## Claims

**1.** A method for determining the biological activity of defibrotide, which comprises the steps of:

a) bringing into contact defibrotide, mammalian euglobulin and a substrate specific for the plasmin which, by reaction with the plasmin, provides a measurable product; and

b) measuring the amount of product formed at successive times, to thereby determine the biological activity of the defibrotide.

**2.** The method according to claim 1, wherein the euglobulin is a mammalian euglobulin.

**3.** The method according to claim 2, wherein the euglobulin is human, rabbit or bovine euglobuline.

**4.** The method according to claim 1, wherein the plasmin which reacts with the substrate specific for the plasmin is released by the plasminogen contained in euglobulin.

**5.** The method according to claim 1, wherein the substrate specific for the plasmin is a cromogenic substrate.

**6.** The method according to claim 1, wherein the substrate specific for the plasmin is a compound of formula $A_1$-$A_2$-$A_3$-X in which $A_1$ and $A_2$ are non-polar amino acids, $A_3$ is lysine or arginine and X is the measurable product.

**7.** The method according to claim 6, wherein the measurable product X is selected from the group consisting of para-nitroaniline and 2-naphthylamine.

**8.** The method according to claim 4, wherein the substrate specific for the plasmin is H-D-Valyl-L-Leucyl-L-Lysine-p-nitroaniline.

**9.** The method according to claim 6, wherein the measurable product X is measured by spectrophotometry or spectfofluorimetry.

**10.** The method according to claim 2, wherein the mammalian euglobulin is reconstituted to the same volume of the originating plasma or diluted up to 1:10 with suitable buffer and chromogenic/fluorogenic substrate has a concentration of from 2.5 to 3.5 mM, preferably 3 mM.

**11.** The method according to claim 1, wherein said method is carried out in a reaction medium which is an aqueous solution buffered to a pH of from 7 to 8, preferably to a pH of 7.4.

**12.** The method according to claim 1, wherein the temperature is maintained at from 35 to 39 ℃, preferably at 37 ℃.

**13.** The method according to claim 1, wherein the concentration of the substrate specific for the plasmin is from 0.3 to 4 mM, preferably from 2.5 to 3.5 mM, more preferably 3 mM.

**14.** The method according to claim 1, which method comprises the steps of: c) determining the rate of release of the measurable product during the course of the enzymatic reaction of both a standard sample and a test sample; d) correlating, mathematically and/or graphically, the rate of release with the corresponding defibrotide concentration to obtain the biological activity of the test sample of defibrotide.

**15.** The method according to any of the preceding claims, wherein defibrotide is in the form of a liquid defibrotide formulation having a biological activity of 25 to 35 IU/mg of defibrotide, preferably from 27.5 to 32.5 IU/mg, more preferably, from 28 to 32 IU/mg.

**16.** The method according to claim 15, wherein said liquid defibrotide formulation is a water solution.

**17.** The method according to claim 16, wherein said defibrotide water solution is buffered.

**18.** The method according to claim 17, wherein said buffered defibrotide water solution has a pH of from 6.5 to 8.5, preferably from 7 to 8.