CLAIMS

1. A lyophilised formulation prepared by lyophilising an aqueous formulation having a pH of 5.0-7.0 and comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of 20-150 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) a stabiliser,

(iii) a buffering agent,

(iv) a surfactant, and optionally

(v) an amino acid.

2. The lyophilised formulation of claim 1, wherein said formulation is prepared from an aqueous formulation having a pH of 5.0-7.0 and comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of 20-150mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) sucrose or trehalose as a stabiliser,

(iii) histidine as a buffering agent,

(iv) polysorbate 20 as a surfactant, and optionally

(v) an amino acid selected from arginine, methionine and glycine.

3. The lyophilised formulation of claim 1 or claim 2, wherein said formulation is prepared from an aqueous formulation having a pH of 5.0-7.0 and comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of 20-150 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 3-300 mM sucrose or trehalose as a stabiliser,

(iii) 1-60 mM histidine as a buffering agent,

(iv) up to 0.2% polysorbate 20 as a surfactant, and optionally

(v) 2-80 mM arginine, methionine or glycine.

4. The lyophilised formulation as claimed in any previous claim, wherein said formulation is prepared from an aqueous formulation having a pH of 6.0 and comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 90 mM sucrose as a stabiliser,

(iii) 10 mM histidine as a buffering agent,

(iv) 0.02% polysorbate 20 as a surfactant.

5. The lyophilised formulation as claimed in any previous claim, wherein said formulation is prepared from an aqueous formulation having a pH of 6.0 and comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 90 mM sucrose as a stabiliser,

(iii) 10 mM histidine as a buffering agent,

(iv) 0.02% polysorbate 20 as a surfactant, and

(v) 17 mM arginine.

6. The lyophilised formulation as claimed in any previous claim, wherein said formulation is prepared from an aqueous formulation having a pH of 6.0 and comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of 150 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 270 mM sucrose as a stabiliser,

(iii) 30 mM histidine as a buffering agent, and

(iv) 0.06% polysorbate 20 as a surfactant.

7. An aqueous pharmaceutical composition obtained by reconstituting a lyophilised formulation of any one of the preceding claims, wherein the reconstitution factor is between 1:0.5 to 1:6.

8. The aqueous pharmaceutical composition of claim 8, wherein the reconstitution factor is 1:3.

9. An aqueous pharmaceutical composition having a pH of 5.0 to 7.0 comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of at least 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) a stabiliser,

(iii) a buffering agent,

(iv) a surfactant, and optionally

(v) an amino acid.

10. The aqueous pharmaceutical composition of claim 9 comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of at least 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) sucrose or trehalose as a stabiliser,

(iii) histidine as a buffering agent,

(iv) polysorbate 20 as a surfactant, and optionally

(v) an amino acid selected from arginine, methionine or glycine.

11. The aqueous pharmaceutical composition of claim 9 or 10 comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of at least 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 200-300 mM sucrose as a stabiliser,

(iii) 25-35 mM histidine as a buffering agent,

(iv) up to 0.2% polysorbate 20 as a surfactant, and optionally

(v) 10-80 mM arginine, methionine or glycine.

12. The aqueous pharmaceutical composition of any one of claims 9 to 11, wherein the composition has a pH of 6.0 and comprises

(i) an anti-CD40 antibody wherein the antibody has a concentration of at least 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 270 mM sucrose as a stabiliser,

(iii) 30 mM histidine as a buffering agent, and

(iv) 0.06% polysorbate 20 as a surfactant.

13. The aqueous pharmaceutical composition of any one of claims 9 to 11, wherein the composition has a pH of 6.0 and comprises

(i) an anti-CD40 antibody wherein the antibody has a concentration of at least 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 270 mM sucrose as a stabiliser,

(iii) 30 mM histidine as a buffering agent,

(iv) 0.06% polysorbate 20 as a surfactant, and

(v) 51 mM arginine.

14. The aqueous pharmaceutical composition of any one of claims 9 to 13, wherein the anti-CD40 antibody has a concentration of 150 mg/ml.

15. The lyophilised formulation of any one of claims 1 to 6 or the aqueous pharmaceutical composition of any one of claims 7 to 14, wherein the anti-CD40 antibody comprises a V_H domain having the amino acid sequence of SEQ ID NO: 1 and a V_L domain having the amino acid sequence of SEQ ID NO: 2.

16. The lyophilised formulation of any one of claims 1 to 6 or the aqueous pharmaceutical composition of any one of claims 7 to 14, wherein the anti-CD40 antibody comprises a heavy chain region of SEQ ID NO: 9 and a light chain region of SEQ ID NO: 10.

17. The lyophilised formulation of any one of claims 1 to 6 or the aqueous pharmaceutical composition of any one of claims 7 to 14, wherein the anti-CD40 antibody comprises a heavy chain region of SEQ ID NO: 13 and a light chain region of SEQ ID NO: 14.

18. The lyophilised formulation of any one of claims 1 to 6 or the aqueous pharmaceutical composition of any one of claims 7 to 14, wherein the anti-CD40 antibody comprises a heavy chain region of SEQ ID NO: 17 and a light chain region of SEQ ID NO: 18.

19. A delivery device including the aqueous pharmaceutical composition of any one of claims 7 to 18.

20. A pre-filled syringe including the aqueous pharmaceutical composition of any one of claims 7 to 18.

21. A method for delivering an anti-CD40 antibody to a mammal, comprising a step of administering to the mammal an aqueous pharmaceutical composition as claimed in any one of claims 7 to 18.

22. A lyophilised formulation of any one of claims 1 to 6 or an aqueous pharmaceutical composition of any one of claims 7 to 14 for use in treating a disease or disorder that is mediated by CD40.

23. The lyophilised formulation or aqueous pharmaceutical composition according to claim 22 for use in the treatment of autoimmune diseases.

24. The lyophilised formulation or aqueous pharmaceutical composition according to claim 23 for use in the treatment of rheumatoid arthritis, systemic lupus erythematosus, or Pemphigus vulgaris.

CLAIMS

1. A lyophilised formulation prepared by lyophilising an aqueous formulation having a pH of 5.0-7.0 and comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of 20-150 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) a stabiliser,

(iii) a buffering agent,

(iv) a surfactant, and optionally

(v) an amino acid.

2. The lyophilised formulation of claim 1, wherein said formulation is prepared from an aqueous formulation having a pH of 5.0-7.0 and comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of 20-150mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) sucrose or trehalose as a stabiliser,

(iii) histidine as a buffering agent,

(iv) polysorbate 20 as a surfactant, and optionally

(v) an amino acid selected from arginine, methionine and glycine.

3. The lyophilised formulation of claim 1 or claim 2, wherein said formulation is prepared from an aqueous formulation having a pH of 5.0-7.0 and comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of 20-150 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 3-300 mM sucrose or trehalose as a stabiliser,

(iii) 1-60 mM histidine as a buffering agent,

(iv) up to 0.2% polysorbate 20 as a surfactant, and optionally

(v) 2-80 mM arginine, methionine or glycine.

4. The lyophilised formulation as claimed in any previous claim, wherein said formulation is prepared from an aqueous formulation having a pH of 6.0 and comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 90 mM sucrose as a stabiliser,

(iii) 10 mM histidine as a buffering agent,

(iv) 0.02% polysorbate 20 as a surfactant.

5. The lyophilised formulation as claimed in any previous claim, wherein said formulation is prepared from an aqueous formulation having a pH of 6.0 and comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 90 mM sucrose as a stabiliser,

(iii) 10 mM histidine as a buffering agent,

(iv) 0.02% polysorbate 20 as a surfactant, and

(v) 17 mM arginine.

6. The lyophilised formulation as claimed in any previous claim, wherein said formulation is prepared from an aqueous formulation having a pH of 6.0 and comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of 150 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 270 mM sucrose as a stabiliser,

(iii) 30 mM histidine as a buffering agent, and

(iv) 0.06% polysorbate 20 as a surfactant.

7. An aqueous pharmaceutical composition obtained by reconstituting a lyophilised formulation of any one of the preceding claims, wherein the reconstitution factor is between 1:0.5 to 1:6.

8. The aqueous pharmaceutical composition of claim 8, wherein the reconstitution factor is 1:3.

9. An aqueous pharmaceutical composition having a pH of 5.0 to 7.0 comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of at least 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) a stabiliser,

(iii) a buffering agent,

(iv) a surfactant, and optionally

(v) an amino acid.

10. The aqueous pharmaceutical composition of claim 9 comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of at least 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) sucrose or trehalose as a stabiliser,

(iii) histidine as a buffering agent,

(iv) polysorbate 20 as a surfactant, and optionally

(v) an amino acid selected from arginine, methionine or glycine.

11. The aqueous pharmaceutical composition of claim 9 or 10 comprising

(i) an anti-CD40 antibody wherein the antibody has a concentration of at least 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 200-300 mM sucrose as a stabiliser,

(iii) 25-35 mM histidine as a buffering agent,

(iv) up to 0.2% polysorbate 20 as a surfactant, and optionally

(v) 10-80 mM arginine, methionine or glycine.

12. The aqueous pharmaceutical composition of any one of claims 9 to 11, wherein the composition has a pH of 6.0 and comprises

(i) an anti-CD40 antibody wherein the antibody has a concentration of at least 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 270 mM sucrose as a stabiliser,

(iii) 30 mM histidine as a buffering agent, and

(iv) 0.06% polysorbate 20 as a surfactant.

13. The aqueous pharmaceutical composition of any one of claims 9 to 11, wherein the composition has a pH of 6.0 and comprises

(i) an anti-CD40 antibody wherein the antibody has a concentration of at least 50 mg/ml, and wherein said anti-CD40 antibody includes heavy chain CDR1, CDR2 and CDR3 of SEQ ID NOs 3, 4 and 5 respectively, and light chain CDR1, CDR2 and CDR3 of SEQ ID NOs: 6, 7 and 8,

(ii) 270 mM sucrose as a stabiliser,

(iii) 30 mM histidine as a buffering agent,

(iv) 0.06% polysorbate 20 as a surfactant, and

(v) 51 mM arginine.

14. The aqueous pharmaceutical composition of any one of claims 9 to 13, wherein the anti-CD40 antibody has a concentration of 150 mg/ml.

15. The lyophilised formulation of any one of claims 1 to 6 or the aqueous pharmaceutical composition of any one of claims 7 to 14, wherein the anti-CD40 antibody comprises a V_H domain having the amino acid sequence of SEQ ID NO: 1 and a V_L domain having the amino acid sequence of SEQ ID NO: 2.

16. The lyophilised formulation of any one of claims 1 to 6 or the aqueous pharmaceutical composition of any one of claims 7 to 14, wherein the anti-CD40 antibody comprises a heavy chain region of SEQ ID NO: 9 and a light chain region of SEQ ID NO: 10.

17. The lyophilised formulation of any one of claims 1 to 6 or the aqueous pharmaceutical composition of any one of claims 7 to 14, wherein the anti-CD40 antibody comprises a heavy chain region of SEQ ID NO: 13 and a light chain region of SEQ ID NO: 14.

18. The lyophilised formulation of any one of claims 1 to 6 or the aqueous pharmaceutical composition of any one of claims 7 to 14, wherein the anti-CD40 antibody comprises a heavy chain region of SEQ ID NO: 17 and a light chain region of SEQ ID NO: 18.

19. A delivery device including the aqueous pharmaceutical composition of any one of claims 7 to 18.

20. A pre-filled syringe including the aqueous pharmaceutical composition of any one of claims 7 to 18.

21. A lyophilised formulation of any one of claims 1 to 6 or an aqueous pharmaceutical composition of any one of claims 7 to 14 for use in treating a disease or disorder that is mediated by CD40.

22. The lyophilised formulation or aqueous pharmaceutical composition according to claim 21 for use in the treatment of autoimmune diseases.

23. The lyophilised formulation or aqueous pharmaceutical composition according to claim 22 for use in the treatment of rheumatoid arthritis, systemic lupus erythematosus, or Pemphigus vulgaris.