Streamlined and Cost-effective Formulation Development for DPI Products

Your Partner and CRO for Inhalation Product Development

www.mvic.se
Formulation Development (FD) for DPI Products

MVIC FD concept offers streamlined, cost-effective and high-quality performed inhalation formulation development packages to customers that either lack resources to perform a development program and/or require cutting edge input for e.g. problem solving. The size and design of the development program is tailor-made together with the customer. Furthermore, MVIC can manufacture batches according to GMP.

MVIC offers its services as a single company

- One CDA
- One proposal
- One supplier agreement
- One invoice
- One contact person
- One project manager
- One accountable supplier

Example of Project Work Flow:

1. Agreement of scope and timing
2. Characterisation of input material
3. Micronisation of API
4. Performance analysis
5. Restoration of crystallinity
6. Formulation processing
7. Filling/blistering
8. Stability testing
9. Report and Tech Transfer
Specialised MVIC Skills that are Integrated in the Development Program

**SOLID STATE CHARACTERISATION**
Fundamental characterisation of critical inherent and induced material properties all the way from raw material to the final processed formulations e.g.;
- Particle size distribution determination
- Visualisation using different microscopical techniques (E.g. SEM)
- Crystallinity and form assessment
- Thermal properties determination
- Humidity interaction characterisation
- Specific surface area determination
- Inherent and induced amorphicity detection
- Excipient compatibility evaluation

**RESTORATION OF CRYSTALLINITY (CONDITIONING)**
Material may have inherent amorphicity as received or obtain induced amorphicity from processing. In case the amorphicity is located on particle surfaces it is vital to control and/or restore the crystallinity.
- Detection and quantification of extremely small amount of amorphicity
- Development of tailor-made conditioning method used to restore surface crystallinity
- Actual conditioning of partly amorphous material in laboratory development scale
- Providing state of the art conditioning equipment suitable also in production environment

**FORMULATION PROCESSING**
Compounds intended for inhalation need to be processed with great care, using specialised equipment and environmental conditions (like controlled RH) and fulfilling harsh quality attributes.
- Laboratory scale fluidized jet mill capability including various internal surface options
- Homogeneous mixing of micron sized primary particles
- Intensive mixing of adhesive (ordered) mixtures with scale up options
- Filling capability (manual or semi-automated)
- Full analytical capability assessing e.g. content, homogeneity or degradation products
- Complete stability study facilities and capabilities including GMP manufacturing storage and analyses

**INHALER TESTING**
A genuine inhaler performance testing through the development process is vital so that the impact of formulation changes is monitored. This enables fulfilment of the project end points and prediction of outcome in e.g. BE PK studies.
- Delivered dose testing
- Aerodynamic particle size distribution testing, with the NGI impactor
- Performance at different inhalation air flows
- In vivo relevant in vitro testing, such as different anatomical throat sizes in combination with different patient air flow profiles

**PROJECT MANAGEMENT**
New prerequisites, project objectives or revised business cases require a smooth and swift interaction between customer and service provider.
- The dedicated MVIC FD project manager will engage in the initial design and scope of the program and will drive the project from start to finalisation. The project manager will coordinate the work within MVIC and will be one person contact for the customer.
- Knowledge transfer between MVIC and customer is performed continuously during the entire development program.
Contact

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