Claims

1. A method of viral inactivation in FSH, the method comprising a step of treating the FSH with a combination of caprylic acid and ethanol.

2. A method according to claim 1 which comprises treating a solution of the FSH (e.g. in a buffer) with a combination of caprylic acid and ethanol.

3. A method according to any preceding claim wherein the FSH is recombinant FSH.

4. A method according to any preceding claim wherein the FSH is recombinant FSH produced in a cell by a method comprising culturing the cell in a suitable medium and harvesting the recombinant FSH from said cell and/or said medium.

5. A method according to claim 4 wherein the cell is a mammalian cell.

6. A method according to any preceding claim wherein treating the FSH with a combination of caprylic acid and ethanol takes place at pH 2 to pH 6.5, for example pH 3 to pH 6.5, for example pH 4 to pH 6, for example pH 4.5 to pH 5.5.

7. A method according to any preceding claim wherein the caprylic acid concentration is 10 mM to 30 mM caprylic acid and/or the ethanol is 20% to 50% EtOH.

8. A method according to any preceding claim which comprises: (a) treating the FSH with ethanol and caprylic acid for 1 minute to 6h incubation at a temperature 23±2ºC with stirring; (b) treating the FSH with ethanol and caprylic acid at a temperature of 4º-8ºC for incubation of 1 minute to 32h, without stirring; (c) treating the FSH with ethanol and caprylic acid for 0.5h to 1h incubation at a temperature 23±2ºC with stirring, followed by reduction to a temperature of 4º-8ºC and subsequent incubation for 14h to 18h, without stirring; or (d) treating the FSH with ethanol and caprylic acid for a duration of 1h±10min at a pH of 5.5±0.1 and a temperature of 23±2ºC.

9. A method according to any preceding claim comprising a further step of filtering the FSH following treatment with caprylic acid and ethanol.

10. A method according to claim 9 wherein the FSH is filtered using a glass fibre filter.

11. A method according to any preceding claim comprising a further step of concentrating the FSH to the desired concentration and/or subsequent formulation steps.