

Temperature Mapping of Autoclaves and Sterilizers

Honeyman Validation offers a variety of thermal mapping and validation services designed to meet your requirements and to ensure you meet cGMP, Eur.Ph and USP requirements.

Thermal Qualification

Thermal mapping of sterilisation processes is a key part of the overall sterility assurance program for sterile products. Historically, Europe has placed more reliance on the use of physical parameters (e.g. temperature and pressure data) to demonstrate that the sterilisation process is effective, and the U.S. has historically placed more emphasis on demonstrating a Sterility Assurance Level for the product through the use of biological indicators.

The Recent 2017 revision to Eur.Ph. 5.1.1 Methods of preparation of sterile products requires that the *'calculated effectiveness from physical parameters $F(Phys)$ is correlated with biological effectiveness (F_{bio})'*¹). The new Chapter USP Chapter for Sterilisation 1229.1 also requires that correlation between biological and physical parameters is required wherever possible. So the cGMP requirements for Sterilisation processes are now aligned.

Porous Load Sterilisation

For Porous Load Sterilisation EN285 requires the measurement of physical parameters only to demonstrate the repeatability of the process using a standard test pack, this includes measurements of:-

- Equilibration time
- Temperature stability during sterilisation
- Verification that the process controls within the desired temperature band

When these initial tests have demonstrated suitable steriliser performance, then cycle development of process loads can begin.



Terminal Sterilisation of Product

For terminal sterilisation of heat sensitive products, its critical to measure the total heat input into the load over the duration of the whole cycle and F_0 is often used to measure this. Thermal mapping is used to determine the location of slow to heat points within the load, to determine appropriate location for cycle control and to determine the effect of different load presentations on cycle performance.

Typical thermal mapping activities include:-

- Determination of slow to heat locations within the product or load items
- Determination of worst case challenges to perform during Cycle Development and PQ
- Verification of repeatable process performance and achievement of thermal acceptance criteria
- Verification of correlation between temperature and biological data
- Calculation of Sterility Assurance Level for the product or process.

The Honeyman Group has worked with a vast range of finished products, medical devices and sterile components and has the experience to quickly design and test cycles using a Doing It Right First Time (DIRFT) approach.

Our approach will ensure that the testing is performed quickly, without error in a cGMP compliant manner, giving you confidence that the process will meet your sterility assurance objectives during initial qualification and routine operation.

Whether you require regular contract work, short-term validation resource, consultancy or training, Honeyman has you covered.

To speak to one of our validation experts regarding your qualification and validation needs, please contact us with your details and a brief introduction, so we can arrange a call back at a time convenient to you.



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¹⁾. Ph.Eur. 5.1.1 Biological Indicators of Sterilisation 01/2011:50102