Claims

1. An aqueous pharmaceutical composition comprising:

(i) adalimumab; and

(ii) an ionic excipient;

wherein the composition is free of buffer, has a pH of about 5 to about 6, and is stable for one week at 40° C or two weeks at 25° C.

2. The composition of claim 1 which is (1) free of polyol; or (2) free of surfactant; or (3) free of both polyol and surfactant.

3. The composition of claim 1, wherein the ionic excipient comprises a stabilizer.

4. The composition of claim 1, wherein the ionic excipient comprises an amino acid.

5. The composition of claim 4, wherein the amino acid is selected from glycine, alanine, glutamate, arginine, methionine, serine, lysine, proline, and combinations thereof.

6. The composition of claim 4, wherein the amino acid is glycine, arginine or a combination thereof.

7. The composition of claim 1, wherein the ionic excipient comprises a salt.

8. The composition of claim 7, wherein the salt is selected from sodium chloride and sodium sulfate.

9. The composition of claim 1, wherein the composition has osmolality of about 180 to 420 mOsM; the composition is suitable for administration to a subject as a single dosage; the composition has a concentration of adalimumab in the range of 30 to about 50 mg/ml; and the dosage contains about 10 to 80 mg of adalimumab.

10. The composition of claim 9, wherein the ionic excipient comprises a salt.

11. The composition of claim 9, wherein the ionic excipient comprises an amino acid.

12. The composition of claim 9, wherein the ionic excipient is arginine and sodium chloride.

13. The composition of claim 9, wherein the ionic excipient is glycine and sodium chloride.

14. The composition of claim 9, free of both surfactant and polyol.

15. The composition of claim 9, wherein the dosage is about 40 mg and results in less pain upon administration to a subject in comparison to an adalimumab composition having a buffer comprising citrate.

16. The composition of claim 9, wherein the concentration of adalimumab is about 50 mg/ml and the dosage is about 40 mg of adalimumab.

17. The composition of claim 7, wherein the composition comprises an amino acid.

18. The composition of claim 17, wherein the composition is (1) free of polyol; or (2) free of surfactant; or (3) free of both polyol and surfactant.

19. The composition of claim 17, wherein the composition has osmolality of about 180 to 420 mOsM; the composition is suitable for administration to a subject as a single dosage; the composition has a concentration of adalimumab in the range of 30 to about 50 mg/ml; and the dosage contains about 10 to 80 mg of adalimumab.

20. The composition of claim 19, wherein the concentration of adalimumab is about 50 mg/ml and the dosage is about 40 mg of adalimumab.

1. A stable aqueous pharmaceutical composition comprising:

i) adalimumab;

ii) a single buffer;

iii) a surfactant; and

iv) a tonicity modifier,

wherein the composition is free of mannitol and has a pH of about 5 to about 6.

2. The composition of claim 1, wherein the composition is free of citrate buffer.

3. The composition of claim 1, wherein the tonicity modifier is a sugar.

4. The composition of claim 1, wherein the composition is free of sodium chloride.

5. The composition of claim 1, wherein the composition has osmolality of about 180 to 420 mOsM; the composition is suitable for administration to a subject as a single dose; and the dose contains about 40 mg of adalimumab.

6. The composition of claim 2, wherein the composition is free of sodium chloride.

7. The composition of claim 6, wherein the composition has osmolality of about 180 to 420 mOsM; the composition is suitable for administration to a subject as a single dose; and the dose contains about 40 mg of adalimumab.

8. The composition of claim 2, wherein the tonicity modifier is a sugar.

9. The composition of claim 8, wherein the composition has osmolality of about 180 to 420 mOsM; the composition is suitable for administration to a subject as a single dose; and the dose contains about 40 mg of adalimumab.

10. The composition of claim 8, wherein the composition is free of sodium chloride.

11. The composition of claim 10, wherein the composition has osmolality of about 180 to 420 mOsM; the composition is suitable for administration to a subject as a single dose; and the dose contains about 40 mg of adalimumab.