LEAK TESTING OF SINGLE-USE BIOCONTAINER FOR BULK PRODUCT STORAGE AND TRANSPORT USING FLOW MEASUREMENT INSTRUMENT

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For some bulk drug products, the biopharmaceutical industry requires a complex transportation network for global shipping and storage under cold temperatures. With the growing demand for single-use technologies, there is need of an accurate method for assuring that single-use biocontainers remain integral throughout such transport and storage.

Our research focuses on evaluating the integrity of 200L polyethylene biocontainers using an electronic flow measurement instrument. The study was performed by installing single-use biocontainers in a steel transportation tote and filling them with water at room temperature. A series of leak tests were performed by pressurizing the biocontainer and measuring the air flowrate required to hold the internal pressure. The biocontainers were then stored overnight in cold storage and leak tested again afterwards to assess the effects of temperature on the flow measurement instrument.

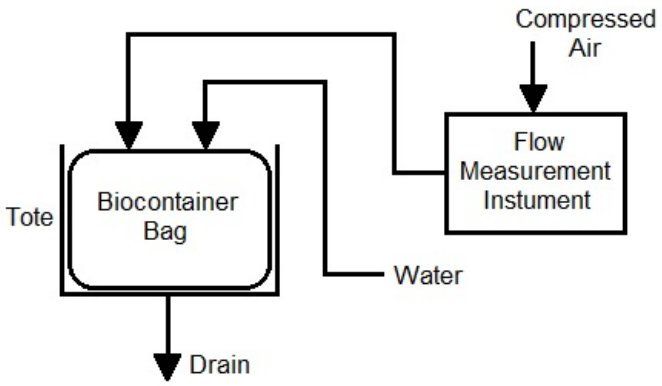

Figure 1 – Diagram of leak test system process

Leak Test Number	Bag State	Fill Volume	Cold Storage
1	Empty	0L	No
2	Filled	100L	No
3	Filled	200L	No
4	Filled	200L	Yes
5	Filled	100L	Yes
6	Empty	0L	Yes

Figure 2 – Leak Test Conditions

The flow measurement instrument was found to be effective for assessing biocontainer integrity at all stages: prior to filling, post filling, post storage, and post drainage. Results were reproducible with high accuracy for all leak tests and it was found that cold temperature has no adverse effects on the results. The flow measurement instrument itself also maintained full functionality when stored in cold temperature with the biocontainers. During our presentation, we will present test data for several biocontainers, the process stability, and suitability for commercial implementation.

Based on the objective and results of this study, we recommend this submission for the Advances in application of single use technology session. By combining the convenience of single-use technologies with an in situ leak test, the transportation and storage of bulk drug product can be simplified and more reliable. Real-time monitoring of biocontainer integrity will allow pharmaceutical manufacturers to assess their operations and identify the stages where the bulk drug product is most at risk of damage. Further development of this process will provide an efficient solution for integrating single-use technologies into manufacturing and logistical operations.