Claims

【Claim 1】 A liquid formulation of etanercept, comprising etanercept; and methionine or pharmaceutically acceptable salts thereof as a stabilizer, wherein the formulation has increased storage stability of etanercept compared to the formulation having no stabilizers, by reducing etanercept by-products that are produced due to denaturation during storage.

【Claim 2】 The liquid formulation according to claim 1, which further comprises one or more stabilizers selected from the group consisting of lysine, histidine, and pharmaceutically acceptable salts thereof.

【Claim 3】 The liquid formulation according to claim 1, wherein the stabilizer is present in an amount of 0.1 to 250 mM.

【Claim 4】 The liquid formulation according to claim 1, wherein the etanercept is present in an amount of 1 to 100 mg/mL.

【Claim 5】 The liquid formulation according to claim 1, which further comprises one or more materials selected from the group consisting of a buffer, an isotonic agent, an excipient, or a preservative.

【Claim 6】 The liquid formulation according to claim 5, wherein the buffer is selected from the group consisting of citrate, phosphate, succinate, tartrate, fumarate, gluconate, oxalate, lactate, acetate, histidine, and Tris.

【Claim 7】 The liquid formulation according to claim 5, wherein the buffer is present in an amount of 0.1 to 100 mM.

【Claim 8】 The liquid formulation according to claim 5, wherein the isotonic agent is selected from the group consisting of sodium chloride, potassium chloride, boric acid, sodium borate, mannitol, glycerin, propylene

glycol, polyethylene glycol, maltose, sucrose, erythritol, arabitol, xylitol, sorbitol, and glucose.

【Claim 9】 The liquid formulation according to claim 5, wherein the isotonic agent is present in an amount of 1 to 1000 mM.

【Claim 10】 The liquid formulation according to claim 1, comprising 1 to 100 mg/mL of etanercept, 0.1 to 250 mM of methionine or pharmaceutically acceptable salts thereof, 0.1 to 100 mM of phosphate buffer, and 1 to 1000 mM of sodium chloride.

【Claim 11】 The liquid formulation according to claim 2, comprising 1 to 100 mg/mL of etanercept, 0.1 to 250 mM of lysine or pharmaceutically acceptable salts thereof, and 0.1 to 250 mM of methionine or pharmaceutically acceptable salts thereof.

【Claim 12】 The liquid formulation according to claim 2, comprising 1 to 100 mg/mL of etanercept, 0.1 to 250 mM of histidine or pharmaceutically acceptable salts thereof, and 0.1 to 250 mM of methionine or pharmaceutically acceptable salts thereof.

【Claim 13】 The liquid formulation according to claim 2, comprising 1 to 100 mg/mL of etanercept, 0.1 to 250 mM of histidine or pharmaceutically acceptable salts thereof, 0.1 to 250 mM of methionine or pharmaceutically acceptable salts thereof, 0.1 to 100 mM of phosphate buffer, and 1 to 1000 mM of sodium chloride.

【Claim 14】 The liquid formulation according to claim 2, comprising 1 to 100 mg/mL of etanercept, 0.1 to 250 mM of methionine or pharmaceutically acceptable salts thereof, 0.1 to 250 mM of lysine or pharmaceutically acceptable salts thereof, 0.1 to 100 mM of phosphate buffer, and 1 to 1000 mM of sodium chloride.