Claims

1. A preparation of purified, human plasma-derived Apolipoprotein A-I (Apo A-I), wherein the Apo A-I preparation contains IgA, wherein the IgA is present in the Apo A-I preparation in an amount less than 0.3 mg of IgA per gram of Apo A-I.

2. The Apo A-**1** preparation of claim 1, wherein the preparation comprises:

(a) less than 0.7 mg of IgG per gram of Apo A-I;

(b) less than 0.05 mg of IgM per gram of Apo A-I;

(c) less than 4.9 mg of haptoglobin per gram of Apo A-I;

(d) less than 2.7 mg of hemopexin per gram of Apo A-I;

(e) less than 6.4 mg of fibrinogen per gram of Apo A-I;

(f) less than 0.9 mg of ceruloplasmin per gram of Apo A-I;

(g) less than 14.6 mg of albumin per gram of Apo A-I;

(h) less than 2.3 mg of alpha-2-macroglobulin per gram of Apo A-I;

(i) less than 12 mg of alpha-1-antitrypsin per gram of Apo A-I; and/or

(j) less than 3.9 mg of transferrin per gram of Apo A-I.

3. A pharmaceutical composition comprising the Apo A-1 preparation of claim 1.

4. A reconstituted high density lipoprotein (rHDL) formulation comprising the Apo A-I preparation of claim 1.

5. The rHDL formulation of claim 4, further comprising one or more of a lipid, a detergent, and a stabilizer.

6. The rHDL formulation of claim 4, further comprising a lipid selected from phospholipids, cholesterol, cholesterol-esters, fatty acids and triglycerides.

7. The rHDL formulation of claim 6, wherein the lipid is a phospholipid.

8. The rHDL formulation of claim 7, wherein the phospholipid is selected from phosphatidylcholine, phosphatidic acid, phosphatidylethanolamine, phosphatidylglycerol, phosphatidylserine, phosphatidylinositol, and sphingomyelin.

9. The rHDL formulation of claim 4, further comprising a detergent selected from cationic detergents, anionic detergents, Zwitterionic detergents, and non-ionic detergents.

10. The rHDL formulation of claim 9, wherein the detergent is selected from bile acid and salts thereof.

11. The rHDL formulation of claim 10, wherein the detergent comprises sodium cholate.

12. The rHDL formulation of claim 4, further comprising a carbohydrate stabilizer.

13. The rHDL formulation of claim 12, wherein the carbohydrate stabilizer is selected from sugars and sugar alcohols.

14. The rHDL formulation of claim 13, wherein the carbohydrate stabilizer is one or more selected from sucrose, mannitol, and sorbitol.

15. The rHDL formulation of claim 4, further comprising a phospholipid, a detergent selected from a bile acid or salt thereof, and a carbohydrate stabilizer.

16. A pharmaceutical composition comprising the rHDL formulation of claim 4.

17. A pharmaceutical composition comprising the rHDL formulation of claim 15.

18. A process of obtaining the Apo A-I preparation of claim 1 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.

19. The process of claim 18, wherein step (a) comprises suspending 50 kg or more of the Apo A-I containing protein fraction (A) in buffer solution (B) to form a suspension comprising solubilized Apo A-I obtained from 50 kg or more of a starting fraction.