

Case Study

Pharma Automated Powder Dosing Solutions



Capsule Filling with QUANTOS – for pre-clinical trials

Discover how a top pharmaceutical company automated the slow, unsafe and expensive process of capsule filling for their pre-clinical trials.

The main goals of pre-clinical studies are to determine a product's ultimate safety profile. Studies involve in vitro and in vivo experiments, through dynamic weighing, using wide-ranging doses of the study drug to obtain preliminary data.

Depending on the nature of drug and test subject, new pharmaceuticals are often administered via gelatine capsules, where the fill weight of each capsule must be accurately calculated and prepared according to the test object's weight. This involves manually weighing in highly potent, hazardous substances precisely with a spatula.

Pharma

New Drug Development

Clinical Trials



Cassette for 5 bottles in Autosampler QS30

METTLER TOLEDO

Controlled handling of potential new pharmaceuticals

■ For this pre-clinical trial, size 12 capsules were used (outer diameter 15.3mm, height or locked length 40.5mm, actual volume 5ml). The manual preparation would have involved:

- Placing one capsule onto an analytical balance
- Manually weighing in the calculated dose for the specific animal by hand
- Recording the weight
- Removing the capsule from the balance
- Capping

The study lasted for 28 days and involved 30 test subjects. The dose of the new pharmaceutical was calculated according to 70 mg of drug per kg animal or participant weight. Between 1 and 3 capsules were applied to each test object per day, totalling 1680 capsules over the course of the trial.

Each manual dose on a balance takes 2-3 minutes per capsule and if the whole study had been prepared manually, it would have taken 84 hours to dose the samples.

Study duration	28 days
Number of participants	30
Participant weights	4 to 16 kg
Sample amount	70 mg/kg
(range)	30/60/120 mg/kg
Applied samples per day	1 to 3

Capsules per study	1680 capsules
Used API	around 1.2 kg

Size 12 capsules may each be filled with up to 5.2 g of compound; hence depending on the stage of the study and weight of the animal, more than one capsule may need to be filled per administration.

Challenge

■ Why did this customer look for an automated solution?

Firstly, the task of manually filling each capsule with a different drug dose according to the target animal weight required great concentration from the researcher preparing the capsules. This was one point where risk of human error was higher, and overdosed capsules were withdrawn and repeated.

Secondly, a list of doses for up to 90 capsules per day was created and each dose was processed one at a time. This is a large number of capsules that led to capsule filling becoming a time consuming and tiring task.

Finally, the pharmaceuticals that were being dosed into the capsules and handled by the researchers on a daily basis were not yet fully characterised. For this reason, the drugs needed to be handled as a high, unknown potency class to protect the researcher.

The METTLER TOLEDO automated dosing solution with Quantos

■ The Quantos QB1 automated powder dosing system, set up with disposable dosing heads for 250 doses and combined with a QS30 Autosampler for up to 30 unattended doses, was an ideal solution.

The biggest value to this customer is the increased throughput and time savings that automation brings. For this 28 day project, they saved a third of the time for filling 1680 capsules. Alongside these savings, the Autosampler enabled the researcher to work on other tasks whilst up to 30 capsules were being filled in one go.

To minimise the time the researcher is in contact with API, the dosing is performed in a closed system, and the entire Quantos dosing unit can be placed inside a safety enclosure. Process safety is also a valuable benefit, and this is guaranteed with the RFID chip in the dosing head that stores all the key information on the substance used, e.g. Lot number or powder characteristics. Actual fill weights of each individual capsule are also captured electronically and can be printed if required. Unlike manual weighing, the Quantos system doses to an accuracy of $\pm 0.5\text{mg}$, independent of substance characteristics and operator experience.

► www.mt.com/quantos

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