Claims

1. A process of obtaining Apo A-I from an Apo A-I containing protein fraction (A), comprising:

   (a) suspending the Apo A-I containing protein fraction (A) in a buffer solution (B) comprising 15 to 30% (w/w) of a linear or branched C1 to C4 alcohol to form a suspension comprising solubilized Apo A-I, wherein the suspension has a pH in the range from 6.4 to 10.0,

   (b) removing impurities from the suspension while keeping the Apo A-I solubilized,

   (c) precipitating Apo A-I from the suspension, and

   (d) collecting the Apo A-I precipitate.

2. The process of claim 1, wherein the buffer solution (B) comprises 20% (w/w) of the linear or branched C1 to C4 alcohol.

3. The process according to claim 1, wherein the suspension comprising solubilized Apo A-I has a pH in the range from 7.2 to 8.8.

4. The process according to claim 1, wherein the suspension comprising solubilized Apo A-I has a pH in the range from 8.1 to 8.5.

5. The process according to claim 1, wherein the suspension comprising solubilized Apo A-I has a pH in the range from 7.0 to 7.6.

6. The process according to claim 1, wherein the buffer solution (B) comprises 5 mM to 35 mM $NaHCO_3$.

7. The process according to claim 1, wherein the linear or branched C1 to C4 alcohol is ethanol.

8. The process according to claim 1, wherein in step (a), the volume ratio of Apo A I protein fraction (A) to buffer solution (B) is from 1:1 to 1:5.

9. The process according to claim 1, wherein the conductivity of the suspension comprising solubilized Apo A-I formed at step (a) is less than 5 mS/cm.

10. The process according to claim 1, wherein in step (b), impurities are removed by precipitation by adding linear or branched C1 to C4 alcohol to an alcohol concentration of 55 to 65% (w/w).

11. The process according to claim 10, wherein in step (b) the linear or branched C1 to C4 alcohol added to the suspension has a temperature of about −5° C. to 15° C.

12. The process according to claim 1, wherein in step (b), impurities are removed by precipitation followed by filtration, centrifugation, decantation, ultrafiltration and/or sedimentation.

13. The process according to claim 1, wherein in step (c), the pH of the suspension is adjusted to be in the range from 4.6 to 5.6.

14. The process according to claim 1, wherein in step (c), the temperature of the suspension is adjusted to be in the range from −2 to 20° C. to precipitate Apo A-I.

15. The process according to claim 1, further comprising step (e), comprising delipidating the collected Apo A-I precipitate by adding ethanol in an amount within the range from 40 to 96% (w/w).

16. A method of producing a pharmaceutical composition, comprising producing Apo A-I according to the method of claim 1 and combining the Apo A-I with a pharmaceutically acceptable carrier or diluent.

17. A method of producing reconstituted HDL, comprising producing Apo A-I according to the method of claim 1 and combining the Apo A-I with a lipid to thereby produce reconstituted HDL.

18. A method of producing a pharmaceutical composition, comprising producing Apo A-I according to the method of claim 1; combining the Apo A-I with a lipid to thereby produce reconstituted HDL; and combining the reconstituted HDL with a pharmaceutically acceptable carrier or diluent to thereby produce the pharmaceutical composition.