CLAIMS:

1. A pharmaceutical formulation comprising: (i) a human antibody that specifically binds to human interleukin-6 receptor (hIL-6R); (ii) histidine; and (iii) a carbohydrate.

2. The pharmaceutical formulation of claim 1, wherein the carbohydrate is a sugar selected from the group consisting of sucrose, glucose, mannitol, lactose and trehalose.

3. The pharmaceutical formulation of claim 1, wherein the carbohydrate is sucrose.

4. The pharmaceutical formulation of any one of claims 1-3, wherein said human antibody that specifically binds to hIL-6R comprises a heavy chain variable region (HCVR) and a light chain variable region (LCVR), wherein the HCVR comprises heavy and light chain complementarity determining regions (HCDR1-HCDR2-HCDR3 / LCDR1-LCDR2-LCDR3) having the amino acid sequences of: (i) SEQ ID NOs:4 – 6 – 8 / SEQ ID NOs:12 – 14 – 16; (ii) SEQ ID NOs:20 – 22 – 24 / SEQ ID NOs:28 – 30 – 32; (iii) SEQ ID NOs:36 – 38 – 40 / SEQ ID NOs:44 – 46 – 48; or (iv) SEQ ID NOs:52 – 54 – 56 / SEQ ID NOs:60 – 62 – 64.

5. The pharmaceutical formulation of claim 4, wherein said human antibody that specifically binds to hIL-6R comprises heavy chain and light chain variable region (HCVR / LCVR) amino acid sequence pairs selected from the group consisting of: (i) SEQ ID NOs:2/10; (ii) SEQ ID NOs:18/26; (iii) SEQ ID NOs:34/42; and (iv) SEQ ID NOs:50/58.

6. The pharmaceutical formulation of any one of claims 1-5, wherein said human antibody that specifically binds to human interleukin-6 receptor (hIL-6R) is at a concentration of about 5 to 200 mg/mL.

7. The pharmaceutical formulation of any one of claims 1-6, wherein the histidine is at a concentration of about 5 to 50 mM.

8. The pharmaceutical formulation of any one of claims 1-7, wherein the carbohydrate is at a concentration of about 1 to 20%.

9. The pharmaceutical formulation of any one of claims 1-8, further comprising a non-ionic surfactant.

10. The pharmaceutical formulation of claim 9, wherein said non-ionic surfactant is selected from the group consisting of polysorbate 20, polysorbate 80 and polyoxyethylene sorbitan monooleate.

11. The pharmaceutical formulation of claim 9, wherein said non-ionic surfactant is polysorbate 20.

12. The pharmaceutical formulation of any one of claims 9-11, wherein said non-ionic surfactant is at a concentration of about 0.01 to 1%.

13 The pharmaceutical formulation of any one of claims 9-12 comprising: (i) about 25 to 200 mg/mL of said human antibody that specifically binds to hIL-6R; (ii) about 10 to 25 mM histidine; (iii) about 5 to 10% sucrose; and (iv) about 0.1 to 0.2% polysorbate 20.

14. The pharmaceutical formulation of any one of claims 9-12, comprising: (i) about 100 mg/mL of a human antibody that specifically binds to hIL-6R; (ii) about 10 mM histidine; (iii) about 10% sucrose; and (iv) about 0.2% polysorbate 20.

15. The pharmaceutical formulation of any one of claims 9-14, further comprising arginine.

16. The pharmaceutical formulation of claim 15, wherein the arginine is at a concentration of about 5 to 100 mM.

17. The pharmaceutical formulation of claim 15, wherein the arginine is at a concentration of about 25 to 50 mM.

18. The pharmaceutical formulation of claim 15, comprising: (i) about 150 mg/mL of said human antibody that specifically binds to hIL-6R; (ii) about 25 mM histidine; (iii) about 5% sucrose; (iv) about 0.2% polysorbate 20; and (v) about 25 mM arginine.

19. The pharmaceutical formulation of claim 15, comprising: (i) about 175 mg/mL of said human antibody that specifically binds to hIL-6R; (ii) about 25 mM histidine; (iii) about 5% sucrose; (iv) about 0.2% polysorbate 20; and (v) about 50 mM arginine.

20. The pharmaceutical formulation of claim 19, wherein said human antibody that specifically binds to human interleukin-6 receptor (hIL-6R) comprises a heavy chain and light chain variable region (HCVR / LCVR) amino acid sequence pair of SEQ ID NOs:18/26.

21. The pharmaceutical formulation of claim 19 or claim 20, wherein at least 90% of native form of said antibody is recovered after nine months of storage at 5ºC, as determined by size exclusion-high performance liquid chromatography (SE-HPLC).

22. The pharmaceutical formulation of claim 19 or claim 20, wherein at least 95% of native form of said antibody is recovered after nine months of storage at 5ºC, as determined by size exclusion-high performance liquid chromatography (SE-HPLC).

23. The pharmaceutical formulation of claim 19 or claim 20, wherein at least 96% of native form of said antibody is recovered after nine months of storage at 5ºC, as determined by size exclusion-high performance liquid chromatography (SE-HPLC).

24. The pharmaceutical formulation of any one of claims 19-23, wherein the formulation exhibits a viscosity of less than about 15 cPoise.

25. The pharmaceutical formulation of any one of claims 19-23, wherein the formulation exhibits a viscosity of less than about 12 cPoise.

26. The pharmaceutical formulation of any one of claims 19-23, wherein the formulation exhibits a viscosity of less than about 9 cPoise.

27. The pharmaceutical formulation of any one of claims 16-26 contained in a glass vial.

28. The pharmaceutical formulation of any one of claims 16-26 contained in a syringe.

29. The pharmaceutical formulation of any one of claims 16-26 contained in a microinfusor.

30. The pharmaceutical formulation of claim 28, wherein said syringe comprises a fluorocarbon-coated plunger.

31. The pharmaceutical formulation of claim 28, wherein said syringe is a low tungsten syringe.

32. A pharmaceutical formulation comprising: (i) about 5 to 200 mg/mL of a human antibody that specifically binds to human interleukin-6 receptor (hIL-6R); (ii) about 5 to 50 mM histidine; (iii) about 1 to 20% sucrose; and (iv) about 0.01 to 1% polysorbate 20.

33. A pharmaceutical formulation comprising: (i) about 175 mg/mL of a human antibody that specifically binds to human interleukin-6 receptor (hIL-6R), wherein said antibody comprises a heavy chain and light chain variable region (HCVR / LCVR) amino acid sequence pair of SEQ ID NOs:18/26; (ii) about 25 mM histidine; (iii) about 5% sucrose; (iv) about 0.2% polysorbate 20; and (v) about 50 mM arginine.

CLAIMS

1. A stable pharmaceutical formulation comprising:

(i) a human antibody that specifically binds to human interleukin-6 receptor (hIL-6R), wherein the antibody is at a concentration of from 5 mg/ml to 200 mg/ml and comprises a heavy chain variable region having the amino acid sequence of SEQ ID NO:18 and a light chain variable region having the amino acid sequence of SEQ ID NO:26;

(ii) histidine at a concentration of from 25 mM to 100 mM;

(iii) arginine at a concentration of from 25 mM to 50 mM;

(iv) sucrose in an amount of from 2% to 10% w/v; and

(v) polysorbate in an amount of from 0.1% to 0.2% w/v.

2. The pharmaceutical formulation of claim 1, wherein the histidine is at a concentration of 25 mM.

3. The pharmaceutical formulation of claim 1 or 2, wherein the arginine is present at a concentration of 50 mM.

4. The pharmaceutical formulation of any one of claims 1 to 3, wherein the sucrose is present in an amount of 5% w/v.

5. The pharmaceutical formulation of any one of claims 1 to 4, wherein the polysorbate is present at a concentration of 0.2% w/v.

6. The pharmaceutical formulation of any one of claims 1 to 5, wherein the formulation has a pH of 6.

7 The pharmaceutical formulation of any one of the preceding claims comprising 25 to 200 mg/mL of said human antibody that specifically binds to hIL-6R.

8. The pharmaceutical formulation of claim 7 comprising from 50 mg/mL to 180 mg/mL of the human antibody that specifically binds to hIL-6R.

9. The pharmaceutical formulation of claim 8, comprising 150 mg/mL of said human antibody that specifically binds to hIL-6R.

10. The pharmaceutical formulation of claim 8, comprising 175 mg/mL of said human antibody that specifically binds to hIL-6R.

11. The pharmaceutical formulation of any one of the preceding claims, wherein at least 90% of the native form of said antibody is recoverable after nine months of storage at 5ºC, as determined by size exclusion-high performance liquid chromatography (SE-HPLC).

12. The pharmaceutical formulation of claim 11, wherein at least 95% of the native form of said antibody is recoverable after nine months of storage at 5ºC, as determined by size exclusion-high performance liquid chromatography (SE-HPLC).

13. The pharmaceutical formulation of claim 12, wherein at least 96% of the native form of said antibody is recoverable after nine months of storage at 5ºC, as determined by size exclusion-high performance liquid chromatography (SE-HPLC).

14. The pharmaceutical formulation of any one of the preceding claims, wherein the formulation exhibits a viscosity of less than about 15 cPoise.

15. The pharmaceutical formulation of any one of claims 1 to 13, wherein the formulation exhibits a viscosity of less than about 12 cPoise.

16. The pharmaceutical formulation of claim 15, wherein the formulation exhibits a viscosity of less than about 9 cPoise.

17. A stable pharmaceutical formulation comprising:

(i) 5 to 200 mg/mL of a human antibody that specifically binds to human interleukin-6 receptor (hIL-6R), wherein the antibody comprises a heavy chain variable region having the amino acid sequence of SEQ ID NO:18 and a light chain variable region having the amino acid sequence of SEQ ID NO:26;

(ii) 25 mM histidine;

(iii) 5% w/v sucrose;

(iv) 0.2% w/v polysorbate 20; and

(v) 50 mM arginine.

18. A stable pharmaceutical formulation comprising:

(i) 175 mg/mL of a human antibody that specifically binds to human interleukin-6 receptor (hIL-6R), wherein said antibody comprises a heavy chain and light chain variable region (HCVR / LCVR) amino acid sequence pair of SEQ ID NOs:18/26;

(ii) 25 mM histidine;

(iii) 5% sucrose;

(iv) 0.2% polysorbate 20; and

(v) 50 mM arginine.

19. The pharmaceutical formulation of any one of claims 1 to 18, wherein the formulation is contained in a stacked needle prefilled syringe.

20. The pharmaceutical formulation of any one of claims 1 to 18, wherein the formulation is contained in a glass vial, a syringe, or microinfusor.

21. The pharmaceutical formulation of claim 20, wherein said syringe comprises a fluorocarbon-coated plunger.

22. The pharmaceutical formulation of claim 20, wherein said syringe is a low tungsten syringe.

23. The pharmaceutical formulation of claim 17 or 18, wherein at least 96% of the native form of said antibody is recoverable after two months of storage at 5°C, as determined by size exclusion-high performance liquid chromatography.

24. Use of the stable pharmaceutical formulation of any one of claims 1 to 18 or 23 in the manufacture of a medicament of the treatment, prevention and/or amelioration of a disease or disorder associated with IL-6 activity including diseases or disorders mediated by activation of the IL-6 receptor (IL-6R).

25. The use of claim 24, wherein the disease or disorder is selected from the group consisting of rheumatoid arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, pancreatitis, juvenile idiopathic arthritis, vasculitis, Kawasaki disease, systemic lupus erythematosis, psoriasis, psoriatic arthritis, Sjogren syndrome, Still's disease, Castleman's

disease, multiple sclerosis, diseases associated with abnormal blood coagulation or fibrinolysis, cancer, cachexia, chronic rejection of transplanted organs and cells, cardiopathy, viral infection, plasmacytosis, hyperimmunoglobulinemia, anemia, nephritis, mesothelioma, hearing loss, and other inner ear disorders.