

# UPDATE

## Primary Packaging India



**GERRESHEIMER**

Customer Newsletter  
February 2019



## Plastic Packaging registered with own company in China

The building of a new satellite plant for US bottle production in Changzhou, China started at the end of 2018.



The product range will consist of plastic pharmaceutical containers with closures, and dropper bottles with accessories.

The containers will be available in sizes from 30 ml – 3800 ml and will consist of our leading Duma Twist-Off containers as well as containers with induction seals from Triveni. All containers can be supplied with different closure options (for example tamper-evident, child-resistant or senior-friendly) and with different desiccant sizes (integrated/mounted) and adsorbents.

The dropper bottles will be available in sizes from 5 ml – 15 ml with different dropper, nozzle and cap options.

The plant is certified in accordance with ISO standards (ISO 9001, ISO 14001, ISO 15378 and ISO 18001) and production will be carried out in a modern class 7 (10.000) classified cleanroom.

We ensure full conformity of our products with the European Pharmacopoeia, the United States Pharmacopoeia and FDA requirements for registration with a Drug Master File as standard. Knowing the extensive requirements of our customers, we focus on providing a high level of documentation with our products.

We expect production to start in the second half of 2019 and, in view of this, we have engaged Paul Chen as Plant Manager.



## Kundli (India): Triveni US type container range now CFDA registered for China



At the end of 2018, Gerresheimer applied for a China Food and Drug Administration (CFDA) registration of our white products manufactured at the Triveni plant in Kundli to be submitted for administrative evaluation by the Center for Drug Evaluation (CDE).

On 4th January we received a message from the consulting company, stating that the dossier had passed the administrative review and our Drug Master file (DMF) numbers have been officially published on the CDE website.

The next step is the technical evaluation to be carried out by CDE when a customer has submitted the drug dossier together with the Letter of Authorization (LoA) for our DMF.

Several Chinese customers have now started their registration process and once their dossiers pass this technical evaluation, our DMF will get active status, and the information will be listed on the platform with an "A" mark.

This means that our packaging can legally be used as a reference by our customers.

## Ophthalmic production is moving in the right direction

For some years now, we have produced ophthalmic products at our plant in Kundli. Following our growth strategy and in line with our aim to manufacture our products closer to our clients, we increased our capacity in order to supply our Asian customers with our ophthalmic range from India, where we have ISO class 7 production conditions. The Gerresheimer plant in India is the only local manufacturer of ophthalmic applications to have this production set-up in India.

It revolves around our System A dropper bottles in 5, 10 and 15 ml sizes with different dropper, nozzle and cap options. One of the cap options is the modified TE-ring that stays locked onto the bottle and meets FDA requirements. Ring retention requirements suddenly became an issue for our customers, meaning that



they quickly had to find packaging development solutions to meet this requirement. Thanks to our R&D department and our ability to adapt the product to these new requirements, we were quickly able to introduce this improvement to our caps. This solution is now also available from our plant in India in order to support the product range with single source supplies.

We offer total solutions as non-irradiated or irradiated, depending on our customers' requirements. The closeness of our irradiation partner facilitates the process of customer audits as well as logistics for supplies.

The plant in Kundli has gone through successful customer validations and we are very much looking forward to working with our customers to grow the market in the region.

### Neutral Glass & Allied Industries Our Moulded Glass plant at Kosamba (India)

The 80,000 m<sup>2</sup> site at Kosamba consists of about 36,000 m<sup>2</sup> of manufacturing facilities with a team of 460 professionals. The site has four furnaces with 14 production lines, giving us with the capacity to produce 100 million vials and bottles per year in sizes ranging from 2 ml to 540 ml.

The Neutral glass plant has the flexibility to produce three different glass types at the same time, including glass for the cosmetics sector. The manufacturing site is well equipped with world-class facilities such as the newly constructed furnace K which produces Type I Glass. The latest in glass manufacturing technology, it has a closed working end, closed forehearths and electrical heating, as well as an IS machine and a lehr for annealing.

We also have a white room inspection facility in the cold end as well as ware inspection equipment, camera inspection machines for fully automated inspection of finished articles, air compressors with oil-free clean air for processing, inspection equipment and much more.

Strict inspections and controls at every stage of the process using globally recognized quality systems such as clean room technology and camera inspection ensure that, at Neutral Glass everything we produce is of superior quality.



**IN THE NEXT ISSUE**

Increasing sales of our own CR closures