

UPDATE

Primary Packaging Asia



GERRESHEIMER

Customer Newsletter

July 2020

Gerresheimer Kosamba successfully conducts virtual customer audit during Covid-19 pandemic



During the Covid-19 crisis, it has been difficult to conduct physical audits because of travel restrictions. Just like all other Gerresheimer plants, our facility in Kosamba, India, has solved this problem by carrying out a virtual audit.

Kosamba is a relatively new plant within the Primary Packaging Plastics unit and, in order to start supplying products, we needed our customers to perform an audit and approve the new site.

We began the process by preparing an SOP for the virtual customer audit. This was shared with the customer and, a week before the audit, they picked up all the required quality documents for the GMP audit. A virtual meeting invitation was then set up.

On the day of the virtual audit, the site master file for Kosamba was shared to give the customer an overview of all activities being carried out at the facility.

The next step was to conduct a virtual plant tour, during which the customer had the opportunity to see the whole facility – from the changing room to the production system, the clean room, and the warehouse, etc.

After the plant tour, the customer communicated with the respective departments, covering a range of topics including quality approvals, calibrations, manufacturing, packaging, vendor approvals, dispatching, and validation documents for machines and moulds.

The virtual audit was a great success and the customer approved the site in Kosamba.

Gerresheimer Kosamba achieved ISO certification



Our new Primary Packaging Plastics facility in Kosamba (India) has achieved ISO 9001:2015 and ISO 15378:2017 certification by SGS, after having completed a two-day certification audit. Due to the coronavirus situation, the certification audit was performed as a virtual audit via MS Teams. The preparations for the ISO 45001 certification are in progress and will be completed this year.



Gerresheimer Kundli has started dispatching from Kosamba

The first customer delivery has been made from Kosamba, our second Primary Packaging Plastics (PPP) production site in India. This new site in Western India will enable us to ensure our growth, further strengthen our position in the Indian market, and get closer to our customers.



Gerresheimer Kundli (India) obtains "A" status from Chinese Center for Drug Evaluation (CDE)



Containers and closures produced at Gerresheimer Kundli have now obtained "A" status from the Chinese CDE.

This means that the products have been successfully filled with a drug at the CDE and can be used without any limitation as packaging material for the market in China.

The "A" status will also benefit any of our European customers who are planning to sell their drugs on the Chinese market, as using packaging material suppliers with "A" status means they will not encounter any risk in terms of packaging during the registration phase for their drugs. This will save the customers time with their own registration process.

GLASS PACKAGING

Gerresheimer Kosamba (India) achieved ISO 45001



Gerresheimer Primary Packaging Glass is extending its reach to every pharmaceutical industry by providing high-quality packaging materials. Our state-of-the-art tubular glass facility in Kosamba specializes in producing vials and ampoules for pharmaceutical packaging. All glass tubing used in the converting process complies with USP, JP and EP standards. In addition, our products such as glass ampoules and vials are DMF Type III registered, and all processes are carried out in controlled or ISO class environments, with clean rooms regulated by ISO and GMP standards.

Earlier this year, we launched our objective of achieving ISO 45001:2018 certification. This is a new international standard that provides a framework for organizations to manage risks and opportunities in order, for example, to prevent work-related injuries to workers. We achieved this certification in April 2020.

Our management system is now certified to ISO 9001:2015, ISO 15378:2017, and ISO 45001:2018 standard.

Primary Packaging Glass India committed to its responsibilities regarding Covid-19



The entire world is currently going through an extremely difficult time full of uncertainty and concerns due to Covid-19. However, these times are also giving rise to mutual support and solidarity, giving us the strength we need to battle through the difficulties and emerge victorious.

We promise all pharmaceutical customers that we will provide them with continuous support by meeting their pharmaceutical primary packaging requirements. All our plants are running on full capacity without restrictions, with products being delivered on time so you do not have to change your filling plans.

Our employees are fully committed to their responsibility for helping to provide essential services for the health and wellbeing of society. As well as taking care of the quality of

our products, we have also been looking after our employees by implementing the necessary precautionary measures against the coronavirus.

In addition, we have carried out comprehensive, systematic risk analyses and are prepared for any future risks.

Our focus is on fulfilling your needs without interruption and maintaining our relationship while supporting each other in this uncertain environment.

Furthermore, our plants have distributed more than 2,500 food packages to the local community, which is affected by the Covid-19 situation. We are proud and glad to help families through this extremely difficult time.

