

WHAT IS CLAIMED IS:

1. A formulation comprising:

- i. an anti-RSV monoclonal antibody; and
- ii. an ionic excipient;

wherein the monoclonal antibody is present at a concentration of about 50mg/ml or greater and the ionic excipient is present at a concentration of about 50 to about 150 mM and the formulation has a pH of about 5.5 to about 7.5.

2. A formulation according to claim 1, wherein the monoclonal antibody has a pI in the range of pH 6.4 to pH 7.5, preferably about pH 6.4.

3. A formulation according to any one of the preceding claims, wherein the monoclonal antibody is an IgG1 monoclonal antibody.

4. A formulation according to any one of the preceding claims, wherein the monoclonal antibody has light chain CDR sequences:

CDR-L1 of SEQ ID NO: 3

CDR-L2 of SEQ ID NO: 4

CDR-L3 of SEQ ID NO: 5

and heavy chain CDR sequences:

CDR-H1 of SEQ ID NO: 6

CDR-H2 of SEQ ID NO: 7

CDR-H3 of SEQ ID NO: 8.

5. A formulation according to any one of the preceding claims, wherein the monoclonal antibody has a light chain variable region sequence of SEQ ID NO: 9 and a heavy chain variable region sequence of SEQ ID NO: 10.
6. A formulation according to any one of the preceding claims, wherein the monoclonal antibody has a light chain sequence of SEQ ID NO: 1 and a heavy chain sequence of SEQ ID NO: 2.
7. A formulation according to any one of the preceding claims, wherein the monoclonal antibody is present in the formulation at a concentration of about 100 mg/ml to about 165 mg/ml, preferably at a concentration of about 100 mg/ml.
8. A formulation according to any one of the preceding claims, wherein the formulation has a pH in the range of about pH 5.7 to about pH 6.1, preferably has a pH of about pH 6.0.
9. A formulation according to any one of the preceding claims, wherein the ionic excipient is a salt, preferably wherein the salt is arginine hydrochloride.
10. A formulation according to any one of the preceding claims, wherein the ionic excipient is present at a concentration of about 75 mM to about 100 mM, preferably at a concentration of about 80 mM.

11. A formulation according to any one of the preceding claims, wherein the formulation further comprises a sugar, preferably wherein the sugar is sucrose.
12. A formulation according to claim 11, wherein the sugar is present at a concentration of about 100 mM to about 140 mM, preferably at a concentration of about 120 mM.
13. A formulation according to any one of the preceding claims, wherein the formulation further comprises one or more buffers, preferably selected from histidine, histidine hydrochloride, and histidine/ histidine hydrochloride.
14. A formulation according to claim 13, wherein the one or more buffers is L-histidine/ L-histidine hydrochloride monohydrate.
15. A formulation according to claim 13 or 14, wherein the one or more buffers is present at a concentration of about 10 mM to about 50 mM, preferably at a concentration of about 30 mM.
16. A formulation according to any one of the preceding claims, wherein the formulation further comprises a surfactant, preferably wherein the surfactant is a polysorbate, such as polysorbate-80.

17. A formulation according to claim 16, wherein the surfactant is present in the formulation at a concentration from about 0.001 % (w/v) to about 0.07 % (w/v), preferably at a concentration of about 0.02% (w/v).
18. A formulation according to any one of the preceding claims, wherein the formulation further comprises one or more additional excipients, including for example, one or more sugars, salts, amino acids, polyols, chelating agents, emulsifiers and/or preservatives.
19. A formulation according to any one of claims 1 to 18, which is a pharmaceutical formulation.
20. A pharmaceutical formulation according to claim 19 for use as a medicament.
21. A pharmaceutical formulation according to claim 19 for use in the treatment of a disease.
22. A pharmaceutical formulation according to claim 19 for use in the treatment or prevention of a disease in a subject, wherein the pharmaceutical formulation is to be administered to the subject.
23. Use of a pharmaceutical formulation according to claim 19 in the manufacture of a medicament for the treatment or prevention of a disease in a subject, wherein the medicament is to be administered to the subject.
24. A lyophilized cake capable of being reconstituted using only sterile water into a formulation as defined in any one of claims 1 to 19.

25. A composition capable of being lyophilized to form a lyophilized cake, wherein the lyophilized cake is capable of being reconstituted using only sterile water into a formulation as defined in any one of claims 1 to 19.
26. A formulation comprising:
an anti-RSV monoclonal antibody; and
an ionic excipient;
wherein the anti-RSV monoclonal antibody comprises the MEDI 8897 monoclonal antibody having a light chain of SEQ ID NO: 1 and a heavy chain of SEQ ID NO: 2;
wherein the MEDI 8897 monoclonal antibody has a pI of 6.4 to 6.7;
wherein the monoclonal antibody is present at a concentration of 75 mg/ml to 200 mg/ml;
wherein the ionic excipient comprises arginine hydrochloride at a concentration of 75 mM to 100 mM;
wherein the formulation further comprises 10 mM to 50 mM L-histidine/L-histidine hydrochloride monohydrate, 100 mM to 140 mM sucrose, and 0.02% to 0.04% (w/v) polysorbate 80; and
wherein the formulation has a pH of 5.7 to 6.1.
27. A formulation according to claim 26, wherein the monoclonal antibody has a pI of about 6.4.
28. A formulation according to claim 26 or 27, wherein the formulation further comprises one or more additional excipients, including for example, one or more sugars, salts, amino acids, polyols, chelating agents, emulsifiers and/or preservatives.
29. A formulation according to any one of claims 26 to 28, which is a pharmaceutical formulation.
30. A pharmaceutical formulation according to claim 29 for use as a medicament.

31. A formulation as defined in any one of claims 26 to 30, wherein the formulation is lyophilized.