intravacc

innovating vaccines

Formulating and drying vaccines

Introduction

A consistent drying process such as freeze-drying (lyophilization) or spray-drying combined with an optimized formulation is required to assure high quality standards. The stability of liquid vaccines can be improved by adding stabilisers and/or by drying. At Intravacc we have state of the art ML-II facilities to help you develop a fill & finish process from scratch to GMP production. We can also help you to improve your existing process.

Formulation development

Intravacc has key knowledge in the stabilization of bacterial and viral vaccines for (pre-)clinical development. Our experience in the development of thermostable products after lyophilization is extensive. Being a translational institute, we have successfully developed formulations and implemented lyophilization processes at the client's production sites.

Product Design

We design thermostable formulations for bacterial- and viral vaccines, taking into account delivery route and dosage form.

Process Design

At Intravacc we have experience in optimization of the freezing step (for both liquid and dried formulations). Furthermore we can increase process efficiency through minimization of the process time of new and existing lyo-cycles.

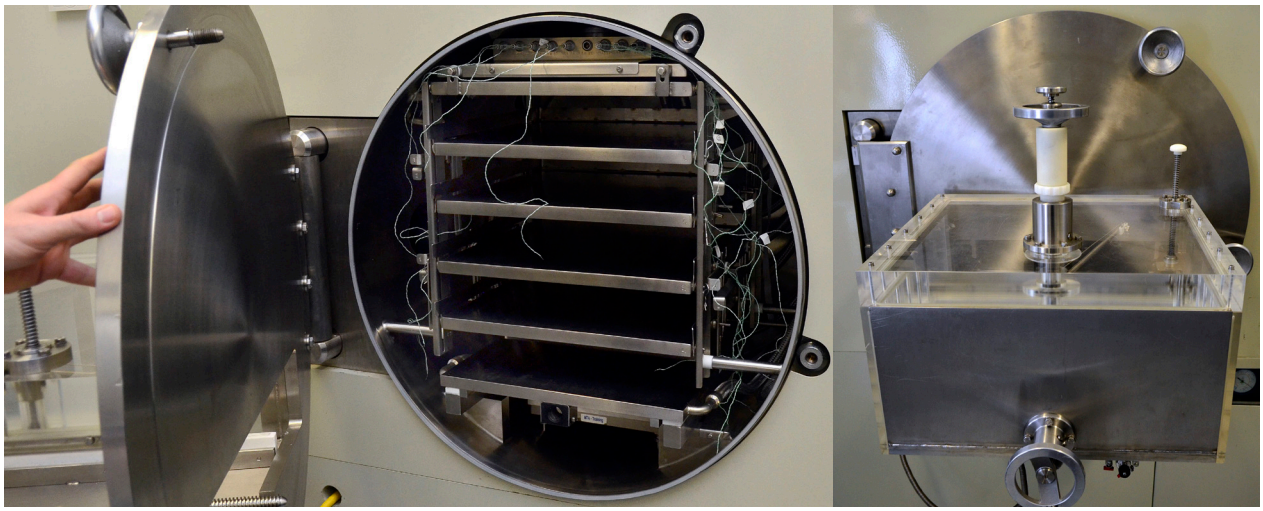
Drying

Drying to improve product stability is a well-accepted strategy in the pharmaceutical industry. Intravacc offers both freeze-drying and spray-drying to obtain dried product. Spray-drying provides an alternative drying manner in case your product cannot be frozen.

Benefits:

- Extensive experience in vaccine formulation development
- Access to wide range of analytics
- GMP production facilities
- Patented formulation technology

intravacc



Left: Freeze dryers with temperature sensors. Right: Sample thief that allows examination during lyophization

Our expertise

Via rational experimental design followed by a design of experiment approach we can compose a stable formulation. At Intravacc we can use a quality by design approach to obtain a robust production process. Our analytical tools and capabilities include:

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

- Product temperature (thermocouples)
- Estimation on the average drying speed (balance shelf)
- Sample extraction and examination during lyophilization (sample thief)

Post-drying analysis

- Karl Fischer water determination to determine the residual moisture content (RMC)
- Glass transition temperature (T_g) by dynamic scanning calorimetry (DSC)

Facilities

- 1 spray-dryer, including a closed loop system, placed in a downflow booth, and glove box for sample handling under a N_2 atmosphere
- 3 pilot freeze-dryers with a maximum loading capacity of 2500 – 3000 DIN R2 vials
- Freeze-drying in ampoules or vials

Intravacc's services and products:

- Prophylactic and therapeutic vaccine development
- Development of animal component free production processes and analytical methods
- Adjuvant technology and alternative delivery systems
- Contract based process development and consultancy on production and purification of both bacterial and viral vaccines

Please contact Intravacc for more information and tailor-made solutions.

Intravacc

Intravacc operates under the Ministry of Public Health, Welfare and Sport, The Netherlands. Intravacc has an extensive infrastructure for translational vaccine R&D and has proficient knowledge in the field of vaccine development and production. Typical clients of Intravacc are companies, governments and public institutions.

Contact

Dr. Ivo Ploemen
Program Manager
T: +31 (0) 30 7920 496
ivo.ploemen@intravacc.nl

Intravacc
Antonie van Leeuwenhoeklaan 9
T: +31 (0) 30 7920 300
P.O. Box 450
3720 AL BILTHOVEN
info@intravacc.nl www.intravacc.nl