

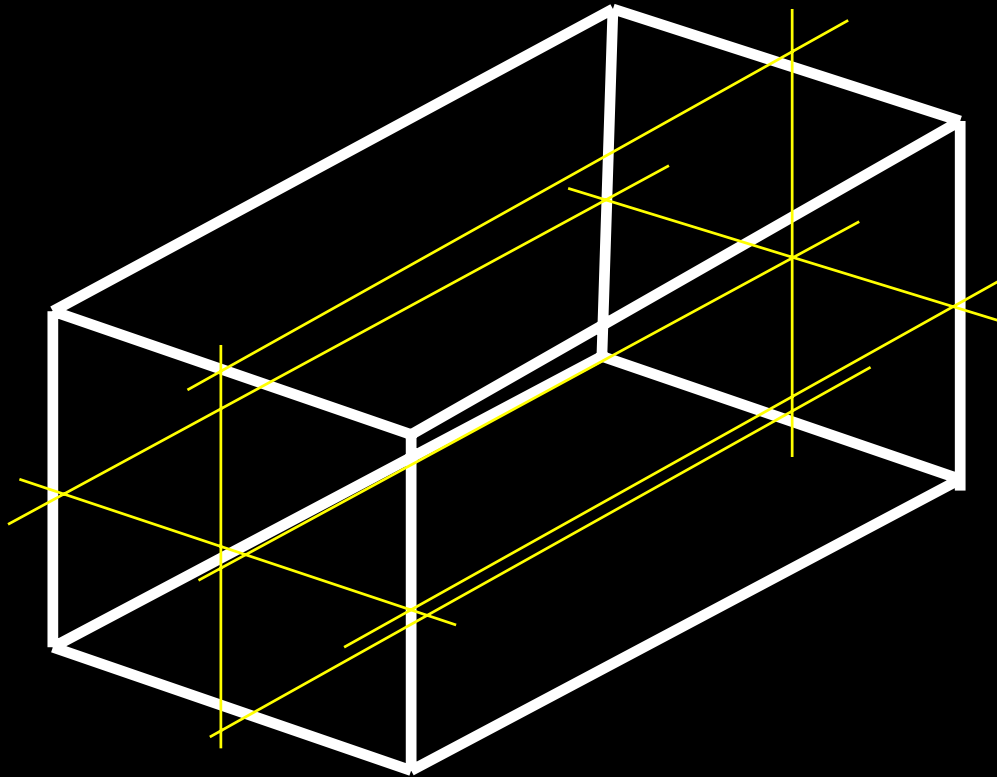
DISTRIBUTION TEST

Used to validate the uniformity and stability of the sterilizing vessel to manufacturers specifications.

- ◆ **Number of sensors depends upon size of vessel; GMP's recommend no less than 10 probes**
- ◆ **Suspend thermocouples avoiding any contact with solid surfaces**

DISTRIBUTION TEST

Thermal Mapping



- ◆ **Thermocouples are distributed geometrically in horizontal and vertical planes throughout the sterilizer.**

DISTRIBUTION TEST

- ◆ **Uniformity should be less than $\pm 1\text{C}$ of the mean temperature (steam)**
- ◆ **Test must be performed under minimum and maximum loads using actual production cycles**
- ◆ **Test must be performed for each different sized container**
- ◆ **Test results must be repeatable (3 times)**

PENETRATION TEST

- ◆ **Conducted to assure that the coolest container within the load will consistently be exposed to sufficient heat for proper sterilization of the drug.**
- ◆ **A product is considered sterile when the probability of survival of any microorganism is reduced to 10^{-6} regardless of the number and resistance of the microorganisms.**

PENETRATION TEST

- ◆ **Evenly distribute probed containers between pallets or layers ensuring coolest spot in vessel is represented.**
- ◆ **For solutions use maximum fill volume**
- ◆ **Microbiological Challenge Studies use calibrated biological indicators (min 10) positioned adjacent to probed containers**
 - **Inoculate spores into the solution or for solids onto precut samples of the same composition**

PENETRATION TEST

- ◆ **Calculate Lethality for probed containers using normal production cycle**
- ◆ **Under minimum and maximum loads**
- ◆ **For each product and container size or type**
- ◆ **Repeat test to ensure repeatability**

Pharmaceutical Industry

