LCP
LIFECYCLE PHARMA

Improving Treatments
Improving Lives

MELTDOSE® – A BETTER WAY TO BETTER DRUG ABSORPTION

FIVE REASONS TO CHOOSE MELTDOSE®

Clinically Proven

- The ability of MeltDose® technology to increase bioavailability and/or reduce food effect has been confirmed in numerous clinical studies with a range of poorly soluble compounds
- MeltDose® technology is the basis for partnerships between LifeCycle Pharma (LCP) and several leading international pharmaceutical companies

Commercially Viable

- The first MeltDose® based product, Fenoglide™, is approved by the FDA and marketed in the USA
- Several MeltDose® based products are in late stage development and have already been manufactured on a commercial scale
- The MeltDose® manufacturing process has been inspected by the FDA and is fully validated in commercial scale
- The approval process is facilitated by the fact that MeltDose® uses exclusively GRAS excipients

Patent Protected

- MeltDose® basic patents do not expire until 2022
- MeltDose® is an efficient Life Cycle Management tool allowing patent life extension of marketed products

Scalable and Transferable

- MeltDose® employs conventional manufacturing equipment, does not require significant additional investment and is easily scalable to commercial batch sizes
- LCP can offer a customized technology transfer program to allow you to manufacture your own MeltDose® based products
- MeltDose® manufacturing process has already been established at leading CMOs in both Europe and the USA

Cost Effective and Flexible

- The cost of goods of MeltDose® based tablets is comparable to that of conventional plain tablets
- MeltDose® can be used to create customized release profiles including immediate or controlled release and is suitable for enteric coating
- MeltDose® is a solvent-free, one-step process that can also be carried out in an inert atmosphere. The resulting granulate is suitable for direct compression to tablets

LCP OFFERS CUSTOMIZED DEVELOPMENT PROGRAMS TO IMPROVE ORAL BIOAVAILABILITY OF POORLY SOLUBLE COMPOUNDS

Now there is a faster and more cost-effective way to enhance absorption in order to improve drug availability and clinical profile.

Improving drug absorption can:

- increase a drug's efficacy
- enable lower dosing
- reduce food effect
- and in some cases, even reduce side effects

MeltDose® technology is a one-step industrial process designed to enhance the oral bioavailability of poorly water soluble drugs.

MeltDose® has been validated:

- in numerous clinical studies
- in partnerships with several leading pharmaceutical companies
- by the FDA approval and launch of Fenoglide™ on the US market

The first MeltDose® base product Fenoglide™, is on the market in the US.

MELTDOSE® – IMPROVE DRUG SOLUBILITY AND YOU IMPROVE THE PATIENT'S QUALITY OF LIFE

Low bioavailability of poorly soluble drugs is a common problem in drug development and can have negative consequences for patients. Independent studies have shown that approximately 30% of existing drugs have poor absorption due to low water-solubility*. This is critical because the efficacy of a drug depends on how well the body absorbs and circulates the active substance to the treatment site. Low water solubility often results in large variations in the drug's bioavailability and creates "food effect" or different absorption when the drug is taken with or without food.

Reduced bioavailability means the difference between getting too much medication or not enough. Too much medication can lead to adverse side effects while too little often results in reduced efficacy. These variations can compromise patient compliance and potentially diminish the quality of life for patients who depend on the effectiveness of their medication.

LCP (LifeCycle Pharma) has developed a revolutionary new and proprietary technology called MeltDose®. Unlike other more costly and complex technologies, MeltDose® is a one-step process designed to enhance the absorption of drug substances in the body by incorporating a more soluble form of the drug in the tablet matrix.

* Technology Catalysts International: Delivery of Poorly soluble of Poorly Permeable Drugs, 4 ed.

MELTDOSE® – BREAKTHROUGH TECHNOLOGY THAT'S MORE EFFECTIVE

The majority of conventional drug delivery technologies aimed at increasing bioavailability of compounds with low water-solubility rely on reduction of the particle size of the drug substance. Such processes can be costly to control and implement and difficult to manage. MeltDose® technology does not rely upon a complex milling process to achieve particle size reduction, but involves creation of a solid dispersion, or a solid solution, of the drug substance through a simple physical process. This makes it easy to implement using conventional manufacturing equipment and more flexible to work with than other technologies used to improve solubility.

MELTDOSE® – HOW IT WORKS

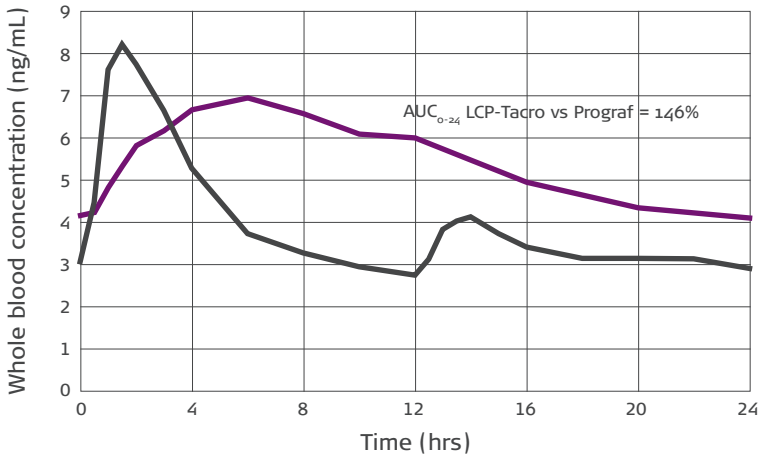
The process patented as "Controlled Agglomeration**" works by incorporating the drug substance with low water-solubility into a "meltable" vehicle. It is then sprayed on an inert particulate carrier using fluid bed equipment. The melt is solidified when deposed on the particle carrier, and thus captures the active drug in a solid dispersion either as a solid solution or in a nano-crystalline state. The particle size is then increased by controlling and optimizing the product temperature and feed rate of the melt. The granulate can be directly compressed into tablets without additional processing steps besides blending with a lubricant. In addition, the technology allows for customization of the release profile, to create various profiles including immediate and controlled release versions. Once in tablet form, the dissolution profile and the particle size of drugs manufactured using MeltDose® technology remain stable allowing for a long shelf-life.

** US patent No. 7.217.431.

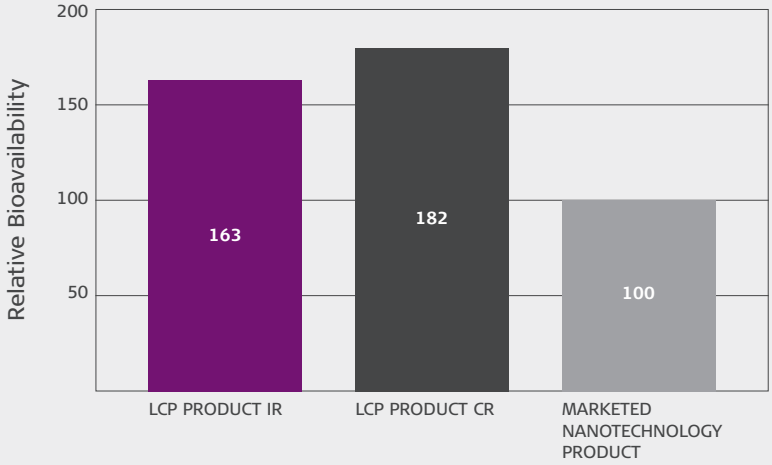
Multi-dose Steady State (Day 10) – 2 mg LCP-Tacro qd vs 1 mg Prograf® bid

(N=25, normal healthy volunteers)

- Treatment A: 1 LCP-Tacro 2 mg Tablet (q.d.)
- Treatment B: 1 Prograf 1 mg Capsule (b.i.d.)

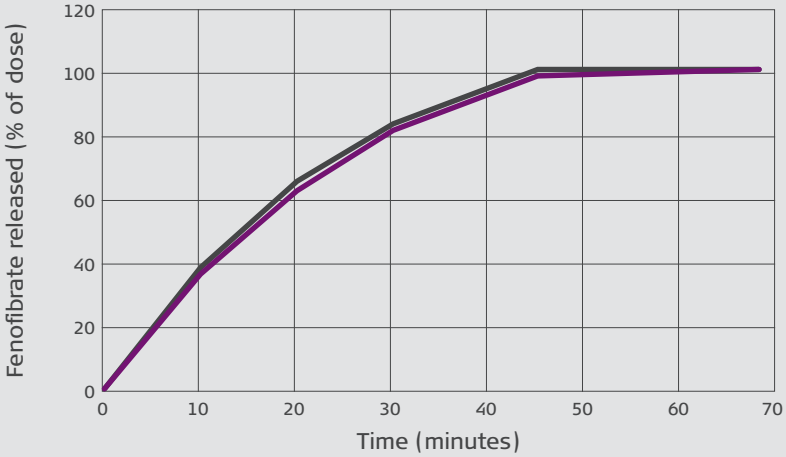


PK Study in Healthy Volunteers; Comparison of Oral Biovailability of LCP-CR and LCP-IR Product and Marketed Nanotechnology Product



Dissolution Profiles of LCP-Fenofibrate 120 mg Tablets – Initially and After 18 Months Storage at 25°C / 60% RH

- 0 months
- 18 months

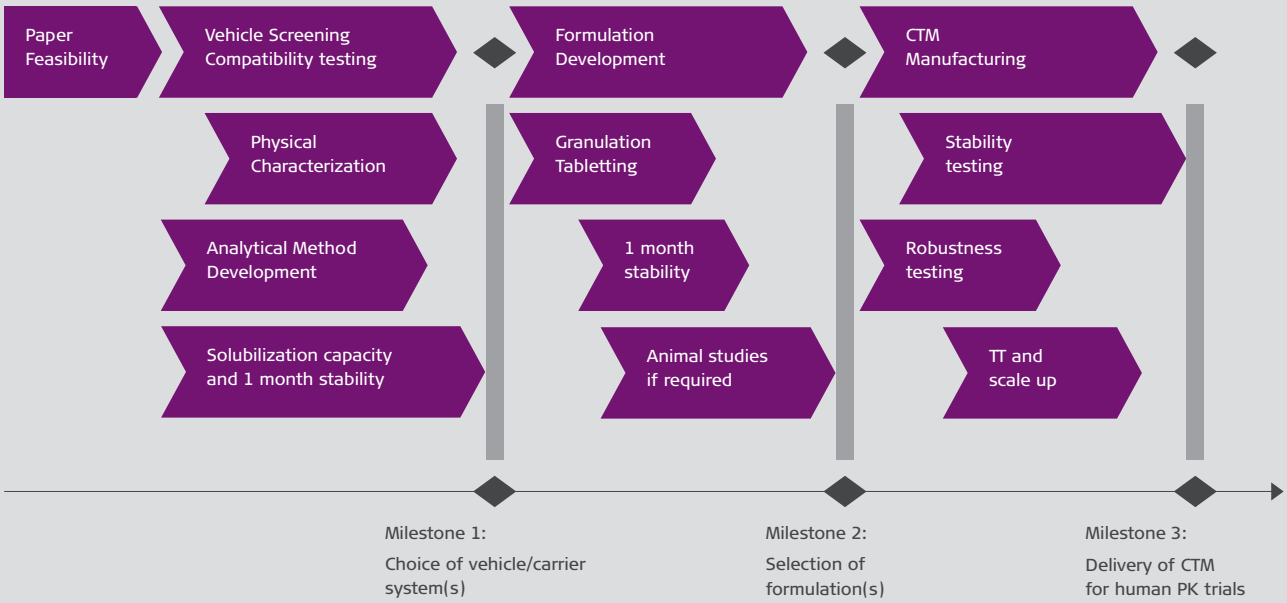


MELTDOSE® FOR YOUR PRODUCT – HOW TO GET STARTED

LCP offers a customized development program to improve oral bioavailabity of drug compounds. A typical project starts with a three month feasibility program where we take a given API and evaluate the possibilities to develop and manufacture using MeltDose®. In the next phase, which takes approximately three months, we deliver several non-GMP prototypes for animal trials.

Next step is the GMP manufacture of clinical trial supplies for human trials, allowing you to be in clinical trials with your new MeltDose® based product within approximately nine months from start. Finally, we assist you in technical transfer to the facility of your choice. The entire process is illustrated below.

Feasibility programs



LCP AND MELTDOSE® – HELPING YOU MEET THE UNIQUE NEEDS OF KEY THERAPEUTIC MARKETS AND PATIENT POPULATIONS

Whether you are looking to develop new formulations or to improve the efficacy of existing ones, MeltDose® technology gives you a cost-effective way to deliver innovative products that will help improve the quality of life for patients.

LCP is an emerging specialty pharmaceutical company, focused on certain cardiovascular indications and organ transplantation in particular. Our proprietary MeltDose® technology platform is designed to enhance the release and absorption of drugs in the body by incorporating the drug in a soluble form in a tablet matrix.

LCP is an international company with headquarters in Copenhagen, Denmark and a fully owned subsidiary in New York, in the United States. The Company was founded in June 2002 as a spin-off from Lundbeck A/S and is listed on the OMX Nordic Exchange (OMX: LCP). LCP is a member of the MidCap+ index.

LEARN MORE ABOUT LCP AND MELTDOSE®

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Learn more about LCP and MeltDose®

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