

## TECHNOLOGY OFFER

### Continuous manufacturing of porous pharmaceutical dosage forms via hot-melt extrusion (HME)

It is to be expected that porous carriers loaded with drug candidates can be used as advanced drug delivery systems or medical devices in order to achieve a desired release profile by specific adaptation of the pore profile. Until now, it has not been possible to continuously and precisely produce specific pore systems in pharmaceutical dosage forms. This technology enables the manufacturing of porous pharmaceutical dosage forms or medical devices in a controlled manner while at the same time taking into account the desired release profile of an active ingredient.

#### BACKGROUND

Currently, scCO<sub>2</sub> and chemical blowing agents are used in hot melt extrusion (HME) for plasticizing. This usually leads to the formation of pores in the extrudate, but these are a "random by-product" and their distribution and properties are not uniform.

#### TECHNOLOGY

The core of this technology is the continuous production of differently shaped porous extrudates by means of HME using blowing agents such as gas or gas-emitting substances. The extrudates are made of thermoplastic polymers, which are biocompatible and biodegradable (e.g. ethylene vinyl acetate, polyurethane, polyglycolic acid, caprolactone and other absorbable and non-absorbable polymers). Loading of both small and large molecules is achieved by direct addition of the candidate during the manufacturing process or by subsequent processes such as impregnation. The controlled pore system allows the release profile of the active ingredients to be tailored to different specific requirements (e.g. prolonged release, immediate release, etc.).

#### ADVANTAGES

- Continuous manufacturing of porous extrudates saves time and resources
- Access to a variety of drug-release profiles
- Processing of "challenging" drugs
- Various advanced drug delivery dosage forms including implants, tablets, pellets, films etc. can be manufactured

#### FURTHER DEVELOPMENT

- Testing of various polymers under controlled conditions
- Characterization platform for pore systems correlated with drug release profiles
- Loading with small as well as large molecules using different loading options

#### MARKET

Development of new drugs such as biologics as well as advances in the understanding of human biology and disease are market drivers that require new strategic approaches to drug delivery. For the forecast period 2019-2024, it is proposed that the global market for advanced drug delivery systems will register itself with a compound annual growth rate of 5 percent\*. These facts clearly show that there is an urgent need for individually dosable and applicable systems such as the one described here.

\*<https://www.arrowedge.co.uk/growth-and-trends-advanced-drug-delivery-system-market-from-2019-2024/>



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#### KEYWORDS:

HOT-MELT EXTRUSION (HME)  
CONTINUOUS HME  
CONTROLLED DRUG RELEASE  
DRUG DOSAGE  
POROUS DOSAGE FORMS  
DEVELOPMENT OF DOSAGE FORMS  
IMPLANTS  
TABLETS  
PELLETS  
FILMS

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#### COOPERATION OPTIONS:

LICENSE AGREEMENT  
OWNERSHIP AGREEMENT  
R & D AGREEMENT

#### DEVELOPMENT STATUS:

TRL-3 TO 4

#### STATUS OF PATENTS:

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