



UNLOCKING THE SOFTGEL FORMULATION OPTION USING
SERANOVO'S DEEP EUTECTIC SOLVENT TECHNOLOGY

SeraNovo

A CASE STUDY WITH FEXOFENADINE

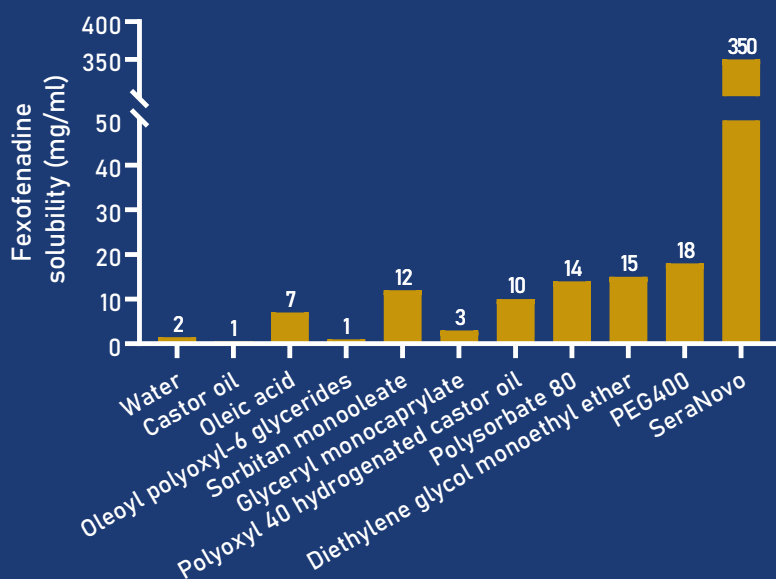
FEXOFENADINE

Fexofenadine is a widely used over-the-counter (OTC) drug to treat hay fever, seasonal allergies and urticaria. It is commercially available in a variety of presentations, including tablets, powder-filled capsules and suspensions. However, there is no fexofenadine softgel formulation on the market, in spite of a strong preference for this type of dosage form by the consumer healthcare market. This is related to the low solubility of fexofenadine in liquid excipients, combined with a high dose requirement (180 mg).

CREATING UNPARALLELLED SOLVENT CAPACITY USING SERANOVO'S TECHNOLOGY

The data in the figure below show fexofenadine's solubility in water and a range of common liquid excipients. Fexofenadine's solubility in water is high enough to allow complete dissolution of the highest unit dose (180 mg) in the gastrointestinal fluids and its *bioavailability* is therefore *not solubility-limited*. However, its solubility in liquid excipients is too low to enable the design of a liquid-filled softgel that can contain a 180 mg dose in a single unit of acceptable size.

Fexofenadine solubility



Using our deep eutectic solvent technology, we have developed a physically and chemically stable liquid fill, containing 350 mg/ml of fexofenadine. This enabled us to fill a 180 mg dose in a single size 10 softgel.

CONCLUSION

The current results illustrate that our technology may be usefully applied to unlock certain formulation options for drugs with *low solubility in liquid excipients*. In this case, we have enabled the development of a single-unit softgel containing 180 mg of fexofenadine, which conventional solubilisation technologies have been unable to do. The ability of our deep eutectic solvent based formulation platform to create highly solubilising formulations for the most physicochemically diverse drugs opens up myriad new product development opportunities in both the prescription drug as well as the consumer healthcare market.

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