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.

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