CLAIMS

1. An aqueous pharmaceutical composition comprising tranexamic acid (TXA) or a pharmaceutically acceptable salt thereof and a pH modifying agent, in which the concentration of TXA or pharmaceutically acceptable salt thereof in the composition is around 2.9 M, in which the pH of the composition is about 4, and in which the composition is substantially free from any other pharmaceutical excipient.

2. A composition according to Claim 1, in which the pH modifying agent is an acid.

3. A composition according to Claim 1 or 2 for parenteral administration, preferably for intramuscular administration.

4. A composition according to Claim 1, 2 or 3 for use in the treatment or prevention of a disease or disorder in a subject.

5. A composition according to any preceding claim for use in treating or preventing haemorrhage in a subject.

6. A composition according to Claim 4 or 5, in which the composition is administered parenterally to the subject, optionally intramuscularly to the subject.

7. A composition according to Claim 4, 5 or 6, in which the composition comprises TXA and the amount of TXA administered to the subject is within about a 10% range around 1g.

8. A composition according to any of Claims 4 to 7, in which the composition is administered to the subject in a single dose, and/or in which the volume of the composition administered to the subject is about 1.5 mL to about 2.5 mL in total, about 2 mL to about 2.5 mL in total, preferably about 2.2 mL in total.

9. A composition according to any of Claims 4 to 8, in which the subject has not been administered TXA or a pharmaceutically acceptable salt thereof in the previous 24 hours, 12 hours, 6 hours, 3 hours, 1.5 hours, 1 hour or 0.5 hours.

10. A container containing one dose or a plurality of doses of a composition according to Claim 1, 2 or 3 or a composition for use according to any of Claims 4 to 9, optionally in which the composition comprises TXA and the amount of TXA in a dose is within about a 10% range around 1g.

11. An injection device for single or multiple use, in which the injection device comprises an injection needle and a container according to Claim 10, and/or in which the injection device is for parenteral administration of the pharmaceutical composition, preferably for intramuscular administration.

12. A method of preparing a composition according to Claim 1, 2 or 3, in which the method comprises:

(a) providing an aqueous acid solution; and

(b) adding TXA or a pharmaceutically acceptable salt thereof to the aqueous acid solution,

optionally in which the method further comprises adding concentrated acid, further aqueous acid solution, base and/or water until the pH of the solution reaches about 4, optionally in which the acid is an inorganic acid or organic acid, preferably an inorganic acid such as hydrochloric acid.

13. A method of preparing a container according to Claim 10, in which the method comprises:

A) (a) sterilising an aqueous solution comprising TXA or a pharmaceutically acceptable salt thereof; and

(b) adding the sterilised solution comprising TXA or a pharmaceutically acceptable salt thereof to a (sterilised) container; or

B) (a) adding an aqueous solution comprising TXA or a pharmaceutically acceptable salt thereof to a container; and

(b) sterilising the container with the aqueous solution comprising TXA or a pharmaceutically acceptable salt thereof comprised therein.

14. A method of preparing a composition according to Claim 1, 2 or 3, in which the method comprises:

(a) providing an aqueous acid solution;

(b) adding TXA or a pharmaceutically acceptable salt thereof to the aqueous acid solution to dissolve the TXA and obtain a solution of pH about 4, in which the acid to

TXA ratio is 1.1:1 to 1.3:1 by mass, preferably in which the acid to TXA ratio is around 1.2:1 by mass; and

(c) adding water as needed to make up the solution to the final volume; and optionally in which the method further comprises filtering the composition.

15. A method according to Claim 14, in which the acid is HCl, preferably 4N HCl.