Recipharm

SOLUBILITY ENHANCEMENT

Today many new drug candidates have a low aqueous solubility. This causes several problems. For example, in oral administration it often results in low and variable bioavailability. For intravenous administration it is difficult to deliver the intended dose in a suitable volume. When it comes to addressing these issues there are two widely adopted approaches, the solid state properties of the drug substance can be modified in order to increase solubility or the drug product can be modified in order to limit the effects of the low solubility.

Solubility issues affect all stages of drug development from preclinical through to late phase and commercial manufacture. The potential impact at each phase is outlined below:

- In the preclinical stage, solubility enhancement may be needed to achieve sufficient exposure for *in vivo* studies
- In the early clinical stage, non-complex approaches to enhance solubility are needed in order to be able to perform phase I studies
- In the later clinical phase and for commercial manufacture, technology that is well suited for routine production is needed

A range of technologies, with varying degree of complexity, are available for solubility enhancement. Which technology to choose will depend on the development stage you are in, the chemistry of the drug substance and the patient needs and market considerations. This means in-depth knowledge and experience of solving solubility issues is essential.

At Recipharm, we focus on well proven technologies for each stage. In the early product development stage, we prioritise solutions that allow you to perform the desired preclinical or clinical studies without adding unnecessary complexity while keeping an eye on later stages and manufacturability. Our chemists can also work with you to fine tune the solid-state properties of your molecule if desired.

In late stage development, our focus is on effective scale-up and robust manufacturing methods. We have an experienced team of formulation scientists that will help you to find the right solution to your solubility problem. We offer a package including a number of related services such as analytical chemistry, clinical manufacture, packaging and labeling.

At Recipharm we offer:

- Solubility enhancement using well-established methods, including those listed below:
- Methods focusing on the drug product services
  - pH-adjustment
  - Co-solvent
  - Surfactants
  - Polymers
  - Lipid systems
  - Cyclodetxrin complexes
- Methods focusing on the drug substance
  - Micronisation (in collaboration with partner)
  - Solid-state studies and modification of the drug substance
  - Salt formation
- Solubility enhancements for different administration routes, from oral to parenteral
- Solutions that are well adapted to the stage of the project, from phase I to full scale manufacture
- Fee for service, no royalties
- Complete end-to-end service from development to commercial manufacture

About Recipharm: Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and are continuing to grow and expand our offering for our customers.

Employing around 9,000 people, we are focused on supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 25 years we have been there for our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. Despite our growing global footprint, we conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do. That's the Recipharm way.

For more information contact: info@recipharm.com

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