Siegfried

Spray Drying API and Drug Product Services

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Does your drug molecule require enhanced physical properties to improve its solubility and bioavailability? Or perhaps your API is thermally sensitive requiring an appropriate alternative isolation and drying method? Need an amorphous physical form or control of your product's particle distribution?

With our continuing investments in large scale cGMP commercial pharmaceutical spray-drying as well as lab scale development equipment, Siegfried is your partner to help take your product from early development through all clinical stages to commercialization.

Facilities in the USA (pilot & commercial) and Switzerland (development scale) cater for both drug substance and drug product applications.

Contact us for an informed and open discussion regarding how we can meet your requirements.

The benefits gained from using spray drying
Whenever for example thermo-labile drug substances, homogeneous mixtures or difficult to isolate APIs need to be produced at commercial scale, spray drying provides a valid cost efficient alternative to other drying techniques such as lyophilization.

Spray-drying gives you high precision control over:

- Particle size
- Particle design (shape)
- Bulk density
- Degree of crystallinity
- Bioavailability improvement by e.g. isolation of amorphous products
- Low temperature stress for sensitive materials due to a rapid drying processes
- Organic volatile impurities (OVI) and residual solvents

If these are key factors you require for ensuring the requisite function of your product, then consider spray-drying.

Spray Drying at Siegfried

Applications

Drug Substance

– Thermo-labile substances
– Biomolecules
– Non crystalline material
– Amorphous substances
– Homogeneous mixtures
– Particle Design

Drug Product

– Enhanced Bioavailability
– Solid Dispersion
– Nano Suspension
– Matrix
– Encapsulation
– Agglomeration
– Taste Masking

For spray-drying Siegfried brings its experience of continuous commercial scale cGMP operation at its US facility (Pennsville NJ) together with considerable chemical engineering expertise, excellent quality compliance and broad knowledge in developing complex pharmaceutical formulations. This makes Siegfried well suited for commercializing new applications that require spray drying. Our pilot & commercial spray dryers in the US are complemented by laboratory scale spray drying in Zofingen Switzerland, enabling direct support of combined chemical and pharmaceutical development activities across both sites.

Siegfried's spray dryers are designed to manufacture amorphous spray dried dispersions (ASD) to improve bioavailability of low solubility products. We can safely manage the large amounts of flammable solvents within our infrastructure, which is one of the main challenges in manufacturing ASD at commercial scale.

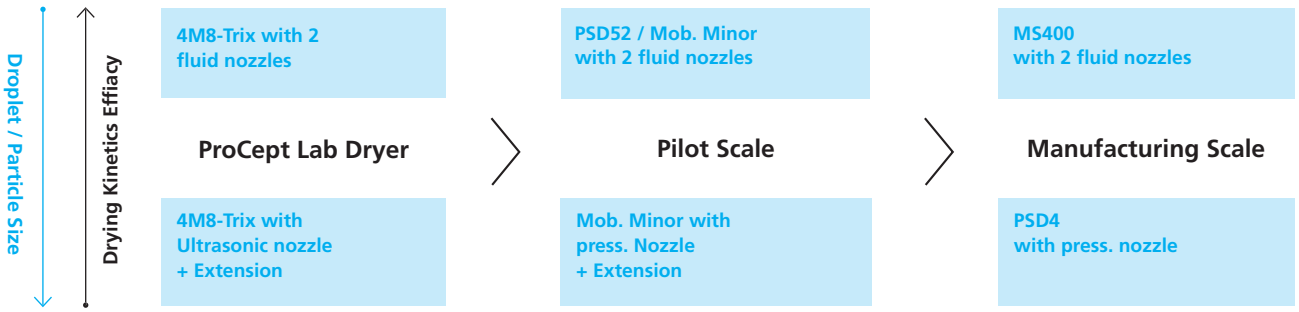
Equipment overview

Spray Dryer	Supplier	Scale	Drying Gas N_2	Evaporation Capacity*		Siegfried Site
				Water	Acetone	
4M8-TriX Spray dryer	ProCept	Laboratory	48 m³/h	1–2 kg/h	8 kg/h	Zofingen Switzerland
Mobile Minor	Niro	Laboratory/Pilot	80 m³/h	3 kg/h	14 kg/h	Pennsville USA
PSD 52cc	Anhydro	Pilot	150 m³/h	5 kg/h	26 kg/h	Pennsville USA
MS 400	Anhydro	Commercial Medium scale	400 m³/h	14 kg/h	70 kg/h	Pennsville USA
PSD 4	Niro	Commercial Large scale	1250 m³/h	44 kg/h	219 kg/h	Pennsville USA

* calculated, based on a Delta T of 120°C. Will vary with inlet and outlet temperature and final composition of the solution

Further secondary drying (vacuum dryers) capacity complements the above equipment. All spray dryers can handle flammable solvents.

Scale-up approach



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