

Patent Claims

1. An aqueous pharmaceutical antibody formulation, comprising

(i) Avelumab in a concentration of 1 mg/mL to about 20 mg/mL as the antibody;

5 (ii) glycine in a concentration of about 10 mM as the buffering agent, and not comprising any other buffering agent;

(iii) lysine monohydrochloride in a concentration of about 140 mM as the stabiliser, and not comprising any other stabiliser;

10 (iv) polyoxyl 35 castor oil in a concentration of about 0.5 mg/mL as the surfactant, and not comprising any other surfactant;

wherein the formulation has a pH of 4.2 to 4.6.

2. An aqueous pharmaceutical antibody formulation, comprising

(i) Avelumab in a concentration of 1 mg/mL to about 20 mg/mL as the antibody;

15 (ii) glycine in a concentration of about 10 mM as the buffering agent, and not comprising any other buffering agent;

(iii) lysine acetate in a concentration of about 140 mM as the stabiliser, and not comprising any other stabiliser;

20 (iv) polyoxyl 35 castor oil in a concentration of about 0.5 mg/mL as the surfactant, and not comprising any other surfactant;

wherein the formulation has a pH of 4.2 to 4.6.

3. An aqueous pharmaceutical antibody formulation, comprising

(i) Avelumab in a concentration of 1 mg/mL to about 20 mg/mL as the antibody;

25 (ii) histidine in a concentration of about 10 mM as the buffering agent, and not comprising any other buffering agent;

(iii) sucrose in a concentration of about 280 mM as the stabiliser, and not comprising any other stabiliser;

30 (iv) polyoxyl 35 castor oil in a concentration of about 0.5 mg/mL as the surfactant, and not comprising any other surfactant;

wherein the formulation has a pH of 4.8 to 5.2.

4. An aqueous pharmaceutical antibody formulation, comprising

(i) Avelumab in a concentration of 1 mg/mL to about 20 mg/mL as the antibody;

- (ii) succinate in a concentration of about 10 mM as the buffering agent, and not comprising any other buffering agent;
 - (iii) lysine monohydrochloride in a concentration of about 140 mM as the stabiliser, and not comprising any other stabiliser;
 - 5 (iv) polyoxyl 35 castor oil in a concentration of about 0.5 mg/mL as the surfactant, and not comprising any other surfactant;
- wherein the formulation has a pH of 4.8 to 5.2.

5. The formulation of claim 1, consisting of:

- 10 (i) Avelumab in a concentration of 20 mg/mL;
 - (ii) glycine in a concentration of 10 mM;
 - (iii) lysine monohydrochloride in a concentration of 140 mM;
 - (iv) polyoxyl 35 castor oil in a concentration of 0.5 mg/mL;
 - (v) HCl or NaOH to adjust the pH;
 - 15 (vi) water (for injection) as the solvent;
- wherein the formulation has a pH of 4.4 (± 0.1).

6. The formulation of claim 2, consisting of:

- (i) Avelumab in a concentration of 20 mg/mL;
- 20 (ii) glycine in a concentration of 10 mM;
- (iii) lysine acetate in a concentration of 140 mM;
- (iv) polyoxyl 35 castor oil in a concentration of 0.5 mg/mL;
- (v) HCl or NaOH to adjust the pH;
- (vi) water (for injection) as the solvent;
- 25 wherein the formulation has a pH of 4.4 (± 0.1).

7. The formulation of claim 3, consisting of:

- (i) Avelumab in a concentration of 20 mg/mL;
 - (ii) histidine in a concentration of 10 mM;
 - 30 (iii) sucrose in a concentration of 280 mM;
 - (iv) polyoxyl 35 castor oil in a concentration of 0.5 mg/mL;
 - (v) HCl or NaOH to adjust the pH;
 - (vi) water (for injection) as the solvent;
- wherein the formulation has a pH of 5.0 (± 0.1).

8. The formulation of claim 4, consisting of:

(i) Avelumab in a concentration of 20 mg/mL;

(ii) succinate in a concentration of 10 mM;

5 (iii) lysine monohydrochloride in a concentration of 140 mM;

(iv) polyoxyl 35 castor oil in a concentration of 0.5 mg/mL;

(v) HCl or NaOH to adjust the pH;

(vi) water (for injection) as the solvent;

wherein the formulation has a pH of 5.0 (± 0.1).

10