

Oral drug delivery technologies

EUDRATEC® SoluFlow

Our solubility enhancement service for particle-engineered free-flowing amorphous solid dispersions



Solubility enhancement is still one of the key challenges in oral small molecule drug development. Over 70 percent of all small molecule new chemical entities are poorly soluble. Yet these molecules are important for therapeutic areas such as cancer, cardiovascular disease, infectious diseases, diabetes, and the central nervous system. EUDRATEC® SoluFlow is a process technology and service package that produces particle-engineered, free-flowing amorphous solid dispersions (ASDs) for oral drug delivery.

ORAL DRUG SOLUBILITY CHALLENGES

- A large number of poorly soluble new chemical entities
- Solubilization of highly challenging compounds is still difficult
- Existing manufacturing technologies cannot solve all solubility hurdles
- Particle engineering control is very complex
- Therapeutic potential is dependent on formulation and process
- FIH (first in human) requires a larger amount of API than available from discovery

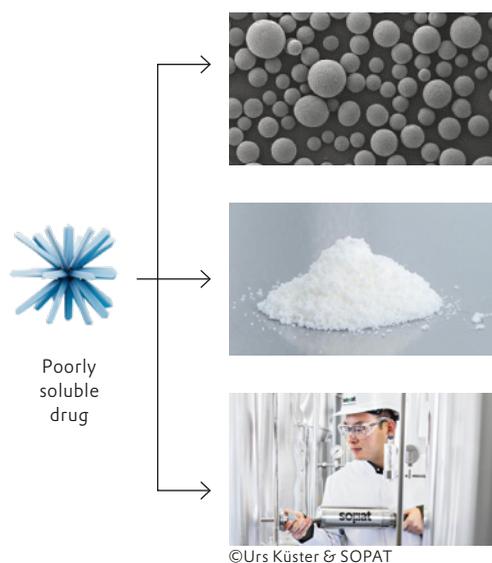
BENEFITS OF EUDRATEC® SOLUFLOW

Solubilizes highly challenging compounds

Creates free-flowing powder through lean process with advanced particle-engineering control

Leverages full therapeutic potential

Pharmaceutical processing technology turns poorly soluble drugs into soluble intermediates



Process

Unique emulsion-based process based on standard pharma equipment to manufacture uniform microparticles with a controlled target particle size at high yield

Product

Soluble free-flowing amorphous solid dispersion intermediates that can easily be compressed to tablets or filled into capsules

Phases

Development and manufacturing services of soluble intermediates from lab to commercial scale using mathematical scale-up models and online droplet size measurements

Seamless transition from pre-selection to clinical and commercial is key

SOLUBILIZE EXTREME APIs	LEAN PARTICLE-ENGINEERING CONTROL	LEVERAGE FULL THERAPEUTIC POTENTIAL
<ul style="list-style-type: none"> ▪ Low temperatures and low mechanical stress ▪ Broad range of suitable solvents ▪ High API/carrier solution concentrations ▪ Convenient HPAPI handling 	<ul style="list-style-type: none"> ▪ Controlled particle-engineering ▪ Uniform free-flowing powder ▪ Ready-to-fill solid dispersions 	<ul style="list-style-type: none"> ▪ Seamless scalability ▪ One process from pre-clinics to commercial ▪ FIH (first-in-human) with low amount of API

EUDRATEC® SoluFlow enables superior pharmacokinetic performance

Explore the benefits of EUDRATEC® SoluFlow to:

- Design powders under controlled conditions with precise particle size and shape
- Optimize manufacturing processes for stress conditions and process steps
- Scale from early preclinical development to production scale with mathematical scaling model

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 express 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
evonik.com/healthcare