trehalose, increase the complexity of the product and can lead to problems for patients with intolerances to the additives.

[0005] For the above reasons, it is desirable to provide improved hemostatic compositions, methods of making these compositions, and related methods of using the compositions for preventing excessive bleeding and promoting healing following surgery or other trauma using powdered formulations that may be provided in powdered form and dissolved and reconstituted quickly and effectively. These compositions do not require additional additives in order to perform well.

## SUMMARY

[0006] To improve medical treatment, especially to prevent excessive bleeding and promote healing, new hemostatic compositions and methods of making and using the same are described herein. The present disclosure seeks to implement new hemostatic compositions that eliminate undesirable features of current compositions, such as a long time to reconstitute, and the addition of ingredients that may not be tolerable to all patients.

[0007] The present disclosure sets forth methods for inhibiting bleeding by providing a spray-dried powdered thrombin material that is reconstituted and applied topically to a wound site in one example. The thrombin material is aseptically spray-dried and does not require the addition of trehalose or a similar carbohydrate, e.g. a stabilizing sugar. The new and improved fast-reconstituting thrombin is spray-dried and contains an unexpectedly reduced amount of albumin.

[0007a] In one aspect of the present disclosure, there is provided a hemostatic composition comprising spray-dried thrombin and less than 5% by weight albumin, wherein said composition is substantially free of trehalose and mannitol.

[0007b] In another aspect of the present disclosure, there is provided a thrombin feedstock solution for spray-drying comprising 1.5% to 2% by weight albumin, 2% to 2.5% by weight albumin, 2.5% to 3.5% by weight albumin, 2.5% to 3% by weight albumin, or 2.2% to 2.5% by weight albumin prior to spray-drying.

[0007c] In a further aspect of the present disclosure, there is provided a spray-dried thrombin material obtained by spray-drying the thrombin feedstock solution disclosed herein.

[0007d] In another aspect of the present disclosure, there is provided a spray-dried thrombin material obtained by spray-drying the thrombin feedstock solution disclosed herein.

[0007e] In a further aspect of the present disclosure, there is provided a use of a spray-dried thrombin material in the manufacture of a medicament for inhibiting bleeding, wherein:

the spray-dried thrombin material is reconstituted in less than sixty seconds and said material is substantially free of trehalose and mannito;

the reconstituted spray-dried thrombin material is to be applied to a wound site; and

a biologically compatible polymer is to be optionally administered to the wound site.

[0008] In light of the disclosure herein, and without limiting the scope of the invention in any way, in a first example of the present disclosure, which may be combined with any other example listed herein unless specified otherwise, a hemostatic composition includes spray-dried thrombin and less than 5% by weight albumin, for example, less than 3% by weight albumin less than 2.5 % by weight albumin, 1.5% to 2% by weight albumin, 2% to 2.5% by weight albumin, 2.5% to 3.5% by weight albumin, 2.5% to 3% by weight albumin, and/or 2.2% to 2.5% by weight albumin.

[0009] In a second example of the present disclosure, which may be combined with any other example listed herein unless specified otherwise, the hemostatic composition may be substantially free of carbohydrates.

CLAIMS

The invention is claimed as follows:

1. A hemostatic composition comprising spray-dried thrombin and less than 5% by weight albumin, wherein said composition is substantially free of trehalose and mannitol.

2. The hemostatic composition of claim 1, comprising less than 3% by weight albumin.

3. The hemostatic composition of claim 1, comprising less than 2.5 % by weight albumin.

4. The hemostatic composition of claim 1, wherein the composition is substantially free of carbohydrates.

5. A thrombin feedstock solution for spray-drying comprising 1.5% to 2% by weight albumin, 2% to 2.5% by weight albumin, 2.5% to 3.5% by weight albumin, 2.5% to 3% by weight albumin, or 2.2% to 2.5% by weight albumin prior to spray-drying.

6. A spray-dried thrombin material obtained by spray-drying the thrombin feedstock solution of claim 5.

7. The composition of claim 6, wherein the thrombin is aseptically spray-dried.

8. A spray-dried thrombin material comprising 75 to 90% by weight total protein based on the total solids content of the material, wherein said material is substantially free of trehalose and mannitol.

9. Use of a spray-dried thrombin material in the manufacture of a medicament for inhibiting bleeding, wherein:

the spray-dried thrombin material is reconstituted in less than sixty seconds and said material is substantially free of trehalose and mannitol;

the reconstituted spray-dried thrombin material is to be applied to a wound site; and a biologically compatible polymer is to be optionally administered to the wound site.

10. The use of claim 9, wherein the biologically compatible polymer is a gelatin.

11. The use of claim 10, wherein the gelatin is cross-linked.

12. The use of claim 9, wherein the spray-dried thrombin material is reconstituted in less than 1% NaCl by weight.

13. The use of claim 9, wherein the spray-dried thrombin material is reconstituted in less than thirty seconds.

14. The use of claim 9, wherein the spray-dried thrombin material is reconstituted in ten to twenty seconds.

15. The use of claim 9, wherein the spray-dried thrombin material is obtained by spray-drying the thrombin feedstock composition of claim 5.

16. The use of claim 9, wherein the spray-dried thrombin material comprises 75 to 90% by weight total protein based on the total solids content of the composition.