Set vaccines free

Vaccines formulated as dry powders can be transported anywhere in the world, to every child in the world With no cold chain required

Background

- LaminarPace technology developed at Inhalation Sciences AB
 - Micronized powder for inhalation
 - Early test with animal vaccines showed great temperature stability
- Technology spun-out into a newly created company: Ziccum AB
 - 2017

LaminarPace Process:

Spray (Air) drying process:

- Room temperature
- Gentle process
- High process yield (80-90%)
- Well defined powder size distribution (From 2 to 10 μm)
- Low energy cost







Particle engineering



Trehalose characteristics after spray drying:

Trehalose shows a typical glass transition after spray drying



microscopy of Dihydrate trehalose

Quality by design approach:

Process — Risk analysis — Design of experiement — Design space definition





<u>Quality target product profile and Critical Quality</u> <u>Attributes (Initial Design Space)</u>

QTTP: Air dried powder of heat stable vaccine, with low moisture content, high Tg temperature. The powder contains a embedded vaccines within the sugar matrix.

Powder:

- Glass transition temperature: > 20°C above the storage temperature
- Moisture content: minimize %
- Size: Well defined
- Yield: More than 80%

Vaccine/antigen:

- Antigenicity: Limit the lost
- Integrity: Keep integrity of the antigen
- In-vivo study: Keep Immune responses
- Stability: at 40 °C for a longer period (min 3 days CTC)



DOE results: Moisture (Water) content model

Moisture content (%)







Light Microscopy observation of the air dried powder: Effect of nebulizer mesh size

Air dried **trehalose** with different nebulizer mesh **20% Feed stock** (Obj x20)



Fill and finish concept :



<u>Initial air dried powder filling assesment (Using</u> <u>Dosator unit, air dried powder mixed with carrier)</u>





LAPA; a new Unit operation for the Pharma industry

- 100+ small molecules
- Peptides
- Live attenuated viruses
- Inactivated viruses
- VLP
- Subunit/conjugate to model vaccines
- (LNP)

<u>Stability assessment using thermal shift assay (TSA)</u> of spray dried formulation containing Ovalbumin:



<u>Stability assessment using AF4-MALS</u> <u>of air dried formulation containing Ovalbumin:</u>



Thanks

Fabrice Rose Louise Egeblad