

TECHNOLOGY SHOWCASE: Röchling Medical's Sympfyny®

Röchling

Multiparticulates for direct oral delivery are an emerging technology with many advantages over traditional dosage forms, including extended shelf life, no refrigeration requirements in storage and transport and tasteless formulations. Yet widespread use of multiparticulate drugs has been limited due to the lack of an accurate and easy-to-use dosing and dispensing device.

In collaboration with HS Design, Röchling Medical has developed Sympfyny®, an innovative system for dosing and delivering multiparticulate, dry powder, and microsphere drug formulations for oral delivery.

Benefits in Paediatrics

Multiparticulates are particularly suited for use in paediatric medicine. Commonly, drugs for paediatric patients are administered orally as liquids, rapid-dissolve tablets or chewable tablets. The problem:

- Children do not like the taste – a major cause of incomplete dosing in children
- Masking bitter tastes requires large amounts of sugar and flavourings
- There are significant inaccuracies in dosing with liquid syringes.

Formulating to solve taste, storage, and dosing issues results in high development costs, extended research time and trade-offs with other drug features.

Multiparticulates are bead-like drug formulations akin to microspheres with coated and/or matrix architecture (Figure 1), which offer a wide range of drug release profile flexibility for single or multiple drug combinations. Multiparticulates do not have an inherent taste, eliminating the need to reformulate for various tastes. They are shelf-stable without refrigeration, allow for high dose flexibility and may be dosed with or without water.

Multiparticulate Drug Delivery Challenges

The control of multiparticulate drugs is not easy. They are complex microspheres of

Modified-release layer

Coating substrate

Drug Layer

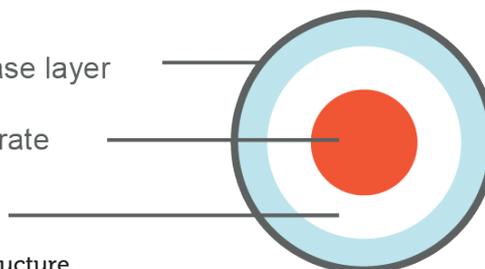


Figure 1: Multiparticulate structure.

solid medication surrounded by a coating that prevents them from dissolving until they reach the stomach. These spheres behave like tiny ball-bearings, flow more readily than water and pour out of small openings. Compressed as solid particles they “lock” together. Multi-particulates can also stick together if they become damp or statically charged. This presents a range of challenges:

- Multiparticulates display the properties of both liquids and solids
- Solutions for liquid dosing are poorly suited for multiparticulates
- Existing delivery systems (e.g. sachets, stick packs, straws, break-open capsules) are limited to single dose or require complex preparation steps by caregivers.

Sympfyny®: Accurate Dosing & Delivery

The Sympfyny® system is a first-of-its-kind innovation in the delivery of multiparticulates. The system, comprising oral syringe and container, enables caregivers to store, extract, and deliver dry drugs with the same, familiar technique used with liquid oral drugs. The patent pending design allows controlled and precise dosage and ensures that an untrained caregiver can dispense the medication directly and accurately into the patient's mouth.

The Sympfyny® syringe, available in 1 and 2 mL, has an innovative dose-setting capability for dosing with multiparticulates. A dose-setting clip is fixed to the syringe that slides along the plunger rod and locks into place at the required dose amount.

To deliver a dose, users simply set the dose clip, insert the plunger into the barrel and pull out the plunger until it stops at the pre-set

dosing volume. Then the syringe is inserted into the bottle until it engages, locking the syringe into place. With the dose setting clip in place users are guaranteed consistently accurate delivery volume.

With the bottle vertical, multiparticulates will freely flow into the syringe. When the syringe is removed by pulling downwards, the valves on the bottle and syringe seal automatically and no multiparticulate leaks.

This convenient and reliable system allows parents to deliver taste-masked medication to their children without the emotional or physical strain currently felt with bad-tasting liquid drugs.

The Sympfyny® system fits standard bottle sizes but can also be customised to accommodate different dosing volumes or container sizes and forms.

Michael Quinn

Vice-President, Design & Engineering
T: +1 908 234 2331 Ext 17

HS Design, Inc

906 Mt Kemble Ave
Morristown, NJ 07960
United States

www.hs-design.com

Ms Valérie Duval

Head of Sales Global Accounts
T: +49 151 26652789

Röchling Medical Brensbach GmbH

Höchster Str 100
64395 Brensbach
Germany

www.sympfyny.com

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The innovative multiparticulate drug delivery system

for dosing and dispensing dry powder,
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Available as 1 ml and 2 ml