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Case study
Steam Sterilisation 2018-11

Steam Sterilisation

INSTALLATION, OPERATION AND PERFORMANCE QUALIFICATIONS

The use of steam to sterilise pharmaceutical products, equipment and reagents is the most common sterilization method. Much lower temperatures are required compared to dry heat sterilises due to the latent heat released when the steam condenses on the items to be sterilised. This is advantageous, particularly for pharmaceutical products, which may be destroyed by the higher temperatures required for dry heat sterilisation.

Steam sterilisers (or autoclaves) come in a wide variety of sizes, from small bench-top laboratory autoclaves to large production autoclaves as big as 17m3 in volume. The larger autoclaves are used for sterilising large volume parenterals such as those found in pouches, up to 5L in volume. These autoclaves can sterilize up to 5 Tonnes of product per batch. They tend to be cylindrical in shape as they are almost modular. Bottles and ampoules are sterilised in smaller autoclaves, generally, although these are often up to 2.5m3. Whatever the nature of the load, the product is loaded in trays or cages to optimise the distribution of the load. It is important for validation purposes that the load is standardised, therefore full loads are usually used. The value of the content of a sterilizer can vary enormously but batches of new product can be worth in excess of Euro 500,000.

Many pharmaceutical and healthcare products are manufactured in sterile form. The manufacturers will obviously have equipment for sterile production. The focus of the regulatory agencies such as MCA or FDA has largely been on secondary production, i.e. the formulation of product into the dosage form that the user will see. As a consequence much emphasis has been placed on the production of sterile products and all organisations producing sterile products will already be validating their sterilizers. FDA has committed to inspect suppliers to FDA markets every 2 years. This is true generally for sterile production units.

An important factor when performing validation studies is that all the temperature probes must have been calibrated shortly before the validation run (referred to as Pre Cal). They must also be checked afterwards to ensure that they are still within predefined tolerances (referred to as Post Cal). Generally, thermocouples must be +/- 0.5°C. Pressure gauges should be +/- 0.25% of maximum scale range.

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Although some sites may not have any sterile production facilities, all bulk manufacture (or primary production) will require a significant degree of microbiological support. Water and several other raw materials will require regular microbial analysis. Also, environmental monitoring (final product areas) may also be required. It is highly likely that bulk production facilities will have a microbiological laboratory, unless this work is contracted out.

Typical steam sterilization cycles as recommended in HTM 2010, are given in the table below:

Sterilization Temperature (°C)	115	121	126	134
Max. Allowable Temperature (°C)	118	124	129	137
Holding Time (Min)	30	15	10	3

The most common temperatures used are 121 and 134°C. Please note that there is a definite upper limit to the target temperature range.

But with the much improved EBI 12 Series in the ebro validation package, a more flexible and accurate solution is made available for this application.

ebro's validation software, the Winlog.Validation and the Winlog. PRO, further makes Validation procedures in Sterilization processes even more accurate and reliable with its report generation features that can be customized based on user-specified acceptance criteria and/or as based on the relevant and available norms.

For more information on ebro's validation products contact us at: analytics.asia-pacific@xyleminc.com

EBI-12 series: EBI 12-TP231, EBI 12-T441, EBI 12-TP45X

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