

CLAIMS

1. A formulation comprising a wild type complement factor I (CFI) or a variant thereof (CFI variant), wherein the formulation comprises a buffering agent, a surfactant, and a tonicity modifier.
2. The formulation of claim 1, wherein the formulation comprises one or more of a bulking agent, a cryoprotectant, and a lyoprotectant.
3. The formulation of claims 1 or 2, wherein the concentration of the CFI or variant thereof is present at about 10 mg/ml to about 300 mg/ml.
4. The formulation of any one of claims 1-3, wherein the buffering agent comprises acetate, histidine, or succinate.
5. The formulation of any one of claims 1-4, wherein the buffering agent is present at about 1mM to about 50mM.
6. The formulation of any one of claims 1-5, wherein the surfactant is polysorbate 80, polysorbate 20, polysorbate 80/20, or poloxamer F68.
7. The formulation of claim 6, wherein the surfactant is present at about 0.001% to about 0.1% v/v.
8. The formulation of any one of claims 1-7, wherein the tonicity modifier is sorbitol, trehalose, sodium chloride, or arginine hydrochloride.
9. The formulation of any one of claims 1-8, wherein the bulking agent is trehalose or glycine.
10. The formulation of claim 1, wherein the tonicity modifier is selected from:

- (i) sorbitol, wherein the soribtol is present at about 1% to about 10% v/v;
- (ii) trehalose, wherein the trehalose is present at about 1% to about 15% v/v;
- (iii) sodium chloride, wherein the sodium chloride is present at about 1mM to about 500mM; and
- (iv) arginine hydrochloride, wherein the arginine hydrochloride is present at about 10 mM to about 200 mM.

11. The formulation of claim 9, wherein the glycine is present at about 1% to about 5% v/v or about 1mM to about 100mM.

12. The formulation of any one of claims 2-11, wherein the cryoprotectant or lyoprotectant is selected from glucose, sucrose, glycine, sorbitol, trehalose, sucrose, or mannitol.

13. The formulation of claim 12, wherein:

- (a) the glucose is present at about 4% v/v;
- (b) the sucrose is present at about 1% to about 10% v/v;
- (c) the glycine is present at about 50 mM to about 150 mM;
- (d) the trehalose is present at about 1% to about 10% v/v;
- (e) the mannitol is present at about 1mM to about 100mM; or
- (f) the sorbitol is present at about 1% to about 5% v/v.

14. The formulation of any one of claims 1-13, wherein the formulation is selected from the formulations presented in Table 2.2 or Table 3.3.

15. The formulation of any one of claims 1-14, wherein the formulation is in a solid form, a lyophilized form, or a liquid form.

16. The formulation of any one of claims 1-15, wherein the formulation is stable at any one or more of -80°C +/- 2°C, -20°C +/- 2°C, 0°C +/- 2°C, 4°C +/- 2°C, 25°C +/- 2°C, 37°C +/- 2°C, 45°C +/- 2°C, or at 60°C +/- 2°C.

17. The formulation of any one of claims 1-16, wherein the formulation is stable for at least 1 week, for at least one month, or at least one year.

18. The formulation of any one of claims 1-17, wherein the formulation comprises wild type CFI.

19. The formulation of any one of claims 1-20, wherein the formulation comprises a CFI variant comprising at least one modification with respect to a wild type CFI, wherein the CFI variant is capable of modulating the complement system, and wherein the CFI variant has at least one improved characteristic as compared to the wild type CFI.

20. The formulation of claim 19, wherein the CFI variant is selected from those presented in Table 2.

21. The formulation of any one of claims 1-20, wherein the wild type CFI or CFI variant is a first component of a fusion construct comprising a first component and at least a second component, and the wild type CFI or CFI variant is fused to the second component.

22. A formulation comprising a fusion construct comprising a wild type CFI or variant thereof (CFI variant), where the wild type CFI or CFI variant is fused to a human serum albumin, and the formulation is selected from those presented in Table 2.2 or Table 3.3.

23. The formulation of claim 22, wherein the fusion construct comprises the amino acid sequence of SEQ ID NO: 21.

24. The formulation of any one of claims 1-23 for use in therapy.