CLAIMS

What is claimed is:

1. An anti-PRLR antibody formulation, comprising:
   a. 0 mM to 70 mM histidine;
   b. 50 ppm to 300 ppm of a non-ionic surfactant;
   c. 34 mM to 292 mM of a sugar 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 270 mM glycine or alanine;
   g. 0 mM to 10 mM methionine; and
   h. 1 mg/ml to 150 mg/ml of an anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

2. The anti-PRLR antibody formulation of claim 1 wherein said anti-PRLR formulation contains substantially no inorganic salt other than an organic salt or an inorganic salt that buffers said formulation.

3. The anti-PRLR antibody formulation of claim 1 wherein said anti-PRLR formulation contains substantially no inorganic salt selected from the group consisting of sodium chloride (NaCl), sodium sulfate (Na_2SO_4), sodium thiocyanate (NaSCN), magnesium chloride (MgCl), magnesium sulfate ($MgSO_4$), ammonium thiocyanate (NH_4SCN), ammonium sulfate ($(NH_4)_2SO_4$), ammonium chloride (NH_4Cl), calcium chloride ($CaCl_2$), calcium sulfate ($CaSO_4$), and zinc chloride ($ZnCl_2$).

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

5. The anti-PRLR antibody formulation of claim 1 wherein said formulation has and osmolality ranging from 240 to 380 mmol/kg.

6. The anti-PRLR antibody formulation of any of claim 1 wherein said non-ionic surfactant is a polysorbate selected from polysorbate 20 and polysorbate 80.

7. The anti-PRLR antibody formulation of claim 1 wherein said sugar is sucrose or trehalose.

8. The anti-PRLR antibody formulation of claim 1 comprising between 10 mM and 50 mM arginine.

9. The anti-PRLR antibody formulation of claim 1, comprising:

a. 30 mM histidine,

b. 100 ppm polysorbate 80,

c. 292 mM sucrose, and

d. 20 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

10. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 80 ppm polysorbate 80,

c. 234 mM sucrose,

d. 60 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.0.

11. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 234 mM sucrose, and

d. 60 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

12. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 88 mM sucrose,

d. 270 mM glycine, and

e. 60 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

13. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 20,

c. 88 mM sucrose,

d. 133 mM glycine, and

e. 60 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

14. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 200 ppm polysorbate 20,

c. 88 mM sucrose,

d. 133 mM glycine, and

e. 60 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

15. The anti-PRLR antibody formulation of claim 1, comprising:

a. 70 mM histidine,

b. 80 ppm polysorbate 80,

c. 200 mM sucrose, and

d. 60 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

16. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 292 mM sucrose,

d. 10 mM arginine, and

e. 60 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

17. The anti-PRLR antibody formulation of claim 1, comprising:

a. 70 mM histidine,

b. 75 ppm polysorbate 80,

c. 176 mM sucrose,

d. 30 mM lysine, and

e. 60 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

18. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10mM histidine,

b. 75 ppm polysorbate 80,

c. 234 mM sucrose,

d. 30mM arginine, and

e. 10mM methionine, and

f. 60 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

19. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10mM histidine,

b. 75 ppm polysorbate 80,

c. 234 mM sucrose,

d. 30mM arginine, and

e. 10mM methionine, and

f. 2 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

20. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 234 mM sucrose,

d. 20 mM arginine, and

e. 10 mM methionine, and

f. 150 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

21. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 205 mM sucrose,

d. 20 mM arginine,

e. 10 mM methionine, and

f. 1 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

22. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 80ppm polysorbate 80,

c. 205 mM sucrose,

d. 20 mM arginine, and

e. 10 mM methionine, and

f. 60 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

23. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 205 mM trehlose,

d. 20 mM arginine, and

e. 10 mM methionine, and

f. 60 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

24. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10 mM histidine,

b. 75 ppm polysorbate 80,

c. 205 mM trehalose,

d. 30 mM arginine,

e. 10 mM methionine, and

f. 2 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

25. The anti-PRLR antibody formulation of claim 1, comprising:

a. 10 mM histidine,
b. 234 mM sucrose,
c. 80 ppm polysorbate 80,
d. 30 mM arginine,
e. 5 mM methionine, and
f. 7.5 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

26. The anti-PRLR antibody formulation of claim 1, comprising:
a. 10 mM histidine,
b. 234 mM sucrose,
c. 80 ppm polysorbate 80,
d. 30 mM arginine,
e. 5 mM methionine, and
f. 60 mg/mL anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

27. The anti-PRLR antibody formulation of claim 1, comprising:
a. 10 mM histidine,
b. 234 mM sucrose,
c. 75 ppm polysorbate 80,
d. 30 mM arginine,
e. 10 mM methionine, and
f. 60 mg/mL anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

28. The anti-PRLR antibody formulation of claim 1, comprising:
a. 10 mM histidine,
b. 263 mM sucrose,

c. 80 ppm polysorbate 80, and

d. 60 mg/mL anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.

29. The anti-PRLR antibody formulation of claim 1 wherein said anti-PRLR antibody is a human IgG2 monoclonal antibody.

30. The anti-PRLR antibody formulation of claim 29 wherein said human IgG2 monoclonal antibody comprises a light chain sequence and a heavy chain sequence presented in one or more of PCT Patent Publication NOs. WO/2011/069799, WO/2011/069798, WO/2011/069797, WO/2011/069796, WO/2011/069795, and WO/2011/069794.

31. The anti-PRLR antibody formulation of claim 29 wherein said human IgG2 monoclonal antibody comprises a light chain sequence of SEQ ID NO: 1 and a heavy chain sequence of SEQ ID NO: 7.

32. A method for the non-hormonal treatment of endometriosis in a patient, said method comprising administering to said patient a therapeutically effective amount of an anti-PRLR antibody formulation comprising between 0 mM and 70 mM histidine, between 50 ppm and 200 ppm polysorbate 80 or polysorbate 20, between 34 mM and 292 mM sucrose or trehalose, between 0 mM and 50 mM arginine, between 0 mM and 50 mM lysine, between 0 mM and 270 mM glycine or alanine, 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 5.0 and pH 6.5, wherein said anti-PRLR antibody formulation contains substantially no inorganic salt.

33. The method of claim 32 wherein said anti-PRLR antibody formulation is administered intravenously, subcutaneously, or intramuscularly.

34. The method of claim 33 wherein said anti-PRLR antibody is a human IgG2
monoclonal antibody.

35. The method of claim 34 wherein said human IgG2 monoclonal antibody comprises a light chain sequence and a heavy chain sequence presented in one or more of PCT Patent Publication NOs. WO/2011/069799, WO/2011/069798, WO/2011/069797, WO/2011/069796, WO/2011/069795, and WO/2011/069794.

36. The method of claim 34 wherein said human IgG2 monoclonal antibody comprises a light chain sequence of SEQ ID NO: 1 and a heavy chain sequence of SEQ ID NO: 7.

CLAIMS

1. An anti-PRLR antibody formulation, comprising:
10 to 70 mM histidine,
50 to 300 ppm polysorbate 80,
34 to 292 mM sucrose, and
1 to 150 mg/ml anti-PRLR antibody;
wherein said anti-PRLR antibody formulation has a pH of 5.0 to 6.5.

2. The anti-PRLR antibody formulation of claim 1, comprising:
10 mM histidine,
80 ppm polysorbate 80,
234 mM sucrose,
60 mg/ml anti-PRLR antibody.

3. The anti-PRLR antibody formulation of claim 1, comprising:
10 mM histidine,
75 ppm polysorbate 80,
234 mM sucrose, and
60 mg/ml anti-PRLR antibody.

4. The anti-PRLR antibody formulation of claim 1, further comprising 133 to 270 mM glycine.

5. The anti-PRLR antibody formulation of claim 4, comprising:
10 mM histidine,
75 ppm polysorbate 20,
88 mM sucrose,
133 mM glycine, and
60 mg/ml anti-PRLR antibody.

6. The anti-PRLR antibody formulation of claim 4, comprising:
10 mM histidine,
200 ppm polysorbate 20,

88 mM sucrose,
133 mM glycine, and
60 mg/ml anti-PRLR antibody.

7. The anti-PRLR antibody formulation of claim 1, comprising:
70 mM histidine,
80 ppm polysorbate 80,
200 mM sucrose, and
60 mg/ml anti-PRLR antibody.

8. The anti-PRLR antibody formulation of claim 1, further comprising:
a) 10 to 50 mM arginine,
b) 5 to 10 mM methionine, or
c) 10 to 50 mM arginine and 5 to 10 mM methionine.

9. The anti-PRLR antibody formulation of claim 1, further comprising 30 to 50 mM lysine.

10. The anti-PRLR antibody formulation of claim 8, comprising:
10 mM histidine,
75 ppm polysorbate 80,
234 mM sucrose,
30 mM arginine,
10 mM methionine, and
60 mg/ml anti-PRLR antibody.

11. The anti-PRLR antibody formulation of claim 8, comprising:
10 mM histidine,
75 ppm polysorbate 80,
234 mM sucrose,
30 mM arginine,
10 mM methionine, and
2 mg/ml anti-PRLR antibody.

12. The anti-PRLR antibody formulation of claim 8, comprising:

10 mM histidine,
75 ppm polysorbate 80,
234 mM sucrose,
20 mM arginine,
10 mM methionine, and
150 mg/ml anti-PRLR antibody.

13. The anti-PRLR antibody formulation of claim 8, comprising:
10 mM histidine,
75 ppm polysorbate 80,
205 mM sucrose,
20 mM arginine,
10 mM methionine, and
1 mg/ml anti-PRLR antibody.

14. The anti-PRLR antibody formulation of claim 8, comprising:
10 mM histidine,
80 ppm polysorbate 80,
205 mM sucrose,
20 mM arginine,
10 mM methionine, and
60 mg/ml anti-PRLR antibody.

15. An anti-PRLR antibody formulation, comprising:
10 to 70 mM histidine,
50 to 300 ppm polysorbate 80,
34 to 292 mM trehalose,
10 to 50 mM arginine, and
5 to 10 mM methionine, and
1 to 150 mg/ml anti-PRLR antibody;
wherein said anti-PRLR antibody formulation has a pH of 5.0 to 6.5.

16. The anti-PRLR antibody formulation of claim 15, comprising:
10 mM histidine,

75 ppm polysorbate 80,
205 mM trehalose,
30 mM arginine,
10 mM methionine, and
2 mg/ml anti-PRLR antibody.

17. The anti-PRLR antibody formulation of claim 8, comprising:
10 mM histidine,
234 mM sucrose,
80 ppm polysorbate 80,
30 mM arginine,
5 mM methionine, and
7.5 mg/ml anti-PRLR antibody.

18. The anti-PRLR antibody formulation of claim 8, comprising:
10 mM histidine,
234 mM sucrose,
80 ppm polysorbate 80,
30 mM arginine,
5 mM methionine, and
60 mg/mL anti-PRLR antibody.

19. The anti-PRLR antibody formulation of claim 8, comprising:
10 mM histidine,
234 mM sucrose,
75 ppm polysorbate 80,
30 mM arginine,
10 mM methionine, and
60 mg/mL anti-PRLR antibody.

20. The anti-PRLR antibody formulation of claim 1, comprising:
10 mM histidine,
263 mM sucrose,
80 ppm polysorbate 80, and

60 mg/mL anti-PRLR antibody.

21. The anti-PRLR antibody formulation of claim 1, wherein said anti-PRLR antibody is a human IgG2 monoclonal antibody comprising a light chain sequence of SEQ ID NO: 1 and a heavy chain sequence of SEQ ID NO: 7.

22. The anti-PRLR antibody formulation of claim 1, comprising:
30 mM histidine,
100 ppm polysorbate 80,
292 mM sucrose, and
20 mg/ml anti-PRLR antibody.

23. The anti-PRLR antibody formulation of claim 4, comprising:
10 mM histidine,
75 ppm polysorbate 80,
88 mM sucrose,
270 mM glycine, and
60 mg/ml anti-PRLR antibody.

24. The anti-PRLR antibody formulation of claim 8, comprising:
10 mM histidine,
75 ppm polysorbate 80,
292 mM sucrose,
10 mM arginine, and
60 mg/ml anti-PRLR antibody.

25. The anti-PRLR antibody formulation of claim 9, comprising:
70 mM histidine,
75 ppm polysorbate 80,
176 mM sucrose,
30 mM lysine, and
60 mg/ml anti-PRLR antibody.

26. The anti-PRLR antibody formulation of claim 15, comprising:

10 mM histidine,

75 ppm polysorbate 80,

205 mM trehalose,

20 mM arginine, and

10 mM methionine, and

60 mg/ml anti-PRLR antibody;

wherein said anti-PRLR antibody formulation has a pH ranging from pH 5.0 to pH 6.5.