

Functional ready-to-fill capsules for preclinical trials

EUDRACAP® preclinic enteric

From preclinical to commercial. Optimize drug development by reducing risks and variables in preclinical trials.



Designed specifically for preclinical trials

Preclinical trials are an essential step in the development of new drug products. It is often necessary to target the enteric release of drug candidates in these studies.

EUDRACAP® preclinic enteric is a size 9h, coated, empty, ready-to-fill gelatin-based hard capsule designed to provide robust low gastrointestinal delivery in rats, hamsters and guinea pigs in the non-clinical phase.

Key facts about EUDRACAP® preclinic enteric

- Ready to fill
- Enteric functionality with no additional coating steps
- Reduces variables in the preclinical phase
- Suitable for dry powders in any form
- Banding free process
- Simplifies formulations in the non-clinical phase
- No additional excipients needed
- Approximate capsule volume is 13 μ L

Eudracap® preclinic

Length: 5.1 mm

Targeted low gastrointestinal delivery for:

Rat 150 g+

Hamster 150 g+

Guinea pig 300 g+



without EUDRACAP® preclinic



Empty capsule



Filling



Locking



Coating



Analytics



Final functional filled capsule

with EUDRACAP® preclinic



Empty functional capsule



Filling



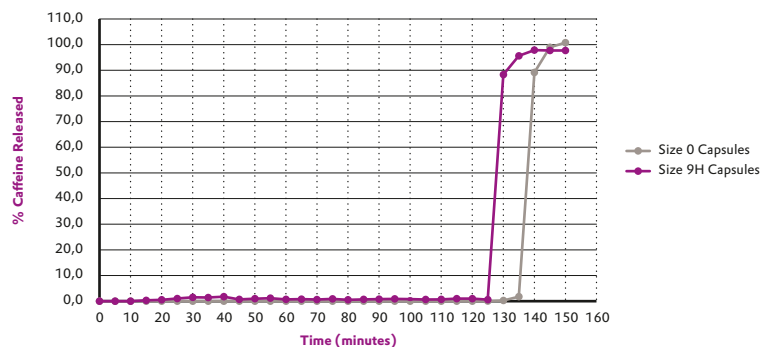
Locking

- Ready-to-fill
- No additional process needed
- Easily scalable technology
- Drug is not subjected to unnecessary stress conditions
- Reduces number of variables

Seamless transition to first-in-human trials

The EUDRACAP® platform offers the same delivery technology from preclinical to commercial phase.

- **EUDRACAP® preclinic enteric:** size 9h gelatin capsules in technical grade for preclinical trials
- **EUDRACAP® enteric:** size 0 HMPC capsules GMP grade for clinical and commercial phases
- Tailor-made dissolution profiles, sizes and colors
- Same coating technology, similar dissolution profile from non-clinical to clinical and commercial phase



Dissolution profile of caffeine:lactose filled capsules EUDRACAP® preclinic enteric (purple) and EUDRACAP® enteric (grey).

This information and all further technical advice are based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third-party intellectual property rights, especially patent rights. In particular, no warranty, whether expressed or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used.

Evonik Operations GmbH
Health Care Business Line

healthcare@evonik.com
www.evonik.com/healthcare