



Lyophilization Considerations

Headspace Pressure/Moisture Analyzer

West Pharmaceutical Services, Inc. utilizes a nondestructive Headspace Pressure/Moisture Analyzer to measure and monitor moisture and pressure in sealed parenteral containers. The system uses frequency modulation spectroscopy (FMS) as an optical measurement method that offers high sensitivity and rapid noninvasive analysis. This system can be equipped with custom fixtures to analyze any transparent vial (clear glass, colored glass or plastic) that has an outside diameter less than 30 mm. The instrument is calibrated against National Institute of Standards and Technology (NIST) traceable flame-sealed standards that have known pressure and moisture values. The system can measure headspace pressures ranging from 0 to 1.0 atm. The true advantage of this system is the fast, accurate and nondestructive nature of the testing. West Pharmaceutical Services can provide this testing through its West Analytical Services laboratories. Additionally, West can assist with the development of sealing optimization/validation protocols.” For more information, request technical support bulletin 2007/026

Lyophilization Stoppers and End-Product Moisture Evaluation

Residual moisture in elastomeric stoppers can cause degradation of lyophilized drug product. Prior to packaging the drug product, stoppers are typically washed, steam sterilized and dried. The steam sterilization process drives moisture into the stopper. If the drying conditions for the stopper are not optimized, residual moisture can transfer into the lyophilized drug product over time.

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This study evaluates stoppers made with 4432/50 Gray, 4432/50 Gray with fluoropolymer laminate, D21-7S with fluoropolymer laminate, D777-1 with fluoropolymer laminate and 4023/50 Gray. The stoppers were subjected to a pharmaceutical wash process. Analysis of the stoppers took place prior to and after a typical steam sterilization cycle of 121 °C for 1 hour and three drying cycles of 105 °C for 1 hour, 4 hours and 8 hours. Initially, a study was conducted on sealed vials to confirm container-closure integrity using helium leak detection. Stoppers were placed on a vial containing 5% lactose solution and lyophilized. The amount of moisture in the stopper and in the lactose was measured over 24 months, with samples being stored at 25 °C/60% relative humidity (± 2 °C/ ± 2 % RH). A coulometric Karl Fischer titrator with a drying oven was used to determine the moisture content of the stoppers and lyophilized lactose. The moisture content of the stoppers and lactose are graphed for comparison. For more information, request technical support bulletin 2007/116.

Medimop Vial Adapter Spiking Study

The forces experienced by the end user of a medical device are critical to successful use of the device as well as market acceptance of the device. West Pharmaceutical Services' (West) Technical Support Group performed a study to determine the spike penetration force of Medimop's Vial Adapter and Vented Vial Adapter. The vial adapters were used with and without siliconization for comparison. The testing was done in two phases; Phase I used stoppers with the same formulation with different configurations of varying thickness and in Phase II different stopper formulations were introduced. For more information, request technical support bulletin 2007/117.

Elastomeric Closure Storage and Processing Recommendations

The time that elastomeric components continue to maintain their characteristics is directly related to storage conditions such as, temperature and exposure to light, oxygen and ozone. Processing parameters can also impact the properties of elastomeric components. This document outlines general guidelines for handling and processing West elastomeric components. For more information, request technical support bulletin 2001/001.