Claims

[Claim 1]

An aqueous pharmaceutical formulation comprising:

a fusion protein dimer comprising an extracellular domain of an alpha subunit of an IgE Fc receptor (FcεRIα ECD),

wherein, the pH of the formulation is from 6.0 to 7.0.

[Claim 2]

The aqueous pharmaceutical formulation according to claim 1, wherein the formulation is for subcutaneous injection.

[Claim 3]

The aqueous pharmaceutical formulation according to claim 1, wherein the fusion protein dimer comprises two monomers, each of which comprises the extracellular domain of the alpha subunit of the IgE Fc receptor.

[Claim 4]

The aqueous pharmaceutical formulation according to claim 3,

wherein the monomer comprises a modified Fc region, and

the modified Fc region and the extracellular domain of the alpha subunit of the IgE Fc receptor are linked via a hinge.

[Claim 5]

The aqueous pharmaceutical formulation according to claim 4, wherein the modified Fc region consists of SEQ ID NO: 2.

[Claim 6]

The aqueous pharmaceutical formulation according to claim 4, wherein the hinge is a hinge region derived from immunoglobulin IgD or a variant thereof.

[Claim 7]

The aqueous pharmaceutical formulation according to claim 1, wherein the extracellular domain of the alpha subunit of the IgE Fc receptor consists of the amino acid sequence of SEQ ID NO: 1 or a fragment thereof.

[Claim 8]

The aqueous pharmaceutical formulation according to claim 1, wherein the fusion protein dimer is at a concentration of 50 mg/mL to 150 mg/mL.

[Claim 9]

The aqueous pharmaceutical formulation according to claim 1, wherein the formulation further comprises a buffer and a stabilizer.

[Claim 10]

The aqueous pharmaceutical formulation according to claim 9, wherein the buffer is histidine.

[Claim 11]

The aqueous pharmaceutical formulation according to claim 10, wherein the histidine is at a concentration of 10 mM to 100 mM.

[Claim 12]

The aqueous pharmaceutical formulation according to claim 9, wherein the stabilizer is proline.

[Claim 13]

The aqueous pharmaceutical formulation according to claim 12, wherein the proline is at a concentration of 200 mM to 300 mM.

[Claim 14]

The aqueous pharmaceutical formulation according to claim 1, wherein the formulation further comprises an antioxidant.

[Claim 15]

The aqueous pharmaceutical formulation according to claim 14, wherein the antioxidant is methionine.

[Claim 16]

The aqueous pharmaceutical formulation according to claim 15, wherein the methionine is at a concentration of 10 mg/mL to 30 mg/mL.

[Claim 17]

The aqueous pharmaceutical formulation according to claim 1, wherein the formulation further comprises a surfactant.

[Claim 18]

The aqueous pharmaceutical formulation according to claim 17, wherein the surfactant is poloxamer 188.

[Claim 19]

The aqueous pharmaceutical formulation according to claim 18, wherein the poloxamer 188 is at a concentration of 0.01 w/v% to 1 w/v%.

[Claim 20]

An aqueous pharmaceutical formulation comprising:

i) a fusion protein dimer comprising an extracellular domain of an alpha subunit of an IgE Fc receptor at a concentration of 50 mg/mL to 150 mg/mL;

ii) histidine at a concentration of 10 mM to 100 mM;

iii) proline at a concentration of 200 mM to 300 mM;

iv) methionine at a concentration of 10 mg/mL to 30 mg/mL; and

v) poloxamer 188 at a concentration of 0.01 w/v% to 1 w/v%,

wherein the pH of the formulation is from 6.0 to 7.0.

[Claim 21]

The aqueous pharmaceutical formulation according to claim 20, wherein the formulation is present in a container selected from the group consisting of a vial, a cartridge, a syringe, and an autoinjector.

[Claim 22]

The aqueous pharmaceutical formulation according to claim 20, wherein the formulation is for subcutaneous administration.

[Claim 23]

The aqueous pharmaceutical formulation according to claim 20, wherein the formulation is for use in the prevention or treatment of an allergic disease.

[Claim 24]

Use of the aqueous pharmaceutical formulation according to claim 20 in the manufacture of a medicament for prevention or treatment of an allergic disease.

[Claim 25]

The aqueous pharmaceutical formulation according to claim 23 or the use of the aqueous pharmaceutical formulation according to claim 24, wherein the allergic disease is one selected from the group consisting of food allergy, atopic dermatitis, asthma, allergic rhinitis, allergic conjunctivitis, allergic dermatitis, chronic idiopathic urticaria, chronic spontaneous urticaria, and allergic contact dermatitis.