American Rescue Plan

DEVELOPING NEXT-GENERATION VACCINES WITH IMPROVED MANUFACTURING AND STABILITY PERFORMANCE

ADVANCED CHARACTERIZATION AND MANUFACTURING METHODS FOR mRNA VACCINE DEVELOPMENT

NIIMBL® The National Institute for Innovation in Manufacturing Biopharmaceuticals

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Academic Research Institution

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INDUSTRY NEED

mRNA vaccines are the first and most widely used vaccines for COVID-19, a triumph for public health and the pharmaceutical industry. However, the rapid deployment of these mRNA vaccines has forced the use of frozen solution formulations that must be shipped and stored at ultracold temperatures. The requirement for ultracold shipping and storage increases the risk of inactivation between the manufacturing site and the patient, strains distribution networks and logistics, and compromises global access. Refrigeration also accounts for a large portion of the costs associated with vaccine shipment and storage.

SOLUTION

This project focused on new formulation and manufacturing methods to improve the stability of mRNA-LNP vaccines. Both traditional and advanced analytical methods were used to characterize mRNA formulations, providing information about the location of the mRNA in the lipid nanoparticles. This project demonstrated that freeze dried formulations using 5% (w/v) or 10% (w/v) sucrose stored at room temperature maintained better integrity when compared to solution formulations stored at the same temperature.

> *“Our research will enable companies to develop the next generation of vaccines.”*

OUTCOME

This project’s simple and short lyophilized cycle may allow mRNA/LNP formulations to be stored at room temperature during long-term storage and possible vaccine stockpiling. These results will improve long-term stability, speed up development and manufacturing, and require less reliance on the cold chain, thus offering greater pandemic preparedness with improved safety and global access for life-saving vaccines. The results also offer possible applications to other vaccines and biologics formulations.

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