

ABSTRACT

The present disclosure relates to a nucleic acid-lipid nanoparticle composition and a lyophilized preparation thereof, and further relates to a preparation method for the composition and a use of the composition. The nucleic acid-lipid nanoparticle composition of the present disclosure comprises lactate, so that the stability of nucleic acid-lipid nanoparticles is improved in a lyophilization process and a prepared lyophilized preparation. According to the present disclosure, the total time of a freeze-drying process for the nucleic acid-lipid nanoparticles can be shortened, and energy consumption and the time cost of product scale-up production can be greatly reduced; the rehydration of lyophilized nucleic acid-lipid nanoparticles is quick, and the total amount of nucleic acids, the encapsulation efficiency, and the nucleic acid integrity are high; in addition, a lyophilized and rehydrated preparation has cell transfection efficiency not significantly different from that of a non-lyophilized nucleic acid-lipid nanoparticle stock solution, and has a high in vivo immune response, even exceeding that of the non-lyophilized nucleic acid-lipid nanoparticle stock solution.