WHAT IS CLAIMED IS:

1. An aqueous etanercept formulation stabilized to reduce instability, aggregation misfolding and/or fragmentation of the etanercept, said formulation comprising 25 to 75 mg/ml of etanercept and one or more stabilizers, wherein the stabilizers are selected from the group consisting of (i) sodium chloride and (ii) sodium chloride in combination with sucrose or trehalose, and (iii) a combination of sodium chloride, sucrose and trehalose.

2. The formulation of claim 1, further comprising one or more additional components selected from: of a buffer, a tonicity modifier and an excipient.

3. The formulation of claim 2 wherein the stabilizer consists essentially of either: (a) sodium chloride; or (b) sodium chloride in combination with sucrose; or (c) sodium chloride in combination with trehalose; and wherein, the formulation, optionally, is free or essentially free of arginine, and the formulation elicits long term storage stability as characterized by at least one of:

   SEC analysis at M_3 or T_2 or T_4 of: monomer content greater than 90%; aggregates content of less than 3 wt%; and fragment 3 content less than 5 wt%: and

   HIC analysis at M_3 or T_2 or T_4 wherein the amount of the composition represented by peak 1 of the HIC chromatogram is less than 3 wt.%; the amount of the composition represented by peak 2 of the HIC chromatogram is greater than 80 wt.%; and the amount of the composition represented by peak 3 of the HIC chromatogram is less than 20 wt.%.

4. The formulation of claim 2 comprising 25 to 75 mg/ml etanercept, sodium chloride in an amount up to 150 mM, 1 to 30 mM sodium phosphate; and 0 to 5 wt.% sucrose or trehalose or combination thereof; wherein the composition has a pH of 6.0 to 6.6; and wherein the composition is characterized by SEC analysis at M_3 or T_2 or T_4 in which: monomer content is greater than 80 wt.%; aggregate(s) content is less than 3 wt.%, and fragment 3 content is less than 8 wt.%.

5. The formulation of claim 4, optionally essentially free of arginine, eliciting long term storage stability characterized by:

(a) an SEC analysis at M_3 or T_2 or T_4 of greater than 90 wt.% monomer content; and less than 3 wt.% aggregate(s) content; and

(b) an HIC analysis at M_3 or T_2 or T_4 wherein the amount of the composition represented by peak 1 of the HIC chromatogram is less than 4 wt.%; the amount of the composition represented by peak 2 of the HIC chromatogram is greater than 80 wt.%; and the amount of the composition represented by peak 3 of the HIC chromatogram is less than 20 wt.%.

6. The formulation of claim 5 having an HIC analysis at M_3 or T_2 or T_4 wherein the amount of the composition represented by peak 1 of the HIC chromatogram is less than 1 wt.%; the amount of the composition represented by peak 2 of the HIC chromatogram is greater than 95 wt.%; and the amount of the composition represented by peak 3 of the HIC chromatogram is less than 3 wt.%.

7. The formulation of claim 2 comprising up to 150 mM sodium chloride, 1 to 30 mM sodium phosphate, and 0-5 wt.% sucrose or trehalose, or combination of sucrose and trehalose, and having a pH of 6.0 to 6.6; and characterized by: an SEC analysis at M_3 or T_2 or T_4 of greater than 95 wt.% monomer content and less than 1 wt.% aggregate(s) content; and an HIC analysis at M_3 or T_2 or T_4 wherein the amount of the composition represented by peak 1 of the HIC chromatogram is less than or equal to 3 wt.%; the amount of the composition represented by peak 2 of the HIC chromatogram is greater than 82 wt.%; and the amount of the composition represented by peak 3 of the HIC chromatogram is less than 15 wt.%.

8. The formulation of claim 3 comprising: about 50 mg/ml of etanercept; about 75 mM sodium chloride; 10 to 30 mM sodium phosphate; and about 3 wt.% sucrose.

9. The formulation of claim 3 comprising: about 50 mg/ml of etanercept; about 75mM sodium chloride; 10 to 30 mM sodium phosphate; and about 3 wt.% trehalose.

10. The formulation of claim 3 comprising: about 50 mg/ml of etanercept; about 75mM sodium chloride; 10 to 30 mM sodium phosphate; about 3 wt.% sucrose and having pH of 6.3 to 6.5.

11. The formulation of claim 2 comprising: about 50 mg/ml of etanercept; about 120mM sodium chloride; 10 to 30 mM sodium phosphate; about 1 wt.% sucrose; about 5 mM arginine, and having pH of 6.3 to 6.5.

12. The formulation of claim 3 comprising: about 50 mg/ml of etanercept; about 150 mM sodium chloride; 10 to 30 mM sodium phosphate, in the absence of sucrose or trehalose.

13. The formulation of claim 3 comprising: about 50 mg/ml of etanercept; about 100 mM sodium chloride; 10 to 30 mM sodium phosphate; and about 2 wt.% sucrose.

14. The formulation of claim 3 eliciting long term storage stability as characterized by: an HIC analysis at M_3 or T_2 or T_4 wherein the amount of the composition represented by peak 2 of the HIC chromatogram is greater than or equal to 95 wt.%; and wherein, if peak 3 is present on the HIC chromatogram, the amount of the composition represented by peak 3 is less than or equal to 1 wt.%.

15. The formulation of claim 3 having, at M_3 or T_2 or T_4 no more than, on average, 10,000 subvisible particles per mL having a size greater than 5µm.

16. The formulation of claim 1, containing no arginine, or essentially free of arginine, wherein the composition, at M_3 or T_2 or T_4, elicits long term storage stability that meets one or both of the following criteria:

(A) stability comparable to or better than commercially available etanercept marketed under the trademark Enbrel®, as measured by (i) SEC analysis of the amounts of aggregate(s), monomer and fragment 3 in the composition (as defined in the specification) and (ii) HIC

analysis of amounts of material in the composition corresponding to peaks 1, 2 and 3 of the HIC chromatogram (as defined in the specification); and

(B) an HIC chromatogram in which (i) peak 3 is absent, or essentially absent and (ii) peak 2 represents greater than 95 wt% of the composition; an SEC chromatogram containing essentially no peak corresponding to aggregate(s); and an SEC chromatogram in which the monomer content represents at least 95 wt% of the composition.

WHAT IS CLAIMED IS:

1. An aqueous etanercept formulation stabilized with sodium chloride, said formulation comprising 25 to 75 mg/ml of etanercept, 75 mM to 150 mM sodium chloride; 1 to 30 mM sodium phosphate, 3% sucrose, wherein the formulation is free of arginine, and where the formulation elicits long term stability.

2. The formulation of claim 1 wherein the formulation elicits long term storage stability as characterized by at least one of:

   SEC analysis at M_3 or T_2 or T_4 of: monomer content greater than 90%; aggregates content of less than 3 wt%; and fragment 3 content less than 5 wt%: and

   HIC analysis at M_3 or T_2 or T_4 wherein the amount of the composition represented by peak 1 of the HIC chromatogram is less than 3 wt.%; the amount of the composition represented by peak 2 of the HIC chromatogram is greater than 80 wt.%; and the amount of the composition represented by peak 3 of the HIC chromatogram is less than 20 wt.%.

3. The formulation of claim 1, wherein the composition has a pH of 6.0 to 6.6; and wherein the composition is characterized by SEC analysis at M_3 or T_2 or T_4 in which: monomer content is greater than 80 wt.%; aggregate(s) content is less than 3 wt.%, and fragment 3 content is less than 8 wt.%.

4. The formulation of claim 1 comprising: 50 mg/ml of etanercept; 75 mM sodium chloride; 10 to 30 mM sodium phosphate; and about 3 wt.% sucrose.

5. The formulation of claim 1 comprising: 50 mg/ml of etanercept; 75mM sodium chloride; 10 to 30 mM sodium phosphate; 3 wt.% sucrose and having pH of 6.3 to 6.5.