BASF
We create chemistry

Processing Aids for Biopharma: Downstream Applications

BASF has a long history of producing high quality urea, a raw material used in a wide range of applications. To better meet the needs of the growing biopharma industry, we now introduce Kollipro™ Urea Granules, a compendial GMP product for use in inclusion body solubilization and chromatography column cleaning. The granules allow for improved flowability, resulting in reduced agglomeration, and decreased preparation and handling time. Kollipro™ Urea Granules is offered in a fit-for-purpose 25 kg plastic box with double PE liners. Kollipro™ Urea Granules is the first offering from our Kollipro™ product family.

Kollipro™ Urea Granules

Inspiring Medicines for Better Lives
www.pharma.basf.com

BASF Pharma Solutions

Kollipro™ Product Family

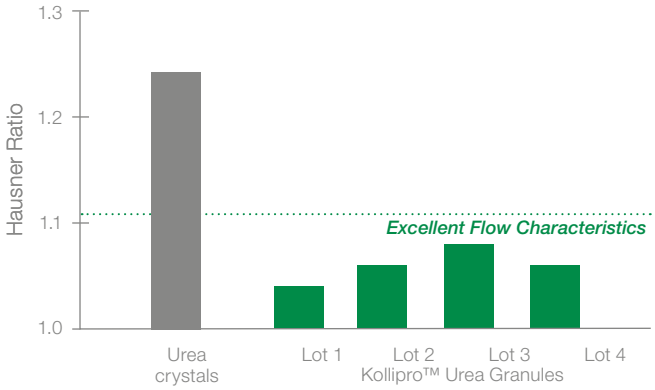
Kollipro™ Urea Granules is BASF's first offering for downstream purification for use in inclusion body solubilization and chromatography column cleaning. Microbial cell fermentation produces proteins that accumulate as inclusion bodies. Urea can be used to solubilize and purify the inclusion bodies from other impurities in the cell matrix. Furthermore, urea is also commonly used to remove lingering proteins from chromatography columns during the purification process.

Durable and wipeable plastic composition allows for easy cleaning, with the added convenience of an identification window and stackable design for optimal organization.

CAS Number	57-13-6
Compendia	Ph. Eur. USP
Packaging	25 kg plastic box with double PE liner
Biological Testing	TYMC, TAMC, endotoxins

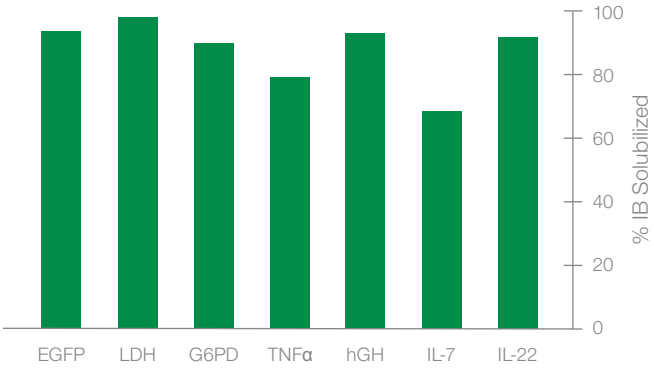
Enabling Enhanced Use as a Processing Aid in Biopharma Applications

Hausner Ratio of Urea Demonstrates Improved Flow Characteristics



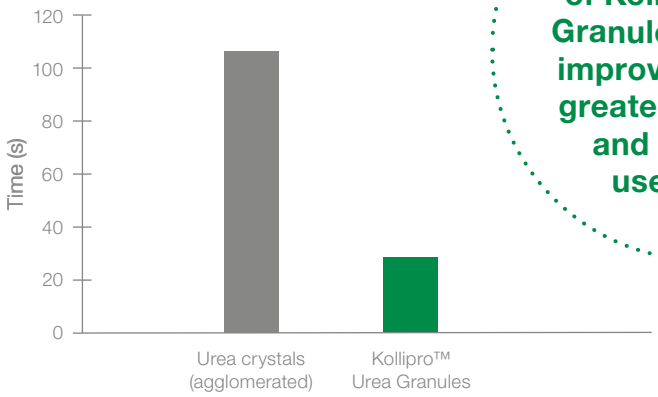
Kollipro™ Urea Granules consistently display excellent flow characteristics by having a Hausner ratio ($\frac{\text{tapped density}}{\text{bulk density}}$) below 1.11, resulting in decreased agglomeration and improved handling and flowability.

Inclusion Body Solubilization



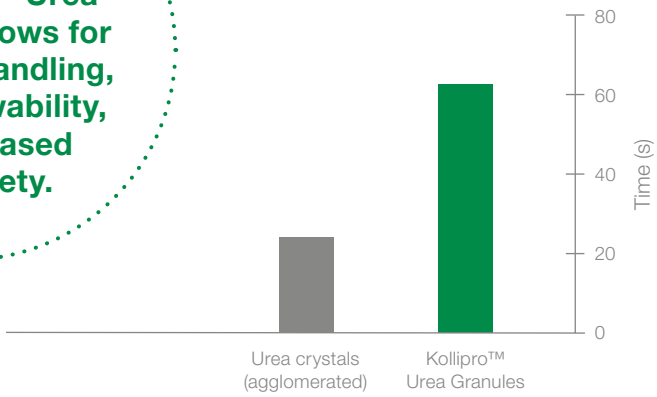
Several proteins were recombinantly expressed in E. coli as inclusion bodies and solubilized using 8 M Kollipro™ Urea Granules and 50 mM Tris, pH 8.0.

Ease of Handling



Decreased agglomeration of Kollipro™ Urea Granules allows for improved handling, greater flowability, and increased user safety.

Dissolution Time



Kollipro™ Urea Granules require significantly less time to handle and measure out. This leads to a decrease in processing time and can increase measurement accuracy. Additionally, operator safety is increased as there is no need to break apart large agglomerations.

Due to the larger particle size and reduced surface area, Kollipro™ Urea Granules dissolve at a slightly slower rate compared to urea crystals. Despite this, overall processing time is lower with Kollipro™ Urea Granules when considering the long crushing and measuring times for urea crystals.

Kollipro™ Urea Granules Production Statement

Product and corresponding manufacturing process essentially comply to relevant quality requirements as formalized within Joint IPEC – PQG Good Manufacturing Practice Guide for pharmaceutical excipients respectively in EXCiPACT GMP standard. The raw material is chemically processed – in compliance to ISO 9001 QM requirements – by reacting carbon dioxide (CO_2) with ammonia (NH_3) in a continuous manufacturing process. Kollipro™ Urea Granules raw material is taken out of the closed manufacturing process and is forwarded for further processing to Custom Powders Ltd, Crewe (UK). Custom Powders Ltd breaks, compacts, frays-out, sieves and packages the raw material to Kollipro™ Urea Granules. All related manufacturing steps at Custom Powders Ltd are executed within GMP environmental conditions using validated and qualified processes and equipment.

Exceptional Quality & Regulatory Support

The Pharma Solutions Regulatory Team has a global and regional presence with a decades-long track record of enabling our Pharma customers to register finished drug products worldwide. We do this by efficiently offering high-quality expert solutions through proactive and transparent communication.

Our global Quality Team supports our customers worldwide with regards to any quality-related questions.

A regional footprint secures quick and regional-specific solutions in alignment with global standards for topics like audits, statements and complaints.

In close exchange with authorities and international associations, we are constantly improving our quality systems to provide the best service to our customers in more and more demanding markets. For this purpose we cooperate closely with the production sites and ensure GMP-compliant production and testing in accordance with the latest requirements of the pharmaceutical authorities.

Access to standard quality and regulatory documentation is now more efficient than ever. Retrieve your documents 24/7 from myBASFWorld or sign-up for RegXcellence®, your free online Quality & Regulatory Assistant that provides a unified platform for compliance documents, filing assistance and audit information.

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BASF Pharma Solutions

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