

# EPAS™ Solubilization Platform

Particle Engineering Technology for Poorly Soluble Compounds



PharmaForm's EPAS Solubilization Platform offers a powerful approach to overcoming solubility challenges and accelerating drug development. EPAS is a patented particle engineering technology that produces nano-structured particles with high surface area, rapid dissolution, improved physical stability, and exceptional bioavailability when compared to conventional formulation technologies. It is designed to transform poorly water-soluble drugs into stable nanostructured particles, without physical milling or grinding procedures.

For molecules with poor solubility, EPAS™ provides significant bioavailability and stability improvements.

## The EPAS Process

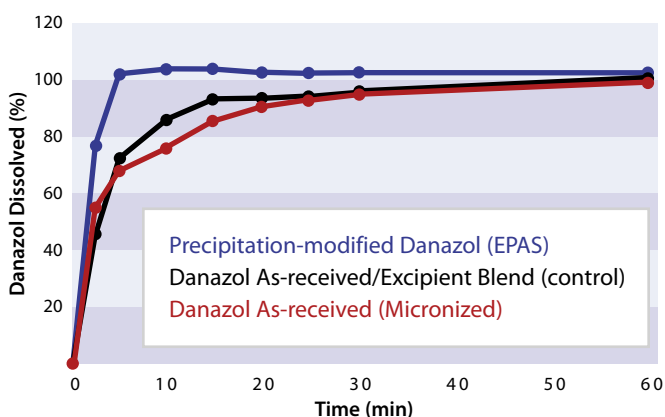
EPAS particle engineering technology uses evaporative precipitation into aqueous solution to generate nano-structured drug particles. The patent protected process involves dissolving the active in non-aqueous solvent followed by precipitation into an antisolvent, such as an aqueous solution. The rapid expansion and atomization of the solvent in the water phase causes the formation of drug particles ranging in size from nano to micro, which are then stabilized using GRAS excipients. The evaporated solvent is recovered, and the stabilized particles isolated from the aqueous phase by standard techniques.

## EPAS Engineered Particles Features

- Particle size in the range of nanometer to low micron size
- Control of particle size
- Narrow particle size distribution
- High surface area improves dissolution rate
- Enhanced bioavailability
- High drug loadings
- Stabilized to prevent agglomeration and particle growth

EPAS engineered particles can be formulated into various dosage forms, including solid oral, liquid, pulmonary and transdermal. EPAS uses conventional equipment that can be directly incorporated into a continuous manufacturing process. The process produces low levels of residual solvent and batches can be produced from pilot to commercial scale avoiding batch-to-batch variations. The EPAS platform is fast, continuous, and scalable providing for an economical manufacturing process

Figure 1: Increase in Dissolution Rate of EPAS Engineered Danazol Particles



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Particle engineering technology for poorly soluble compounds

## EPAS Benefits

EPAS enables poorly soluble compounds to reach their potential therapeutic concentration with the benefits of:

- Improved patient compliance
- Improved clinical profiles
- Reduced dose variability
- Extended patent life and product differentiation

## The EPAS Advantage

Compared to physical methods of micronization, such as wet-milling, EPAS engineered particles demonstrate a very narrow particle size range, do not agglomerate and exhibit improved particle behavior (flow). The added benefit of eliminating the concern for particle contamination observed with milling techniques facilitates high yield and efficient system validation, ensuring a smoother path towards clinical and commercial manufacturing. Unlike other particle sizing technologies, EPAS does not require crystalline API starting material.

## Our Expertise - Your Advantage

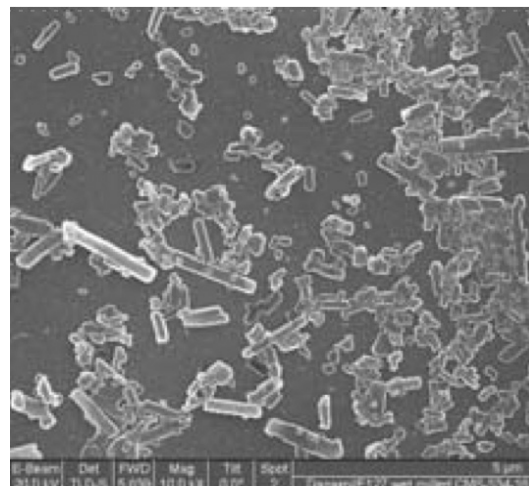
When licensing EPAS you have the option of working with PharmaForm - a seasoned contract development and manufacturing organization with real-world drug development experience. With direct experience working with the EPAS process and formulating EPAS engineered particles you have direct access to the talent you need to drive your molecule through the development process and commercial success.

## About PharmaForm

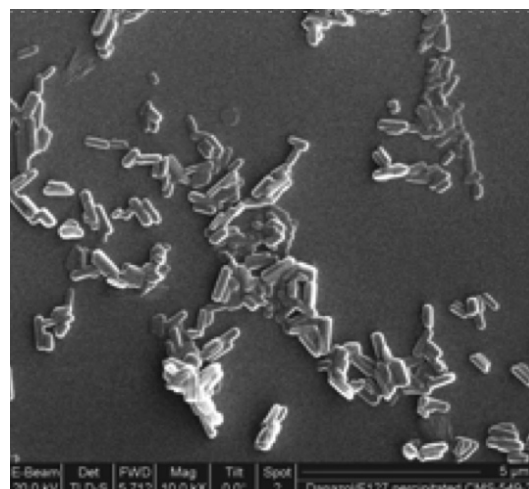
PharmaForm has a proven track record in the development and manufacture of pharmaceutical dosage forms, with complete in-house analytical and formulation development, cGMP manufacturing, stability services and scale-up capabilities. Our fully compliant FDA approved and DEA registered facilities and extensive experience in drug delivery offer companies a broad range of manufacturing options to fit their product requirements.

- 12 years experience in product development and manufacturing
- Integrated capabilities from formulation through scale-up
- Extensive drug delivery experience, including high-performance pharmaceutical formulations

Figure 2: Scanning Electron Micrographs of EPAS Engineered Particles and Wet-Milled Danazol Particles



EPAS Engineered Danazol



Wet-Milled Danazol

## Contact Info

If you would like more information about EPAS or would like to perform a feasibility study using EPAS, please contact us at [ehickman@pharmaform.com](mailto:ehickman@pharmaform.com) or +1 512 834-0449 x246.