CLAIMS

1. A nucleic acid-lipid nanoparticle composition, comprising: a nucleic acid, a lipid, and a lactate, wherein the lactate is selected from sodium lactate or potassium lactate in an amount of 5-100 mM, for example, 5-75 mM, 5-50 mM, or 10-100 mM, preferably 5-50 mM.

2. The nucleic acid-lipid nanoparticle composition according to claim 1, further comprising a buffer, wherein the content ratio of the buffer to the lactate is (0.25-1):1, and wherein the buffer is one selected from or a combination of more selected from the group consisting of an acetate buffer, a PBS buffer, a citrate buffer, a phosphate buffer, a histidine buffer, and a tris buffer; preferably, the content of the buffer is 1.25-50 mM.

3. The nucleic acid-lipid nanoparticle composition according to claim 1 or 2, further comprising a lyoprotectant, wherein preferably, the lyoprotectant is one selected from or a combination of more selected from the group consisting of sucrose, trehalose, lactose, cyclodextrin, and mannitol.

4. The nucleic acid-lipid nanoparticle composition according to any one of claims 1-3, wherein the pH of the nucleic acid-lipid nanoparticle composition is 1.0-14.0, for example, 2.0-13.0, preferably 5.0-9.0, and more preferably 7.0-8.0.

5. The nucleic acid-lipid nanoparticle composition according to any one of claims 1-4, wherein the nucleic acid is selected from the group consisting of ssDNA, dsDNA, mRNA, lncRNA, siRNA, saRNA, shRNA, ASO, plasmid, circRNA, circDNA, miRNA, CRISPR-Cas, ployI:C, SamRNA, and 5'-pppRNA.

6. The nucleic acid-lipid nanoparticle composition according to any one of claims 1-5, wherein the nucleic acid is encapsulated in a lipid nanoparticle (LNP), and wherein the lipid comprises a cationic lipid, a neutral phospholipid, a PEG-lipid, and optionally a steroidal lipid.

7. The nucleic acid-lipid nanoparticle composition according to any one of claims 1-6, wherein the composition is prepared into a lyophilized formulation.

8. The nucleic acid-lipid nanoparticle composition according to claim 7, wherein the content of the lactate is 0.5-10.0 wt%, for example, 0.5-7.5 wt%, 0.5-5.0 wt%, or 1.0-10 wt%, preferably 0.5-5.0 wt%, on dry basis by the weight of the lyophilized formulation, and wherein the content of the buffer is 0.35-10.0 wt%, for example, 0.35-7.5 wt%, 0.35-5.0 wt%, or 1.0-10 wt%, preferably 0.5-5.0 wt%, on dry basis by the weight of the lyophilized formulation.

9. A method for preparing the nucleic acid-lipid nanoparticle composition according to any one of claims 1-8, wherein the composition is prepared into a lyophilized formulation, and the method comprises:
(1) mixing a lactate solution with a nucleic acid-lipid nanoparticle stock solution, or
adding a lactate to a nucleic acid solution before encapsulating the nucleic acid, and adding a lipid, or
ultrafiltering a nucleic acid-lipid nanoparticle into a solution containing lactate,
wherein the lactate is selected from sodium lactate or potassium lactate in an amount of 5-100 mM, for example, 5-75 mM, 5-50 mM, or 10-100 mM, preferably 5-50 mM;
(2) adding a lyoprotectant; and
(3) lyophilizing to give a lyophilized formulation of the nucleic acid-lipid nanoparticle composition.

10. The method according to claim 9, wherein the lyoprotectant is one selected from or a combination of more selected from the group consisting of sucrose, trehalose, lactose, cyclodextrin, and mannitol, and wherein the content of the lyoprotectant is 50-99.9 wt%, on dry basis by the weight of the lyophilized formulation.

11. The method according to claim 9 or 10, wherein step (1) further comprises adding a buffer, the content ratio of the buffer to the lactate being (0.25-1):1, and wherein the buffer is one selected from or a combination of more selected from the group consisting of an acetate buffer, a PBS buffer, a citrate buffer, a phosphate buffer, a histidine buffer, and a tris buffer; preferably, the content of the buffer is 1.25-50 mM.

12. The method according to any one of claims 9-11, wherein the pH of the solution prepared in step (1) is 1.0-14.0, for example, 2.0-13.0, preferably 5.0-9.0, and more preferably 7.0-8.0, wherein in step (1), the nucleic acid is encapsulated in a lipid nanoparticle, and wherein the lipid comprises a cationic lipid, a neutral phospholipid, a PEG-lipid, and optionally a steroidal lipid.

13. Use of the nucleic acid-lipid nanoparticle composition according to any one of claims 1-8 in the manufacture of a medicament, wherein the medicament is a vaccine, and wherein the vaccine is a therapeutic tumor vaccine or a vaccine for preventing a cancer, a viral infection, a bacterial infection, or a fungal infection.

14. The use according to claim 13, wherein the medicament is a formulation for oral administration, intramuscular injection, subcutaneous injection, intravenous injection, or inhalation.

15. The use according to claim 14, wherein the formulation for inhalation is an atomized inhalant or a dry powder inhalant.