

# **Eliminating Inspection Labor Costs On Your Blister Packaging Lines**

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Production of tablets and capsules is carried out in cleanrooms and under stringent procedures as per GMP requirements. However the process also relies on machines and machine operators whereby misappropriate handling can result in a faulty blister pack containing micro leaks in the packaging thus allowing air and moisture to enter the blister and damage the product. What the Q&A department usually does to make sure blister packs are not leaking. This method is to perform a Methylene Blue Dye Test, which consists of placing a sample blister pack in the methylene blue dye for approx. 1 min after which a vacuum is applied to the container. As soon as the vacuum is released, should there be any hole in the blister pack the dye will replace the air that was sucked out under vacuum. The dye enters the blister and usually the tablet inside is stained with color.

The person performing the test has to check each individual blister manually to see which one contains a leak. This is the most commonly test performed on blister packs. It gives good results however it is messy and destructive and no data can be electronically documented.

Recently an innovative technological concept has been introduced to the pharmaceutical industry whereby Blister packs can be sample tested or even 100% tested for micro leaks. The process is clean, fast, precise and non-destructive.

There are different machines with various testing methods on the market. Several inspection machines do not require extra tooling for different sized blister packs as it utilizes a universal test head that accurately detects a leakage on the whole of the blister pack. This is very convenient and economical for blister packers having several size configurations whereby it would be a high investment to purchasing dedicated tooling. Whereas the leak testers for containers are used for in process sample testing, a blister leak testing machine can automatically test a whole batch of blister packs up to 20 blister packs per minute. The blister leak tester can be equipped with a Universal test head which may be used for all blister sizes or the dedicated test head which will pinpoint not only that the blister pack leaks, but will also identify which individual tablet in the pack contains the leak. Dedicated tooling can be purchased to leak test different sizes of blister cells.

The blister packs are automatically inserted in a testing chamber. In the case that dedicated tooling is utilized special sensors analyze the swelling of each blister cavity when set under a predetermined vacuum, thus rejecting faulty blister packs accordingly. Blister leak testing machines are fully

computerized utilizing a SCADA platform. This user friendly software includes utilities such as several password levels, products database, statistical reports etc. A printer is also installed for printing test results and parameters. The technology is fully validated.

With growth in technology comes the inevitable expectation of high standards and improved quality. These production facilities face governmental and industry regulations which might prove very costly if not adhered to. So investing in such technology is not a luxury anymore but a way to stay clear of recalls and also offering the industry a high class product which gives you an edge over your competitor.

Obtaining a high standard of certified products and services means planning from the very beginning in terms of efficiency and respect towards the requested conditions, to this effect at Bonfiglioli Engineering the section dedicated to high quality standards is involved in all the processes and in all aspects of undertaken production.

The first step is to verify that the machine taken under study satisfies totally all the client's requirements and expectations, and which fulfills fully all the enforced norms for that particular sector.

The next step is the production, in line with the latest regulations GMP Manufacturing Practice and the indebt analysis of the project from all aspects.

Production is followed by another important phase of assistance and consultancy, after sales, with the objective to instill with the client, a long lasting excellent rapport throughout the production process.