TAMPER-EVIDENT LABELLING
TAMPER PROOF OF DRUGS

Tamper Evident Labelling with sealing labels for folding boxes - what you should know about

According to the World Health Organization (WHO), every second drug purchased over the Internet is counterfeit. Counterfeit medicines pose enormous health risks for consumers. Active ingredients are often omitted or replaced by ineffective or even harmful substances - this can be life-threatening for the consumer. The trade in counterfeit drugs causes enormous economic damage and damage to the reputation of drug manufacturers.

The counterfeiting directive 2011/62/EU (Falsified Medicines Directive, FMD) of the European Union is intended to counteract the problem. The directive contains two security features: Serialization is usually ensured by, for example, a 2D data matrix code and an individual serial number, as well as a tamper protection. The guideline leaves manufacturers and contract packers a great deal of leeway with regard to the implementation of manipulation protection. One direction is now given by DIN EN 16679.

Possibilities for verifying manipulations of pharmaceutical packaging
Four options are available:
• Special folding box construction
• Folding boxes closed with glue
• Foil wrapping of the folding box
• Sealing labels

Sealing labels are normally the most economical solution, as no changes need to be made to the folding box packaging.

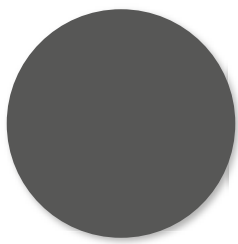one-sided tamper-evident labelling

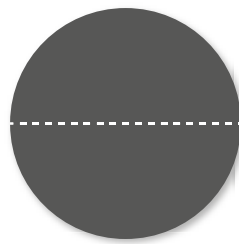two-sided tamper-evident labelling

two-sided tamper-evident labelling

Tamper-Event labels - the right label adhesive

Round or rectangular transparent labels are usually used as tamper-evident labels. The decisive factor here is the label adhesive. This must be highly resistant to various solvents, mechanical manipulation, high temperatures and water - only then can counterfeit protection be guaranteed.

It must not be possible to remove the label from the folding box packaging without leaving any residue. Either it leaves a residue on the label or the cardboard surface of the folding box is destroyed. The sealing label must not be reclosable. Pressure-sensitive adhesives are already available for almost all surfaces. The tamper-evident labels from b+b can be used for a wide range of packaging surfaces.

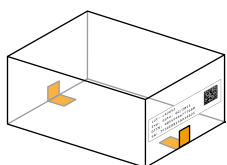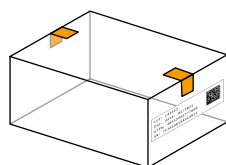|			
Round, transparent tamper-evident Labels	Round, transparent tamper-evident Labels with security perforation	Square, transparent tamper-evident Labels	T-labels for tamper-evident-labelling

The correct labelling

When using seal labelling as protection against tampering, several relevant factors must be taken into consideration:

• A reliable separation of the folding boxes to each other
  This can be done, for example, by the conveyor belt of the plant.
• Precise dispensing of the sealing label
  This can be guaranteed by fixing the folding box.
• Required labelling speed
  The labelling speed must be at least equal to the line speed of production.
• Position of the flaps to be labelled
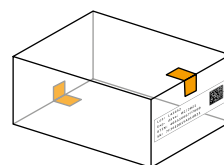 The tuck-in flaps of the folding boxes can be in different positions.
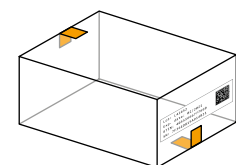
Possible positions of the flap:

Bottom left and right	Top left and right	Bottom left and top right	Top left and bottom right

The labelling process:

With tamper-evident labelling, about 50% of the label is applied to the folding box - the other half protrudes beyond the folding box body. With the help of a pressure roller or bar, the label can be precisely ironed onto the other side of the folding box.

Tamper-evident labelling with standardised machines

The pharmaceutical industry faces complex labelling requirements like almost no other industry. Seamless traceability, measures against counterfeit drugs such as serialization and manipulation features, as well as reliable product labeling pose great challenges for manufacturers and contract packagers.

Manufacturers and contract packers often decide to use expensive special machines to meet the labelling requirements. However, this is usually not necessary. Due to the modular design of b+b machines, individual marking requirements can be implemented economically well. Cost advantages can be achieved by the right degree of standardization. According to the concept of mass customization you will receive a solution adapted to your requirements.

The solution can consist of different modules. Among the modules are:
• labeller
• print systems
• vision inspection
• ejection system
• input and output buffer

Labeller

The core module of the tamper evident system is the labeller. This is where the actual labelling process of the tamper-evident label is carried out. Different folding box formats can also be labelled simply by changing the format.

Due to the modular design, the labeller can be upgraded at any time and additional labelling stations can be installed. Thus, manufacturers and contract packers can react quickly and reliably to the constantly increasing labelling requirements in the pharmaceutical industry with labelers from b+b.

> More informationen about b+b labeller

Print system

The application of variable data can be done directly on the folding box as well as on the label. The correct printing depends on various conditions:
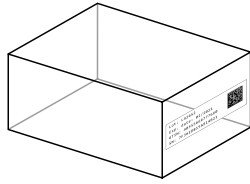• Product format
• Product surface or label material
• Size and type of labels
• Production speed

The printing module is integrated into the labelling system. Here we fall back on print modules from renowned partners. Also existing plants can be upgraded andbe equipped with one or more printing modules. So the user has the option of increasing the number of label-to react flexibly and cost-effectively to changing requirements.
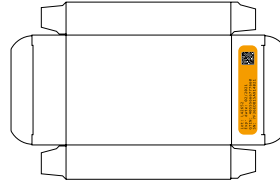

Printing of the folding box

Print the data matrix code and the serial number:

Folding box with data matrix code

Flat folding box with data matrix code

Vision inspection

Depending on the application and requirements, different control systems can be used.

If the data matrix code is actually to be read in the plant vision inspection, corresponding sensors or scanner can be integrated.

A label presence check can also be performed by corresponding sensors on up to four sides.

If only a print presence check is to be carried out simple contrast or colour sensors are sufficient.

A upgrade for existing systems is possible at any time. Faulty products can then be removed from the production line.

Camera inspection system for printing

Ejection station

In case of a damaged or non-functional label, the labelled product is discharged from the production line. Non-sensitive products are transported by air pressure from the conveyor belt and collected in a sealed container. If faulty labels are to be sorted out before they are applied to the label, this can be made possible by a label ejection system. This is usually the case with expensive products.

Implementation of the policy by the serialization module - the turnkey solution

Besides the hardware to make your products tamper proof, b+b also supplies the necessary software. This software is also modular. It can be adapted to existing and future requirements without large investments. Whether it is the adaptation for the administration of production lines or locations as well as the adaptation to new coding and aggregation regulations or an extension of the machinery.

Our b+b Siteserver and its modules ensure a smooth and standardized data exchange between superior data systems, the individual line components up to the reporting of the pedigree of your products.

Furthermore, this software package also serves as a platform for production management. An almost infinite number of hardware components from various manufacturers for automation, coding and aggregation can be controlled and managed in parallel.

For more information about serializing your products, visit www.bb-trace.com.