CLAIMS

1. An aqueous formulation, comprising from 10 mM to 55 mM arginine, from 1% to 3% sucrose (w/v), from 2% to 8% mannitol (w/v) and at least 5 mg/mL of a two-chain polypeptide comprising a first chain comprising the amino acid sequence of SEQ ID NO. 4, a second chain comprising the amino acid sequence of SEQ ID NO. 5, and a disulfide bond between a first Cysteine residue at position 98 (Cys98) of SEQ ID NO. 4 and a second Cysteine residue at position 108 (Cys108) of SEQ ID NO. 5, wherein the formulation has a pH from 7.5 to 8.

2. The aqueous formulation of claim 1, comprising at least 10 mg/mL of the two-chain polypeptide, from 40 mM to 50 mM arginine, from 1.5% to 2.5% sucrose (w/v), and from 4.5% to 5.5% mannitol (w/v).

3. The aqueous formulation of claim 2, comprising at least 18 mg/mL of the two-chain polypeptide.

4. The aqueous formulation of any one of claims 1-3, wherein the two-chain polypeptide comprises an amino acid residue that is modified to be different from natural amino acids.

5. The aqueous formulation of claim 4, wherein the modification is residue Asp29 of the first chain modified to (*3R*)-3-hydroxyAsp at Asp29.

6. The aqueous formulation of claim 1, comprising about 45 mM arginine, about 2% sucrose (w/v), about 5% mannitol (w/v) and about 10 mg/mL or 20 mg/mL of the two-chain polypeptide, wherein the formulation has a pH of about 7.8.

7. A method of preparing a lyophilized formulation, comprising lyophilizing the aqueous formulation of any one of claims 1-6.

8. A lyophilized composition:

(i) obtainable by lyophilizing the aqueous formulation of any one of claims 1-7; or

(ii) comprising at least 10% (w/w) of a two-chain polypeptide comprising a first chain of the amino acid sequence of SEQ ID NO. 4, a second chain of the amino acid sequence of SEQ ID NO. 5, and a disulfide bond between a first Cysteine residue at position 98 (Cys98) of SEQ ID NO. 4 and a second Cysteine residue at position 108 (Cys108) of SEQ ID NO. 5, and L-arginine HCl:sucrose:mannitol in a weight ratio of the range (0.5-1.4):(1-3):(2-8).

9. The lyophilized composition of claim 8(ii):

(i) comprising at least 18% (w/w) of the two-chain polypeptide;

(ii) wherein the weight ratio of L-arginine HCl:sucrose:mannitol is in the range of (0.9-1):(1.5-2.5):(4.5-5.5); or

(iii) wherein L-arginine HCl:sucrose:mannitol have a weight ratio of about 0.95:2:5.

10. A lyophilized composition of any one of claims 8-9 for use in a method of reducing bleeding in a subject undergoing anticoagulant therapy with a factor Xa inhibitor, wherein a solution prepared by dissolving the lyophilized composition in an aqueous solvent is to be administered to the subject.

11. The lyophilized composition for use of claim 10, wherein the factor Xa inhibitor is apixaban, rivaroxaban or betrixaban.

12. An aqueous formulation of any one of claims 1-6, for use in a method of reducing bleeding in a subject undergoing anticoagulant therapy with a factor Xa inhibitor, wherein an effective amount of the formulation is to be administered to the subject.

13. The aqueous formulation for use of claim 12, wherein the factor Xa inhibitor is apixaban, rivaroxaban or betrixaban.

14. Use of the lyophilized composition of any one of claims 8-9 in the manufacture of a medicament for reducing bleeding in a subject undergoing anticoagulant therapy with a

factor Xa inhibitor, wherein a solution prepared by dissolving the lyophilized composition in an aqueous solvent is to be administered to the subject.

15. The use of claim 14, wherein the factor Xa inhibitor is apixaban, rivaroxaban or betrixaban.

16. Use of the aqueous formulation of any one of claims 1-6 in the manufacture of a medicament for reducing bleeding in a subject undergoing anticoagulant therapy with a factor Xa inhibitor, wherein an effective amount of the formulation is to be administered to the subject.

17. The use of claim 16, wherein the factor Xa inhibitor is apixaban, rivaroxaban or betrixaban.