



PHARMACEUTICAL  
MANUFACTURING

MARK RIEMER

SternMaid GmbH & Co.KG  
Am Mühlberg 4  
19243 Wittenburg, Germany  
www.sternmaid.de

# Specific enhancement of product attributes

*From tableting properties, dust reduction, solubility and shelf-life to microencapsulation of active substances, fluid bed technology offers a host of possibilities for optimizing products. In 2012 SternMaid, one of Europe's leading contract manufacturers of foods, food ingredients and food supplements in powder form and also active pharmaceutical ingredients and excipients, invested some € 5 million in a fluid bed processor.*

**F**luid bed technology is a formative drying process enabling a specific influence on the physical properties of solid products and their possible applications. Depending on the customer's requirements, the process results in granulates, agglomerates and coated or microencapsulated particles which facilitate applications and enhance the functional properties of the products. Since it permits very gentle processing and a wide range of applications, fluid bed technology has become one of the most important formulation methods in the food and pharmaceutical industries. Besides drying – including spray granulation – three other production techniques are possible: agglomeration, instantization and coating.

## GENTLE PROCESSING OF THE PRODUCTS

In the fluid bed the product is dried in a controlled environment, which permits

optimum adjustment and standardization of its attributes. Since drying can be carried out in a low and therefore gentle temperature range, the product is usually subjected to only moderate heat between 30 and 50°C. No thermal damage occurs. The method is therefore especially suitable for processing heat-sensitive ingredients such as enzymes, flavourings, vitamins and microorganisms.

## POWDERS WITH A TAILOR-MADE PROFILE

Fluid bed drying has numerous advantages over conventional spray drying. It is not only a case of removing the moisture from a product. The main purpose of the method is to obtain dry products with precisely defined structures and parameters. It is possible, for instance, to produce a dustless powder with a defined particle size, apply vitamins to carriers or encapsulate sensitive substances in a functional shell to protect them against gastric juices. In the case of hygroscopic

substances the absorption of atmospheric moisture can be reduced in order to prevent the formation of lumps.

## OPTIMALLY BLENDED INGREDIENTS

Moreover, the fluid bed is an ideal blender. Several powdered substances can be





mixed in the processor and agglomerated in the same step. If the surface of the particles is moistened and simultaneously dried, the powder particles stick together to form free-flowing agglomerates. Among other things this influences the instantizing properties of the powder. Compared with the fine powders that result from spray drying, the products from the fluidized bed dissolve and disperse much more readily in liquids. This also facilitates handling of the goods, because the agglomerates thus produced contain much less dust, are more suitable for tableting and are easier to dose because of their superior flow properties.

In the case of pharmaceutical products and also food supplements it is essential to ensure a very high level of homogeneity – for all the tablets, capsules or portions must be exactly the same. In the fluid bed processor, even extremely small amounts of the substances are firmly bound in the agglomerate; this

guarantees homogeneity and reliably prevents separation.

### **CERTIFIED PRODUCTION CONDITIONS**

At SternMaid, eight separate blending lines are available to meet all manner of different requirements. The company's modern counter-current container blending line – ideal for blending vitamin compounds – has been qualified retrospectively and certified officially

according to Part II of the EU GMP Guide. It permits blending, processing and filling of active pharmaceutical ingredients and excipients according to strict regulations.

### **TESTING ON FLEXIBLE PILOT PLANT**

With its laboratory-scale fluid bed unit, SternMaid conducts trials in order to develop new products and optimize existing ones. On this equipment, any necessary adjustments to the formulation or process parameters can be made quickly and simply. Subsequent commercial production is carried out with a multi-purpose industrial processor capable of batch or continuous operation. With additional services such as purchase of raw materials, warehousing, co-packing and logistics, the contract manufacturer offers a complete package all from one source.

