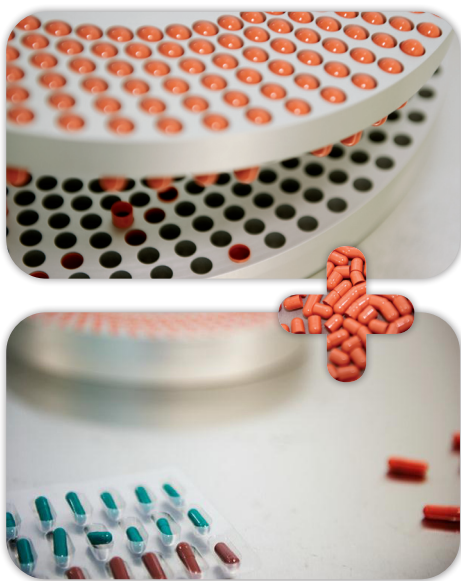


Over-encapsulation/blinding

Requirements for comparative clinical studies are increasing. Over-encapsulation/blinding is a key solution. Hand it over to the European Specialists.



Creapharm brings its expertise to blinding.

Although it has already been used for some time, over-encapsulation is a sophisticated process which needs expertise to meet the requirements of Annex 13 (Manufacture of IMP), notably at 3 steps :

1. Considering key parameters in the choice of the appropriate process

- the clinical protocol and the possible complexities of the treatment to be compared,
- size and shape of IMP and comparators (active and placebo) to select capsules shells and components,
- choice and blending of the excipients to ensure dissolution and bioavailability,
- volumes to apply manual or automated processes.

2. The careful GMP execution

- ensuring 100% count and fill accuracy,
- setting up of appropriate IPCs and reconciliation procedures, coherent with the selected process.

3. The control capabilities

- dissolution tests,
- stability studies for expiry date definition,
- pharmaceutical control and release.

Creapharm facilities and equipments are one of the most powerful and versatile cGMP capacity in Europe.

Creapharm has extended its capacities by building and qualifying a new GMP zone of 520m², dedicated to :

- bulk production and capsule filling (actives and placebos),
- semi-automated capsules filling and over-encapsulation,
- any sizes and types of capsules (coni-snap and DB cap capsules),
- automated or manual deblistering,
- over encapsulation of 1/2 or 1 tablet or multiple units or capsules.

This new area, classified ISO8, includes a sampling and weighing room and four suites with independent airlocks and air treatment systems. One suite is equipped with 100% air renewal and individual protections to handle sensitive hipo products.

A 21 Years' experience and an impressive track record :

- **Close to 200 batches have been produced and released,**
- **Over 4.5 million blinded capsules will have been produced and released in 2011 only.**

creapharm ⁺⁺⁺
international clinical supplies

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