

CLAIMS

1. A formulation comprising:
 - an anti-Respiratory Syncytial Virus (RSV) F protein monoclonal antibody;
 - an ionic excipient comprising lysine hydrochloride or arginine hydrochloride; and
 - one or more buffers comprising histidine,wherein the monoclonal antibody comprises a light chain sequence of SEQ ID NO: 1 and a heavy chain sequence of SEQ ID NO: 2,
wherein the monoclonal antibody is present at a concentration of 75 mg/ml to 200 mg/ml, the ionic excipient is present at a concentration of 75 mM to 120 mM, the one or more buffers is present at a concentration of 10 mM to 50 mM, and the formulation has a pH of about 5.7 to about 6.3.
2. A formulation according to claim 1, wherein the ionic excipient comprises arginine hydrochloride.
3. A formulation according to claim 2, wherein the arginine hydrochloride is present at a concentration of 80 mM.
4. A formulation according to any one of the preceding claims, further comprising sucrose.
5. A formulation according to claim 4, wherein the sucrose is present at a concentration of 100 mM to 140 mM.
6. A formulation according to claim 4 or claim 5, wherein the sucrose is present at a concentration of 120 mM.
7. A formulation according to any one of the preceding claims, wherein the one or more buffers is histidine, histidine hydrochloride, or a combination thereof.

8. A formulation according to claim 7, wherein the one or more buffers is L-histidine, L-histidine hydrochloride, or a combination thereof.
9. A formulation according to claim 8, wherein the L-histidine hydrochloride is L-histidine hydrochloride monohydrate.
10. A formulation according to any one of claims 7 to 9, wherein the one or more buffers is present at a concentration of 30 mM.
11. A formulation according to any one of the preceding claims, further comprising polysorbate-80.
12. A formulation according to claim 11, wherein the polysorbate-80 is present at a concentration of 0.001% (w/v) to 0.07% (w/v).
13. A formulation according to claim 11 or claim 12, wherein the polysorbate-80 is present at a concentration of 0.02% (w/v) to 0.07% (w/v).
14. A formulation according to any one of claims 11 to 13, wherein the polysorbate-80 is present at a concentration of 0.02% (w/v) or 0.04% (w/v).
15. A formulation according to any one of the preceding claims, wherein the monoclonal antibody is present at a concentration of 100 mg/ml to 165 mg/ml.
16. A formulation according to any one of the preceding claims, wherein the monoclonal antibody is present at a concentration of 100 mg/ml.
17. A formulation according to any one of the preceding claims, further comprising one or more additional excipients.

18. A formulation according to claim 17, wherein the one or more additional excipients is selected from one or more sugars, salts, amino acids, polyols, chelating agents, emulsifiers, and/or preservatives.
19. A formulation according to any one of the preceding claims, wherein the formulation has a pH of about 6.0.
20. A formulation comprising:
an anti-Respiratory Syncytial Virus (RSV) F protein monoclonal antibody comprising a light chain sequence of SEQ ID NO: 1 and a heavy chain sequence of SEQ ID NO: 2, wherein the monoclonal antibody is present at a concentration of 75 mg/ml to 200 mg/ml; 75 mM to 100 mM arginine hydrochloride; 10 mM to 50 mM histidine, histidine hydrochloride, or a combination thereof; 100 mM to 140 mM sucrose; and 0.02% (w/v) to 0.07% (w/v) polysorbate-80, wherein the formulation has a pH of about 5.7 to about 6.3.
21. A formulation comprising:
an anti-Respiratory Syncytial Virus (RSV) F protein monoclonal antibody comprising a light chain sequence of SEQ ID NO: 1 and a heavy chain sequence of SEQ ID NO: 2, wherein the monoclonal antibody is present at a concentration of 75 mg/ml to 200 mg/ml; 80 mM arginine hydrochloride; 30 mM histidine, histidine hydrochloride, or a combination thereof; 120 mM sucrose; and 0.02% (w/v) to 0.07% (w/v) polysorbate-80, wherein the formulation has a pH of about 5.7 to about 6.3.
22. A formulation comprising:
an anti-RSV monoclonal antibody at 100 mg/mL, wherein the antibody comprises a light chain sequence of SEQ ID NO: 1 and a heavy chain sequence of SEQ ID NO: 2; 30 mM L-histidine, L-histidine hydrochloride, or a combination thereof;

80 mM L-arginine hydrochloride;
120 mM sucrose; and
0.02% (w/v) polysorbate 80,
wherein the formulation has a pH of about 6.0.

23. A formulation according to claim 22, wherein the L-histidine hydrochloride is L-histidine hydrochloride monohydrate.
24. A formulation according to any one of the preceding claims, wherein the formulation is a pharmaceutical formulation.
25. A pharmaceutical formulation according to claim 24 for use as a medicament.
26. A formulation according to any one of claims 1 to 25, wherein the formulation is liquid.
27. A formulation according to any one of claims 1 to 25, wherein the formulation is lyophilized.
28. Use of a pharmaceutical formulation according to claim 24 in the manufacture of a medicament for the prevention of RSV lower respiratory tract disease in a subject.