READY-TO-USE COMPONENTS

Here, Joël Cotten, Business Development Director, Aptar Pharma, highlights the importance of sterile transfer in parenteral combination product manufacturing, and describes Aptar Pharma's portfolio of ready-to-use delivery device components that are suitable for gamma sterilisation.

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We have observed a strong trend for turn-key solutions in the very conservative pharmaceutical manufacturing field. This trend affects not only the development of drugs with ready-to-use incubators but also fill-and-finish operations, with a large number of newly installed isolators using ready-to-use components. Likewise the trend affects not only legacy glass primary containers (such as vials, bottles, cartridges and prefilled syringes) but also plastic primary containers using ready-to-use sterile closures.

Ready-to-use elastomeric closure solutions present many advantages. One of the main benefits of ready-to-use solutions is to accelerate the time-to-market and delivery of the first industrial batch of final products. Indeed, most of the validation part has been done by the producer of ready-to-use components. Formulation of the elastomer, as well as the validation of the manufacturing operations, including the washing and the sterilisation of the components, are monitored and an access to the Drug Master File (DMF) in the US (or licenses in, for example, China) is established to facilitate registration of the combination drug and primary packaging later on.

Several billion ready-to-use components are produced each year. These components are packaged in a variety of bags (examples shown in Figure 1) that could accommodate the needs of R&D laboratories, medium-sized or large injectable drug producers.

Ready-to-use components have to be processed in a clean environment with a gentle process to ensure an ultra-low level of particle contamination.

Ready-to-use components are sterilised prior to shipping to the pharmaceutical industry. Many accepted sterilisation methods exist, like ethylene oxide (EtO) sterilisation, steam sterilisation or gamma radio-sterilisation. The latter offers the advantage of being performed in leak-free

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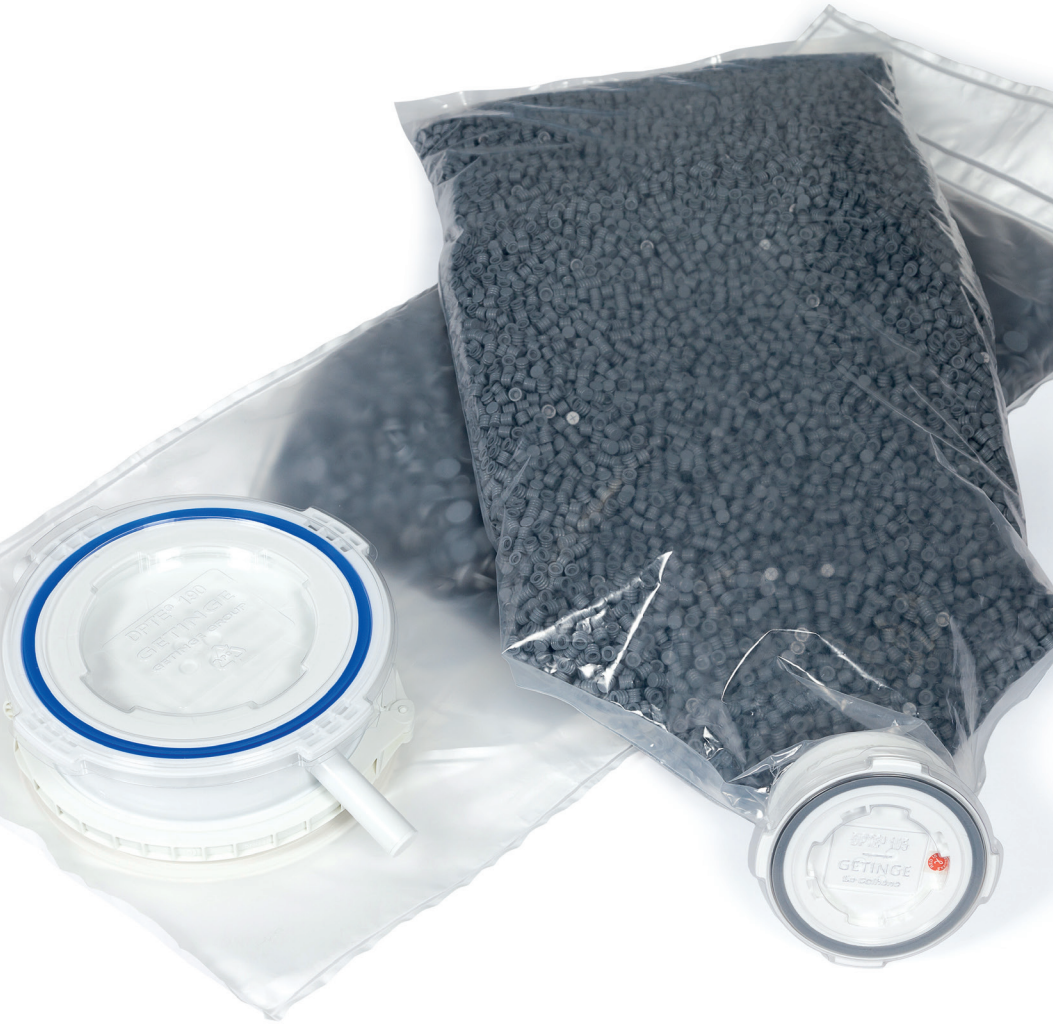

Figure 1: DPTE bags for the aseptic transfer of combination product components. (Image courtesy of Getinge La Calhène)

bags along with a controlled dose of gamma radiation, ensuring 100% sterility and a parametric release of the components.

Obviously each sterilisation method generates a slight stress on the components, and the compatibility of the final components with the drug itself has to be checked by the drug manufacturers. All of the methods are available on the market; steam is still the predominant method of sterilisation.

APTAR PHARMA'S GAMMA STERILISATION AND RTU

Aptar's RTU Gamma products are sterilised via radio sterilisation as this provides the highest level of sterility assurance. In addition, custom packaging has been designed to provide evidence of product integrity prior to its immediate use in sterile products manufacturing.

The large choice of plungers and stoppers available, in addition to the many packaging systems, ensures compatibility with most of the fill-and-finish line equipment that exists on the market, whether standard, restricted access barrier system (RABS) or isolator based.

The data and documentation supporting the RTU Gamma product facilitates its qualification and filing in conjunction with production line optimisation, new line installations and time-sensitive product developments. RTU Gamma is documented, validated and filed with key regulatory agencies to meet the highest quality, compliance and filing needs.

ABOUT THE COMPANY

Aptar Pharma is part of AptarGroup, Inc (NYSE: ATR) a leading global supplier of a broad range of innovative dispensing and sealing solutions for the beauty, personal care, home care, prescription drug, consumer health care, injectables, food and beverage markets. AptarGroup is headquartered in Crystal Lake, IL, US, with manufacturing facilities in North America, Europe, Asia and South America.

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