CLAIMS

Claim 1

An aqueous pharmaceutical composition or lyophilized pharmaceutical composition comprising a protein having physiological activity, a neutral salt, a disaccharide, a buffering agent, and two different nonionic surfactants,

wherein the protein having physiological activity is the fusion protein of an antibody and a lysosomal enzyme,

wherein the antibody is the Fab antibody of humanized anti-human transferrin receptor (hTfR) antibody, the human lysosomal enzyme is human α-L-iduronidase, the fusion protein is a fusion protein of the antibody and the human α-L-iduronidase, and in the fusion protein:

the antibody light chain includes the amino acid sequence set forth as SEQ ID NO: 22, and

the antibody heavy chain is bonded at the C-terminus with human α-L-iduronidase via the amino acid sequence set forth as SEQ ID NO: 4, thereby forming the amino acid sequence set forth as SEQ ID NO: 27.

Claim 2

The aqueous pharmaceutical composition or lyophilized pharmaceutical composition according to claim 1, which includes a polysorbate and poloxamer as the nonionic surfactants.

Claim 3,

The aqueous pharmaceutical composition or lyophilized pharmaceutical composition according to claim 2, wherein:

the polysorbate is polysorbate 20 or polysorbate 80, and

the poloxamer is selected from the group consisting of polyoxyethylene(42) polyoxypropylene(67) glycol, polyoxyethylene(54) polyoxypropylene(39)

glycol, polyoxyethylene(196) polyoxypropylene(67) glycol, polyoxyethylene(42) polyoxypropylene(67) glycol, polyoxyethylene(3) polyoxypropylene(17) glycol, polyoxyethylene(20) polyoxypropylene(20) glycol and polyoxyethylene (120) polyoxypropylene(40) glycol, optionally wherein the polysorbate is polysorbate 80 and the poloxamer is polyoxyethylene(160) polyoxypropylene(30) glycol.

Claim 4

The aqueous pharmaceutical composition or lyophilized pharmaceutical composition according to claim 2, wherein the polysorbate is polysorbate 80 and the poloxamer is polyoxyethylene(160) polyoxypropylene(30) glycol.

Claim 5

The aqueous pharmaceutical composition according to any one of claims 2 to 4, wherein the concentration of the polysorbate is 0.005 to 1.5 mg/mL and the concentration of the poloxamer is 0.05 to 0.6 mg/mL.

Claim 6

The aqueous pharmaceutical composition according to any one of claims 2 to 4, wherein the concentration of the polysorbate is 0.025 to 1.0 mg/mL and the concentration of the poloxamer is 0.1 to 0.5 mg/mL.

Claim 7

The aqueous pharmaceutical composition according to any one of claims 2 to 4, wherein the concentration of the polysorbate is 0.05 to 0.15 mg/mL and the concentration of the poloxamer is 0.15 to 0.45 mg/mL.

Claim 8

The aqueous pharmaceutical composition according to any one of claims 2 to 4, wherein the neutral salt is sodium chloride, the disaccharide is sucrose, and the buffering agent is citrate buffer, and wherein

the concentration of the neutral salt is 0.3 to 1.2 mg/mL, the concentration of the disaccharide is 50 to 100 mg/mL, the concentration of the buffering agent is 10 to 30 mM, the concentration of the polysorbate is 0.005 to 1.5 mg/mL and the concentration of the poloxamer is 0.1 to 0.6 mg/mL.

Claim 9

The aqueous pharmaceutical composition according to any one of claims 2 to 4, wherein the neutral salt is sodium chloride, the disaccharide is sucrose, and the buffering agent is citrate buffer, and wherein the concentration of the neutral salt is 0.5 to 1.0 mg/mL, the concentration of the disaccharide is 55 to 95 mg/mL, the concentration of the buffering agent is 15 to 25 mM, the concentration of the polysorbate is 0.05 to 1.0 mg/mL and the concentration of the poloxamer is 0.25 to 0.45 mg/mL.

Claim 10

The aqueous pharmaceutical composition according to any one of claims 2 to 4, wherein the neutral salt is sodium chloride, the disaccharide is sucrose, and the buffering agent is citrate buffer, and wherein the concentration of the neutral salt is 0.7 to 0.9 mg/mL, the concentration of the disaccharide is 60 to 90 mg/mL, the concentration of the buffering agent is 15 to 25 mM, the concentration of the polysorbate is 0.05 to 0.15 mg/mL and the concentration of the poloxamer is 0.25 to 0.45 mg/mL.

Claim 11

The aqueous pharmaceutical composition according to any one of claims 8 to 10, wherein the pH is 4.5 to 6.5.

Claim 12

The aqueous pharmaceutical composition according to any one of claims 8 to 10, wherein the pH is, 5.0 to 6.0.

Claim 13

The aqueous pharmaceutical composition according to any one of claims 8 to 10, wherein the pH is 5.2 to 5.8.

Claim 14

The aqueous pharmaceutical composition according to any one of claims 1 to 13, which is encapsulated in a container formed of borosilicate glass or a hydrophobic resin.

Claim 15

The aqueous pharmaceutical composition according to claim 14, wherein the container is formed of a cycloolefin copolymer, a cycloolefin ring-opening polymer or a hydrogenated cycloolefin ring-opening polymer.

Claim 16

A lyophilized pharmaceutical composition obtained by lyophilizing the aqueous pharmaceutical composition according to any one of claims 1 to 15.