Anti-counterfeit Technologies for Pharmaceutical Packaging

Shashank Soni

Amity Institute of Pharmacy, Lucknow, Amity University Uttar Pradesh, Noida, U.P. India

ssoni@lko.amity.edu

Abstract

In a pharmaceutical company, the packaging is a labour-intensive, all-encompassing process that involves several functions, from product confinement to protection to delivery. Thus, the importance of packaging in the marketplace cannot be understated. The purpose of packaging is to protect and preserve goods while providing consumers with market information and legal information. A few years ago, the pharmaceutical packaging industry focused on maintaining the standard and quality of the enclosed product. Today, however, that focus has shifted to include the product's stability, shelf life, and convenience as well as protection against product tampering and counterfeiting and assurance of its safety. Hence, future product design will have a calming effect on people; thus, the packaging should match the characteristics. Industries are on the verge of amazing developments in this area to increase patient adherence to prescription regimens since the packaging industries are on the route to inventing newer and more sophisticated approaches.

Key words: *counterfeiting, tampering, product design, packaging science, packaging industries*

Introduction

In the pharmaceutical industry, it is important that the package selected adequately preserves the integrity of the product. The selection of packaging material begins with the determination of the physical and chemical characteristics, its protective needs, and its marketing requirements. Packaging also protects against factors like light, oxygen, moisture, biological contamination, adulteration, and mechanical damage that can change its quality or potency (1). The packaging materials selected have the following attributes:

- protect the formulation from environmental condition
- they must not be reactive with the product
- must not impart taste or odours to the product
- must be non-toxic
- must be FDA approved
- must meet applicable tamper resistant requirement
- must be adaptable to commonly required high speed packaging equipment

Categories of packaging materials

Primary packaging system: It envelops the product and holds it. It protects the inside product from the external environment without affecting its shelf life. Examples include intravenous injections and infusions in ampoules and vials, liquid dosages form, and pre-filled syringes.

Secondary packaging system: It is used to organise primary products, such as cartons, boxes, shipping containers, injection trays, etc., outside of the primary packing.
Tertiary packaging system: For bulk handling and shipment, tertiary packaging systems are utilized, such as barrels, containers, edge guards, etc (2).

Commonly used packaging materials for pharmaceuticals
Traditionally, the bulk of medications has been used orally as tablets or capsules, which are either fed into plastic pharmaceutical bottles (especially in the USA) or packaged in blister packs (which are highly popular in Europe and Asia) (2). However, more people are now utilizing alternative medication administration techniques. These comprise inhalation (17%), transdermal (3%), and parenteral or intravenous (29%) techniques. These pharmaceutical products may be dispensed in tailor-made packaging material which ensures the effectiveness of product and maintain its shelf life (3,4).

Counterfeit pharmaceuticals
Counterfeiting means developing products and making packaging like the originals and selling the fake as authentic products. According to the new guidelines by USFDA, medicines that don't have the manufacturer's name and address are also considered counterfeit.
Counterfeit is associated with product security and patient health. Counterfeit medicines can contain either the same amount of active pharmaceutical ingredients as that of an original brand or incorporate drugs below claimed amount by the manufacturer or without drugs and used sucrose as fillers. It also includes medicines with a post-expiry date. Counterfeit can lead to duplication, substitution, tampering, and returns and warranty threat also called as brand theft of pharmaceuticals (5).

Important anti-counterfeiting technologies used (6-9)
Overt/visible features
End users are supposed to be able to check the legitimacy of a pack using overt features. Such characteristics are typically very noticeable and expensive or difficult to duplicate. To prevent unlawful diversion, they also require the highest level of security in supply, handling, and disposal protocols. An overt device may be placed within a tamper-evident feature for enhanced protection as they are designed to be applied in a way that prevents reuse or removal without being disfigured or damaging the pack.
Covert/hidden features
A covert feature's function is to help the brand owner spot counterfeit goods. The ordinary populace won't be aware of it or have the tools to confirm it. Without specialized knowledge, a hidden feature shouldn't be simple to find or reproduce, and its specifics must be kept under "need to know" restrictions. Most covert features will lose some, if not all, of their security value if they are exposed or hacked.
Forensic markers
These technologies are a subset of covert ones. This contains solutions that call for highly specialized field test kits or laboratory testing to establish authenticity. It contains a chemical, biological, DNA, isotope, and micro-taggants, among others.

Nano printing

The technologies enable microscopic application to each tablet separately. Glass vials and ampoules can be printed invisibly with ultraviolet inks, and they offer exceptional security.

Radio Frequency Identification

It is a system that tracks objects that are placed far away using tiny computer chips. An antenna that detects electromagnetic radiation generated by a reading device is attached to this tiny chip. The reader device picks up the energy and reads the chip's distinctive identifying number. This enables the object to be identified remotely. This technology helps with cost control, patient safety efforts, and effective inventory management.

For object identification, it uses wireless communications. The three most crucial elements of the RFID system are the tag, the reader, and the software. The tag is an integrated circuit with an electronic product code (EPC), which serves as a special tracking identifier. Electromagnetic radiation waves are used to convey this code over the radio spectrum. The reader receives this broadcast signal and uses it to establish connectivity between the system software and the tag data. The software can be enhanced with anti-counterfeiting tools.

Numerous methods employ RFID technology to find fake medications. High-quality labels are encoded and then examined once more by the equipment that encrypts and prints tag-equipped labels. Labels are printed and their barcodes are confirmed when tags are correctly read. A unit that can be encoded, printed, and applied is available for automated applications. It completes all of the RFID printer's checks and applies labels at a maximum speed of 100/min.

RFID and cryptography can be used together to support on- or off-network authentication. This aids in the streamlining of numerous shipping, receiving, and inventory management operations. To prevent counterfeiting and diversion, data is gathered when a product is being tracked through the supply chain. Sensors are also used to keep an eye on the environment during shipment and storage and to provide alarms if certain conditions are exceeded.

Trace-track technologies

Every stock unit created using these technologies receives a unique identity, which is maintained for the duration of the manufacturing process until it is consumed. The product's name, strength, lot number, and expiration date are all included in this identity.

Security labels

Security labels and tamper-evident seals are crucial in protecting consumers from spurious goods. In self-adhesive labels, the substrate primarily serves as a complementary component of the pressure-sensitive adhesive and the substrate. While passive security labels have been widely utilized, functional labels with printing and anti-theft are becoming more widely applied.

Hologram based labels

The labels are a perfect option for product authentication and make up a sizable and significant portion of the security label market. A polyester film base is used to create the

holographic foil, an optically changeable device. Holographic images are excellent for brand marketing and security due to the optical interaction between them and the human eye. When tilted in light, these products display a holographic image. To maximize impact, the picture that has been revealed can be tailored to the needs of the brand owners. To make hologram creation challenging for counterfeiters to replicate, complicated origination processes and a lot of innovation is developed. Numerous holograms are made with tamper-evident characteristics in addition to brand authentication. If the hologram is attempted to be erased, a unique coating on the top polyester layer causes the top layer to peel off, leaving the hologram on the product.

Barcodes

The tiny string of data is encoded using a barcode, which is a pattern of parallel, contiguous bars, and spaces. Currently, 2-D codes are also an alternative for anti-counterfeiting because they can encode vast amounts of information.

Bar-coding allows for universal and distinct identification of goods, services, assets, etc. when used in conjunction with GS-1 standards. The intensity of the light reflected is used by a bar code reader (scanner) to decode the bar code. Barcodes collect specific information that may pertain to track and trace traceability, inventory management, security, identity, etc., whereas package printing emphasizes the product's consumer appeal and acceptability. Bar-coding offers the capability for automatic data capture of information.

It enables global and distinctive identification and security of packed goods when combined with international numbering standards. For example, UPC bar code scanners employ a helium-neon (red) laser emitting at 660 nm to assess the contrast between the reflected light from the dark bars and light spaces. In essence, barcoding uses optical scanning technologies. To use them as a system, decoders and coding software are also required. GS-1 barcodes offer universal access that can be used by users and countries that are GS-1 members. However, many retail chains utilize their proprietary codes for a variety of reasons. Barcodes are used as a possible anti-counterfeiting measure, especially with the option to use 2-D codes

Mass serialization of digits/alpha numeric values

A random, pseudo-random code is generated by the technology supplier and sequentially inserted into their or the customer's database for further verification. Customers receive these codes, which they can then use in various ways. These codes may be subtly used on a pack or printed on labels before being attached to the item. The unique code on a product is compared to those in the database as part of the authentication procedure. The product is authentic if the code can be found in the database. For this technology to be successful, appropriate procedures and SOPs must be implemented, as well as security features for its database.

FDA regulations

The FDA does not approve containers as such but only the material used in the container. A list of substances considered “generally recognized as safe” (GRAS) has been published by the FDA. In the opinion of qualified experts, they are safe under specified conditions, assuming they are of good commercial quality. A material that is not included under GRAS or prior sanction, and is

intended to be used with food, must be tested by the manufacturer, and the data must be submitted to the FDA.

The FDA has published a regulation (part 133) that implements the current good manufacturing practice requirement of section 501 (a) of the act. Part 133.9 of these regulations set forth criteria concerning product containers, which manufacturers, processors, packers, or holders of drug use as guidelines. The specific FDA regulation related to drug states that “container, closure and other parts of packaging material, to be suitable for their intended use, must not be reactive, additive or absorptive to an extent that the identity, strength, quality or purity of the drug will be affected” (10).

Conclusion

The manufacture of pharmaceuticals is connected to the packaging business. So, including ethical and scientific practices in the packaging have become essential. The trends in pharmaceutical packaging are expanding quickly. This is possible if the requirements of the product, its price, security, and user-friendliness are considered while creating a brand identity. Ideas poured out of the frameworks and from the package designers. The laws imposed on the packaging business have created several obstacles for them to overcome. These rules are crucial to guarantee consumers that the goods they purchase are entirely safe, display all required characteristics, and meet industry standards for quality. As material science develops, we can anticipate cleaner elastomeric formulations by using blow fill seal (BFS) technology to produce the main parts of packaging and delivery systems, such as RespulesTM and Twist TipTM. There may be a future market for coatings with nearly 100% barrier qualities, like plasma impulse chemical vapor deposition (PICVD) coatings.

References

1. Keerthi M, Prasanna JL, Sharuna KS, Rao NR. A Review on Packaging for Different Formulations. Asian Journal of Research in Pharmaceutical Science. 2014;4(3):141-51.
2. Carter SJ. Copper and Gunn’s Packaging in Tutorial Pharmacy, structural approaches to texture. Proceedings of the IEEE. 2005;67(5):786-804.
3. Pareek VI, Khunteta A. Pharmaceutical Packaging: Current Trends and Future. International Journal of Pharmaceutical Sciences. 2014 Jun 6;6(6):480-485.
4. Bauer E. Pharmaceutical Packaging Handbook. CRC Press; 2016 Apr 19; 1 (19): 585-597.
5. Dobrucka R. Recent Trends in Packaging Systems for Pharmaceutical Products. LogForum. 2014 Dec 1;10(4): 194-219.
6. Reed CH. Recent Technical Advancements in Blow-Fill-Seal Technology. Business Briefing: Pharmagenerics. 2002:1-4.
7. Segner J. Plasma Impulse Chemical Vapour Deposition-A Novel Technique for the Production of High Power Laser Mirrors. Materials Science and Engineering: A. 1991 Jul 7;140:733-40.
8. Mittal S, Wadhwani B, Lakhani M. Innovations in Pharma Packaging Technologies. Journal of Young Pharmacists. 2021;13(3):197-210.
9. Zadbuke N, Shahi S, Gulecha B, Padalkar A, Thube M. Recent Trends and Future of Pharmaceutical Packaging Technology. Journal of Pharmacy & Bioallied Sciences. 2013 Apr;5(2):98-110.
10. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy. Philadelphia: Lea & Febiger; 1976: 731-732.