

MG2 AUTOMATION SOLUTIONS FOR INHALATION

MG2

Keeping ahead for you

Since 1990, MG2 has been developing automation solutions for inhalation applications, which meet the most demanding requirements of formulations on the capsule filling process. When handling powders for inhaled pharmaceutical products, there are several challenges that affect the development of the filling process.

The filling process is a critical phase due to the product low dosages involved (ranging from 5 mg to 40 mg), and the weight changes. In fact, in the development of low dosage units, both the required mechanical stress to withdraw powders and then the transfer into capsules must be considered. It is necessary to identify the correct machine set-up to achieve accurate dosing without compromising the aerodynamic profile of the formulation and with it the end product's inhalation performance.

MG2 addresses and solves these issues by applying both volumetric technology in its dosator (see Figure 1) and an in-process system to control the net weight of the powder filled into each capsule.

A MODUS OPERANDI FOCUSED ON R&D AND ACADEMIC PARTNERSHIPS

In addition to its technological experience, MG2's customers can make use of the Pharma Zone, an area which totally complies with relevant pharmaceutical standards and thus offers a simulation environment particularly suitable for R&D purposes, not only for preclinical tests but also for the development of technical batches. The MG2 Pharma Zone provides an excellent level of safety for operators in all working conditions, such as either handling dangerous powders or running tests on powder behaviour under different environmental (relative humidity and temperature) conditions.



Figure 1: MG2 dosators incorporate volumetric technology.

“The Inhalation Consortium was conceived specifically to share knowledge and solve issues related to inhalation powders filled into capsules.”

The Pharma Zone is a real trump card. It facilitates a constant dialogue between MG2 technicians and the customer. The continuous

changes, also in progress, together with the evaluation of both test development and real production, mean the Pharma Zone is



Figure 2: The Pharma Zone area facilitates a constant dialogue between MG2 technicians and the customer.

a perfect environment for 360-degree trials. This pharmaceutical area (Figure 2) also serves as a strategic tool for both the research MG2 undertakes and the partnerships that it has established with many academic

institutions and pharmaceutical suppliers.

For several years MG2 has adopted a scientific approach to the new challenges of the pharmaceutical market, including in particular the specific demands of

inhalation applications, by both taking part in international research projects and establishing relationships with some of the most important operators in this field.

Arising from one such partnership, the Inhalation Consortium was conceived specifically to share knowledge and solve issues related to inhalation powders filled into capsules. In addition to MG2, the consortium includes: RCPE (Graz, Austria), Meggle (Wasserberg, Germany), Qualicaps (Madrid, Spain), University of Parma's Department of Food and Drug (Italy), and Insud Pharma (formerly Gruppo Chemo, Madrid, Spain).

The Inhalation Consortium has also started a three-year research program focused on capsule behaviour during the filling phase and interaction with the physical-chemical characteristics of the powders to be dosed.

CASE HISTORIES WITH PROMINENT PLAYERS

MG2 has struck up several direct co-operations with leading companies in the inhalation market.



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Multinational Pharma Company

Among them there is an important Italian multinational pharmaceutical company, which has chosen MG2 as its cutting-edge technology supplier.

The decision results from the pharma company's need to test new formulations that have not yet been launched onto the market, studying their behaviour during both the delicate capsule-filling stage and the weight-control phase. This co-operation took shape not only with an analytical and chemical-pharmaceutical point of view, but also under the technological profile, thus providing benefits in terms of production standard. MG2's cross-functional experience, strong position in the market and the presence of the Pharma Zone all benefit the collaboration. Activities carried out include:

- Laboratory tests, particularly focused on machine set-up logic, with manual tests (Figure 3), which allow selection of the best dosator and the necessary adjustments to be defined in order to arrive at the required net weight.



Figure 3: Manual tests allow the best dosator to be selected.

- Short runs, made under different operation conditions, necessary to identify the best machine set-up by considering the particularly small quantities of the involved material.
- Long runs, i.e. simulation of an actual batch which will be produced by the customer at a later stage.

The constant co-operation between MG2 technicians and chemists from one side and the customer from the other side has made it possible to mitigate many of the usual issues faced during the development of a new formulation, by rationalising the resources in all the experimental phases in order to achieve the common goal of defining the ideal recipe.

International CDMO

An international CDMO with numerous European and North American sites installed an MG2 capsule filler, in a containment configuration, suitable for low-dose powders for inhalation, after having successfully assessed MG2's technology. In this case, the customer firstly started with a FlexaLAB

model equipped with MultiNETT, the MG2 patented in-process net weight control system, then the customer continued the production stage by inserting a new high-speed capsule filler suitable for handling high-potency drugs. Thanks to the scalability of MG2 machines, the CDMO had the chance to complete its innovation path from R&D to production.

These two different experiences shared a common cornerstone: MG2's technological excellence in the inhalation drug filling process.

ABOUT THE COMPANY

MG2 supplies automatic machines for the pharmaceutical, cosmetic and food industries. Machines include containment solutions, and capsule fillers for oral dosage forms and, since 1990, the company's capsule filler offering broadened to include inhalation applications.

In the late 1990s, the company entered the packaging market and now offers complete primary and secondary packaging solutions for pharma (as well as the cosmetics and food industries).

MG2 was founded in 1966 by Ernesto Gamberini, who patented and introduced the first continuous-motion capsule filler on the market (Model G36). The company is based in the Italian "Packaging Valley" region.

In 1987, MG2 founded a US sister company, MG America, Inc, in New Jersey, that supplies European processing, packaging, inspection and material handling equipment throughout the US, Canada and Puerto Rico.

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