



Lyophilization

Basis of a consistent and predictable product quality



Introduction

Freeze-drying, or lyophilization, is a renowned stabilization method for antibodies, vaccines and other biological products. Lyophilization is a proven drying method that guarantees product excellence in vaccine development and production. A consistent production process and optimized formulation assure quality and regulatory assurance, fitting the customer needs.

This stabilization method is an answer to the risks of cold chain storage and logistics in an increasing amount of product development processes.

Lyophilization and spray drying

Intravacc specialises in stabilization of (live) attenuated bacterial and viral vaccines for pre-clinical development. We build on state of the art MLII facilities.

Our experience in the development of (thermo)stable products obtained after lyophilisation or spray drying is extensive. These products are developed according to common pharmaceutical regulations (EMA, FDA, ICH). In the formulation and process design for these products, Design of Experiment (DoEs) and Quality by Design (QbD) are keywords.

Product excellence

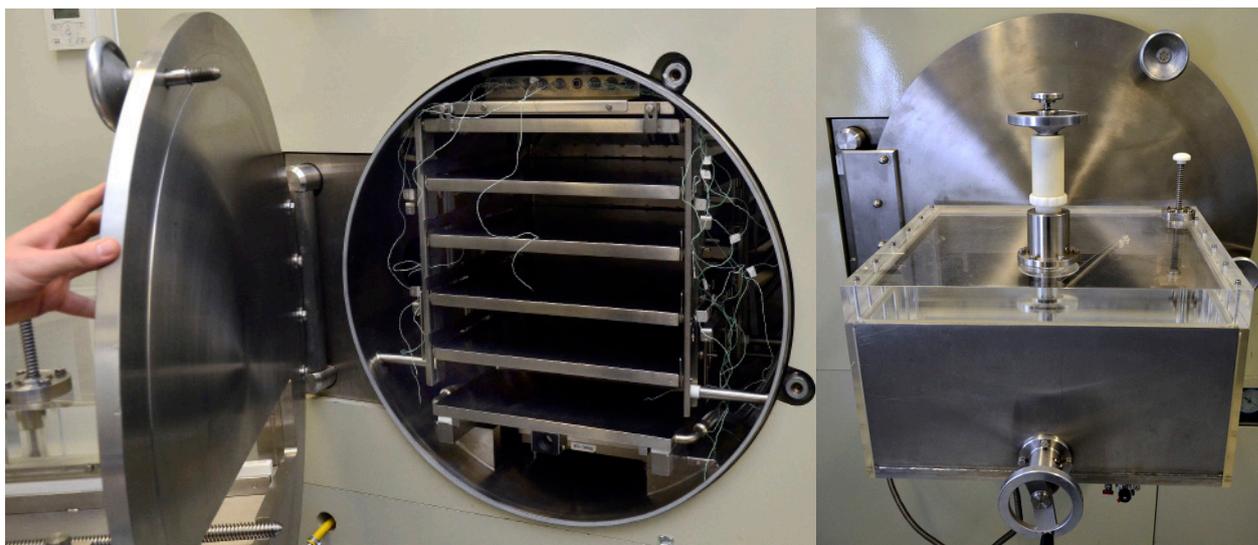
Lyophilization

Lyophilization guarantees product excellence regarding increase of shelf life and product quality. Proper formulation enables quick reconstitution of a product which is particularly important in case when fast administration of vaccines and antibodies is required.

Lyophilization can be part of a consistent and predictable production process and therefore be critical in the clinical development phase of a vaccine and thereafter.

Spray drying

Spray drying is an excellent method for fast and easy generation of (vaccine) formulations in powder form. Innovative research on spray drying is carried out in our laboratories, including testing new applications of this promising stabilization method. Especially for generation of bulk powders for further processing, for example for alternative routes of delivery and specialized dosage forms, spray drying offers a solution.



What Intravacc can offer you

We offer you a selection of excipients and optimization of composition for a lyophilized or spray dried product as well as design and optimization of accompanying processes. To this extent, we have several facilities and capabilities available, including:

MLII facility for spray- and freeze-drying

- 2 spray dryers: Buchi B190 & Buchi nanospraydryer, including closed loop system, downflow booth
- 3 pilot freeze dryers with a loading capacity of 2500-3000 DIN R2 vials
- Freeze-drying of ampoules.

Physical formulation parameters

- Collapse temperature (T_c) by freeze-drying microscopy (FDM)
- Glass Transition Temperature (T_g) by Dynamic Scanning Calorimetry (DSC).

In-process Measurements

- Manometric Temperature Measurement (MTM)
- Product Temperature (thermocouples)
- Drying speed by mass (sublimation rate)
- Sample extraction and examination during lyophilisation (sample thief).
- Post-drying analysis
- Karl Fischer Water Determination (or residual moisture content - RMC)
- Particle Size Measurement by laser diffraction
- Non-invasive Measurement by near infrared spectroscopy.

Furthermore, Intravacc has a wide scala of analytics to determine the quality of the vaccine antigen (protein, glucoconjugate, bacteria, virus) or biopharmaceutical products. Besides formulation and process design Intravacc offers troubleshooting and scale up consultancy both from a distance as well as on site.

Intravacc

The Institute for Translational Vaccinology is an experienced, not-for-profit R&D organization. With our unique capabilities and infrastructure, we are able to optimize vaccines, vaccine processes and vaccine technologies. Our aim is to increase equality in access to vaccines throughout the world in order to contribute to public health. We achieve this by transferring our knowledge and technologies to public and private partners worldwide and collaborative R&D. A team of 150 professionals is at your disposal at Science Park Bilthoven in The Netherlands.

Contact

Dr. Ivo Ploemen

Business Development
T: +31 (0) 30 7920 496
ivo.ploemen@intravacc.nl

Intravacc

Antonie van Leeuwenhoeklaan 9
3721 MA BILTHOVEN
T: +31 (0) 30 7920 300
info@intravacc.nl

www.intravacc.nl