AUTOCLAVE

TECHNICAL SERIES-2

Steam Sterilization Validation

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A Brief Overview of Steam Sterilization:

Sterilization: **Validated process used to render a product free of living microorganisms including bacterial endospores.**

Depyrogenation: **Removal or inactivation of bacterial endotoxin.**

Various types of steam sterilizer:

- Saturated Steam
- Water Immersion
- Water Cascade System
- Air-Steam Mixtures
- Gravity Air Displacement (unpacked materials sterilization)
- Vacuum air Displacement (Packed materials)

The basic principles for validation are:

1. Must use BIs to demonstrate lethality
2. Must use thermometric/ thermocouples
3. Cycle development and description of load patterns are pre-requisites
4. Can do time/temperature or Fo approach for control
5. Calibrate thermocouples both pre and again post
6. Must include "worst case" conditions
   -Maximum and minimum loads/ patterns
   -One run of reduced cycle time / temperature
   -Cold start for at least one of three runs per load pattern

Microbiological aspects of Steam Sterilization:

-D Value ,Z Value ,-Tb = 121 Degree C & Lethality (F0)

- **What is the D value?**

  -Decimal reduction time - The time required at a certain temperature to kill 90% (eg..reduce population by log 1) of the organisms being studied. Thus, after an organism is reduced by 1 D, only 10% of the original organisms remain. Dependant on microbe and initial numbers. The D value of 1.5 means it takes 1.5minutes to reduce 1 log (to 10%) @121 Degree. D value of 2.0 means more resistant while a D value of 1 min means less resistant.

- **What is a Z value?**

-Temperature change required to produce a 1 log reduction in D value.

- **What is F_0?**

-The number of minutes to kill a specified number of microbes with a Z value of 10°C at a temp of 121.1°C.

$$F_0 = \Delta t \sum 10^{\frac{T-121}{z}}$$

where delta t = time interval between measurement of T
T = temperature of the sterilized product at time t
z = temperature coefficient, assumed to be equal to 10

If we assume a sterilization lasting 15 minutes, constantly at 121°C, we obtain:

$$F_0 = 15x10^{\frac{121x121}{10}} = 15x10 = 5x1 = 15\,\text{min}\,utes$$

indeed according to the definition of F_0

If we assume sterilization lasts 15 minutes, constantly at 111°C, we instead obtain:

$$F_0 = 15x10^{\frac{111x121}{10}} = 15x10^{\frac{-10}{10}} = 15x10 = 10^{-1}$$

$$F_0 = \frac{15}{10} = 1.5\,\text{min}\,utes$$

Therefore, a 15-minute sterilization at 111°C is equivalent, in terms of lethal effect, to 1.5 minutes at 121°C; this can be easily expected if z=10.

- **Overkill**
  - **Use many more microbes than would find on items typically autoclaved. Negates the need to test sample for bio load before running the cycle.**
  - **Use a sterilisation time exceeding what is necessary to kill a large number of microbes. Negates the need to determine D value of microbe.**
  - **Overkill is generally defined as a 12-log reduction in bio load**