CLAIMS

What is claimed is:

1. A formulation comprising a polypeptide and a hydroxypropyl methylcellulose acetate succinate (HPMCAS).

2. The formulation of claim 1, wherein the HPMCAS comprises from 8% to 12% acetate and from 7% to 15% succinate, optionally the HPMCAS comprises about 8% acetate and about 15% succinate (HPMCAS-LF) or about 12% acetate and about 7% succinate (HPMCAS-HF).

3. The formulation of any one of claims 1 or 2, wherein the ratio of the HPMCAS to protein in the formulation is from 4:1 (mg/mg) to 1:4 (mg/mg), optionally wherein the ratio is about 4:1 (mg/mg), about 1:1 (mg/mg), or about 1:4 (mg/mg).

4. The formulation of any one of claims 1-3, wherein the formulation further comprises a histidine buffer, optionally,

the histidine buffer is a histidine HCl buffer, and/or

the histidine buffer is in the formulation at a concentration of 5 mM to 20 mM, optionally wherein the histidine buffer is in the formulation at a concentration of about 10 mM.

5. The formulation of any one of claims 1-4, wherein the formulation further comprises a polysorbate, optionally

the polysorbate is polysorbate 20, and/or

the polysorbate is in the formulation at a concentration of 0.005% (w/v) to 0.5% (w/v), and/or

the polysorbate is in the formulation at a concentration of about 0.01% (w/v).

6. The formulation of any one of claims 1-5, wherein the pH of the formulation is 5.5 to 7.0, optionally the pH of the formulation is about 6.5.

7. The formulation of any one of claims 1-6, wherein the polypeptide is an antibody, optionally the polypeptide is a monoclonal antibody, a human antibody, a chimeric antibody

or a humanized antibody, an antibody fragment selected from a Fab, Fab'-SH, Fv, scFv, and (Fab')2 fragment, optionally wherein the antibody fragment is a (Fab')2 fragment.

8. The formulation of any one of claims 1-7, wherein the polypeptide is in the formulation at a concentration of 5 mg/mL to 100 mg/mL, optionally the polypeptide is in the formulation at a concentration of about 10 mg/mL.

9. A formulation comprising:
an antibody at a concentration of 5 mg/mL to 50 mg/mL,
an HPMCAS-LF, wherein the ratio of the HPMCAS-LF to antibody in the formulation is about 4:1 (mg/mg), about 1:1 (mg/mg), or about 1:4 (mg/mg),
a histidine-HCl buffer at a concentration of 5 mM to 20 mM,
polysorbate 20 at a concentration of 0.005% (w/v) to 0.5% (w/v), and
wherein the pH of the formulation is 5.5 to 7.0.

10. A formulation comprising:
an antibody at a concentration of about 10 mg/mL,
an HPMCAS-LF, wherein the ratio of the HPMCAS-LF to antibody in the formulation is about 4:1 (mg/mg), about 1:1 (mg/mg), or about 1:4 (mg/mg),
a histidine-HCl buffer at a concentration of about 10 mM,
polysorbate 20 at a concentration of about 0.01% (w/v), and
wherein the pH of the formulation is about 6.5.

11. A formulation comprising:
an antibody at a concentration of 5 mg/mL to 50 mg/mL,
an HPMCAS-HF, wherein the ratio of the HPMCAS-HF to antibody in the formulation is about 4:1 (mg/mg), about 1:1 (mg/mg), or about 1:4 (mg/mg),
a histidine-HCl buffer at a concentration of 5 mM to 20 mM,
polysorbate 20 at a concentration of 0.005% (w/v) to 0.5% (w/v), and
wherein the pH of the formulation is 5.5 to 7.0.

12. A formulation comprising:
an antibody at a concentration of about 10 mg/mL,

an HPMCAS-HF, wherein the ratio of the HPMCAS-HF to antibody in the formulation is about 4:1 (mg/mg), about 1:1 (mg/mg), or about 1:4 (mg/mg),
a histidine-HCl buffer at a concentration of about 10 mM,
polysorbate 20 at a concentration of about 0.01% (w/v), and
wherein the pH of the formulation is about 6.5.

13. The formulation of any one of claims 9-12, wherein the antibody is a monoclonal antibody, a human antibody, a chimeric antibody or a humanized antibody, an antibody fragment selected from a Fab, Fab'-SH, Fv, scFv, and (Fab')2 fragment, optionally wherein the antibody fragment is a (Fab')2 fragment.

14. The formulation of any one of claims 1-13, wherein the formulation is spray dried to form a spray dried formulation of a polypeptide or antibody, optionally the polypeptide or antibody in the formulation is stable at about 90°C for at least about 5 hours and/or is stable at about 37°C for at least about 4 weeks.

15. The spray dried formulation of a polypeptide or antibody of claim 14, wherein the polypeptide or antibody in the formulation shows reduced aggregation and/or reduced chemical degradation, optionally the reduced chemical degradation comprises reduced formation of succinimide variants of the polypeptide and/or reduced formation of pyroglutamate variants of the polypeptide.

16. The spray dried formulation of a polypeptide or antibody of claim 14 or 15, wherein the formulation is an amorphous glassy formulation.

17. The spray dried formulation of a polypeptide or antibody of any one of claims 14-16, wherein the spray dried formulation of a polypeptide or antibody is encapsulated in a polymer system that produces acidic microclimate.

18. The spray dried formulation of a polypeptide or antibody of any one of claims 14-17, wherein the spray dried formulation of a polypeptide or antibody is encapsulated in lactic acid/glycolic acid polymer system.

19. The spray dried formulation of a polypeptide or antibody of any one of claims 14-18, wherein the spray dried formulation of a polypeptide or antibody is encapsulated in poly(lactic-co-glycolic acid) (PLGA) or in a PLGA rod.

20. A composition comprising the formulation of any one of claims 1-14.

21. A composition comprising the spray dried formulation of a polypeptide or antibody of any one of claims 14-19.

22. A composition comprising a lactic acid/glycolic acid polymer particle comprising the formulation of any one of claims 1-14.

23. A composition comprising a lactic acid/glycolic acid polymer particle comprising the spray dried formulation of any one of claims 14-19.

24. The composition of claim 22 or 23, wherein the lactic acid/glycolic acid polymer particle is a PLGA particle, optionally a PLGA rod.

25. A method of preparing a spray dried polypeptide, the method comprising preparing a formulation of any one of claims 1-8, and subjecting the formulation to spray drying.

26. A method of preparing a spray dried antibody, the method comprising preparing a formulation of any one of claims 9-13, and subjecting the formulation to spray drying.

27. The method of claim 25 or 26, wherein the spray drying is performed using a spray dryer comprising an inlet and an outlet, optionally

the inlet has a temperature of 90°C to 120°C, about 100°C, or about 110°C , or

the outlet has a temperature of about 60°C.

28. A method of preparing a lactic acid/glycolic acid polymer particle comprising a polypeptide, the method comprising encapsulating the formulation of any one of claims 1-13 in a lactic acid/glycolic acid polymer system.

29. A method of preparing a lactic acid/glycolic acid polymer particle comprising a polypeptide, the method comprising encapsulating the spray dried formulation of any one of claims 14-15 in a lactic acid/glycolic acid polymer system.

30. The method of claim 28 or 29, wherein the lactic acid/glycolic acid polymer particle is a PLGA particle.

31. An article of manufacture comprising the formulation of any one of claims 1-14, the spray dried formulation of any one of claims 14-19, or the composition of any one of claims 20-24.

32. An article of manufacture comprising spray dried formulation prepared by the method of any one of claims 25-27.

33. An article of manufacture comprising lactic acid/glycolic acid polymer particle encapsulated polypeptide prepared by the method of any one of claims 28-30.