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Leakage analysis of LLDPE/Nylon flexible packaging by mass extraction leakage test and bioaerosol challenge test

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A common problem encountered when designing a new product for demanding environmental conditions is specifying its leak tightness and measuring seal integrity. Package integrity implies the maintenance of the sterile barrier property of the package. In recent years, the medical device industry has worked with the FDA by providing test data to move away from biological challenge testing of finished sterile medical device packages and toward physical test methods for measuring package integrity. This study presents an overview of what mass extraction leak testing is and how it can be implemented as a test method to determine the integrity of the flexible packages in quality control or development laboratory. This presentation mainly focused on testing pouches and the correlation between mass extraction rates and microbial ingress. Furthermore, it investigates the ability of VE2 mass extraction test instrument, to identify the defected samples from good samples of LLDPE/nylon laminated pouches and compares the results of this test with bioaerosol challenge test results. To accomplish this, four types of defective pouches with micro-channel are produced in a sealed area of pouches using tungsten wire with 0.10, 0.050, 0.025 and 0.015 mm diameter with 5 mm of seal length (ASTM F1929). The results of these two different tests show the VE2 instrument can detect all defected pouch with the hole bigger than 5 μm, but the results of microbial test indicated the critical size of leak for these types of packaging is 15 μm. Therefore, for testing the flexible package integrity, it is adequate that the mass extraction instrument can detect micro-channel bigger than 15 μm.

Biography

Nastaran Moghimi is working as a Research Scholar at Yonsei University, Republic of Korea. Her experience includes various programs, contributions and participation in different countries for diverse fields of study.

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