

mM L-lysine or a pharmaceutically acceptable salt of L-lysine; and e) about 0.01% to about 0.10% (w/v) polysorbate 80.

In one aspect, the disclosure provides an anti-RSV antibody formulation comprising: a) 50 mg/mL to 250 mg/mL of an anti-RSV antibody, or antigen-binding fragment thereof; b) 5 mM to 20 mM histidine; c) 4% to 8% (w/v) sucrose; d) 70 mM of L-arginine or a pharmaceutically acceptable salt of L-arginine; and e) 0.01% to 0.10% (w/v) polysorbate 80, wherein the anti-RSV antibody comprises CDRs having the amino acid sequences of SEQ ID NOs: 1-6.

In one example, the anti-RSV antibody formulation comprises: a) about 50 mg/ml to about 250 mg/ml of an anti-RSV antibody, or antigen-binding fragment thereof; b) about 5 mM to about 20 mM histidine; c) about 4% to about 8% (w/v) sucrose; d) about 25 mM to about 75 mM of L-arginine or a pharmaceutically acceptable salt of L-arginine; and e) about 0.01% to about 0.10% (w/v) polysorbate 80. In one example, the anti-RSV antibody formulation comprises: a) 50 mg/ml to 250 mg/ml of an anti-RSV antibody, or antigen-binding fragment thereof; b) 5 mM to 20 mM histidine; c) 4% to 8% (w/v) sucrose; d) 25 mM to 75 mM of L-arginine or a pharmaceutically acceptable salt of L-arginine; and e) 0.01% to 0.10% (w/v) polysorbate 80.

In one example, the anti-RSV antibody formulation comprises: a) about 50 mg/ml to about 250 mg/ml of an anti-RSV antibody, or antigen-binding fragment thereof; b) about 5 mM to about 20 mM histidine; c) about 4% to about 8% (w/v) sucrose; d) about 25 mM to about 75 mM of L-lysine or a pharmaceutically acceptable salt of L-lysine; and e) about 0.01% to about 0.10% (w/v) polysorbate 80. In one example, the anti-RSV antibody formulation comprises: a) 50 mg/ml to 250 mg/ml of an anti-RSV antibody, or antigen-binding fragment thereof; b) 5 mM to 20 mM histidine; c) 4% to 8% (w/v) sucrose; d) 25 mM to 75 mM of L-lysine or a pharmaceutically acceptable salt of L-lysine; and e) 0.01% to 0.10% (w/v) polysorbate 80.

WHAT IS CLAIMED IS:

1. An anti-RSV antibody formulation comprising:
 - a) 50 mg/mL to 250 mg/mL of an anti-RSV antibody, or antigen-binding fragment thereof;
 - b) 5 mM to 20 mM histidine;
 - c) 4% to 8% (w/v) sucrose;
 - d) about 70 mM of L-arginine or a pharmaceutically acceptable salt of L-arginine; and
 - e) 0.01% to 0.10% (w/v) polysorbate 80,wherein the anti-RSV antibody comprises CDRs having the amino acid sequences of SEQ ID NOs: 1-6.
2. The anti-RSV antibody formulation of claim 1, comprising 125 mg/mL to 175 mg/mL of the anti-RSV antibody, or antigen-binding fragment thereof.
3. The anti-RSV antibody formulation of claim 1, comprising about 150 mg/ml of the anti-RSV antibody, or antigen-binding fragment thereof.
4. The anti-RSV antibody formulation of claim 1, comprising 150 mg/mL to 200 mg/mL of the anti-RSV antibody, or antigen-binding fragment thereof.
5. The anti-RSV antibody formulation of claim 1, comprising about 175 mg/ml of the anti-RSV antibody, or antigen-binding fragment thereof.
6. The anti-RSV antibody formulation of claim 1, comprising 175 mg/mL to 225 mg/mL of the anti-RSV antibody, or antigen-binding fragment thereof.
7. The anti-RSV antibody formulation of claim 1, comprising about 200 mg/ml of the anti-RSV antibody, or antigen-binding fragment thereof.
8. The anti-RSV antibody formulation of any one of claims 1-7, further comprising 25 to 75 μ M diethylenetriamine pentaacetate (DTPA).

9. The anti-RSV antibody formulation of any one of claims 1-8, further comprising 1 mM to 20 mM L-methionine.
10. The anti-RSV antibody formulation of any of claims 1-9, wherein the pH is 5.5 to 6.5.
11. The anti-RSV antibody formulation of any of claims 1-10, wherein the pH is 6.0.
12. The anti-RSV antibody formulation of any of claims 1-11, wherein the anti-RSV antibody comprises a heavy chain variable region having the amino acid sequence of SEQ ID NO: 7 and a light chain variable region having the amino acid sequence of SEQ ID NO: 8.
13. The anti-RSV antibody formulation of any of claims 1-11, wherein the anti-RSV antibody comprises a heavy chain immunoglobulin consisting of the amino acid sequence set forth in SEQ ID NO: 9 and a light chain immunoglobulin consisting of the amino acid sequence set forth in SEQ ID NO: 10.
14. The anti-RSV antibody formulation of any one of claims 1-13, wherein the (w/v) of the polysorbate 80 is 0.02%.
15. The anti-RSV antibody formulation of any one of claims 1-14 for use in treating or preventing RSV infection in a human patient.
16. Use of the anti-RSV antibody formulation of any one of claims 1-14 in the manufacture of a medicament for the treatment or prevention of RSV infection in a human patient.
17. The use of claim 16, wherein the effective amount of the anti-RSV antibody formulation comprises a fixed dose of anti-RSV antibody or antigen-binding fragment thereof of 10 mg to 150 mg.
18. The use of claim 16, wherein the effective amount of the anti-RSV antibody formulation comprises a fixed dose of anti-RSV antibody or antigen-binding fragment thereof between 25 mg and 125 mg.

19. The use of claim 16, wherein the effective amount of the anti-RSV antibody formulation comprises a fixed dose of anti-RSV antibody or antigen-binding fragment thereof between 50 mg and 100 mg.
20. The use of claim 16, wherein the effective amount of the anti-RSV antibody formulation comprises a fixed dose of anti-RSV antibody or antigen-binding fragment thereof of about 100 mg.
21. The use of any of claims 16-20, wherein the anti-RSV antibody formulation is to be administered by intramuscular administration.