Coming clean

Sterility is the absolute criterion of an injectable product. Pathogenic elements are essentially neutralised by exposure to heat[1]. Sylvie Ponlot, Technoflex Autoclave says terminal sterilisation is essential for the safety of patients and does not allow the slightest error. She discusses the risks and best practices

In the bag: Sterilisation is a critical process in the pharmaceuticals industry. Technoflex inspects and tests its bags under the real-life conditions of use of the products

Sterilisation is a critical process in the pharmaceuticals industry that demands in-depth knowledge of all the parameters in play. Technoflex inspects and tests its bags under the real-life conditions of use of the products. Strict monitoring and regular checks of the autoclaves are also necessary. All new appliances must undergo initial qualification, or retrospective qualification for autoclaves that are already routinely used[2]. The conformity, quality and safety of the injectable products depend on it.

The lack of knowledge of the polymers that make up the bags or connectors can result in burst or deformed bags, damage to the twist-off or a milky appearance during terminal sterilisation. But these problems can be avoided. How? First, by gaining a better understanding of the molecules' resistance to heat, and by using sterilisation methods that are adapted to the contents. But also through the perfect command of the sterilisation cycle, from the temperature and the length of the cycle phases, to the pressure, the volume and shape of the bags to be sterilized, the number of bags in each load, etc.

PVC bags with over-packaging may turn white when terminal sterilisation takes place in a spray or stream autoclave. This occurs when the vapour works its way between the macromolecules that make up the material. The only alternative is an air-vapour autoclave with ventilation that cools down the load.

The solution itself represents another threat. When the solution is exposed to heat, it expands and applies pressure to the walls of the bag. This pressure results in deformation that can sometimes cause the bag to burst. Regulating the pressure inside the autoclave can solve this problem.

And when it comes to the temperature, each material has its own limits. Polypropylene bags must not be heated to more than 125°C, while the limit for PVC bags is just 122°C.

There are also a few special cases. Proteins that do not tolerate severe heat, such as albumin, must be pasteurised. In this case, stream autoclaves are used to expose the solution to a temperature of 60°C for about 10 hours.

[1] *Apart from molecules that do not tolerate heat and are conditioned in aseptic media*

[2] *GMP recommendations, Chapters 3 and 4 - § 4.26 & 4.28*

The three terminal sterilisation processes

Air-vapour autoclaves, with a ventilation system that drives the fluid flow, are commonly used in the pharmaceuticals industry. The solutions are heated by directly injecting saturated vapour into the sterilisation chamber. The autoclave's internal heat exchangers are filled with chilled water and the flow of cold air cools down the load.

The two other processes, which use stream or spray autoclaves, involve spraying the load with water. After being superheated in the heating phase, the water is chilled in the cooling phase. The only notable difference between these systems lies in the fact that, in the former, the fluids are dispersed by gravity, while, in the latter, the water is sprayed by jets.

Each system has its subtle differences when it comes to installing the load. Tiling consists in stacking the bags on the sterilisation trays in an air-vapor autoclave. Enough space must be left between the trays to allow the vapor to circulate optimally. This technique cannot be used in spray or stream autoclaves, because the stacked bags interfere with the free flow of the heating fluids. In these cases, the bags are placed side by side on the trays.

Gas safe

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With its extra free radical oxygen molecule, ozone is able to destroy germs, viruses, and microbes that may cause surface or air contamination. It leaves no chemical residue typical of alternative detergent or synthetic cleaners, and if handled properly - by converting ozone back to oxygen molecules - it can be one of the most effective sterilising tools. Ozone is a powerful and natural purifier, and now with the Ozilla Ozone Sterilizer, it is safer and easier than ever to use ozone gas for sterilising and deodorising lightly contaminated pipettes, pipette tips, gloves, plates, small instruments, and even personal items such as keys and glasses.