

# Indian pharmaceutical plants serve the world

Gerresheimer's new plant in Kosamba, India has received ISO 15378 certification for the production of vials and ampoules, while a new furnace at the group's Neutral Glass factory will make type I glass.

Gerresheimer owns two plants at its Kosamba site in India: Neutral Glass and the recently completed Gerresheimer Pharmaceutical Packaging Mumbai factory to make vials and ampoules from tubular glass. Neutral Glass manufactures moulded glass products for the pharmaceutical industry. The plant will soon receive a high performance furnace to make type I glass.

## ISO 15378 certification

"Our new plant in Kosamba produces ampoules and vials made from borosilicate glass to the same high standards as apply in Europe or the Americas" says Saibal Sengupta, Sales Director. "All of our production and inspection processes are standardised and certified worldwide. In February, we received ISO 15378 certification."

The plant is already certified in accordance with the following standards: ISO 9001:2015, US DMF Type III and Health Canada (DMF). Phase I for certification in accordance with the ISO standard 15378 has been completed. The final audit was carried out by the end of January, meaning that the plant's certification runs from February.

ISO 15378 applies to primary packaging that comes into direct contact with medication. The standard covers all materials commonly used to make primary packaging such as glass, rubber, aluminium and plastic. ISO 15378 gives all contract manufacturers and all manufacturers that package such materials themselves an opportunity to secure a high

Bottles, vials and ampoules made from tubular glass for India.



GMP standard and gain international acceptance at an early stage. Suppliers of primary packaging for

pharmaceutical products benefit from the fact that the standard incorporates all the relevant GMP requirements and facilitates compliance with international, European and national law.

## Glass vials

Vials are among the world's most popular pharmaceutical packaging solutions and Gerresheimer produces versions in clear and amber glass that can hold between 1ml and 50ml. The range of tubular glass vials on offer in Asia includes clear and amber glass types I and II. All manner of different shapes are available, either with or without blowback and compliant with either international standards or the customer's own specifications.

## Ampoules

The company also offers a wide range of high quality pharmaceutical ampoules made from pharmaceutical glass type I. The standard portfolio includes ampoules made from clear and amber glass that can hold between 1ml and 30ml. Among these ▶



A diverse portfolio of glass pharmaceutical bottles is offered.

## Factory Spotlight

products are straight stem, funnel-type and closed ampoules that comply with the relevant ISO standards (types B, C and D) with various break systems such as OPC (one point cut), CBR (colour break ring) and score ring. Customer-specific requirements can also be implemented alongside the customary ISO standards.

### Camera inspection systems

Gx Rhoc, the camera inspection system developed by Gerresheimer, ensures exceptional dimensional quality for vials. Several HD cameras detect every flaw.

### Furnace rebuild

“Constructing a new furnace for type I glass will significantly enhance our quality” says Sachin Sule, Head of Sales and Marketing for moulded glass. In India, for example, Gerresheimer manufactures clear and amber glass infusion and injection bottles from type I borosilicate glass. The company also produces type III glass containers for a large number

Bottles and vials made from moulded glass for India.



Vials and ampoules made from tubular glass are produced at the new Kosamba facility.

of medications. The production line at this factory is certified in accordance with DMF (Drug Master File) type III requirements.

Gerresheimer's complete range encompasses all classes of glass used for pharmaceuticals – types II and III sodium silicate, as well as type I borosilicate. This enables the company to supply the perfect glass packaging to suit drugs of any shape or size. Its extensive glass range means that appropriate packaging solutions can be found for even the most sensitive pharmaceuticals.

A diverse portfolio of glass pharmaceutical bottles is offered, extending from the smallest glass cartridges made from tubular glass up to large acid-resistant chemicals bottles. Gerresheimer employs cutting edge techniques and monitoring technology from the development stage right through to production and packing for delivery. With bases in the Americas, Asia and Europe, the company specialises in manufacturing primary packaging for pharmaceuticals in line with the relevant pharmacopeia. All of its factories are currently certified to standards including ISO 9001. ●



The Neutral Glass plant for the production of moulded glass in Kosamba.



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### Further information:

Gerresheimer Pharmaceutical Packaging Mumbai Pvt Ltd/Neutral Glass & Allied Inds Pvt Ltd, Mumbai, India  
tel: +91 22 2926 2323  
email: [info@gerresheimer.com](mailto:info@gerresheimer.com)  
web: [www.gerresheimer.com](http://www.gerresheimer.com)