The solution for leak testing of FFS/Strips/Plastic Ampoules

Form – Fill - Seal machines use heat sealable flexible plastic package, which is then filled, heat sealed and cut off. FFS are widely used as medicinal packaging. For any manufacturer of medical products Quality Assurance is particularly important. It is imperative to strictly adhere to established and validated methods of preparation and procedure.

Though all filling procedures are carried out in cleanrooms, one cannot exclude potential risks, such as:

- Leakage in hydraulic and cooling system
- Particle generation may have an impact on air cleanliness standards
- Leakage in the actual packaging due to mishandling.

For the latter Bonfiglioli provides a solution. The LPS micro leak tester checks strips for micro leaks that might compromise the product. Strips are usually checked by pressing each strip manually. Apart from being time consuming, this method is subject to human error and in the pharmaceutical industry no manufacturer can afford errors that might result in expensive recalls and bad reputation.

The LPS is an inline machine with speed of 60 strips per min. The strips are fed in the machine via a conveyor and are tested using a force sensor. This kind of testing is non destructive, fast and reliable. The measurement of the resulting force after being pressed repeatedly will determine the seal integrity of the ampoule. This machine is equipped with SCADA platform based software configurable to comply with CFR 21 part 11 norms. Validation Documents to comply with FDA protocols are available on request.

Further information with regards to Bonfiglioli Engineering Leak Testers may be obtained from our website [www.bonfiglioli.com](http://www.bonfiglioli.com)

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