Claims

1. A stable antibody-comprising formulation comprising histidine-aspartate buffer, histidine-glutamate buffer, arginine-aspartate or arginine-glutamate, wherein an isoelectric point (pI) of the antibody is not 4 to 9.

2. A stable antibody-comprising formulation comprising histidine-aspartate buffer, histidine-glutamate buffer, arginine-aspartate or arginine-glutamate, wherein an isoelectric point (pI) of the antibody is 9.

3. The formulation according to claim 1 or 2, which comprises histidine-aspartate buffer or histidine-glutamate buffer, and arginine-aspartate or arginine-glutamate.

4. The formulation according to any one of claims 1 to 3, which does not substantially comprise chloride ion and acetate ion.

5. The formulation according to any one of claims 1 to 4, which additionally comprises a sugar.

6. The formulation according to any one of claims 1 to 5, wherein the antibody is a humanized antibody or a human antibody.

7. The formulation according to any one of claims 1 to 6, wherein the antibody concentration is 50 mg/ml or more.

8. The formulation according to any one of claims 1 to 7, wherein the antibody concentration is 50 to 250 mg/ml.

9. The formulation according to any one of claims 1 to 8, which is a liquid formulation.

10. The formulation according to claim 9, wherein the viscosity of the liquid formulation is 30 mPa·s or less.

11. The formulation according to claim 9 or 10, wherein the liquid formulation is stable at 2°C to 8°C for at least six months.

12. The formulation according to any one of claims 9 to 11, which has not been subjected to lyophilization during preparation of the formulation.

13. The formulation according to any one of claims 9 to 12, which is frozen stored at -30°C to -10°C.

14. The formulation according to any one of claims 1 to 8, wherein the formulation is a lyophilized formulation.

15. The formulation according to any one of claims 1 to 14, wherein the buffer concentration is 5 to 100 mM.

16. The formulation according to any one of claims 1 to 15, wherein the arginine concentration is 5 to 300 mM.

17. The formulation according to any one of claims 1 to 16, wherein the antibody is an anti-IL-6 receptor antibody.

18. The formulation according to any one of claims 1 to 17, wherein the buffer substantially comprises only amino acid(s).

19. The formulation according to any one of claims 1 to 18, which is for subcutaneous administration.

20. A method for suppressing aggregation formation during frozen storage of a highly-concentrated antibody-comprising formulation by using a histidine-aspartate buffer, histidine-glutamate buffer, tris(hydroxymethyl)aminomethane-aspartate buffer, or tris(hydroxymethyl)aminomethane-glutamate buffer, wherein an isoelectric point (pI) of the antibody is not 4 to 9.

21. A method for suppressing aggregation formation during liquid storage of a highly-concentrated antibody-comprising formulation by using a histidine-aspartate buffer, histidine-glutamate buffer, tris(hydroxymethyl)aminomethane-aspartate buffer, or tris(hydroxymethyl)aminomethane-glutamate buffer, wherein an isoelectric point (pI) of the antibody is not 4 to 9.

22. A method for suppressing aggregation formation during frozen storage of a highly-concentrated antibody-comprising formulation by using arginine-aspartate or arginine-glutamate, wherein an isoelectric point (pI) of the antibody is not 4 to 9.

23. A method for suppressing aggregation formation during liquid storage of a highly-concentration antibody-comprising formulation by using arginine-aspartate or arginine-glutamate, wherein an isoelectric point (pI) of the antibody is not 4 to 9.

24. A method for suppressing aggregation formation during frozen storage of a highly-concentrated antibody-comprising formulation by using a histidine-aspartate buffer, histidine-glutamate buffer, tris(hydroxymethyl)aminomethane-aspartate buffer, or tris(hydroxymethyl)aminomethane-glutamate buffer, wherein an isoelectric point (pI) of the antibody is 9.

25. A method for suppressing aggregation formation during liquid storage of a highly-concentrated antibody-comprising formulation by using a histidine-aspartate buffer, histidine-glutamate buffer, tris(hydroxymethyl)aminomethane-aspartate buffer, or tris(hydroxymethyl)aminomethane-glutamate buffer, wherein an isoelectric point (pI) of the antibody is 9.

26. A method for suppressing aggregation formation during frozen storage of a highly-concentrated antibody-comprising formulation by using arginine-aspartate or arginine-glutamate, wherein an isoelectric point (pI) of the antibody is 9.

27. A method for suppressing aggregation formation during liquid storage of a highly-concentration antibody-comprising formulation by using arginine-aspartate or arginine-glutamate, wherein an isoelectric point (pI) of the antibody is 9.