Claims

1. A stable freeze-dried formulation comprising FGF-18, ~~a buffer, a poloxamer surfactant and a sugar as stabilizing agent, wherein the buffer is~~ a phosphate buffer keeping the pH comprised between ~~6~~ 7.0 and ~~8~~ 7.5, ~~wherein the poloxamer surfactant is~~ poloxamer 188 and ~~wherein the sugar is~~ sucrose.

2. The stable freeze-dried formulation according to claim 1, wherein the phosphate buffer keeps the pH at 7.2.

3. The stable freeze-dried formulation according to any of the preceding claims, wherein the concentration of the buffer is at 5 to 100 mM.

4. The stable freeze-dried formulation according to any of the preceding claims, wherein the concentration of ~~the~~ poloxamer 188 ~~surfactant~~ is at 0.1 to 0.4 mg/vial.

5. The stable freeze-dried formulation according to any of the preceding claims, wherein the concentration of ~~the stabilizing agent~~ sucrose is at 10 to 60 mg/vial.

6. The stable freeze-dried formulation according to any one of the preceding claims, wherein the concentration of FGF-18 is at 20 to 300 mcg/ vial.

7. The stable freeze-dried formulation according to any one of the preceding claims, wherein the formulation comprises 20, 30, 60, 100, 200 or 300 mcg/vial of FGF-18, 10 mM phosphate buffer which keep the pH at 7.2, 30 mg/vial of sucrose and 0.2 mg/vial of poloxamer 188.

8. The stable formulation according to any of the preceding claims, wherein the formulation further comprises a 5% overage of FGF-18.

9. The stable freeze-dried formulation according to any of the preceding claims, wherein FGF-18 is selected from the group consisting of :

   a. a polypeptide comprising or consisting of the amino acid residues 28-207 of SEQ ID NO:1,

   b. a polypeptide comprising or consisting of the amino acid residues 28-196 of SEQ ID NO:1, and

   c. a polypeptide comprising or consisting of SEQ ID NO:2.

10. A method for producing the stable freeze-dried formulation according to any of the preceding claims, comprising the steps of:

a. forming a mixture of FGF-18 together with the phosphate buffer, the ~~surfactant~~ poloxamer 188 and the ~~stabilizing agent~~ sucrose, and

b. subjecting the mixture to lyophilization.

11. An article of manufacture comprising a first container comprising the stable freeze-dried formulation according to any one of claims 1-9 and a second container comprising a solvent for reconstitution.

12. The article of manufacture according to claim 11, wherein the container comprising the stable freeze-dried formulation and the one comprising a solvent for reconstitution are the two compartments of a dual-chamber system.