PRODUCING STABLE VACCINES TO IMPROVE ACCESS

DEVELOPMENT OF SCALABLE, THERMOSTABLE, SPRAY DRIED VACCINE FORMULATIONS APPLICABLE FOR CORONAVIRUS VACCINES

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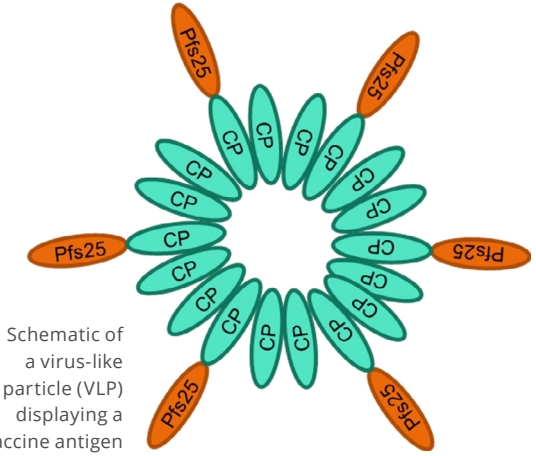
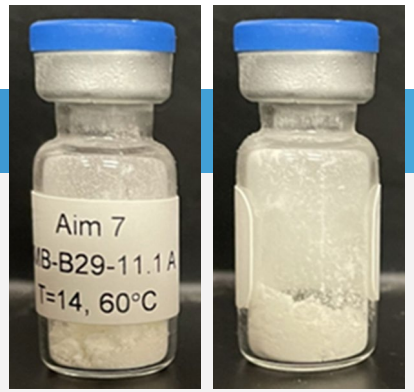


Schematic of a virus-like particle (VLP) displaying a vaccine antigen



R&D scale spray dryer of the general type used for the project

INDUSTRY NEED

Most licensed vaccines are liquid formulations that require cold storage and transport, which limits their distribution. Dry formulations are more stable at higher temperatures, but the current process—lyophilization—is time- and energy-intensive and can alter vaccine structure and function. Spray drying is the leading alternative approach to generating dry vaccine formulations. Not only is it less expensive than lyophilization, but it is also scalable and can be run in-line with other downstream processes.

SOLUTION

The team at Fraunhofer investigated various conditions and components for spray drying two types of vaccines: a protein subunit vaccine of the SARS-CoV-2 receptor binding domain (RBD) and a more complex virus-like particle (VLP) vaccine for malaria. They generated the RBD and VLP vaccine antigens with a range of excipients, buffers, adjuvants, and spray drying conditions and temperatures and performed stability studies at storage temperatures of up to 60°C for 14 days. Through several rounds of testing, the team aimed to find the most stable and reproducible spray dried vaccine formulations. As some commonly used assays were incompatible with specific excipients or adjuvants, the team also developed alternative assays for selection of the most stable formulation components.

OUTCOME

An initial set of 24 different formulations of the RBD and VLP vaccines were generated. Three rounds of testing and improvements narrowed down the field to three candidates of the RBD and VLP vaccines that were stable at up to 60°C and 37°C, respectively, for 2 weeks. The results showed that spray dried product, which is less expensive and quicker to produce, meets a stability standard comparable to the lyophilized product.

Next steps include extending stability testing of the lead spray dried vaccine candidates to 30 days at up to 60°C for the RBD vaccine and up to 37°C for the VLP vaccine. The team will also test the immunogenicity and protective efficacy of the lead spray dried vaccine formulations in animal models. Future studies will examine other components for spray dried formulations, and apply spray drying to other vaccines, such as a VLP-based COVID-19 vaccine

> *“Compared to lyophilization, spray drying is a rapid, controllable, single-step process that reduces time and energy consumption. It is scalable and can be run in-line with downstream manufacturing processes.”*

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