Innovation Experience GMP-Manufacture

Making your Drug soluble with the Dispersome® Technology

An integrated path to market with Zerion and Hovione

The Dispersome® technology was developed by Zerion Pharma to address one of the most prevalent drug development challenges: poor drug solubility. The majority of novel small molecule drugs with poor solubility require substantial efforts and sophisticated formulation work to enable them to enter clinical development.

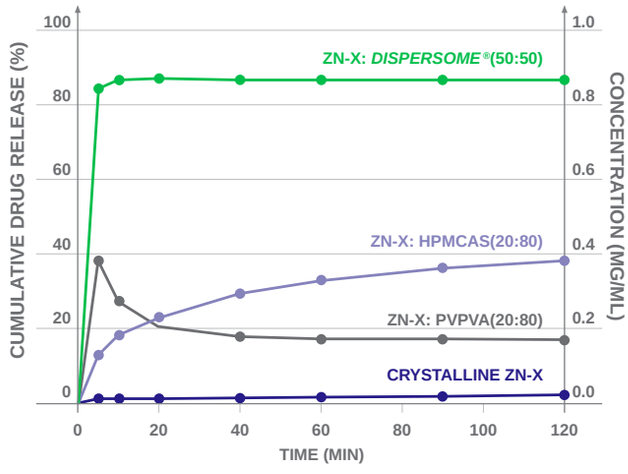
Supporting Drug Development with the Dispersome® technology

The innovative Dispersome® technology is capable of solving the poor solubility issues of your drug candidate, presenting clear performance benefits when compared to traditional excipients or enabling technologies. The Dispersome® technology can be applied at any stage of drug development including preclinical tox studies, First-in-human, replacement of existing drug formulations that present suboptimal bioavailability and life cycle management.

Zerion-Hovione Strategic Partnership

Zerion Pharma and Hovione are offering pharma and biotech companies worldwide access to an innovative drug delivery platform combined with an unparalleled experience in development, scale up and GMP manufacturing. This unique combination provides customers with a line of sight over the entire development life cycle of oral solid dosage forms from API to commercial drug product.

By partnering with us, you are ensured the best possibilities for developing a feasible drug formulation and scalable manufacturing process in the shortest time.



Drug dissolution of the poorly soluble drug, ZN-X, from different amorphous solid dispersions.

From API to GMP

Feasibility Formulation → **Animal PoC** → **Process development** → **Upscaling** → **Clinical trial material (GMP)** → **Commercial production (GMP)**

The Dispersome® technology

Zerion Pharma has pioneered the Dispersome® technology that addresses and greatly enhances poor drug solubility, one of the most prevalent drug development challenges. The API is formulated with novel protein-based excipients into amorphous solid dispersions called Dispersomes®. The technology aims to replace traditionally used polymers, achieving a higher increase in drug loading, solubility and drug bioavailability.

High solubility - High drug loading

The use of Dispersome® technology enables drug loadings above 50% w/w while maintaining stability and improving API solubility. These results have been demonstrated and proven with a wide diversity of drug entities.

BLG, an alternative to polymer excipients

Beta-Lactoglobulin (BLG), the main component in whey protein isolate (WPI), is the key excipient used in the Dispersome® technology. BLG is a natural ingredient used in both food and nutrition products, offering an alternative which is safe, easy to integrate and easy to be used in existing applications.

Processability by Spray Drying

Dispersome® formulations can be manufactured at a large-scale using Spray Drying, the most widely used and accepted particle engineering technology. Leveraging Hovione's extensive Spray Drying experience and expertise, this strategic partnership offers a clear path to clinical supplies and commercialization.

Leveraging the proprietary position of your drug

The Dispersome® technology is protected by several patent families and available for licensing on an exclusive basis within your product scope, securing a unique protection with possible life cycle extension beyond 2040.

The Leader in Spray Drying

Hovione has more than 15 years of accumulated experience and expertise in Spray Drying development and manufacture. Hovione offers a clear path to clinical supplies and commercialization of amorphous solid dispersions by Spray Drying by combining modeling capabilities and extensive process knowledge with manufacturing capacity and an excellent approval track record.

Faster time to market with a Specialized Integrated CDMO

Hovione provides integrated services for drug substance, drug product intermediate and drug product for oral and inhalation solutions. Hovione offers all capabilities at the same site, providing a safer and less complex supply chain towards commercial manufacturing, helping customers bring new medicines to patients in an unprecedented speed.

Worldwide capacity to meet your needs

Hovione is an international company with over 60 years of experience as a CDMO with four FDA inspected sites in the USA, China, Ireland and Portugal and development laboratories in Lisbon, Portugal and New Jersey, USA. Hovione provides services for the development and compliant manufacture of innovative drugs including highly potent compounds. The company also offers niche off-patent API products and provides proprietary product development.

A culture based on innovation, quality and delivery

Hovione offers your project the best scale-up science, the most up-to-date technologies and methodologies, multidisciplinary and highly experienced teams, state-of-the-art facilities, and an unblemished regulatory track record regarding products and inspections.

Contact us today to solve your solubility challenges:

info@zerion.eu I **www.zerion.eu**

dispersome@hovione.com I **www.hovione.com**