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 ~~and~~ keepsing the pH comprised between 6 and 8, 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 poloxamer surfactant is poloxamer 188.~~

~~5.~~4. The stable freeze-dried formulation according to any of the preceding claims, wherein the concentration of the poloxamer surfactant is at 0.1 to 0.4 mg/vial.

~~6. The stable freeze-dried formulation according to any of the preceding claims wherein the stabilizing agent is sucrose.~~

~~7.~~5. The stable freeze-dried formulation according to any of the preceding claims, wherein the concentration of the stabilizing agent is at 10 to 60 mg/vial.

~~8.~~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.

~~9.~~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.

~~10.~~8. The stable formulation according to any of the preceding claims, wherein the formulation further comprises a 5% overage of FGF-18.

~~11.~~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.

~~12.~~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 buffer, the surfactant and the stabilizing agent, and

b. subjecting the mixture to lyophilization.

~~13.~~11. An article of manufacture comprising a first container comprising the stable freeze-dried formulation according to any one of claims 1-~~11~~9 and a second container comprising a solvent for reconstitution.

~~14.~~12. The article of manufacture according to claim 1~~3~~1, 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.