Claims

1. A reconstituted high density lipoprotein (rHDL) formulation comprising an apolipoprotein, a lipid, and a lyophilization stabilizer, wherein the ratio between the apolipoprotein and the lipid is from about 1:20 to about 1:120 (mol:mol) and the lyophilization stabilizer comprises sucrose present in a concentration of from about 1.0% to less than 6.0% w/w of the rHDL formulation, and wherein the lyophilization stabilizer is present in a total concentration of from about 1.0% to less than 6.0% w/w of the rHDL formulation.

2. The rHDL formulation according to claim 1, wherein the ratio between the apolipoprotein and the lyophilization stabilizer is from about 1:1 to about 1:3 (w:w).

3. The rHDL formulation according to claim 1, wherein the lyophilization stabilizer is present in a concentration from about 4.0 to 5.5% (w/w).

4. The rHDL formulation according to claim 1, wherein the formulation further comprises a detergent.

5. The rHDL formulation according to claim 4, wherein the detergent comprises sodium cholate.

6. The rHDL formulation according to claim 1, wherein the ratio between the apolipoprotein and the lipid is from about 1:20 to about 1:100 (mol:mol).

7. The rHDL formulation according to claim 1, wherein the concentration of the apolipoprotein is from about 5 to about 50 mg/ml.

8. The rHDL formulation according to claim 1, wherein the apolipoprotein comprises apolipoprotein A-I (Apo A-I).

9. The rHDL formulation according to claim 8, wherein the Apo A-I is selected from the group consisting of Apo A-I purified from plasma and recombinant Apo A-I.

10. The rHDL formulation according to claim 9, wherein the Apo A-I comprises the wild type or Milano Apo A-I sequence.

11. The rHDL formulation according to claim 1, wherein the lipid comprises at least one charged or non-charged phospholipid or a mixture thereof.

12. The rHDL formulation according to claim 11, wherein the lipid comprises a phosphatidylcholine.

13. The rHDL formulation according to claim 1, wherein the apolipoprotein is Apo A-I purified from plasma, the lipid is phosphatidylcholine, the lyophilization stabilizer is sucrose and the formulation further comprises sodium cholate detergent.

14. The rHDL formulation according to claim 13, wherein the ratio between the apolipoprotein and the lipid is from 1:45 to 1:65 (mol:mol); the lyophilization stabilizer is present in a concentration of 4.6 to 4.8% (w/w); and the sodium cholate is present at a concentration of 0.5 to 1.5 mg/mL.

15. The rHDL, formulation according to claim 1, wherein the formulation has a pH in the range of 6 to 8.

16. The rHDL formulation according to claim 1, wherein the formulation is lyophilized.

17. A method of producing a rHDL formulation comprising combining an apolipoprotein, a lipid, and a lyophilization stabilizer comprising sucrose such that the ratio between the apolipoprotein and the lipid is from 1:20 to 1:120 (mol:mol), and the sucrose is present at a concentration of from about 1.0% to less than 6.0% (w/w) of the formulation, and wherein the lyophilization stabilizer is present in a total concentration of from about 1.0% to less than 6.0% w/w of the rHDL formulation.

18. The rHDL formulation according to claim 1, wherein the formulation is suitable for parenteral administration.

19. The rHDL formulation according to claim 1, wherein the formulation is suitable for intravenous administration.

20. The rHDL formulation according to claim 1, wherein the ratio between the apolipoprotein and the lyophilization stabilizer is from about 1:1 to about 1:2.4 (w:w).

21. The rHDL formulation according to claim 19, wherein the ratio between the apolipoprotein and the lyophilization stabilizer is from about 1:1 to less than 1:2 (w:w).

22. The rHDL formulation according to claim 1, wherein the lyophilization stabilizer is present in a concentration from 4.3 to 5.3% (w/w).

23. The rHDL formulation according to claim 21, wherein the lyophilization stabilizer is present in a concentration from 4.6 to 4.8% (w/w).