CLAIMS

1. A lyophilized pharmaceutical composition comprising plasmid DNA, wherein the lyophilized pharmaceutical composition is obtained by lyophilizing a liquid composition that comprises, prior to lyophilization:

a. DNA of a first plasmid, wherein the first plasmid is selected from the group consisting of VM202, pTx-HGF-X7, pTx-IGF-1Ec, pTx-IGF-1Ea, pTx-IGF-1X6, pTx-IGF-1X10, and pCK-SDF-1α;

b. potassium phosphate buffer with pH in the range from 7.0 to 9.0;

c. mannitol at a concentration in the range from 2% to 3% (w/v);

d. sucrose at a concentration of about 1.0% (w/v); and

e. NaCl at a concentration in the range from 0.1 % to 0.6% (w/v).

2. The lyophilized pharmaceutical composition of claim 1, wherein the first plasmid is VM202, optionally wherein the composition further comprises DNA of a second plasmid, wherein the second plasmid is selected from the group consisting of pTx-HGF-X7, pTx-IGF-1Ec, pTx-IGF-1Ea, pTx-IGF-1X6, pTx-IGF-1X10, and pCK-SDF-1α.

3. The lyophilized pharmaceutical composition of claim 1, wherein at least 90%, 95%, 97%, or 98% of the plasmid DNA in the liquid composition is supercoiled.

4. The lyophilized pharmaceutical composition of claim 1, wherein at least 90%, 95%, 97%, or 98% of the plasmid DNA remains supercoiled 30 minutes after reconstitution of the lyophilized pharmaceutical composition.

5. The lyophilized pharmaceutical composition of claim 1, wherein at least 90% or 95% of the plasmid DNA remains supercoiled after storage at 25°C for 3 to 7 days following reconstitution of the lyophilized pharmaceutical composition.

6. The lyophilized pharmaceutical composition of claim 1, wherein at least 80% of the plasmid DNA remains supercoiled 30 minutes after reconstitution of the lyophilized

pharmaceutical composition, wherein the lyophilized pharmaceutical composition had been stored at 40°C for 10 weeks before reconstitution.

7. The lyophilized pharmaceutical composition of claim 1, wherein the lyophilized pharmaceutical composition comprises supercoiled DNA in an amount of at least 90% or 95% of a total amount of supercoiled DNA in the liquid composition.

8. The lyophilized pharmaceutical composition of claim 1, wherein the liquid composition comprises the first plasmid at a concentration in the range from 0.1 to 1 mg/ml.

9. The lyophilized pharmaceutical composition of claim 1, wherein the liquid composition comprises potassium phosphate at a concentration in the range from 5 mM to 15 mM.

10. The lyophilized pharmaceutical composition of claim 1, wherein the liquid composition comprises potassium phosphate buffer with pH in the range from 7.0 to 8.0, or pH 8.0.

11. The lyophilized pharmaceutical composition of claim 1, wherein the liquid composition comprises mannitol at a concentration of 2 % (w/v).

12. The lyophilized pharmaceutical composition of claim 1, wherein the liquid composition comprises sucrose at a concentration of 1.0 % (w/v).

13. The lyophilized pharmaceutical composition of claim 1, wherein the liquid composition comprises NaCl at a concentration in the range from 0.4% to 0.5% (w/v), or at a concentration of 0.45 % (w/v).

14. A lyophilized pharmaceutical composition comprising plasmid DNA, wherein the pharmaceutical composition is obtained by lyophilizing a liquid composition that comprises, prior to lyophilization:

a. DNA of a first plasmid at a concentration of 0.5 mg/ml, wherein the first plasmid is selected from the group consisting of VM202, pTx-HGF-X7, pTx-IGF-1Ec, pTx-IGF-1Ea, pTx-IGF-1X6, pTx-IGF-1X10, and pCK-SDF-1α;

b. 10mM potassium phosphate buffer of pH 8.0;
c. mannitol at a concentration of 2 % (w/v);
d. sucrose at a concentration of 1.0 % (w/v); and
e. NaCl at a concentration of 0.45 % (w/v),

wherein at least 95% of the plasmid DNA in the liquid composition is supercoiled, and at least 90% of the plasmid DNA remains supercoiled after storage at 25°C for 7 days following reconstitution of the lyophilized pharmaceutical composition.

15. A reconstituted composition produced by dissolving the lyophilized pharmaceutical composition of claim 14 in water.

16. The reconstituted composition of claim 15, wherein light absorbance of the reconstituted composition at 450nm is less than 0.002 wherein the light absorbance is measured on the day of reconstitution or after storage of the lyophilized pharmaceutical composition for 10 weeks.

17. A lyophilized pharmaceutical composition comprising plasmid DNA in a unit dose, wherein the pharmaceutical composition is obtained by lyophilizing a liquid composition that comprises, prior to lyophilization:

a. DNA of a first plasmid at a concentration of 0.5 mg/ml, wherein the first plasmid is selected from the group consisting of VM202, pTx-HGF-X7, pTx-IGF-1Ec, pTx-IGF-1Ea, pTx-IGF-1X6, pTx-IGF-1X10, and pCK-SDF-1α;
b. 10mM potassium phosphate buffer of pH 8.0;
c. mannitol at a concentration of 2 % (w/v);
d. sucrose at a concentration of 1.0 % (w/v); and
e. NaCl at a concentration of 0.45 % (w/v),

wherein the lyophilized pharmaceutical composition is in a vial and the vial contains 2.5 mg of plasmid DNA in total.

18. A reconstituted composition produced by dissolving the lyophilized pharmaceutical composition of claim 17 in water.