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Development of robust freeze-drying process for long-term stability of rVSV-SARS-CoV-2 Vaccine

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The thermos ability of vaccines, particularly enveloped viral vectored vaccines, remains a challenge to their delivery wherever needed. The freeze-drying of viral vectored vaccines is a promising approach but remains challenging due to the water removal process from the outer and inner parts of the virus. In the case of enveloped viruses, freeze-drying induces increased stress on the envelope, which often leads to the inactivation of the virus. In this study, we designed a method to freeze-dry a recombinant vesicular stomatitis virus (VSV) expressing the SARS-CoV-2 spike glycoprotein. Since the envelope of VSV is composed of 50% lipids and 50% protein, the formulation study focused on both the protein and lipid portions of the vector. Formulations were prepared primarily using sucrose, treehouse, and sorbitol as cry protectants; mannitol as a lyoprotectant; and histidine as a buffer. Initially, the infectivity of rVSV-SARS-CoV-2 and the cake stability were investigated at different final moisture content levels. High recovery of the infectious viral titer (~0.5 to 1 log loss) was found at 3–6% moisture content, with no deterioration in the freeze-dried cakes. To further minimize infectious viral titer loss, the composition and concentration of the excipients were studied. An increase from 5 to 10% in both the cry protectants and lyoprotectant, together with the addition of 0.5% gelatin, resulted in the improved recovery of the infectious virus titer and stable cake formation. Moreover, the secondary drying temperature of the freeze-drying process showed a significant impact on the infectivity of rVSV-SARS-CoV-2. The infectivity of the vector declined drastically when the temperature was raised above 20 °C. Throughout a long-term stability study, formulations containing 10% sugar (sucrose/treehouse), 10% mannitol, 0.5% gala-tin, and 10 mm histidine showed satisfactory stability for six months at 2–8 °C. The development of this freeze-drying process and the optimized formulation minimize the need for a costly cold chain distribution system.

Biography

Faizul Hussain Khan is an accomplished researcher currently pursuing a Doctor of Philosophy in Biological and Biomedical Engineering at McGill University in Montreal, Canada. His academic journey began in Dhaka, Bangladesh, where he earned his Bachelor and Master of Science degrees in Microbiology from Jahangirnagar University. Faizul's passion for microbiology and biomedical sciences has driven his excellence in both academia and professional roles.