GERRESHEIMER

SAFE & RELIABLE PRIMARY DRUG CONTAINER MANUFACTURING

All wearable bolus injection devices must use a primary drug container at some stage. Some are used in conjunction with standard primary drug containers, from which the patient transfers the drug into the device at the point of use. Other wearable bolus injectors incorporate prefilled primary drug containers – standard or customised – into the device body itself. Here, Gerresheimer, a global leader in the manufacture of parenteral drug delivery systems and primary packaging, including standard and customised glass vials, ampoules and cartridges, provides a brief overview of the manufacturing process.

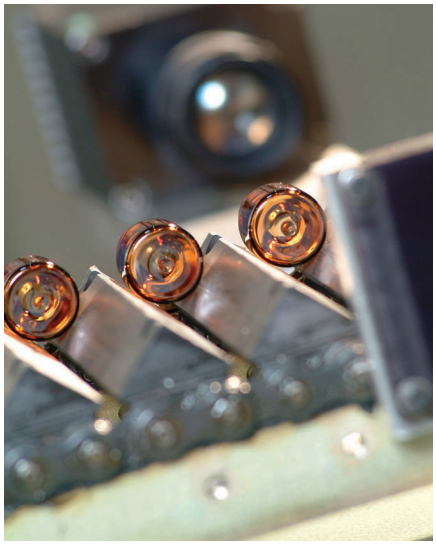

Figure 1: Vials are inspected for cosmetic defects.

Like syringes, ampoules and cartridges, vials are made of glass tubing. Vertical or horizontal production technology is used to make them, depending on whether the glass tubes are positioned vertically or horizontally in the machine.

On a horizontal forming machine, a thermal-shock process is used to cut the glass tube to the required length when it has been fed into the machine. One length of cut tube is then used to make two vials. Tiny glass splinters or dust are sometimes created when the tube is cut, which are immediately removed with pressurised air. After the tube cutter, the tube sections are transported on a conveyor belt along flames where both ends of the tube are heated and converted to create the shoulder, neck and lip in the required geometry.

In the next step, the tube is heated at the centre, pulled apart, and the two ends are formed to create the bottom. During the entire converting process, the tube sections are transported horizontally orientated, hence the name of the procedure.

In vertical manufacturing, the glass tubes are positioned vertically into chucks of the forming machine. Unlike the conveyor belt in the horizontal process, the forming machine has a rotary design like a carousel. The end of the glass tube is heated and the shoulder, neck and lip are formed by using forming tools. Then, the glass tube is heated and pulled apart. To finalise the conversion of the new vial from the short section, the other end is heated to form the bottom. During the process, glass tubes and sections are located in a vertical position, hence the name of the procedure.

After the converting process, each vial is precisely measured. If even one measurement is outside the defined tolerance limits, the vial is rejected. Then the vials go into the annealing oven to eliminate any stress in the glass caused by the converting process. This is particularly important because stress in the glass can cause cracks at a later time and render the content of the vial unusable.

When the vials have come out of the annealing oven they are inspected for cosmetic defects (Figure 1). These include cracks and scratches, as well as impurities or bubbles. After an initial camera inspection they are also inspected visually by a member of staff. Defective vials are rejected. The good vials are sealed in shrink wrap and stacked onto pallets. Geometric and cosmetic inspections of each individual vial are also performed in process (100% inline control), as well as additional random quality checks. Polarised light is used to show whether all the stress has been eliminated from the glass.

Chemical tests are used to assess the glass's hydrolytic resistance and at times a pressure test is used to measure the vial's mechanical resistance. All these quality inspections are very important to ensure that the vials don't interact with the medication, that they don't cause any problems on our customers' machines and that they don't break during transportation.

Figure 2: Traditionally vials are the storage container for parenteral drugs that are ultimately transferred into a syringe at the point of use but increasingly vials are used to transfer parenteral formulations into new-generation self-injection devices.

Gerresheimer ensures that the vials make safe packaging and that the medications arrive intact at the pharmacy, doctor's office, hospital and ultimately at the patient. Whilst traditionally vials have been used as the storage container for parenteral drugs that would ultimately be transferred into a syringe by a medical professional at the point of use (as shown in Figure 2), increasingly vials are used to transfer parenteral formulations into new-generation injection devices such as wearable bolus injectors. Similarly, drug cartridges commonly used in pens and auto-injectors are now also being incorporated into wearable injection devices. Whatever the intended end-use, patient safety is the highest priority in every single stage of the primary container production process.

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