CESSTM FOR THE PRODUCTION OF NANOPARTICLES



About Nanoform

Nanoform Finland Ltd has developed a proprietary technology called Controlled Expansion of Supercritical Solutions (CESS[™]) that allows nanonization of drug particles. Implementing CESS[™] offers new technological and business advantages for the pharmaceutical industry.

The CESS[™] technology

The patented CESSTM technology is based on supercritical CO₂. The drug solution is expanded through a controlled process to produce pure drug nanoparticles.

The process is more controlled than conventional supercritical technologies, and it produces smaller and more uniformly sized particles. Besides the particle size, also crystal polymorphism and morphology can be controlled. Several active pharmaceutical ingredients have been successfully nanonized using our technology. We have produced particles ranging from 10 nm to 2 μ m from both test molecules as well as proprietary APIs.

The reduction of particle size increases the active surface area of API and thus also the dissolution rate and bioavailability of the drug – a feature evident especially with APIs from BCS class II with poor water solubility.



Key features of the technology

- 1. Nanoparticles are made directly from solution using supercritical CO₂.
- 2. Low micron sized particles can also be produced.
- 3. Crystalline and amorphous material can be created.
- 4. The polymorphic form is controlled.

- 5. The particle size and shape can be tuned.
- 6. No excipients are used in the process.
- 7. The technology is scalable and patent protected.

Nanoforms Quality-by-Design (QbD) approach

Our process to address the nanonization of the API in a structured way is aligned with Nanoforms Quality-by-Design Principles. The overall approach starts with a scientific evaluation of the physico-chemical properties of the drug substance and the preliminary assessment of its potential processing behavior in the different steps of the CESS[™] process. Subsequently we take the API through our Proof-of-Concept steps shown in the figure below. After the initial PoC stage the readiness to enter the Proof-of-Process (PoP) step will be evaluated.



Case study 1 – Crystalline nanoparticles

Piroxicam was used as a model compound in the process and the particle size, solidstate properties, the dissolution rate, bioavailability in rats of the produced particles were evaluated. The average nanoparticle diameter was 176 nm \pm 53 nm for the batches 1-3. In comparison, the particle size of the bulk material was 7106 \pm 5639 nm



Case study 2 – Amorphous nanoparticles

Budesonide was used as model compound to demonstrate the generation of amorphous nanoparticles with different particle size distributions. The process parameters were set in the way that it was possible to nanonize tunable particle sizes of amorphous particles from the crystalline bulk budesonide as presented in the figure below.





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