

## **Contract Studies**

By Paul Nirgenau

Mesa Laboratories Contract Studies Department provides valuable assistance to customers in verifying the sterility of their products. This Spore News gives an overview the services the Contract Studies Department can provide.

### **D-value Analysis on Liquid Pharmaceutical Products**

Mesa Labs performs steam D- and Z-value analysis on pharmaceutical products using *Geobacillus stearothermophilus*, or *Bacillus subtilis* “5230” spores for heat sensitive products. Onionskin glass ampoules containing the pharma product and  $10^6$  spores are manufactured and exposed to gradient cycles in a steam resistometer (formerly referred to as Biological Indicator Evaluator Resistometer (BIER) test systems). Four ampoules per cycle are exposed, and population assays are performed immediately after exposure. The D-value for liquid pharmaceutical products is calculated using the Survivor Curve Method.

The low volume of product, use of onionskin glass ampoules, and square wave steam cycle of the resistometer generates data that can be used for multiple volume configurations if the time to temperature is known for each volume. If this information is not known, D-value analysis can also be performed with direct inoculation into the customer’s product configuration.

### **D-value Analysis on Pharmaceutical Stopper/Piston/Vial Components**

Inoculating the septum or most difficult location of the component to sterilize, D-value analysis is performed using the fraction/negative method with 10 or 20 components per cycle. Components are exposed to gradient cycles in a resistometer, aseptically cultured, and monitored for growth. D-values are calculated using either the Limited Holcomb-Spearman-Karber or Stumbo-Murphy-Cochran method.

### **D-value Analysis on Custom Biological Indicators**

Mesa Labs can perform resistance testing on custom biological indicators. Analysis can be performed using the customer's specified inoculation location, or Mesa can determine the most resistant inoculation location. In the past, we have performed resistance testing on syringes, powders, membranes, medical devices, lumens, and Process Control Devices.

### **Bioburden Resistance Testing**

Spore forming bacteria that has been identified by the customer can be sent to Mesa Labs on a plate or slant. The bacteria will be grown targeting a  $10^8$  population, harvested, and inoculated into WFI (Water for Injection) or product ampoules. D-value analysis is conducted using the Survivor Curve Method.

### **Third Party Verification**

Verification of D-value, Survival/Kill time, population, purity, and microbial identification listed on the Certificate of Analysis can be performed on other manufacturers' biological indicators.

### **Custom Studies**

We can work with you to design a study around your product and sterilization method. Mesa can perform testing in steam, ethylene oxide, dry heat, and VHP processes.

Paul Nirgenau graduated with a B.S. degree in Environmental Science from Creighton University. He has worked at Mesa Labs since 2004. He has held positions in Research and Development, Contract Studies and is currently the Contract Studies Manager. Paul is Bozeman's resident Eagle Scout and accomplisher of the impressive 2200 mile hike of the Appalachian Trail.