CLAIMS

1. A lyophilized formulation comprising:

(1) a hepatic growth factor;

(2) trehalose; and

(3) one or more compounds selected from the group consisting of arginine, histidine, lysine, meglumine, glutamic acid, aspartic acid, proline, creatine, creatinine, tris(hydroxymethyl)aminomethane, and pharmaceutically acceptable salts thereof.

2. A method for producing a lyophilized formulation, comprising the steps of:

(I) prior to addition of (1) a hepatic growth factor, adjusting pH of an aqueous solution comprising at least (3) one or more compounds selected from the group consisting of arginine, histidine, lysine, meglumine, glutamic acid, aspartic acid, proline, creatine, creatinine, tris(hydroxymethyl)aminomethane, and pharmaceutically acceptable salts thereof, to pH 4.5 to 6.5, and preparing an aqueous solution comprising (1) the hepatic growth factor, (2) trehalose and (3) one or more compounds selected from the group consisting of arginine, histidine, lysine, meglumine, glutamic acid, aspartic acid, proline, creatine, creatinine, tris(hydroxymethyl)aminomethane, and pharmaceutically acceptable salts thereof; and

(II) lyophilizing the aqueous solution comprising the hepatic growth factor obtained in the step (I).

3. A method for stabilizing a hepatic growth factor, the method comprising including (2) trehalose and (3) one or more compounds selected from the group consisting of arginine, histidine, lysine, meglumine, glutamic acid, aspartic acid, proline, creatine, creatinine, tris(hydroxymethyl)aminomethane, and pharmaceutically acceptable salts thereof in a lyophilized formulation comprising (1) hepatic growth factor.

4. The lyophilized formulation according to claim 1, wherein the mass ratio of the hepatic growth factor to trehalose is from 1:4 to 1:460.

5. The method for producing a lyophilized formulation according to claim 2, wherein the mass ratio of the hepatic growth factor to trehalose is from 1:4 to 1:460.

6. The method for stabilizing a hepatic growth factor according to claim 3, wherein the mass ratio of the hepatic growth factor to trehalose is from 1:4 to 1:460.

7. A lyophilized formulation produced by the method according to claim 2 or claim 5.