Claims

[Claim 1]

A pharmaceutical formulation having a pH of 4.0 to 8.0, comprising

(a) an anti-FcRn antibody or a fragment thereof,

(b) at least one additive selected from mannitol, sorbitol, arginine, histidine, glycine and salts thereof,

(c) a buffer system selected from citrate or histidine, and

(d) a surfactant.

[Claim 2]

The pharmaceutical formulation according to claim 1, wherein the additive is arginine or a salt thereof, and the buffer system is histidine.

[Claim 3]

The pharmaceutical formulation according to claim 1, wherein the surfactant is polysorbate.

[Claim 4]

The pharmaceutical formulation according to claim 1, further comprising methionine.

[Claim 5]

The pharmaceutical formulation according to claim 1, wherein the pharmaceutical formulation is in the form of an injection.

[Claim 6]

The pharmaceutical formulation according to claim 1, wherein the pharmaceutical formulation has a viscosity of 20 cP or less.

[Claim 7]

The pharmaceutical formulation according to claim 1, wherein the pharmaceutical

formulation has an osmolality of 250 mOs/kg to 500 mOs/kg.

[Claim 8]

The pharmaceutical formulation according to claim 1, wherein the concentration of the anti-FcRn antibody or fragment thereof is 50 mg/mL to 250 mg/mL.

[Claim 9]

The pharmaceutical formulation according to claim 8, wherein the concentration of the anti-FcRn antibody or fragment thereof is 80 mg/mL to 250 mg/mL.

[Claim 10]

The pharmaceutical formulation according to claim 1, wherein the pH of the pharmaceutical formulation is 4.0 to 7.0.

[Claim 11]

The pharmaceutical formulation according to claim 1, wherein the anti-FcRn antibody comprises

a heavy chain variable region comprising H-CDR1 having the amino acid of SEQ ID NO: 5, H-CDR2 having the amino acid of SEQ ID NO: 6, and H-CDR3 having the amino acid of SEQ ID NO: 7; and

a light chain variable region comprising L-CDR1 having the amino acid of SEQ ID NO: 8, L-CDR2 having the amino acid of SEQ ID NO: 9, and L-CDR3 having the amino acid of SEQ ID NO: 10.

[Claim 12]

The pharmaceutical formulation according to claim 1, wherein the pharmaceutical formulation is administered subcutaneously.

[Claim 13]

The pharmaceutical formulation according to claim 1, wherein the pharmaceutical formulation comprises

(a) 50 mg/mL to 250 mg/mL of an anti-FcRn antibody,

(b) 50 to 250 mM L-arginine or a hydrochloride salt thereof,

(c) 50 to 250 mM L-histidine buffer, and

(d) 0.01 to 0.05% polysorbate 20, and

the pharmaceutical formulation has a pH of 4.0 to 7.0.

[Claim 14]

The pharmaceutical formulation according to claim 1, wherein the pharmaceutical formulation has increased stability, wherein the amount of aggregates and fragments of HL161BKN is 10% or less when stored for 6 months under an accelerated condition (25°C, a relative humidity of 60%).

[Claim 15]

The pharmaceutical formulation according to claim 1, wherein the pharmaceutical formulation has increased stability, wherein the amount of aggregates and fragments of HL161BKN is 10% or less when stored for 36 months under a long-term storage condition (5°C).

[Claim 16]

The pharmaceutical formulation according to claim 1, wherein the pharmaceutical formulation has increased stability, wherein the amount of aggregates and fragments of HL161BKN is 5.0% or less when stored for 36 months under a long-term storage condition (5°C).

[Claim 17]

The pharmaceutical formulation according to any one of claims 1 to 16, wherein the pharmaceutical formulation is for use in the treatment of an autoimmune disease selected from the group consisting of myasthenia gravis, thyroid eye disease, warm autoimmune hemolytic anemia, neuromyelitis optica, immune thrombocytopenic purpura, pemphigus vulgaris, chronic inflammatory demyelinating polyneuropathy, lupus nephritis, and membranous nephropathy.

[Claim 18]

Use of the pharmaceutical formulation according to any one of claims 1 to 16 in the preparation of a medicament for the treatment of an autoimmune disease,

wherein the autoimmune disease is selected from the group consisting of myasthenia gravis, thyroid eye disease, warm autoimmune hemolytic anemia, neuromyelitis optica, immune thrombocytopenic purpura, pemphigus vulgaris, chronic inflammatory demyelinating polyneuropathy, lupus nephritis, and membranous nephropathy.