

CLAIMS

1. A ~~stable~~ liquid tocilizumab formulation stabilized in a phosphate – amino acid dual buffer system having pH of 6.0 to 6.5, wherein the concentration of tocilizumab stabilized is ~~about~~ 10 mg/ml to ~~about~~ 200 mg/ml, and the amino acid is selected from the group consisting of histidine, glycine and aspartate.

2. The formulation according to the claim 1, is devoid of ~~anti-oxidant.~~

~~3. The formulation according to claim 2, wherein the anti-oxidant is~~ methionine.

~~4~~3. The formulation according to the claim 1, further comprises one or more pharmaceutically acceptable excipients, the one or more pharmaceutically excipients ~~comprise~~ are selected from the group consisting of sugar, polyol, arginine, ~~or~~ and surfactant.

~~5~~4. The formulation according to claim 1 or ~~4~~3, wherein the antibody formulated in the phosphate-amino acid buffer system remains stable and maintains at least 95% of monomeric content and/or contains less than 5% aggregates of the antibody, after storage under one of the following storage conditions:

at 2-8 °C for at least 6 months, or

at 25 °C for at least 6 months, or

at 40 °C for at least 2 weeks.

~~6. The formulation according to claim 1, wherein the amino acid component acts as counter ion to the phosphate component of the buffer in the formulation.~~

~~7. The formulation according to claim 6, wherein the amino acid is histidine or glycine or aspartate.~~

~~8. The formulation according to claim 1, wherein the phosphate-amino acid dual buffer system is 'phosphate-histidine'.~~

~~9~~5. The formulation according to claim 1, ~~wherein~~ has a viscosity of ~~the formulation is~~ less than 10 cp.

~~10. The formulation according to claim 1 or 4, wherein the concentration of buffer and pharmaceutically acceptable excipients or its salts, in the said formulation is less than 100 mM.~~