EUDRATEC® SoluFlow

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

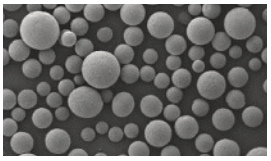
Solubility enhancement is still one of the key challenges in oral small molecule drug development. Over 70 percent of all small molecule new chemical entities are poorly soluble. Yet these molecules are important for therapeutic areas such as cancer, cardiovascular disease, infectious diseases, diabetes, 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	BENEFITS OF EUDRATEC® SOLUFLOW
▪ 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	**Solubilizes highly challenging compounds** **Creates free-flowing powder through lean process with advanced particle-engineering control** **Leverages full therapeutic potential**

EVONIK
Leading Beyond Chemistry

Pharmaceutical processing technology turns poorly soluble drugs into soluble intermediates

Poorly soluble drug



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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
▪ Low temperatures and low mechanical stress ▪ Broad range of suitable solvents ▪ High API/carrier solution concentrations ▪ Convenient HPAPI handling	▪ Controlled particle-engineering ▪ Uniform free-flowing powder ▪ Ready-to-fill solid dispersions	▪ 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

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