Claims

1. A pre-lyophilization formulation comprising:

(a) a Factor IX (FIX) polypeptide at a concentration between about 220 IU/vial to about 1,000 IU/vial, wherein the FIX polypeptide comprises the FIXFc-sc polypeptide of SEQ ID NO: 2, without the C-terminal lysine, and the Fc sc polypeptide of SEQ ID NO:4, without the C-terminal lysine, wherein the FIXFc-sc polypeptide and the Fc sc polypeptide are bound together through two disulfide bonds in the hinge region of Fc;

(b) L-histidine at a concentration between about 3 mg/mL and about 15 mg/mL;

(c) sucrose at a concentration between about 10 mg/mL and about 50 mg/mL;

(d) mannitol at a concentration between about 20 mg/mL and about 100 mg/mL; and

(e) polysorbate 20 at a concentration between about 0.01 mg/mL and about 5 mg/mL,

wherein the formulation has a fill volume of less than about 3 mL; and wherein each of (a) - (e) are at an amount per vial (mg/vial) sufficient to allow reduced reconstitution time of a lyophilate prepared by lyophilizing the formulation compared to a reference pre-lyophilization formulation, wherein, for the purpose of comparison of reconstitution time, the volumes into which each of the lyophilate prepared by lyophilizing the formulation and the lyophilate prepared by lyophilizing the reference pre-lyophilization formulation are reconstituted respectively are the same,

wherein the reference pre-lyophilization formulation comprises (a) - (e) at the amount per vial identical to the pre-lyophilization formulation, but has a 5 mL fill volume.

2. The pre-lyophilization formulation of claim 1, wherein the volumes into which each of the lyophilate prepared by lyophilizing the formulation and the lyophilate prepared by lyophilizing the reference pre-lyophilization formulation are reconstituted respectively are about 5 mL.

3. The pre-lyophilization formulation of claim 1 or claim 2,

wherein the FIX polypeptide is at a concentration between 220 IU/vial to 1,000 IU/vial;

wherein the L-histidine is at a concentration between 3 mg/mL and 15 mg/mL;

wherein the sucrose is at a concentration between 10 mg/mL and 50 mg/mL; wherein the mannitol is at a concentration between 20 mg/mL and 100 mg/mL; or wherein the polysorbate 20 is at a concentration between 0.01 mg/mL and 5 mg/mL.

4. The pre-lyophilization formulation of any one of claims 1 to 3, wherein the L-histidine is at a concentration between about 3.88 mg/mL and about 9.7 mg/mL, wherein the sucrose is at a concentration between about 17.85 mg/mL and about 29.95 mg/mL, or wherein the mannitol is at a concentration between about 35.7 mg/mL and about 59.5 mg/mL.

5. The pre-lyophilization formulation of any one of claims 1 to 4, wherein the L-histidine is at a concentration of about 7.76 mg/mL, wherein the sucrose is at a concentration of about 23.8 mg/mL, wherein the mannitol is at a concentration of about 47.6 mg/mL, or wherein the polysorbate 20 is at a concentration of about 0.2 mg/mL.

6. The pre-lyophilization formulation of any one of claims 1 to 5, wherein the formulation has a fill volume per vial of about 2.65 mL.

7. A lyophilate, which is lyophilized from the pre-lyophilization formulation of any one of claims 1 to 6.

8. A vial comprising the lyophilate of claim 7.

9. A kit comprising a first container comprising the lyophilate of claim 7 and a second container comprising a reconstitution buffer at a volume sufficient to produce a reconstituted formulation, when combined with the lyophilization formulation of the first container.

10. A composition comprising the lyophilate of claim 7, for reconstituting to prepare a pharmaceutical composition for preventing or reducing the frequency or severity of bleeding episodes in a hemophilia B patient.