

Quantos Automated Dosing



Drug Development

Precise preparation

Secure process

Flexible solution



Capsule Filling for Preclinical and Early Clinical Studies

METTLER TOLEDO

Automatic and Precise Individual Capsule Filling

Filling capsules is a frequent and important activity in pre-clinical and early clinical studies. It is often performed manually, usually because batch sizes are too small for filling machines or different quantities are required per capsule, which is not easy to automate. Quantos can handle these challenges.

Dosing substances of unknown potency into capsules by hand can be hazardous, time-consuming, tricky and error-prone. When individual fill weights are required, there is an increased risk of reading, recording or inputting the actual weights incorrectly, with potentially disastrous consequences for the test subject if mistakes are made. However, Good Laboratory Practice (GLP) demands reproducibility, traceability, and full documentation throughout the process.

Quantos is the ideal solution for small batch dispensing. With its great flexibility, it is a compact, affordable investment that fits neatly between manual filling methods and costly high-throughput filling machines. Quantos has the unique ability to dose different amounts per capsule, as well as pure API without excipient. The intelligent dosing head identifies the powder properties and automatically optimizes the parameters to achieve accurate dosing of each powder, ensuring that only the minimum quantity is used. Fill weights are automatically recorded. Quantos also protects the analyst by minimizing exposure to the substances contained in the dosing head. More than 95% of the leading pharmaceutical companies have already made the switch to Quantos.



Enhance Safety

- Protect operators working with highly potent substances
- Avoid cross contamination due to sealed dosing head system
- Sealed dosing head system



Save Time

- Fill 60 capsules in less than 30 min
- At least three times faster than manual filling
- Capsule fill weights captured automatically



Reduce Errors

- All sample information stored on RFID chip
- Traceable, labelled capsules avoid confusion
- Manual transcription errors eliminated



Evolution in the Lab

Balances Have Learned the Skill of Dosing

Whether filling individual capsules or entire series – the XPE offers a modular concept with an effective solution for every application. You can choose to expand your XPE balance into a fully automatic dosing system or a 1-to-1 system for individual filling. Whether 1-to-1, 1-to-12 or 1-to-30: with Quantos you can work more quickly, safely and economically than with a spatula.

Weighing potentially toxic powders into capsules is one of the most common operations in preclinical and clinical studies. It is a routine task that is potentially hazardous. A routine task that takes up a great deal of time and resources.

The modular XPE concept provides a solution to suit every lab. Depending on your project, Quantos can be converted from a manual to a fully automatic system. Each configuration is based around the automated dosing head. The dosing head comes in a sealed,

impact-resistant transport container to protect the valuable sample from moisture. The dosing head is positioned directly above the capsule whilst dispensing the powder and closes automatically once dosing is complete. This minimizes any risk of contamination.



1-to-1

Ideal for use with cytostatic drugs



1-to-12

Manual sample changer

Ideal for small batches



1-to-30

Automatic sample changer

Ideal for use in preclinical studies



METTLER TOLEDO

Small Batch Filling

Fully Automatic and Highly Efficient

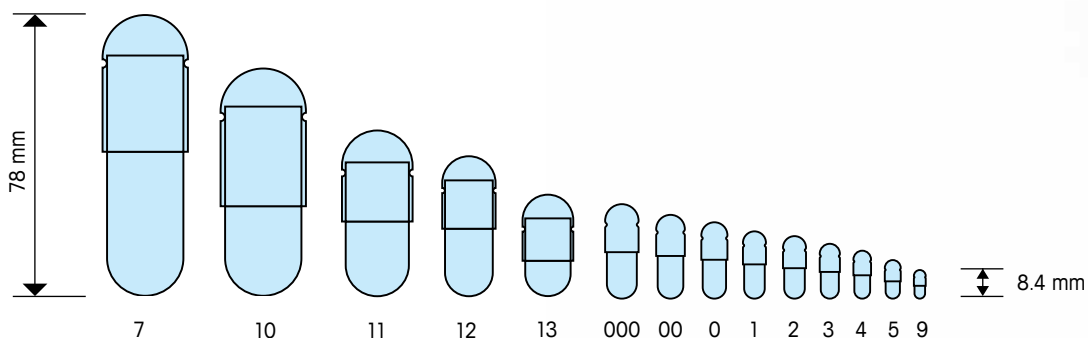
Aliquoting small quantities of potentially toxic substances into small containers is a repetitive, monotonous job. This makes the filling of small batches an ideal candidate for automation. The Quantos dosing system is as adaptable and flexible, filling different amounts per capsule with no segregation of blends. It can fill a range of capsule sizes, as well as vials and containers of any kind, both quickly and automatically.

The Quantos dosing system protects employees from toxic substances and takes care of the repetitive, less challenging jobs you would rather not do by hand. Quantos is flexible and adaptable. Different target containers are no problem. It fills capsules from size

7 down to 9, as well as vials and containers with diameter up to 28mm.

The Quantos Connect application software allows an individual fill quantity to be defined for each capsule and these data records to be

checked against the study protocol. Quantos reliably doses powder quantities of just 1 mg. With such small fill quantities, it is also possible to use the material without an excipient or carrier substance. This allows you to save the formulation and also simplifies stability tests.



CoreRx case study

CoreRx, Inc. is a contract research organization (CRO) for clinical development and manufacturing, based in Clearwater, Florida, USA. They specialize in formulation development, analytical development, stability storage and testing services and clinical manufacturing of various dosage forms for clients in the pharmaceutical industry. CoreRx employs state-of-the-art analytical and automated equipment and have been successfully using Quantos dosing technology for filling capsules and vials since 2009. "We are very happy with the capabilities of Quantos. It has exceeded our expectations with regards to tolerance, along with the ability to dose blends." stated Rob Trivedi, Director of Technical Operations.

According to Mark Licarde, Vice President and co-founder, "In the first project using Quantos, we filled over 60 capsules per hour, a total of 480 capsules per shift, which is 5 times the throughput of a manual process." Matthew Greene, Senior Formulation Scientist concludes that "The Quantos dosing system offers an accurate, safe, quick, and economical means of preparing early phase clinical and pre-clinical trial materials."

Read the full details in a white paper at ► www.mt.com/wp-capsule

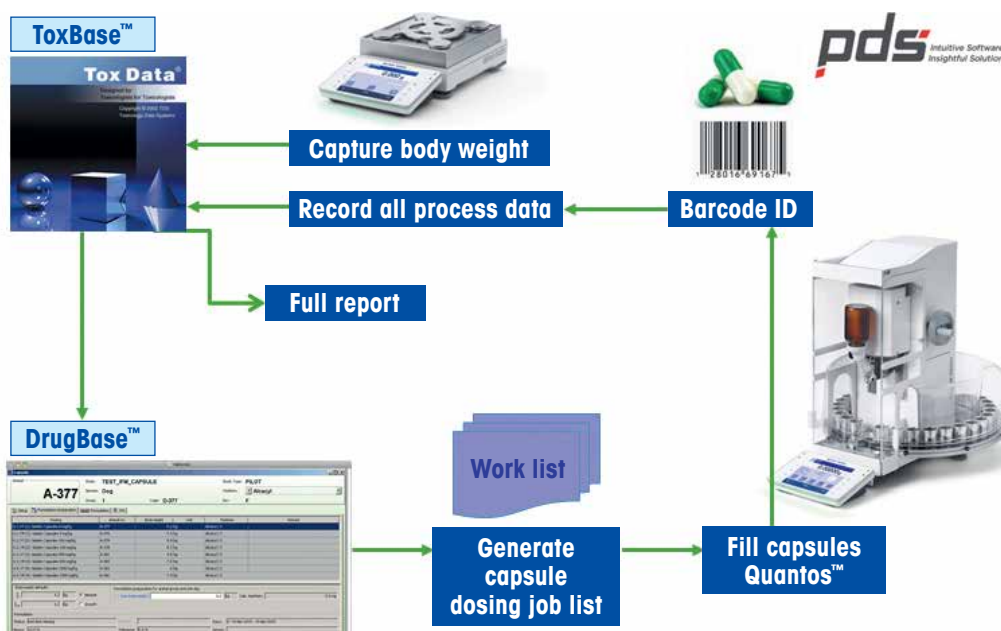


Quantos and ToxData®

an Alliance to Secure Your Process Reliability

Maximum process reliability

Seamless data transfer, automation and plausibility checks prevent errors in the study.



The collaboration between METTLER TOLEDO and Life Sciences (PDS) is characterized by process reliability and user friendliness. The Quantos dosing system and the Ascentos ToxData software for preclinical studies are perfectly compatible. ToxData displays the entire preclinical process and thereby provides comprehensive process reliability. The software is easy to use. It manages the recorded weights and uses these to generate worklists with individual target weights for capsule filling, which are transferred automatically to the Quantos dosing system. Quantos fills the capsules precisely with the target amount specified in the worklists, each of which contains a code to prevent confusion. Once dosing is complete, Quantos sends the individual dose weights back to the ToxData software which checks the barcode and records the data.

The entire procedure is secured and logged through automatic cross validations. ToxData is compliant with 21 CFR Part 11 and automatically drafts a complete report at the end of each study. We offer Service & support for the entire solution is from a single source. The Quantos ToxData system is plug-&-play: simply position, connect and start your study!

► www.pdslifesciences.com

Validation

The Quantos ToxData solution...

- is fully validatable as per 21 CFR Part 11
- is supplied with Installation Qualification (IQ)
- has validation scripts available



Dosing without studying – the dosing head can handle all free-flowing powders. It adapts to the powder characteristics and registers deviations in the particle size.

Intelligent RFID chip

Saves all substance-relevant data and thereby secures traceability.

Intelligent dosing pin

Precisely doses any and all target volumes. Seals off the substance completely for your safety when not dosing.

Intelligent stirrer

Feeds powder continuously and homogeneously.

Quantos

Dosing System

Quantos	XPE206DR	XPE205
Maximum capacity (full range/fine range)	220 g / 81 g	220 g
Readability (full range/fine range)	0.01 mg / 0.005 mg	0.01 mg
Repeatability* (5% load)	0.005 mg	0.007 mg
Settling Time* (full range/fine range)	2.5 s / 3.5 s	2.5 s
Minimum Weight* (U=1.0%, k = 2, 5% load)	1.0 mg	1.4 mg
USP Minimum Weight* (0.10%, k = 2, 5% load)	10 mg	14 mg
Automated Minimum Weight* (U=1.0%, k = 2, 5% load)	0.7 mg	1.0 mg
Automated USP Minimum Weight* (0.10%, k = 2, 5% load)	7 mg	10 mg

*= typical value

1-to-1

XPE balance with powder module	
Number of target containers	1
Sample change	n/a
Footprint	489 x 241 cm



1-to-12

XPE balance with powder module and Ergodisc	
Number of target containers	12
Sample change	manual
Footprint	489 x 241 cm



1-to-30

XPE balance with powder module and auto sampler	
Number of target containers	30
Sample change	automatic
Footprint	610 x 431 cm
Target containers	
Diameter (max)	28 mm
Opening (min)	8 mm
Height (max)	115 mm



Benefits

- Integrated ionizer eliminates adverse effects of any electrostatic charges.
- Possible to dose different amounts per capsule, with no segregation of blends.
- Fits inside standard safety cabinet or enclosure.

Dosing Heads

The Quantos dosing heads allow you to dispense powder in an instant. Each dosing head is filled with one substance. This makes time-consuming cleaning processes a thing of the past and also eliminates the risk of potential cross-contamination. Your valuable or sensitive substances are permanently and securely protected in the storage containers. The Quantos dosing heads employ a high-precision stirrer which provides a homogeneous powder flow, and a dosing pin which seals the head completely before and after each dosing.



Dosing

Substances that can be dosed	Free flowing powders
Dosing repeatability of typical sample sizes (50mg)	< 2%
Speed of dosing (50mg)	20-30 sec
Container volumes	120 ml
Dead volume (CaCO ₃)	0.5 mg
Dosing head capacity	1 mg - 5 g



Robust – Precise - Accurate

A highly precise dosing mechanism guarantees homogeneous flow of the powder. The dosing head learns powder behavior and optimizes dosing accuracy and speed accordingly. Precise dosing targets are achieved with no additional configuration required by the user.



Enhanced Safety

Exposure to potentially toxic substances is reduced because powders remain sealed in the dosing head. An individual dosing head for each powder eliminates cross-contamination risk and impact-resistant transport containers protect the substance from moisture absorption.



Traceable Data

All information relating to the powder (substance ID, batch no., quantity, expiry date, etc.) is saved on the integrated RFID chip in each dosing head. Potential errors due to dosing the wrong substance are avoided. Details can be printed or recalled at the touch of a button.

Quantos

Automation

Automation through Quantos revolutionizes capsule filling in preclinical and early clinical studies.

Quantos is fast, secure and economical.

In creating Quantos, the weighing expertise of METTLER TOLEDO has been combined with intelligent dosing technology. This has led to a product with the typical METTLER TOLEDO characteristics:

- Ease and convenience of use
- Innovation
- Quality

www.mt.com/quantos

For more information

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