In one aspect, there is provided an aqueous composition comprising: an isolated polypeptide that is an extracellular ligand-binding portion of a human p75 tumor necrosis factor receptor fused to the Fc region of a human IgG1; salt present at a concentration of from 80 to 130 mM; an aqueous buffer, wherein the aqueous buffer is sodium and/or potassium phosphate buffer and wherein the aqueous buffer is present at a concentration of 20 to 30 mM; and an excipient which is sucrose, wherein the concentration of sucrose is between 34~~-80~~ 40 mg/mL, characterized in that neither arginine nor cysteine are present in the composition.

In one aspect, there is provided an aqueous composition comprising: an isolated polypeptide that is an extracellular ligand-binding portion of a human p75 tumor necrosis factor receptor fused to the Fc region of a human IgG1; salt present at a concentration of from 80 to 130 mM, wherein the salt is not present at a concentration of 100 mM; an aqueous buffer, wherein the aqueous buffer is succinate buffer; and an excipient selected from the group of trehalose and sucrose or a combination thereof, characterized in that no free amino acids are present in the composition.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a bar chart showing relative unfolding temperatures (T_{onset}/°C) found for all samples with error bars found using the fluorescence ratio between 330 and 310 nm.

CLAIMS

1. An aqueous composition comprising:
   - An isolated polypeptide that is an extracellular ligand-binding portion of a human p75 tumor necrosis factor receptor fused to the Fc region of a human IgG1;
   - Salt present at a concentration of from 80 to 130 mM; and
   - An excipient selected from the group of trehalose and sucrose or a combination thereof,

characterized in that neither arginine nor cysteine are present in the composition.

2. The composition according to claim 1 wherein the salt concentration is 90 mM.

3. The composition according to any of claims 1 to 2, wherein the salt is sodium chloride.

4. The composition according to any of claims 1 to 3 wherein the isolated polypeptide is etanercept.

5. The composition according to any of claims 1 to 4, wherein the excipient is sucrose present at a concentration of from 5 to 80 mg/mL.

6. The composition according to any of claims 1 to 5 wherein the composition further comprises an aqueous buffer.

7. The composition according to claim 6, wherein the aqueous buffer is sodium phosphate, potassium phosphate, sodium or potassium citrate, succinic acid, maleic acid, ammonium acetate, tris- (hydroxymethyl)- aminomethane (tris), acetate, diethanolamine, histidine or a combination thereof.

8. The composition according to any of claims 6 or 7, wherein the aqueous buffer is present at a concentration of 15 mM to 100 mM.

9. The composition according to claim 8 wherein the aqueous buffer is present at a concentration of 20 to 30 mM.

10. The composition according to any one of claims 6 to 9 wherein the aqueous buffer is succinic acid (succinate).

11. The composition according to any of claims 1 to 10 further comprising one or more excipients.

12. The composition of claim 11, wherein the excipient is lactose, glycerol, xylitol, sorbitol, mannitol, maltose, inositol, glucose, bovine serum albumin, human serum albumin, recombinant hemagglutinin, dextran, polyvinyl alcohol, hydroxypropyl methylcellulose (HPMC), polyethylenimine, gelatine, polyvinlylpyrrolidone (PVP), hydroxyethylcellulose (HEC), polyethylene glycol, ethylene glycol, dimethysulfoxide (DMSO), dimethylformamide (DMF), proline, L-serine, glutamic acid, alanine, glycine, lysine, sarcosine, gamma-aminobutyric acid, polysorbate-20, polysorbate-80, sodium dodecyl sulfate, polysorbate, polyoxyethylene copolymer, potassium phosphate, sodium acetate, ammonium sulphate, magnesium sulphate, sodium sulphate, trimethylamine N-oxide, betaine, zinc ions, copper ions, calcium ions, manganese ions, magnesium ions, 3-[(3- cholamidepropyl)- dimethylammonio]-1-propanesulfate, sucrose monolaurate or a combination thereof.

13. The composition according to any of claims 1 to 12, wherein the pH of the composition is from pH 6.0 to pH 7.0.

14. The composition according to any of claims 1 to 13, comprising 50 mg/mL of etanercept, 22 mM succinate, 90 mM NaCl, 10 mg/mL sucrose, wherein the pH of the composition is pH 6.3.

15. The composition according to any of claims 1 to 14, comprising 50 mg/mL of etanercept, 25 mM sodium phosphate buffer, 90 mM sodium chloride, 34 mg/mL sucrose, wherein the pH of the composition is pH 6.3.

AMENDED CLAIMS

1. An aqueous composition comprising:
- An isolated polypeptide that is an extracellular ligand-binding portion of a human p75 tumor necrosis factor receptor fused to the Fc region of a human IgG1;
- Salt present at a concentration of from 80 to 130 mM;
- An aqueous buffer, wherein the aqueous buffer is sodium and/or potassium phosphate buffer and wherein the aqueous buffer is present at a concentration of 20 to 30 mM; and
- An excipient which is sucrose, wherein the concentration of sucrose is between 34-80 mg/mL,

characterized in that neither arginine nor cysteine are present in the composition.

2. The composition according to claim 1, wherein the salt concentration is 90 mM.

3. The composition according to any of claims 1 to 2, wherein the salt is sodium chloride.

4. The composition according to any of claims 1 to 3, wherein the isolated polypeptide is etanercept.

5. An aqueous composition comprising:
- An isolated polypeptide that is an extracellular ligand-binding portion of a human p75 tumor necrosis factor receptor fused to the Fc region of a human IgG1;
- Salt present at a concentration of from 80 to 130 mM, wherein the salt is not present at a concentration of 100 mM;
- An aqueous buffer, wherein the aqueous buffer is succinate buffer; and
- An excipient selected from the group of trehalose and sucrose or a combination thereof,

characterized in that no free amino acids are present in the composition.

6. The composition according to claim 5 wherein the salt concentration is 90 mM.

7. The composition according to any of claims 5 to 6, wherein the salt is sodium chloride.

8. The composition according to any of claims 5 to 7 wherein the isolated polypeptide is etanercept.

9. The composition according to any of claims 5 to 8, wherein the excipient is sucrose present at a concentration of from 5 to 80 mg/mL.

10. The composition according to any of claims 5 to 9, wherein the aqueous buffer is present at a concentration of 15 mM to 100 mM.

11. The composition according to claim 10 wherein the aqueous buffer is present at a concentration of 20 to 30 mM.

12. The composition according to claim 10 wherein the aqueous buffer is present at a concentration of 50 mM.

13. The composition according to any of claims 1 to 12 further comprising one or more excipients.

14. The composition of claim 13, wherein the excipient is lactose, glycerol, xylitol, sorbitol, mannitol, maltose, inositol, glucose, bovine serum albumin, human serum albumin, recombinant hemagglutinin, dextran, polyvinyl alcohol, hydroxypropyl methylcellulose (HPMC), polyethylenimine, gelatine, polyvinylpyrrolidone (PVP), hydroxyethylcellulose (HEC), polyethylene glycol, ethylene glycol, dimethysulfoxide (DMSO), dimethylformamide (DMF), proline, L-serine, glutamic acid, alanine, glycine, lysine, sarcosine, gamma-aminobutyric acid, polysorbate-20, polysorbate-80, sodium dodecyl sulfate, polysorbate, polyoxyethylene copolymer, potassium phosphate, sodium acetate, ammonium sulphate, magnesium sulphate, sodium sulphate, trimethylamine N-oxide,

betaine, zinc ions, copper ions, calcium ions, manganese ions, magnesium ions, 3-[(3- cholamidepropyl)- dimethylammonio]-1-propanesulfate, sucrose monolaurate or a combination thereof.

15. The composition according to any of claims 1 to 14, wherein the pH of the composition is from pH 6.0 to pH 7.0.

16. The composition according to any of claims 5 to 11, 13 to 15, comprising 50 mg/mL of etanercept, 22 mM succinate, 90 mM NaCl, 10 mg/mL sucrose, wherein the pH of the composition is pH 6.3.

17. The composition according to any of claims 1 to 4, 13 to 15, comprising 50 mg/mL of etanercept, 25 mM sodium phosphate buffer, 90 mM sodium chloride, 34 mg/mL sucrose, wherein the pH of the composition is pH 6.3.

CLAIMS

1. An aqueous composition comprising:
- An isolated polypeptide that is an extracellular ligand-binding portion of a human p75 tumor necrosis factor receptor fused to the Fc region of a human IgG1;
- Salt present at a concentration of from 80 to 130 mM;
- An aqueous buffer, wherein the aqueous buffer is sodium and/or potassium phosphate buffer and wherein the aqueous buffer is present at a concentration of 20 to 30 mM; and
- An excipient which is sucrose, wherein the concentration of sucrose is between 34-40 mg/mL,

characterized in that neither arginine nor cysteine are present in the composition.

2. The composition according to claim 1, wherein the salt concentration is 90 mM.

3. The composition according to any of claims 1 to 2, wherein the salt is sodium chloride.

4. The composition according to any of claims 1 to 3, wherein the isolated polypeptide is etanercept.

5. An aqueous composition comprising:
- An isolated polypeptide that is an extracellular ligand-binding portion of a human p75 tumor necrosis factor receptor fused to the Fc region of a human IgG1;
- Salt present at a concentration of from 80 to 130 mM, wherein the salt is not present at a concentration of 100 mM;
- An aqueous buffer, wherein the aqueous buffer is succinate buffer; and
- An excipient selected from the group of trehalose and sucrose or a combination thereof,

characterized in that no free amino acids are present in the composition.

6. The composition according to claim 5 wherein the salt concentration is 90 mM.

7. The composition according to any of claims 5 to 6, wherein the salt is sodium chloride.

8. The composition according to any of claims 5 to 7 wherein the isolated polypeptide is etanercept.

9. The composition according to any of claims 5 to 8, wherein the excipient is sucrose present at a concentration of from 5 to 80 mg/mL.

10. The composition according to any of claims 5 to 9, wherein the aqueous buffer is present at a concentration of 15 mM to 100 mM.

11. The composition according to claim 10 wherein the aqueous buffer is present at a concentration of 20 to 30 mM.

12. The composition according to claim 10 wherein the aqueous buffer is present at a concentration of 50 mM.

13. The composition according to any of claims 1 to 12 further comprising one or more excipients.

14. The composition of claim 13, wherein the excipient is lactose, glycerol, xylitol, sorbitol, mannitol, maltose, inositol, glucose, bovine serum albumin, human serum albumin, recombinant hemagglutinin, dextran, polyvinyl alcohol, hydroxypropyl methylcellulose (HPMC), polyethylenimine, gelatine, polyvinlylpyrrolidone (PVP), hydroxyethylcellulose (HEC), polyethylene glycol, ethylene glycol, dimethysulfoxide (DMSO), dimethylformamide (DMF), proline, L-serine, glutamic acid, alanine, glycine, lysine, sarcosine, gamma-aminobutyric acid, polysorbate-20, polysorbate-80, sodium dodecyl sulfate, polysorbate, polyoxyethylene copolymer, potassium phosphate, sodium acetate, ammonium sulphate,

magnesium sulphate, sodium sulphate, trimethylamine N-oxide, betaine, zinc ions, copper ions, calcium ions, manganese ions, magnesium ions, 3-[(3- cholamidepropyl)- dimethylammonio]-1-propanesulfate, sucrose monolaurate or a combination thereof.

15. The composition according to any of claims 1 to 14, wherein the pH of the composition is from pH 6.0 to pH 7.0.

16. The composition according to any of claims 5 to 11, 13 to 15, comprising 50 mg/mL of etanercept, 22 mM succinate, 90 mM NaCl, 10 mg/mL sucrose, wherein the pH of the composition is pH 6.3.

17. The composition according to any of claims 1 to 4, 13 to 15, comprising 50 mg/mL of etanercept, 25 mM sodium phosphate buffer, 90 mM sodium chloride, 34 mg/mL sucrose, wherein the pH of the composition is pH 6.3.