CLAIMS

1. A lyophilized formulation comprising;

a fusion protein including an anti-human transferrin receptor (hTfR) antibody and a human iduronate-2-sulfatase, as an active ingredient, and further sodium chloride, sucrose, polyoxyethylene(160)polyoxypropylene(30)glycol, and a phosphate buffer,

wherein the pH is 5.5 to 7.5 when the lyophilized formulation is dissolved in pure water, and

wherein the light chain of the anti-hTfR antibody has the amino acid sequence set forth as SEQ ID NO:6, and wherein the heavy chain of the anti-hTfR antibody having the amino acid sequence set forth as SEQ ID NO:10 is linked, on the C-terminal side thereof, to the human iduronate-2-sulfatase via a linker.

2. The lyophilized formulation according to claim 1, wherein the amounts of sodium chloride, sucrose, and polyoxyethylene(160)polyoxypropylene(30)glycol are 0.015 to 2.5 (w/w), 2.5 to 200 (w/w), and 0.005 to 6 (w/w), respectively, relative to the amount of the fusion protein.

3. The lyophilized formulation according to claim 1, wherein the amounts of sodium chloride, sucrose, and polyoxyethylene(160)polyoxypropylene(30)glycol are 0.05 to 0.5 (w/w), 5 to 50 (w/w), and 0.02 to 0.2 (w/w), respectively, relative to the amount of the fusion protein.

4. The lyophilized formulation according to claim 1, wherein the amounts of sodium chloride, sucrose, and

polyoxyethylene(160)polyoxypropylene(30)glycol is 0.1 to 0.25 (w/w), 10 to 25 (w/w), and 0.04 to 0.1 (w/w), respectively, relative to the amount of the fusion protein.

5. The lyophilized formulation according to any one of claims 1 to 4, wherein the linker includes the amino acid sequence of Gly-Ser.

6. The lyophilized formulation according to any one of claims 1 to 5, wherein the light chain of the anti-hTfR antibody has the amino acid sequence set forth as SEQ ID NO:6, and wherein the heavy chain of the anti-hTfR antibody is linked, on the C-terminal side thereof and via a linker sequence of Gly-Ser, to the human iduronate-2-sulfatase, and the whole linked heavy chain has the amino acid sequence set forth as SEQ ID NO:17.

7. The lyophilized formulation according to any one of claims 1 to 6, sealed in a container formed of a borosilicate glass or a hydrophobic resin.

8. The lyophilized formulation according to claim 7, wherein the container is formed by a cycloolefin copolymer, a ring-opened polymer of cycloolefin, or a hydrogenated ring-opened polymer of cycloolefin.