

MERIDION

Lyophilized Microspheres by Spray Freezing and Bulk Freeze Drying

MERIDION develops and manufactures highly innovative spray freeze drying technologies, allowing for significant product innovation and offering further benefits in the areas of production logistics, process technology and costs. Forget about yesterday's typical limitations of conventionally freeze dried products, like poor flowability and poor dosing properties, inhomogeneities and dust emission during handling – and learn about the future of freeze drying!

MERIDION Technologies offer you new opportunities:

- Product Innovation
- Manufacturing Flexibility
- Process Robustness
- Total Containment
- Significant Cost Reductions

The results of MERIDION technologies are worth a closer look





MERIDION Technology

- Manufacturing flexibility and cost savings
 - Filling on demand of lyophilized bulk product
 - Filling quantities as required
 - Fully contained product handling: no need for loading and unloading systems
 - Primary packaging flexibility: no need for freeze drying suitability
 - Cold chain logistics can be eliminated
- Innovation & formulation flexibility
 - High protein concentrations
 - Reconstitution time reduction
 - Combination Products (Multiparticulate Dosage Form concept)
 - Application of Solid Dosage Form technologies to your lyophilized product (e.g. coating, compacting, ODT's)

MERIDION *SprayCon:*Spray Freezing of Microspheres

Frozen microspheres are generated by dispersing the substrate liquid using high precision nozzles into single droplets, which by gravity pass through a cooling zone, congealing to frozen spheres.

MERIDION *SprayCon*Microspheres: Your Advantages

- Narrow particle size distribution
- Size selectable

from 300 $\mu m - 1000 \mu m$

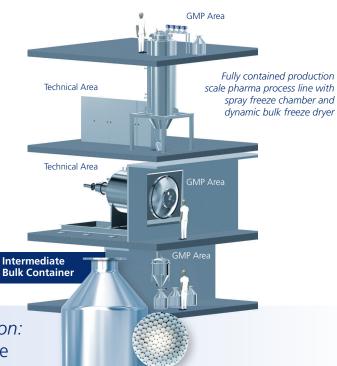
- After freeze drying, the product
 - is homogeneous
 - has excellent **flow** properties
 - is dust free
- Product innovation: after freeze drying, further processing, e.g. coating or combination products, possible
- Highly cost effective utilization of cooling energy – no direct contact with primary cooling agent (no GMP grade LN2 cooling utility required)

The MERIDION process – step by step

Liquid Substrate Transfer (tank to nozzle) Atomization: droplet formation Droplet freezing (to microspheres) Discharging (cold storage or transfer)

Charging of Freeze Dryer Drum Freeze drying of particles Discharging into discharge/ transfer section

Bulk container filling



MERIDION *LyoMotion:*Dynamic Bulk Freeze
Drying

In the dynamic freeze drying process, flowable frozen bulkware is lyophilized in a rotational freeze dryer under constant gentle mixing. Sublimation energy is transferred by radiation and temperature controlled surfaces.

MERIDION *LyoMotion:* Your Advantages

- Strong drying time reduction possible by
 - maximized heat exchange (entire particle surface available)
 - heat transfer directly to the product
 - shorter vapor diffusion length due to particle size



Start your future now – with breakthrough technologies by MERIDION!

- PAT tools directly accessible

Product quality

Process robustness

 Highly homogeneous, dust free product due to constant and gentle mixing – no caking, no variations in product density

- Direct monitoring of product

relevant parameters

- OOS results reduced

 Direct monitoring of product temperature

Innovative MERIDION technology in lab scale: SprayCon LAB and

LyoMotion LAB

Left: MERIDION LyoMotion bulk freeze dryer with IR radiators and double wall drum

Right: line operation control unit

