also been used as a stabilizing agent and as a partitioning agent in the purification of therapeutic human albumin. *See* U.S. Patent Nos. 5,250,663 and 5,561,115.

Human albumin is purified from the Cohn Fraction IV-1 Effluent or Fraction V and includes an acetone drying step to concentrate the albumin and inactivate viruses. The acetone process is expensive and uses large quantities of acetone, which creates a fire or explosion hazard. Accordingly, alternative viral inactivation and concentration procedures are desirable. A method for purifying albumin from human plasma using caprylate viral inactivation under conditions of low pH and elevated temperature followed by ultrafiltration/diafiltration is described herein.

SUMMARY

Described herein are methods for inactivating viruses using caprylate during the purification of albumin from plasma.

One embodiment described herein is a method of preparing albumin from a solution comprising albumin comprising: adjusting the protein concentration of the solution to less than about 5%; adjusting pH of the solution to about pH 5 or less; adding caprylic acid (octanoic acid) or sodium caprylate; raising the solution temperature greater than about 20 °C; and incubating the solution.

In one embodiment, there is provided a method of preparing albumin from a solution comprising albumin, the method comprising:

(i) adjusting the protein concentration of the solution to less than about 5%;

(ii) adding caprylic acid (octanoic acid) or sodium caprylate to the solution obtained in step (i);

(iii) adjusting pH of the solution obtained in step (ii) to about pH 5 or less;

(iv) raising the temperature of the solution obtained in step (iii) to about 27-30° C.; and

(v) incubating the solution obtained in step (iv) for about 30 min to 120 min.

In one embodiment, there is provided a method of preparing albumin from a solution comprising albumin, the method comprising:

(i) adjusting the protein concentration of the solution to less than about 5%;

(ii) adding caprylic acid (octanoic acid) or sodium caprylate to a concentration of about 20 mM to the solution obtained in step (i);

(iii) adjusting pH of the solution obtained in step (ii) to about pH 5 or less;

(iv) raising the temperature of the solution obtained in step (iii) to about 27-30° C.; and

(v) incubating the solution obtained in step (iv) for at least about 30 min to about 120 min.

In one embodiment, there is provided a method of inactivating viruses in a solution comprising albumin, the method comprising:

(i) adjusting the protein concentration of the solution to less than about 5%;

(ii) adding caprylic acid (octanoic acid) or sodium caprylate to the solution obtained in step (i), wherein the caprylic acid or sodium caprylate concentration is greater than about 20 mM;

(iii) raising the solution temperature of the solution obtained in step (ii) to greater than about 20° C.;

iv) incubating the solution;

v) filtering the solution;

vi) performing ultrafiltration and diafiltration;

vii) formulating and bulking the solution; and

viii) sterilizing, filling, and pasteurizing the albumin.

In one embodiment, there is provided a method of inactivating viruses in a solution comprising albumin, the method comprising:

(i) adjusting the protein concentration of the solution to less than about 5%;

(ii) adding caprylic acid (octanoic acid) or sodium caprylate to a concentration of about 20 mM to the solution obtained in step (i);

(iii) raising the temperature of the solution obtained in step (ii) to about 27-30° C.;

(iv) incubating the solution for at least 90 min;

(v) filtering the solution;

(vi) performing ultrafiltration and diafiltration;

(vii) formulating and bulking the solution; and

(viii) sterilizing, filling, and pasteurizing the albumin.

In some aspects described herein, the incubation temperature is 27–30 °C.

In some aspects described herein, the incubation is for about 30 min to about 120 min.

In some aspects described herein, the incubation is for at least about 90 min.

In some aspects described herein, the caprylate concentration is about 10 mM to about 40 mM.