SeraNovo

OVERCOMING POOR SOLUBILITY USING DEEP EUTECTIC SOLVENT TECHNOLOGY

ANSWERS TO THE 10 QUESTIONS WE GET ASKED THE MOST

How does your technology enhance oral bioavailability?

We design formulations that are based on deep eutectic solvents. Our formulations present the API in predissolved form to the gastrointestinal fluids, which generates much higher concentrations than those achievable via dissolution of the crystalline form. These enhanced concentrations increase the driving force for API absorption.

What are the key benefits of your technology?

Our formulations have higher API loading capacity and are easier to manufacture than formulations based on competing technologies.

What is the maximum API loading achievable using your technology?

This is obviously highly API-dependent, but generally our API loadings are in the range of 20-40%. For APIs whose solubility is limited by high melting point (the so-called "brick-dust" APIs), our technology clearly outperforms traditional solubilisation technologies.

How are your formulations manufactured?

The API is mixed with the excipients under mildly elevated temperature until a homogenous solution is formed. This process is conducted using standard pharmaceutical mixers (for example the Ekato Unimix series of mixers).

What type of dosage forms can I develop from your formulation platform?

Our formulations are developed as liquids and can be filled into capsules or used as such. Solidification of our formulations and subsequent tablet compression is also possible, but requires more complex manufacturing techniques.

Do your formulations show side effects?

Our deep eutectic solvents are constructed only from excipients with widely documented safety, such as sugars, sugar alcohols or amino acids. To design our formulations, we use a combination of three to five excipients, which improves tolerability as side effects are typically related to exceeding a threshold level for a single component.

Can I use your formulations in GLP-toxicology studies?

Yes, given the high API payloads achievable using our technology, our formulations are ideally suited to support GLP-toxicology studies or any other preclinical studies where high doses need to be administered. The viscosity of our formulations is compatible with gavage dosing.

Can I use your formulations for parenteral administration?

Yes. Our formulations can be administered via the *intravenous* route. During the formulation design, we narrow down our list of candidate excipients to those that are approved for intravenous use, and pay close attention to endpoints of pH, buffer capacity and osmolality.

Can you also support clinical and commercial manufacturing of your medicinal products?

We do not have GMP-manufacturing capabilities in house at SeraNovo. GMP-manufacturing can either be conducted by our network preferred suppliers or by a supplier of your choice. We guide technology transfer all the way through.

What is the regulatory status of your technology?

Since we *do not make novel excipients* but instead tailor-make formulations using *existing* excipients, regulators evaluate our formulations in the same manner as formulations based on established technologies.

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CONTACT