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NANOMILLING: ENHANCING DRUG SOLUBILITY AND BIOAVAILABILITY

Learn more on the process of nanomilling in this issue of *The Altascientist*.

Nanomilling is a cutting-edge manufacturing technique that addresses the critical challenge of poor water solubility and bioavailability in drug development. The process involves reducing particle size to the nanometer scale, significantly increasing an active pharmaceutical ingredient's (API) surface area and improving its dissolution rate.

ADVANTAGES OF NANOMILLING

Nanomilling offers advantages beyond improved solubility, such as reduced dose volumes for parenteral administration, avoidance of harsh solvents, and the ability to produce inhalable formulations optimized for deep lung delivery. Additional benefits include reduced fed/fasted variability, faster onset of therapeutic action, and the potential for continuous manufacturing processes.

Enhanced Bioavailability

Nanomilling dramatically increases the specific surface area of APIs, leading to improved dissolution rates, enhanced drug absorption, and higher bioavailability. This is particularly beneficial for Biopharmaceutics Classification System (BCS) Class II drugs where dissolution is the rate-limiting step in absorption.

Scalable and Consistent

Nanomilling processes and equipment are easily scalable from laboratory to large-scale pharmaceutical production. Once optimized, the technique produces consistent results with minimal batch-to-batch variation, ensuring reliable drug quality and performance.

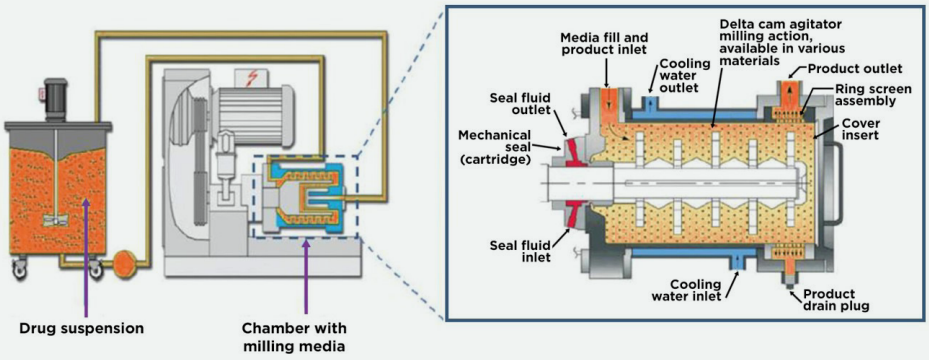
Versatile Application

Suitable for a wide range of drug delivery routes, including oral, injectable, inhalable, and buccal applications. This versatility makes nanomilling a valuable tool in formulating drugs for various therapeutic needs and patient populations.

Safety and Efficiency

The closed system design of equipment controls the milling environment and protects operators from exposure to potent compounds. Additionally, the process allows for continuous manufacturing, potentially reducing production time and costs.

THE NANOMILLING PROCESS



1

Identify Solubility Challenges

Our manufacturing team assesses the API's BCS category, focusing on Class II compounds with low solubility but high permeability as ideal candidates for nanomilling.

2

Particle Size Reduction

Targeting both simple and highly potent APIs with water solubility below 200 µg/mL, our experts use advanced equipment like the NETZSCH DeltaVita® 15-300 mill to break down coarse particles by applying mechanical energy, thus decreasing the API's molecule size to increase specific surface area. This larger surface area improves contact with water and enhances dissolution rate and bioavailability.

3

Formulation and Packaging

Once the formulation has been optimized, our scientists fill vials ranging from 0.3 to 500 ml, and package the nanoparticle suspension for various drug delivery routes.

Altasciences is an integrated CRO/CDMO offering pharmaceutical and biotechnology companies worldwide a proven, flexible approach to preclinical and clinical pharmacology studies, including manufacturing services. Our CDMO solutions encompass drug development and analytical testing services, including formulation development, Phase I through large-scale commercial manufacturing, and ICH stability storage and testing. We also provide analytical method development, qualification, validation, and finished product and release testing.

Our scientists produce nearly every available pharmaceutical dosage form using advanced manufacturing processes, including tablets, liquid- and powder-filled capsules, over-encapsulated capsules, nanomilled suspensions, creams, gels, powders, and terminally sterilized injectables.

Connect with our seasoned experts to explore how our manufacturing solutions can align with your drug development needs.

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