White Paper
June, 2021

Laser Marking in Pharmaceutical Applications

Evolving technologies

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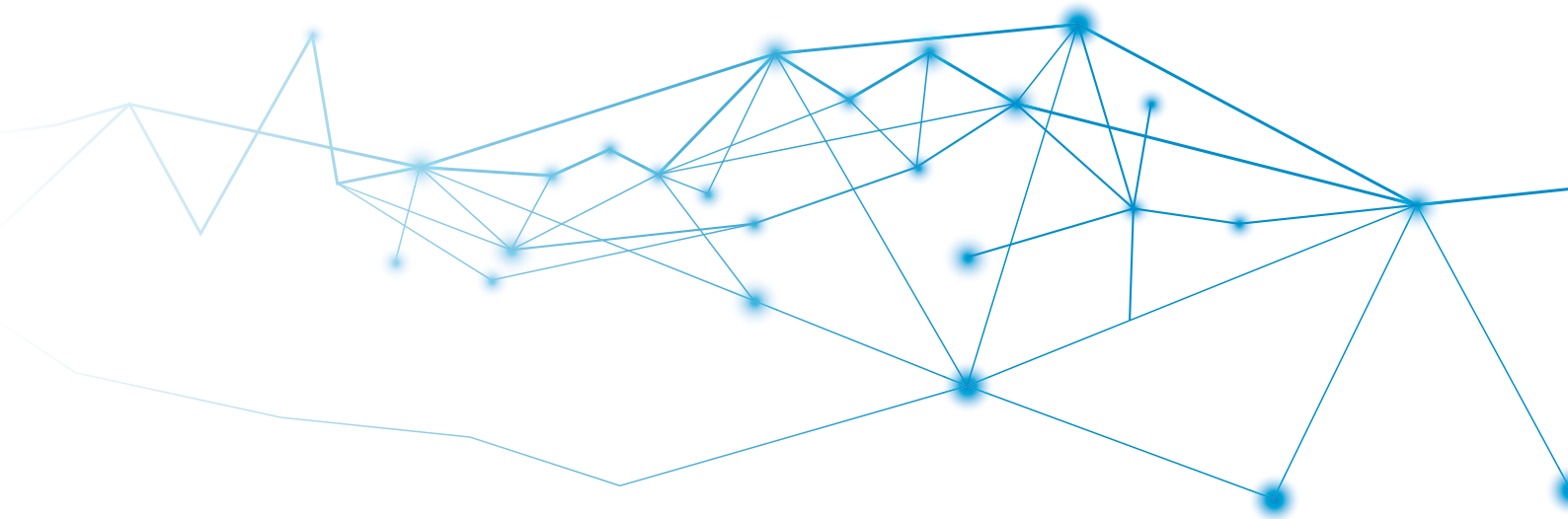


History of pharmaceutical product marking

Product marking has come under increased scrutiny in the pharmaceutical industry due to pressure from three factors: regulations, aesthetics, and cost.

In 2011, the European Commission published Directive 2011/62/EC, the Falsified Medicines Directive (or FMD). Its goal was the fight against counterfeit medicines through serialisation and verification.

Similarly, in the US, the Drug Quality and Security Act (DQSA) was put in place by Congress In November 2013, calling for manufacturers to make prescription drugs traceable on a per-unit basis. The purpose being to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.

This legislation affected packaging aesthetics and design. Laser ablation is sometimes used in drug packaging to create a mark, such as simple alpha numerical characters. Whilst this can offer a degree of effectiveness, the imaging area is often limited, restricting more informative serialisation content, and impacting the choice of colour schemes and branding.

All pharmaceutical manufacturers, even those accustomed to marking products already, were at some risk, since marking additional information takes time and threatens to slow production.

Cost challenges can be an important factor when serialising products that were never designed to be marked. To be able to react to changes and ensure a smooth end-of-line operation, the most desirable stage of serialisation in the manufacturing process is at the point of packaging, where the goods are packaged and ready for dispatch. But serialisation of common product packaging, such as laminated containers or labels, can present challenges for laser ablation marking due to bubble entrapment and damage to the protective laminate layer. In the case of ink-jet printing, adhesion to film surfaces can be difficult (particularly so with water-based inks), and is preferably applied prior to the lamination stage. However, this requires serialisation to be undertaken at an earlier stage in the production process rather than at the point of fill. Difficulty with both laser ablation and serialisation present not only technical challenges but additional costs to the manufacturing process.

Laser technology responds

In response to the US Act and EU FMD, laser-active coatings were introduced as an alternative marking technology, presenting aesthetic and economic advantages in pharmaceutical packaging such as blister packs, labels and folding cartons. These coatings are able to undergo a colour change from colourless (or white) to black upon exposure to specific laser wavelengths. This includes CO_2 and fibre lasers, both of which are commonly used in ablation marking methods.

- **Imaging speed** - inducing a colour change reaction using laser active coatings uses less power than ablating a surface.
- **Code security** - laser pigment reactions can take place under protective laminates without causing any damage; ablation can lead to deformation and loss of laminate integrity.
- **Contrast** - laser-active coatings are a colourless or white film and form grey-scale to black images; ablated codes are white and need a dark background to be legible.
- **By-products** - ablation can produce copious smoke and particulate; laser active colour change coatings can greatly reduce these by-products.

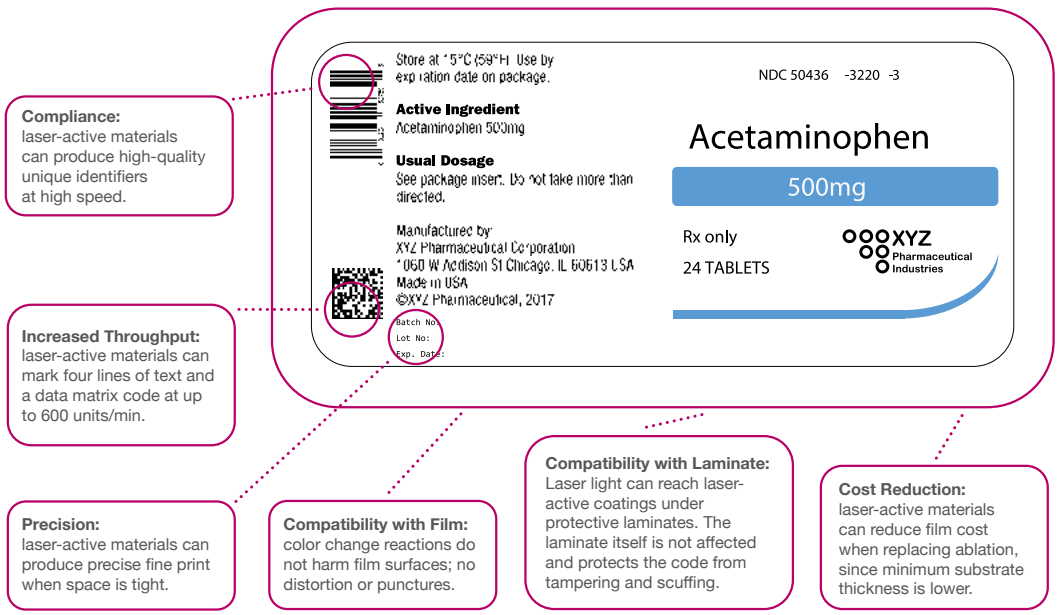
Laser-Active Materials and Pharmaceutical Labels

Leading packaging manufacturers and brands in the pharmaceutical sector have adopted laser-active coatings for two key reasons: to ensure pharmaceutical packaging can be serialised in a manner that responds to, and meets legislative demands and provides consumer reassurance through safe and secure supply chain management - at the same time meeting cost challenges and packaging aesthetics.

Using laser-active coatings and CO_2 laser marking systems, manufacturers are able to mark products at faster speeds than other methods.

Laser-active materials can also image while under laminate films. This has the benefit of being tamperproof - manufacturers therefore can use simpler, packaging constructions and increase the number of labels per roll. Precise printing with these materials helps eliminates rework.

Laser-active materials have been able to produce unique identifiers, such as data matrix codes, in accordance with Drug Quality and Security Act legislation.



Laser-Active Materials and Folding Cartons

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Other benefits include:

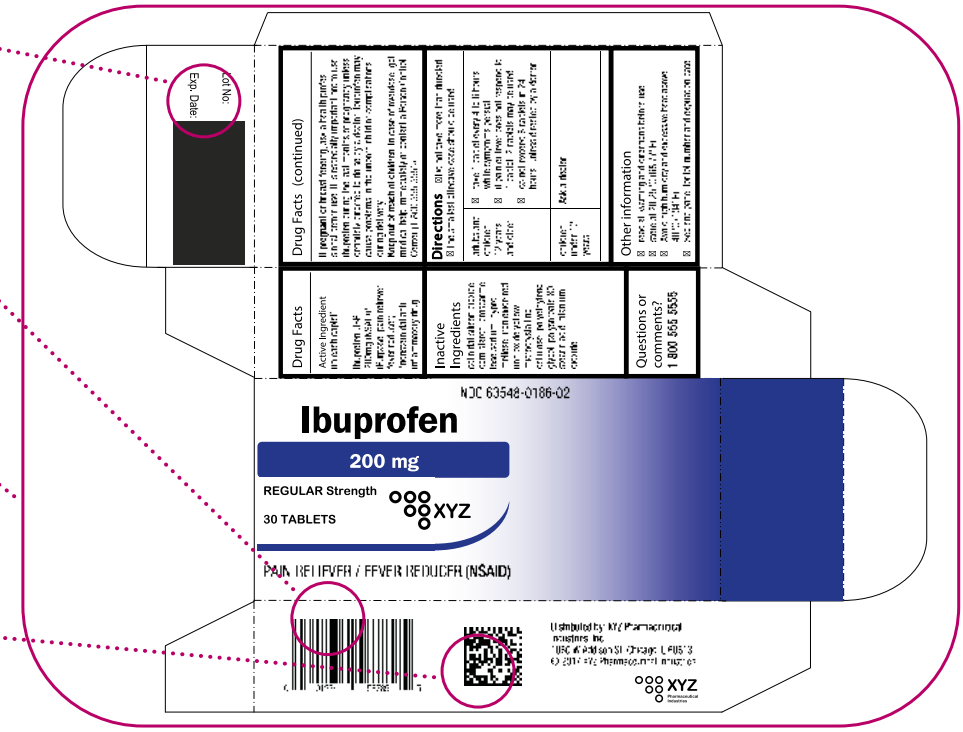
- Laser-active materials can also further upgrade coding lines and package design.
- These materials create marks using less power and more contrasting legibility than ablation. The marking process reduces the generation of particulate matter, lowering the risk of contamination.
- Laser-active materials have been proven to provide a tangible return on investment, since marking takes place at lower power. Operating the laser at reduced power output also increases its life.

Enhanced Appearance: laser-active materials go on colorless, merging seamlessly with the carton colour scheme.

Compliance: laser-active materials can produce high-quality unique identifiers at high speed.

Safe and Clean: The marking process produces no particulate matter, reducing risk of contamination.

Increased Speed: Laser-active materials produce darker codes at faster speeds than ablation.



Laser-Active Materials and Metal Packaging

A metal decoration coating is available for use on offset litho presses equipped with UV curing units. The functional coating can be used for printing QR codes and expiry dates onto primary packaging applications, such as medicinal products for nonparenteral administration, including tubes, packs made from foil or blisters and canned prescription food.

Going one step further

Further advancement in laser technology has recently seen development of a functional masterbatch additive - a pigment designed for integration into plastic products and packaging, for laser coding and marking purposes. The solution is suitable for a wide range of plastics, including pharmaceutical, food & beverage, home and personal care, medical and industrial extruded products.

By addressing the challenges faced by production and pharmaceutical manufacturing companies with product coding applications, such as printing expiry dates and lot numbers, the masterbatch additive has been optimised specifically for extrusion and injection plastic moulding to provide unsurpassed product stability and excellent quality.

In operation, the additive is integrated directly into the masterbatch in pellet form, to provide consistent high quality, high contrast, permanent black-on-white coding. When compared to other coding methods, the masterbatch additive works with standard CO_2 scribing lasers to provide sustainability benefits in production environments by eliminating labels, consumables and waste from the coding and marking process. It can also help streamline supply chains through a reduction in packaging.

With lasers retro fitted to assembly lines, the additive will also deliver a range of efficiency benefits. By having the flexibility to make fast changes to coding and decoration requirements, the coding and marking process can reduce unscheduled downtime, need minimal preventive maintenance and less frequent fume extraction filter changes. Additionally, as the additive is already integrated into the extruded plastic, manufacturers will be able to enhance brand integrity by providing SKU traceability and permanent coding that is tamper proof, anti-counterfeit and impossible to remove. The additive can also assist in improving packaging design by removing unsightly ablation areas; furthermore, it can be printed anywhere on the packaging, with high precision.

Conclusions

With production environments becoming increasingly challenging, both brand owners and converters alike are demanding more robust, high contrast data coding to ensure compliance and traceability of products and packaging, particularly in the pharmaceutical industry.

DataLase has a unique history of creating innovative and technically advanced solutions to some of the major issues faced by supply chains across the globe. Pharmaceutical companies in particular continue to benefit from the integration of highly efficient laser marking systems to provide high contrast black-on-white variable data on a variety of substrates, including plastics. The solution offers a range of advantages, including proven reliability, flexibility and high quality product coding, which consistently outperforms other coding solutions.

To find out more about how DataLase can support your business and help increase your supply chain sustainability

call **0151 423 9360**
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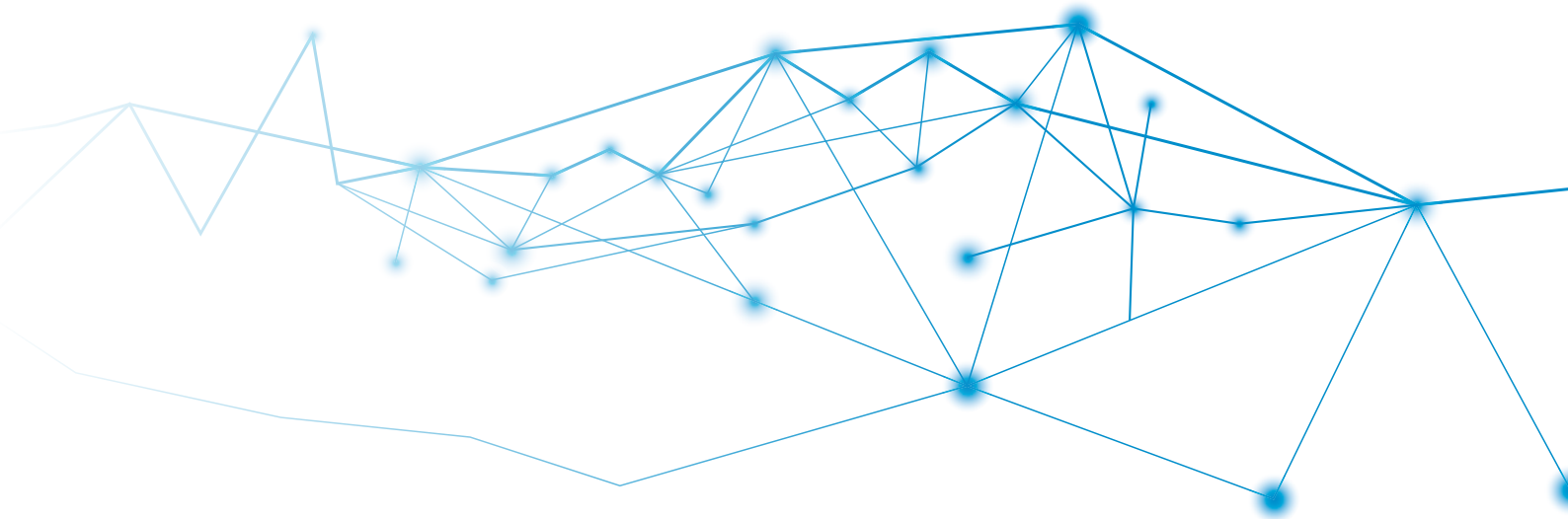

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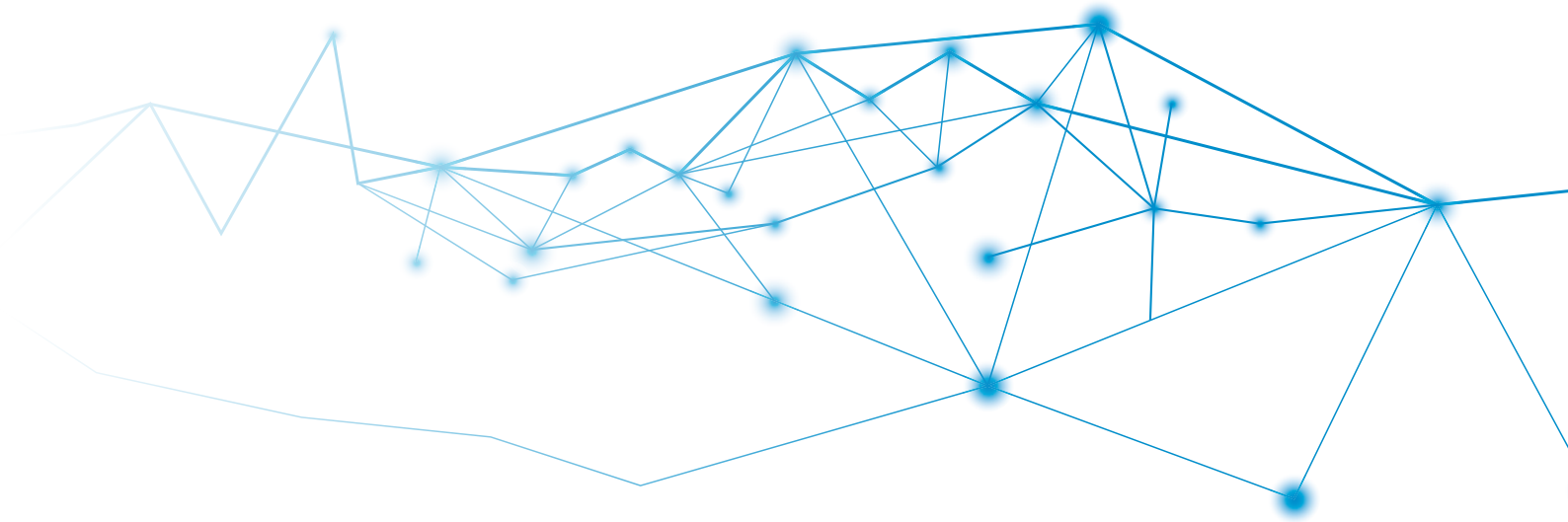

For further information about DataLase Coding & Marking Technologies, please visit: DataLase.com