/kg.

10. The salt-free protein or antibody formulation of any of claim 7 wherein said non-ionic surfactant is a polysorbate selected from polysorbate 20 and polysorbate 80.

11. The salt-free protein or antibody formulation of claim 7 wherein said sugar is sucrose.

12. The salt-free protein or antibody formulation of claim 7 comprising between 10 mM and 50 mM arginine.

13. The salt-free protein or antibody formulation of claim 7, comprising:

a. 30 mM histidine,

b. 100 ppm polysorbate 80,

c. 292 mM sucrose, and

d. 20 mg/ml protein or antibody;

wherein said protein or antibody formulation has a pH ranging from pH 5.0 to pH 6.0.

14. The salt-free protein or antibody formulation of claim 7, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 234 mM sucrose,

d. 50 mg/ml protein or antibody;

wherein said protein or antibody formulation has a pH ranging from pH 5.0 to pH 6.0.

15. The salt-free protein or antibody formulation of claim 7, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 234 mM sucrose, and

d. 100 mg/ml protein or antibody;

wherein said protein or antibody formulation has a pH ranging from pH 5.0 to pH 6.0.

16. The salt-free protein or antibody formulation of claim 7, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 88 mM sucrose,

d. 133 mM glycine, and

e. 100 mg/ml protein or antibody;

wherein said protein or antibody formulation has a pH ranging from pH 5.0 to pH 6.0.

17. The salt-free protein or antibody formulation of claim 7, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 20,

c. 88 mM sucrose,

d. 133 mM glycine, and

e. 100 mg/ml protein or antibody;

wherein said protein or antibody formulation has a pH ranging from pH 5.0 to pH 6.0.

18. The salt-free protein or antibody formulation of claim 7, comprising:

a. 10 mM histidine,

b. 200 ppm polysorbate 20,

c. 88 mM sucrose,

d. 133 mM glycine, and

e. 100 mg/ml protein or antibody;

wherein said protein or antibody formulation has a pH ranging from pH 5.0 to pH 6.0.

19. The salt-free protein or antibody formulation of claim 7, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 88 mM sucrose, and

d. 100 mg/ml protein or antibody;

wherein said protein or antibody formulation has a pH ranging from pH 5.0 to pH 6.0.

20. The salt-free protein or antibody formulation of claim 7, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 88 mM sucrose,

d. 10 mM arginine, and

e. 100 mg/ml protein or antibody;

wherein said protein or antibody formulation has a pH ranging from pH 5.0 to pH 6.0.

21. The salt-free protein or antibody formulation of claim 7, comprising 5 mM to 10 mM methionine.

22. The salt-free protein or antibody formulation of claim 7, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 88 mM sucrose,

d. 30 mM lysine, and

e. 100 mg/ml protein or antibody;

wherein said protein or antibody formulation has a pH ranging from pH 5.0 to pH 6.0.

23. A salt-free anti-TFPI antibody formulation, comprising:

a. 10 mM to 30 mM histidine,

b. 50 ppm to 200 ppm of a non-ionic surfactant,

c. 88 mM to 292 mM of a sugar or sugar alcohol selected from mannitol, dextrose, glucose, trehalose and sucrose,

d. 0 mM to 50 mM arginine,

e. 0 mM to 50 mM lysine,

f. 0 mM to133 mM glycine or alanine

g. 0 mM to 10 mM methionine, and

h. 1 mg/ml to 150 mg/ml of anti-TFPI antibody;

wherein said anti-TFPI antibody formulation has a pH of pH 4.0 to pH 6.0 and wherein said anti-TFPI antibody formulation contains substantially no inorganic salt.

24. The salt-free anti-TFPI antibody formulation of claim 23 wherein said formulation has a viscosity ranging from 1 to 8 mPa-S at 22°C.

25. The salt-free anti-TFPI antibody formulation of claim 23 wherein said formulation has and osmolality ranging from 240 to 380 mmol/kg.

26. The salt-free anti-TFPI antibody formulation of claims 23 wherein said non-ionic surfactant is a polysorbate selected from polysorbate 20 and polysorbate 80.

27. The salt-free anti-TFPI antibody formulation of claim 23 wherein said sugar is sucrose.

28. The salt-free anti-TFPI antibody formulation of claim 23, comprising:

a. 10mM histidine,

b. 75ppm Tween 80,

c. 234 mM sucrose,

d. 30mM arginine, and

e. 10mM methionine, and

f. 100 mg/ml anti-TFPI antibody;

wherein said anti-TFPI antibody formulation has a pH of 5.5.

29. The salt-free anti-TFPI antibody formulation of claim 23 wherein said anti-TFPI antibody is a human IgG_2 monoclonal antibody.

30. The salt-free anti-TFPI antibody formulation of claim 23 wherein said human IgG_2 monoclonal antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO: 1 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 2.

31. The use of a therapeutically effective amount of a protein or antibody formulation comprising between 10 mM and 30 mM histidine, between 50 ppm and 200 ppm polysorbate 80 or polysorbate 20, between 88 mM and 292 mM sucrose, between 0 mM and 50 mM arginine, between 0 mM and 50 mM lysine, between 0 mM and 133 mM glycine, between 0 mM and 10 mM methionine, and between 1

mg/ml and 150 mg/ml of a protein or antibody at a pH of between pH 4.0 and pH 6.0, in the manufacture of a medicament for the treatment of a disorder in a patient, wherein said protein or antibody formulation contains substantially no inorganic salt.

32. The use of claim 31 wherein said protein or antibody formulation is administered intravenously, subcutaneously, or intramuscularly.

33. The use of a therapeutically effective amount of an anti-TFPI antibody formulation that contains between 10 mM and 30 mM histidine, between 50 ppm and 200 ppm polysorbate 80 or polysorbate 20, between 88 mM and 292 mM sucrose, between 0 mM and 50 mM arginine, between 0 mM and 50 mM lysine, between 0 mM and 133 mM glycine , between 0 mM and 10 mM methionine, and between 1 mg/ml and 150 mg/ml of a protein at a pH of between pH 4.0 and pH 6.0, in the manufacture of a medicament for the treatment of hemophilia A or hemophilia B in a patient, and wherein said anti-TFPI formulation contains substantially no inorganic salt.

34. The method of claim 33 wherein said anti-TFPI antibody is a human IgG_2 monoclonal antibody.

35. The method of claim 34 wherein said human IgG_2 monoclonal antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO: 1 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 2.

36. The method of claim 33 wherein said anti-TFPI antibody formulation is administered intravenously, intramuscularly, or subcutaneously.

CLAIMS

1. An anti-TFPI antibody formulation, comprising:

a. 10 mM to 30 mM histidine,

b. 50 ppm to 200 ppm of a non-ionic surfactant,

c. 88 mM to 292 mM of a sugar or sugar alcohol selected from mannitol, dextrose, glucose, trehalose and sucrose,

d. 10 mM to 50 mM arginine,

e. 0 mM to 50 mM lysine,

f. 0 mM to 133 mM glycine or alanine

g. 0 mM to 10 mM methionine, and

h. 1 mg/ml to 150 mg/ml of anti-TFPI antibody;

wherein said anti-TFPI antibody formulation has a pH of pH 4.0 to pH 6.0 and wherein said anti-TFPI antibody formulation contains no inorganic salt; and

wherein said anti-TFPI antibody is a human IgG2 monoclonal antibody and comprises a light chain comprising the amino acid sequence of SEQ ID NO: 1 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 2.

2. The anti-TFPI antibody formulation of claim 1 wherein said formulation has a viscosity ranging from 1 to 8 mPa-S at 22° C.

3. The anti-TFPI antibody formulation of claim 1 wherein said formulation has an osmolality ranging from 240 to 380 mmol/kg.

4. The anti-TFPI antibody formulation of claims 1 wherein said non-ionic surfactant is a polysorbate selected from polysorbate 20 and polysorbate 80.

5. The anti-TFPI antibody formulation of claim 1 wherein said sugar is sucrose.

6. The anti-TFPI antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 75 ppm Tween 80,

c. 234 mM sucrose,

d. 30 mM arginine, and

e. 10 mM methionine, and

f. 100 mg/ml anti-TFPI antibody;

wherein said anti-TFPI antibody formulation has a pH of 5.5.

7. The use of a therapeutically effective amount of a formulation of claim 1 in the manufacture of a medicament for the treatment of hemophilia A or hemophilia B in a patient.

8. The use of claim 7 wherein said protein or antibody formulation is administered intravenously, subcutaneously, or intramuscularly.