WHAT IS CLAIMED IS:

1. A stable aqueous pharmaceutical composition comprising 25 to 75 mg/ml etanercept in combination with a stabilizer to reduce instability, aggregation misfolding and/or fragmentation of the etanercept during storage of the formulation; said stabilizer comprising 1 to 10 wt.% sugar, 1 mM to 30mM sodium phosphate and up to 10 wt.% polyol, wherein said formulation is free or essentially free of arginine.

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

3. The composition of claim 2 eliciting long term storage stability as characterized by:

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

4. The composition of claim 2, wherein the sugar is sucrose, trehalose or dextrose; wherein the polyol is mannitol or sorbitol, and wherein said composition has a pH in the range of 6.0 to 6.6; and wherein the composition is characterized by SEC analysis at T_2 in which: the monomer content is greater than 80 wt.%; aggregates content is less than 3 wt.%, and fragment 3 content less than 10 wt.%.

5. The composition of claim 4 eliciting long term storage stability characterized by:

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

6. The composition of claim 3 comprising: 50 mg/ml of etanercept; 1 to 5 wt.% sucrose, trehalose or dextrose; 1-2 wt.% mannitol or sorbitol, 10-30 mM sodium phosphate, said composition having pH of 6.3 to 6.5.

7. The composition of claim 3 having, at T_2 no more than, on average, 10,000 subvisible particles per mL having a size greater than 5µm.

WHAT IS CLAIMED IS:

1. A stable aqueous pharmaceutical composition comprising 25 to 75 mg/ml etanercept in combination with a stabilizer to reduce instability, aggregation misfolding and/or fragmentation of the etanercept during storage of the formulation; said stabilizer comprising 1 to 10 wt.% sugar, 1 mM to 30mM sodium phosphate and up to 10 wt.% polyol, wherein said formulation is free of arginine.

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

3. The composition of claim 2 eliciting long term storage stability as characterized by:

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

4. The composition of claim 2, wherein the sugar is sucrose, trehalose or dextrose; wherein the polyol is mannitol or sorbitol, and wherein said composition has a pH in the range of 6.0 to 6.6; and wherein the composition is characterized by SEC analysis at T_2 in which: the monomer content is greater than 80 wt.%; aggregates content is less than 3 wt.%, and fragment 3 content less than 10 wt.%.

5. The composition of claim 4 eliciting long term storage stability characterized by:

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

6. The composition of claim 3 comprising: 50 mg/ml of etanercept; 1 to 5 wt.% sucrose, trehalose or dextrose; 1-2 wt.% mannitol or sorbitol, 10-30 mM sodium phosphate, said composition having pH of 6.3 to 6.5.

7. The composition of claim 3 having, at T_2 no more than, on average, 10,000 subvisible particles per mL having a size greater than 5μm.