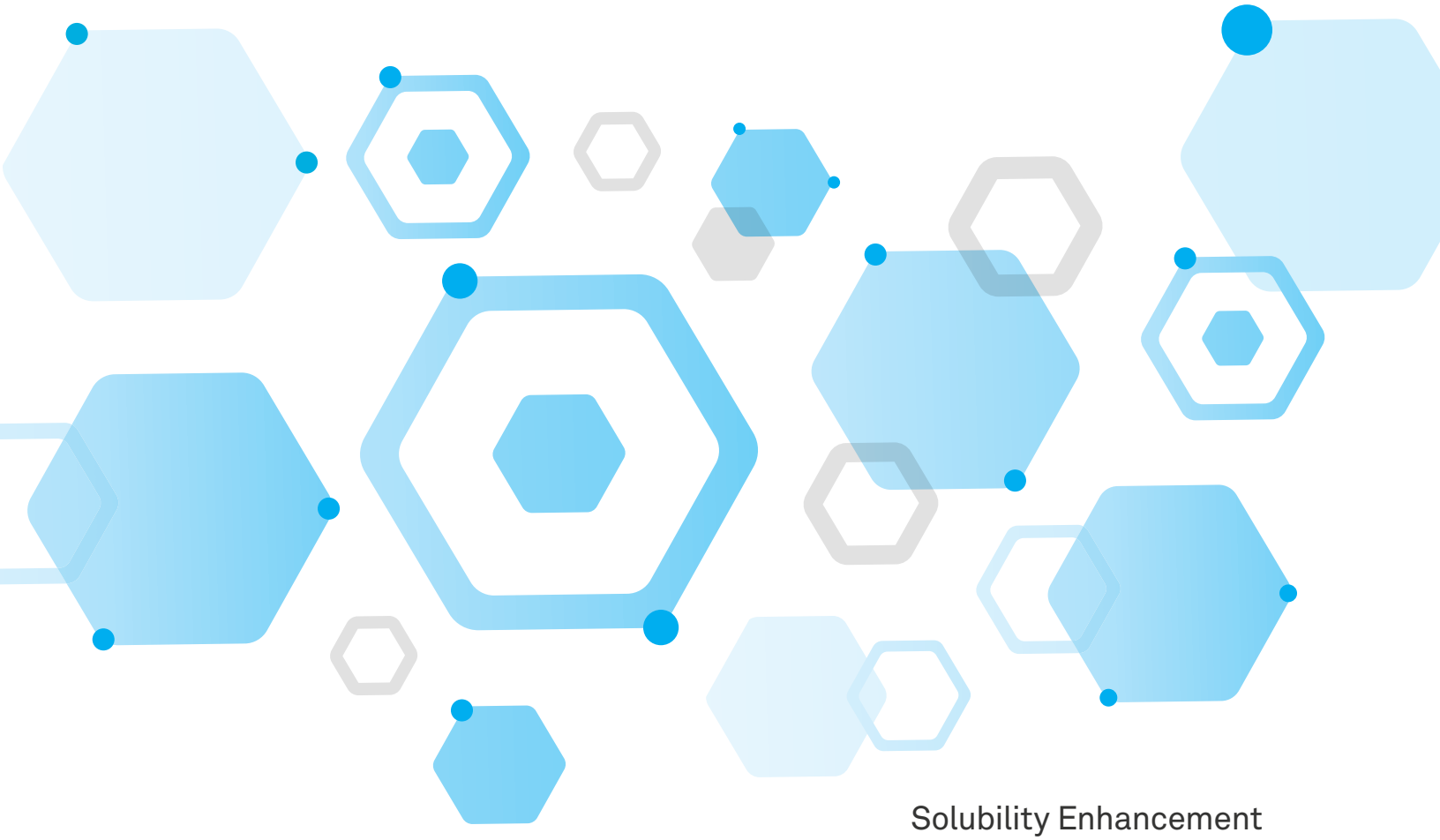
PuroMill™

Pharmaceutical milling media



Solubility Enhancement
Through Advanced Polymeric
Milling Media Technology

Purolite®

What is PuroMill™ Pharmaceutical?

PuroMill Pharmaceutical-grade milling media is an advanced polymer-based bead-form milling media that is extremely durable, reusable and chemically inert. PuroMill enables the preparation of high-purity nanoparticles for the development of small molecule pharmaceutical formulations using conventional nanoparticle milling technologies. PuroMill Pharmaceutical-grade milling media is manufactured in conformance with cGMP guidelines under stringent specifications using advanced copolymer synthesis and purification technologies that assure the highest attainable drug product quality.

PuroMill is an essential element of nanoparticle milling processes used to improve the solubility and bioavailability of poorly soluble small molecules. PuroMill media is ideal for pharmaceutical companies, CMOs and CDMOs engaging in API and formulation development of oral, injectable and inhalation dosage forms based on liquid or solid formulations. Additionally, PuroMill also effectively enables efficient isolation of macromolecules through biological cell disruption.

Improve Bioavailability of Drug Compounds Without Process-Related Contamination

- Highly purified polymeric milling media
- Produced in a cGMP certified, FDA inspected facility
- Ideal for pharmaceutical / biopharmaceutical drug formulations
- Creates drug nanoparticles < 100 nm to enhance absorption of drugs with poor solubility
- Enables efficient biological cell disruption without milling-related contamination
- Smooth, non-porous, non-adsorptive micro surface minimizes contamination
- Exceptional wear resistance minimizes particulate contamination from media attrition and equipment abrasion
- Non-reactive and biologically inert
- Autoclavable / steam sterilizable
- Low density; reduces frictional heat to prevent degradation of heat-sensitive APIs
- Available in sizes from 50 µm – 1,000 µm for optimized milling performance of drug formulations

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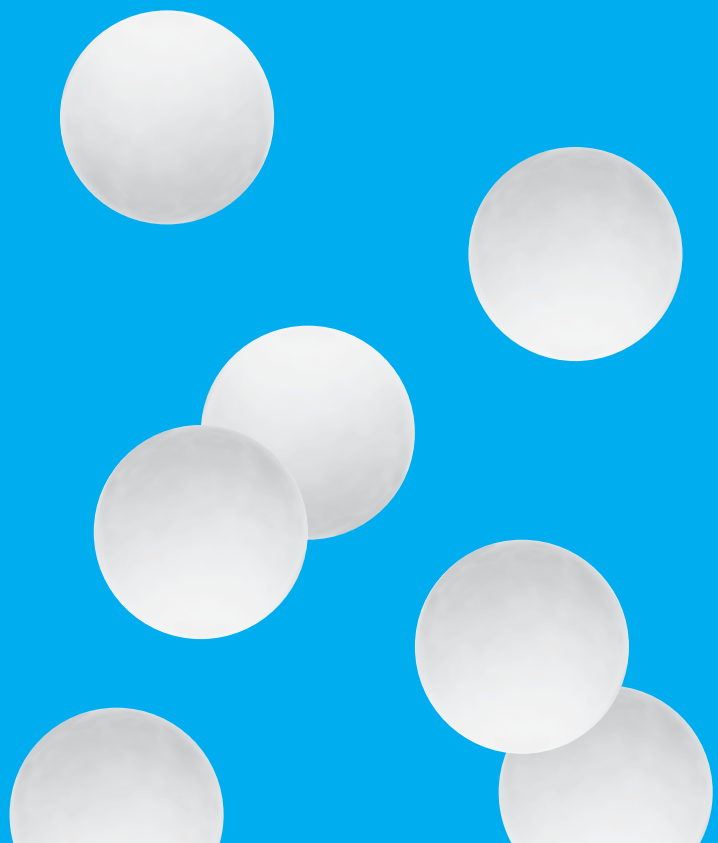
Universal Formulation Approach with Pure Drug Nanoparticles

Because of the high percentage of poorly soluble compounds in the development pipeline, formulation teams have significant challenges advancing drug products for clinical evaluation.

PuroMill Pharmaceutical-grade, high-performance milling media reduces API particles to the nano scale. Pure drug nanoparticles have increased surface area, faster dissolution and improved solubility, which can enhance bioavailability and enable customization of pharmacokinetic profiles. The results include improved drug efficacy, safety and patient compliance.



PuroMill Pharmaceutical advanced high-energy media technology minimizes the risk of contamination due to leaching as well as from attrition of milling media and milling equipment surfaces. With exceptional wear resistance, unmatched purity and milling efficiency, nanoparticles of API compounds can be successfully created with previously unattainable levels of product quality and purity.

PuroMill enables production of pure drug nanoparticles, stabilized by low concentrations of GRAS stabilizers to enable high drug loaded formulations. Pure drug nanoparticle formulations can accelerate in-vivo drug dissolution and improve saturation solubility to maximize the rate and extent of absorption. PuroMill can also help achieve ultra-fine nanoparticle formulations suitable for IV, IM and SC injections.

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Typical Chemical & Physical Characteristics

PuroMill™ Pharmaceutical PM3000

Characteristic	Test Method	Result
< 150 microns	PITM002E	0.01% (max.)
250 – 350 microns	PITM002D	95% (min.)
Volume Median Diameter	PITM002E	250 – 350 µm
Residual Monomers	PITM086B	
- styrene		50 ppm (max.)
- divinylbenzene		50 ppm (max.)
- ethylvinylbenzene		50 ppm (max.)
Residual Solvent - Methanol	PITM057F	100 ppm (max.)
Heavy Metals	PITM017C	10 ppm (max.)
Microbial Limits	PITM055A	
Total Aerobes		10 CFU/g (max.)
Total Yeasts		10 CFU/g (max.)
Total Molds		10 CFU/g (max.)
Escherichia Coli		Negative/10g
Salmonella Species		Negative/10g
Pseudomonas Aeruginosa		Negative/10g
Staphylococcus Aureus		Negative/10g
Bacterial Endotoxins	PITM055B	0.5 EU/g (max.)
Appearance	PITM001	White to off-white, non-aggregated spherical beads

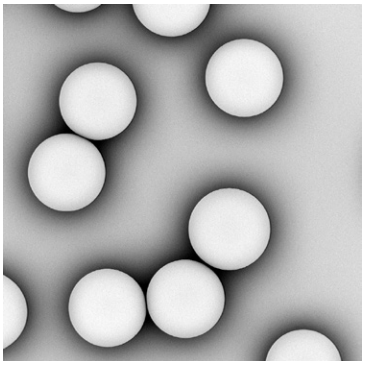
PuroMill™ Pharmaceutical PM5000

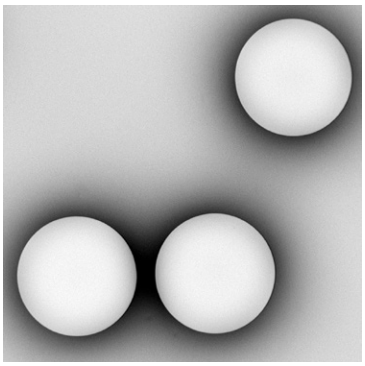
Characteristic	Test Method	Result
< 200 microns	PITM002E	0.02% (max.)
425 – 575 microns	PITM002D	95% (min.)
Volume Median Diameter	PITM002E	450 – 550 µm
Residual Monomers	PITM086B	
- styrene		50 ppm (max.)
- divinylbenzene		50 ppm (max.)
- ethylvinylbenzene		50 ppm (max.)
Residual Solvent - Methanol	PITM057F	100 ppm (max.)
Heavy Metals	PITM017C	10 ppm (max.)
Microbial Limits	PITM055A	
Total Aerobes		10 CFU/g (max.)
Total Yeasts		10 CFU/g (max.)
Total Molds		10 CFU/g (max.)
Escherichia Coli		Negative/10g
Salmonella Species		Negative/10g
Pseudomonas Aeruginosa		Negative/10g
Staphylococcus Aureus		Negative/10g
Bacterial Endotoxins	PITM055B	0.5 EU/g (max.)
Appearance	PITM001	White to off-white, non-aggregated spherical beads

PuroMill™ Pharmaceutical PM7000

Characteristic	Test Method	Result
< 250 microns	PITM002E	0.02% (max.)
600 – 800 microns	PITM002D	95% (min.)
Volume Median Diameter	PITM002E	650 – 750 µm
Residual Monomers	PITM086B	
- styrene		50 ppm (max.)
- divinylbenzene		50 ppm (max.)
- ethylvinylbenzene		50 ppm (max.)
Residual Solvent - Methanol	PITM057F	100 ppm (max.)
Heavy Metals	PITM017C	10 ppm (max.)
Microbial Limits	PITM055A	
Total Aerobes		10 CFU/g (max.)
Total Yeasts		10 CFU/g (max.)
Total Molds		10 CFU/g (max.)
Escherichia Coli		Negative/10g
Salmonella Species		Negative/10g
Pseudomonas Aeruginosa		Negative/10g
Staphylococcus Aureus		Negative/10g
Bacterial Endotoxins	PITM055B	0.5 EU/g (max.)
Appearance	PITM001	White to off-white, non-aggregated spherical beads

The smooth, non-porous, non-adsorptive micro surface of PuroMill™ minimizes contamination while the highly consistent, monodisperse particle size prevents screen binding and ensures reproducible milling performance.





Mill with Confidence

PuroMill™ is a Pharmaceutical-grade, cGMP compliant contact material.

PuroMill Pharmaceutical styrene-divinylbenzene copolymer based milling media is for high-energy wet media milling in pharmaceutical API and formulation development applications and meets exacting standards for new generations of nanomaterials processing.

Highly purified to eliminate leaching and extraction of soluble materials (including solvents and monomers), PuroMill is non-reactive and biologically inert to prevent undesirable chemical reactions and composition changes. The polymer beads generate less heat than traditional media to ensure the processed molecule remains thermodynamically stable and structurally unaltered. Additionally, the low media density (1.07 g/cc) enables high media loads and agitation speeds to maximize particle size reduction without contamination—while reducing scale-up inefficiencies associated with media centrifugation of more dense media. Plus, the monodisperse (uniform) particle size distribution and low fines composition prevents screen binding and enables easy separation from the milled compound.

In addition to use in conventional media mills, PuroMill is compatible with novel nanoparticle milling and cell disruption processes such as high-speed dispersers, homogenizers and rotor-stators.

- The only commercially available cGMP milling media for pharmaceutical and biotechnology applications
- Can be used in AISI 316 stainless steel or other suitable metal alloy mills for sanitary and aseptic applications, eliminating the complexity and cost associated with ceramic media mill equipment designs
- Conforms to stringent USP <61> and USP <85> specifications for microbial limits and endotoxins
- Complies with strict USP <233> specifications for elemental impurities
- Drug Master File registered with the U.S. FDA

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Purolite—the leading manufacturer of quality ion exchange, catalyst, adsorbent and specialty high-performance resins—is the only company that focuses 100% of its resources on the development and production of resin technology.

We're ready to solve your process challenges.
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