CLAIMS

1. A method of polishing albumin to remove contaminants comprising passing an albumin enriched solution through a hydrophobic charge-induction chromatographic resin and recovering the albumin solution which passes through the resin.

2. The method of claim 1, wherein the hydrophobic charge-induction chromatographic resin comprises 4-mercaptoethylpyridine.

3. The method of claim 1 or 2, wherein the albumin enriched solution is selected from Cohn Supernatant I, Cohn Supernatant II+III, Supernatant/Filtrate A, Cohn Supernatant IV and Fraction V.

4. The method of any one of claims 1 to 3, wherein the albumin enriched solution is a diafiltered Cohn Supernatant I.

5. The method of any one of claims 1 to 4, wherein the albumin enriched solution is delipidated and euglobulin depleted.

6. The method of any one of claims 1 to 5 wherein, prior to passing the albumin enriched solution through the hydrophobic charge-induction chromatographic resin, the method comprises the steps of (a) passing the solution through an anion-exchange resin in negative mode with respect to albumin and (b) passing the solution through a cation exchange resin in negative mode with respect to albumin.

7. The method of claim 6 comprising passing the flow through fraction from the anion-exchange resin of step (a) through the cation-exchange resin in step (b).

8. The method of claim 6 comprising passing the flow through fraction from the cation-exchange resin of step (b) through the anion-exchange resin in step (a).

9. A polished albumin solution recovered by the method of any one of claims 1 to 8.

10. The method of any one of claims 1 to 8 comprising pasteurizing the polished albumin solution.

11. A pasteurized albumin solution produced by the method of claim 10.

12. A composition comprising a polished albumin solution and having a turbidity of less than 5 NTU.

13. The composition of claim 12 comprising:
    (a) greater than 80mM sodium;
    (b) greater than 19% w/v albumin;
    (c) less than 4 μg/mL IgA;
    (d) less than 0.1 mg/mL IgG;
    (e) less than 0.03 mg/mL Apolipoprotein A1;
    (f) less than 0.07 mg/mL α1-proteinase inhibitor; and/or
    (g) less than 1% w/v aggregates or polymers.

14. A polished albumin solution comprising at least 19% w/v total protein and characterised by:
    (a) an albumin content of at least 95% of total protein;
    (b) less than 2% w/v aggregate, preferably less than 1% w/v aggregate;
    (c) a dimer content of less than 2% w/v, more preferably less than 1.5% w/v;
    (d) a monomer content of at least 97% w/v;
    (e) a fragment content of less than 0.5% w/v;
    (f) less than 28.6 IU/mL of prekallikrein activator (PKA), more preferably less than 10 IU/mL PKA, even more preferably less than 1 IU/mL PKA;
    (g) less than 0.1% w/v α_2-macroglobulin;
    (h) less than 0.01% w/v Apolipoprotein A1;
    (i) less than 0.05% w/v transferrin;
    (j) less than 5 μg/mL IgA, preferably less than 2 μg/mL IgA;
    (k) less than 0.2 mg/mL IgG, preferably less than 0.01 mg/mL IgG; and
    (l) turbidity of less than 6 NTU, preferably less than 3 NTU.

15. A polished albumin solution as claimed in claim 14 further characterised by:

(m) less than 0.05% w/v α_1-glycoprotein;

(n) less than 0.1% w/v α_1-proteinase inhibitor, preferably less than 0.05% w/v, α_1-proteinase inhibitor;

(o) less than 0.05% w/v haptoglobin; and

(p) less than 0.1% w/v inter-α-trypsin inhibitor.

16. A polished albumin solution as claimed in claim 14 or claim 15 comprising at least 20% w/v albumin.

CLAIMS

1. A method of polishing albumin to remove contaminants comprising passing a plasma-derived albumin enriched solution through a hydrophobic charge-induction chromatographic resin and recovering the albumin solution which passes through the resin, wherein the recovered albumin solution comprises:
   (a) less than 4 μg/mL IgA;
   (b) less than 0.1 mg/mL IgG;
   (c) less than 0.03 mg/mL Apolipoprotein A1; and
   (d) less than 0.07 mg/mL α1-proteinase inhibitor.

2. The method of claim 1, wherein the hydrophobic charge-induction chromatographic resin comprises 4-mercaptoethylpyridine.

3. The method of claim 1 or 2, wherein the albumin enriched solution is selected from Cohn Supernatant I, Cohn Supernatant II+III, Supernatant/Filtrate A, Cohn Supernatant IV and Fraction V.

4. The method of any one of claims 1 to 3, wherein the albumin enriched solution is a diafiltered Cohn Supernatant I.

5. The method of any one of claims 1 to 4, wherein the albumin enriched solution is delipidated and euglobulin depleted.

6. The method of any one of claims 1 to 5 wherein, prior to passing the albumin enriched solution through the hydrophobic charge-induction chromatographic resin, the method comprises the steps of (a) passing the solution through an anion-exchange resin in negative mode with respect to albumin and (b) passing the solution through a cation exchange resin in negative mode with respect to albumin.

7. The method of claim 6 comprising passing the flow through fraction from the anion-exchange resin of step (a) through the cation-exchange resin in step (b).

8. The method of claim 6 comprising passing the flow through fraction from the cation-exchange resin of step (b) through the anion-exchange resin in step (a).

9. A polished albumin solution recovered by the method of any one of claims 1 to 8.

10. The method of any one of claims 1 to 8 comprising pasteurizing the polished albumin solution.

11. A pasteurized albumin solution produced by the method of claim 10.

12. A composition comprising the polished albumin solution of claim 9, wherein the composition comprises:

(a) a turbidity of less than 5 NTU;
(b) less than 4 μg/mL IgA;
(c) less than 0.1 mg/mL IgG;
(d) less than 0.03 mg/mL Apolipoprotein A1; and
(e) less than 0.07 mg/mL α1-proteinase inhibitor.

13. The composition of claim 12, further comprising:

(a) greater than 80mM sodium;
(b) greater than 19% w/v albumin; and/or
(c) less than 1% w/v aggregates or polymers.

14. The polished albumin solution of claim 9 comprising at least 19% w/v total protein and any one or more of the following:

(a) an albumin content of at least 95% of total protein;
(b) less than 2% w/v aggregate, preferably less than 1% w/v aggregate;
(c) a dimer content of less than 2% w/v, more preferably less than 1.5% w/v;
(d) a monomer content of at least 97% w/v;
(e) a fragment content of less than 0.5% w/v;

(f) less than 28.6 IU/mL of prekallikrein activator (PKA), more preferably less than 10 IU/mL PKA, even more preferably less than 1 IU/mL PKA;

(g) less than 0.1% w/v α_2-macroglobulin;

(h) less than 0.01% w/v Apolipoprotein A1;

(i) less than 0.05% w/v transferrin;

(j) less than 0.05% w/v α_1-glycoprotein;

(k) less than 0.1% w/v α_1-proteinase inhibitor, preferably less than 0.05% w/v, α_1-proteinase inhibitor;

(l) less than 0.05% w/v haptoglobin;

(m) less than 0.1% w/v inter-α-trypsin inhibitor;

(n) from about 45 mmol/L to about 100 mmol/L sodium, preferably from about 80 mmol/L to 90 mmol/;

(o) less than 5 µg/mL IgA, preferably less than 2 µg/mL IgA;

(p) less than 0.2 mg/mL IgG, preferably less than 0.01 mg/mL IgG;

(q) less than 110 µg/L aluminium, less than 80 µg/L aluminium, more preferably less than 30 µg/L aluminium;

(r) less than 40 mmol/L caprylate;

(s) osmolality of about 130 mosmol/kg to about 140 mosmol/kg; and

(t) turbidity of less than 6 NTU, preferably less than 3 NTU.