Claims

1. A pharmaceutical composition comprising:
    a. an antibody or an antigen-binding fragment thereof, comprising a light variable region as defined in SEQ ID NO: 7 and a heavy variable region as defined in SEQ ID NO:8;
    b. from 1% to 20% w/v sucrose;
    c. an amino acid or a mixture of amino acids; and
    d. a surfactant, and
    e. a pH of from 4.0 to 7.5.
2. The pharmaceutical composition according to claim 1, wherein the antibody or antigen-binding fragment thereof is at a concentration of from 1 to 200 mg/mL, preferably from 50 to 150 mg/mL, more preferably from 80 to 140mg/mL.
3. The pharmaceutical composition according to any one of the preceding claims, wherein the composition comprises from 5% to 13% w/v sucrose, preferably from 7% to 10% w/v sucrose, more preferably 7% w/v sucrose.
4. The pharmaceutical composition according to any one of the preceding claims, wherein:
    a. the amino acid is histidine or proline; or
    b. the mixture of amino acids comprises histidine and proline.
5. The pharmaceutical composition according to any one of the preceding claims, wherein the composition comprises 0.01 to 1.0%w/v, preferably from 0.01% to 0.5% w/v of the surfactant.
6. The pharmaceutical composition according to claim 5, wherein the surfactant is polysorbate 80.
7. The pharmaceutical composition according to any one of the preceding claims, wherein the antibody is a human or humanised antibody.
8. The pharmaceutical composition according to any one of the preceding claims, wherein the composition comprises from 1mg/mL to 200mg/mL of antibody or antigen-binding fragment thereof, from 10 mM to 50mM histidine, from 10 to 300mM proline, from 1% to 20% w/v sucrose, from 0.01% to 1.0% w/v polysorbate 80, at pH 5.6; preferably the composition comprises from 50mg/mL to 150mg/mL of antibody or antigen-binding fragment thereof, from 20 mM to 40mM histidine, from 50 to 280mM proline, from 5% to 13% w/v sucrose, from 0.01% to 0.5% w/v polysorbate 80, at pH 5.6; more preferably the composition comprises from 80mg/mL to 140mg/mL of antibody or antigen-binding fragment thereof, 30 mM histidine, 180mM proline, 7% w/v sucrose, 0.03% w/v polysorbate 80, at pH 5.6; and even more preferably the composition comprises 100mg/mL of antibody or antigen-binding fragment thereof, 30 mM histidine, 180mM proline, 7% w/v sucrose, 0.03% w/v polysorbate 80, at pH 5.6.

9. The pharmaceutical composition according to any one of the preceding claims, wherein the composition further comprises mannitol and/or arginine and/or glycine.
10. A freeze-dried formulation comprising an antibody or an antigen-binding fragment thereof, sucrose, an amino acid or a mixture of amino acids, and optionally a surfactant, wherein the formulation comprises from 10% to 40% w/w sucrose, preferably from 20% to 40% w/w sucrose and wherein the antibody or antigen-binding fragment thereof comprises a light variable region as defined in SEQ ID NO: 7 and a heavy variable region as defined in SEQ ID NO: 8.
11. A liquid pharmaceutical formulation comprising the freeze-dried formulation according to claim 10 and a solvent.
12. The liquid pharmaceutical formulation according to claim 11, wherein the solvent is water.
13. A container comprising the freeze-dried formulation according to claim 101 or the liquid pharmaceutical formulation according to any one of claims 11 or 12.
14. The pharmaceutical composition according to any one of claims 1 to 9, the freeze-dried formulation according to claim 10 or the liquid pharmaceutical formulation according to any one of claims 11 to 12 for use in therapy.
15. The pharmaceutical composition according to any one of claims 1 to 9, the freeze-dried formulation according to claim 10 or the liquid pharmaceutical formulation according to any one of claims 11 to 12 for use in the treatment of inflammatory or autoimmune diseases selected from myasthenia gravis, Pemphigus vulgaris, Neuromyelitis optica, Guillain-Barré syndrome, lupus, and thrombotic thrombocytopenic purpura, Idiopathic thrombocytopenic purpura (ITP), Chronic inflammatory demyelinating polyneuropathy (CIDP) and combinations thereof.
16. Use of a pharmaceutical composition according to any one of claims 1 to 9, use of the freeze-dried formulation according to claim 10 or use of the liquid pharmaceutical formulation according to any one of claims 11 to 12 in the manufacturing of a medicament for treating an inflammatory or autoimmune disease in a mammalian subject, wherein the inflammatory or autoimmune disease is selected from myasthenia gravis, Pemphigus vulgaris, Neuromyelitis optica, Guillain-Barré syndrome, lupus, and thrombotic thrombocytopenic purpura, Idiopathic thrombocytopenic purpura (ITP), Chronic inflammatory demyelinating polyneuropathy (CIDP) and combinations thereof.
17. A method for reconstituting a pharmaceutical composition according to claim 10 by adding a solvent, wherein the solvent is preferably water.
18. A liquid pharmaceutical formulation obtained by the method according to claim 17.