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Review Article

Pharmaceutical Packaging: A Review of Current Technologies and Future Innovations

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ABSTRACT

The pharmaceutical packaging market has been growing steadily at over five percent annually and is now valued at more than $20 billion. Packaging solutions must be reliable, ensuring product protection, tamper evidence, and patient safety. Innovations like blow-fill-seal (BFS) vials, anti-counterfeit technologies, and child-resistant designs are driving new trends in the industry. Packaging plays a vital role in delivering life-saving medications across the globe in various forms, from pills to syringes. With global distribution, there is a growing need for customizable packaging that addresses sustainability and environmental concerns. As an emerging discipline, packaging is crucial for pharmaceutical success, often representing the largest expenditure in production. The future will likely see more advanced technologies, eco-friendly practices, and enhanced security in packaging..

INTRODUCTION

Packaging is defined as a technique which allows containment of pharmaceutical product from the time of production in a unit till its use. Role of pharmaceutical packaging is to provide lifesaving drugs, surgical devices, blood and blood products, nutraceuticals, powders, poultices, liquid and dosage forms, solid and semisolid dosage forms. Packaging of pharmaceuticals essentially provides containment, drug safety, identity, convenience of handling and delivery. Pharmaceutical packaging has to balance lots of complex considerations. Leaving behind relatively simple issues such as developing good designs and communicating with customers, pharmaceutical packagers are concerned to more pressing concerns which include fighting with counterfeiting, encouraging patient compliance, ensuring drug integrity and balancing child-resistance and accessibility for the elderly. Issue of environment safety is also key concern for both developed and developing countries packaging industry. Pharmaceutical

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packaging firms are some of the industry's leading innovators evident by the recent advancement in technology. The current trends are result of continuous series of challenges faced by industry. Packaging is a science which is continuously evolving and is a major success contributor for pharmaceutical industries

Purpose and scope of the reviwe

The purpose of this review is to provide a comprehensive analysis of the current technologies and future innovations in pharmaceutical packaging. This exploration aims to shed light on how advancements in packaging are enhancing drug safety, efficacy, and patient compliance, as well as addressing emerging challenges within the pharmaceutical industry.

Scope:

1. Current Technologies: This review will cover a broad spectrum of existing packaging solutions, including traditional systems such as blister packs, vials, and ampoules, as well as more recent innovations like prefilled syringes, dual-chamber systems, and tamper-evident packaging. We will discuss their respective advantages, limitations, and applications in various therapeutic areas.

2. Smart and Intelligent Packaging: We will examine the growing role of smart packaging technologies that integrate digital features such as electronic dose counters, temperature indicators, and connectivity for real-time monitoring. These technologies are designed to improve patient adherence, track drug usage, and provide critical data to healthcare providers.

3. Materials and Sustainability: The review will explore advancements in packaging materials, including biodegradable and recyclable options, to address environmental concerns. We will assess how the industry is adapting to increasing pressure for sustainable practices while maintaining the integrity and safety of pharmaceutical products.

4. Future Innovations: Looking ahead, we will investigate cutting-edge developments that are likely to shape the future of pharmaceutical packaging. This includes the potential impact of nanotechnology, advanced polymers, and personalized packaging solutions tailored to individual patient needs.

5. Regulatory and Compliance Considerations: An integral part of this review will be to highlight how packaging technologies align with regulatory requirements and standards across different regions, ensuring that innovations not only meet industry demands but also adhere to stringent safety and quality guidelines. By delineating these areas, this review aims to provide a thorough understanding of the current state of pharmaceutical packaging and offer valuable insights into the technological advancements that will drive the industry forward.

Categorically differentiating pharmaceutical packaging:

Pharmaceutical packaging can be categorized based on various factors, including the type of packaging system, the materials used, the technological features, and the specific application or function. Here's a detailed categorization:

1. Type of Packaging Systems

- Primary Packaging: This is the packaging that directly contacts the pharmaceutical product and is crucial for its protection and preservation. Examples include:

- Blister Packs: Commonly used for tablets and capsules, providing individual compartments.

- Vials and Ampoules: Used for liquid medications, typically glass or plastic containers.

- Syringes and Prefilled Devices: For injectable medications, including both single-use and multi-use devices.

- Pills Bottles and Jars: Used for oral solid doses like tablets and capsules.

- Secondary Packaging: This involves packaging that contains primary packages and serves additional functions such as bulk storage,

branding, and protection during transportation. Examples include:

- **Cartons and Boxes:** Often used for grouping multiple primary packages, providing information and branding.
- **Labels and Leaflets:** Attached to the secondary packaging to provide essential information about the medication, dosage, and administration.
- **Tertiary Packaging:** This is used for the bulk handling and transportation of pharmaceutical products. Examples include:
- **Pallets and Crates:** Used for the storage and transportation of large quantities of secondary packages.
- **Shrink Wraps:** Used to secure and stabilize multiple secondary packages on pallets.

2. Materials Used

- **Glass:** Offers excellent protection and is commonly used for vials and ampoules. Glass is inert and provides a high barrier to gases and moisture.
- **Plastic:** Includes a range of polymers such as polyethylene, polypropylene, and PET. Plastics are used for bottles, blisters, and syringes, offering flexibility and lighter weight.
- **Metal:** Often used in combination with other materials, such as aluminium foils in blister packs and metal caps for bottles. Provides a strong barrier against moisture and light.
- **Paper and Cardboard:** Used in secondary and tertiary packaging for cartons and labels. Paper-based materials are often used for their printability and structural integrity.

3. Technological Features

- **Smart Packaging**: Incorporates electronic elements such as:
- **RFID Tags:** For tracking and inventory management.
- **Sensors:** For monitoring temperature, humidity, and other environmental conditions.
- **Digital Displays:** For providing real-time information to users.
- **Tamper-Evident Packaging:** Designed to indicate if a package has been opened or tampered with, including:
- **Breakable Seals:** For bottles and containers.
- **Shrink Bands:** Wrapped around caps or closures.
- **Child-Resistant Packaging:** Ensures safety by preventing children from accessing medications, such as:
- **Push-and-Twist Caps:** For bottles.
- **Locking Mechanisms:** On various types of containers.

4. Specific Applications

- **Controlled-Release Packaging:** Designed for medications that require controlled release over time, using mechanisms such as:
- **Matrix Systems:** Embedded in tablets to control the release rate.
- **Coated Tablets:** With enteric or sustained-release coatings.\
- **Customized Packaging:** Tailored for specific patient needs or therapeutic areas, such as:
- **Personalized Dosing:** Packaging that adjusts to individual patient prescriptions.
- **Combination Products:** Packaging that includes both medication and delivery device, like inhalers with medication compartments.
- **Sustainable Packaging:** Focuses on environmental impact and includes:
- **Biodegradable Materials:** Such as plant-based plastics.

Recyclable Designs: To reduce waste and encourage recycling.

Pharmaceutical packaging has evolved to enhance drug safety, efficacy, and patient convenience. Key technologies include:

Current Technology in pharmaceutical packaging

1. Blister Packaging

- **Protection:** Shields doses from moisture and contamination.

- **Types:** Thermoformed (PVC/PET) and cold-formed (aluminium foil).

2. Prefilled Syringes

- **Convenience:** Reduces preparation time and ensures accurate dosing.
- **Types:** Single-use syringes and auto-injectors.

3. Smart Packaging

- **Features:** RFID/NFC tags, sensors for temperature/humidity, and digital displays.
- **Applications:** Enhances tracking, compliance, and real-time monitoring.

4. Tamper-Evident and Child-Resistant Packaging

- **Tamper-Evident:** Includes shrink bands and breakable seals.
- **Child-Resistant:** Push-and-turn caps to prevent accidental access.

5. Controlled-Release Systems

- **Types:** Extended-release (ER), sustained-release (SR), and delayed-release (DR).
- **Benefits:** Reduces dosing frequency and provides steady therapeutic effects.

6. Advanced Materials

- **Innovations:** Barrier films, biodegradable plastics, and glass-plastic combinations.
- **Applications:** Enhances protection and supports sustainability.

7. Customizable Packaging

- **Features:** Personalized dosing and patient-centric designs.
- **Benefits:** Improves adherence and usability.

8. Sustainable Packaging

- **Focus:** Recyclable materials and eco-friendly designs.
- **Goals:** Reduce environmental impact and comply with sustainability standards.

Bottle and contener Properties of packaging materials Mechanical Properties: The materials used should possess sufficient mechanical strength to withstand while handling, filling, closing and processing. Typical care is needed during transport, storage and also at the time of usage by the consumer especially in case of glass containers.

Physical Properties

• The packaging must have a suitable size; thus, rubber may present problems if it perishes.

• The material must protect from light, if necessary, that is, it must be ultraviolet absorbent.

• The container must not absorb substances from the products; e.g. absorption of water from creams in to cardboard box.

Chemical properties

• The product should not react with the container or closure, as might happen if alkaline substances are placed in aluminium containers.

• The container or closure must not yield substances to the product; for example, alkali from glass, plasticizers from plastics etc.

Biological properties the material of the container must be able to withstand attack by insects if this hazard is likely to be encountered. The packing should not support mould growth

Eco-Friendly Pharmaceutical Packaging

Eco-friendly, also referred to as environmentally friendly, nature-friendly, or green packaging, refers to packaging materials designed to minimize or eliminate harm to the environment. These materials are typically marked with eco-labels, indicating their sustainability. The pharmaceutical industry is increasingly investing in research and development to create packaging that is biodegradable and eco-friendly. The goal is to replace or supplement existing materials with those that are safer for the environment. One popular option for eco-friendly packaging is paper or cardboard, particularly when sourced from recycled materials or sustainable forests. Another promising material is corn starch, which is biodegradable and can be moulded into bags, trays, and boxes. Corn starch packaging offers a durable, environmentally safe alternative to plastic, retaining similar strength and usability.

When a pharmaceutical product reaches the market, it becomes challenging to enhance its packaging's environmental characteristics. This is why sustainability must be a priority from the early stages of product development. Designing environmentally responsible packaging for pharmaceuticals is no small feat. These designs need to balance reducing the environmental impact with ensuring that the packaging protects and preserves the product. Current eco-friendly packaging solutions aim to reduce the amount of waste generated. Many packaging designs are created to be streamlined, minimizing the total material used, and are made from materials that can be easily recycled or biodegraded. Greener designs often cater to the needs of pharmaceutical manufacturers without compromising environmental sustainability. In some cases, packaging materials are developed to allow for partial recycling or to have a high calorific value, which makes energy recovery more efficient when the materials are incinerated. Key characteristics of eco-friendly pharmaceutical packaging include being biodegradable, recyclable, reusable, and well-designed to meet both industry standards and environmental needs.

Smart packaging and technology

Temperature Monitoring and Control

Many drugs are sensitive to temperature fluctuations, and smart packaging equipped with sensors can continuously monitor and record the environmental conditions. For instance, temperature-sensitive pharmaceuticals, like vaccines or biologics, benefit from packaging that ensures they're maintained within specific ranges, preventing spoilage or loss of potency.

- **Temperature sensors** embedded in the packaging can alert stakeholders (manufacturers, logistics providers, or even patients) if there is a breach in temperature during transit or storage.

2. RFID and NFC for Supply Chain Transparency

Radio-frequency identification (RFID**)** and near-field communication (NFC) tags allow for real-time tracking of pharmaceutical products throughout the supply chain. These technologies provide:

- **Anti-counterfeiting measures:** Each product can be uniquely identified, reducing the risks of counterfeit drugs entering the market.
- **Inventory management:** RFID-enabled packaging helps pharmaceutical companies and retailers maintain accurate inventories.
- **Authentication:** Patients can use their smartphones with NFC to verify that their medication is genuine, giving peace of mind and boosting trust in the product.

3. Adherence Packaging

One of the major challenges in healthcare is ensuring that patients take their medications as prescribed. Smart packaging technologies address this by:

- **Reminders and Alerts:** Packaging equipped with digital components can send reminders to patients, via a connected app or a light/sound system on the package itself, ensuring they take their medication on time.
- **Dosage Monitoring:** Some smart blister packs record when a pill is removed, allowing for both patients and healthcare providers to track medication adherence.

4. Interactive and Connected Devices

Smart pill bottles and dispensers can be part of broader **Internet of Things (IoT)** ecosystems. These connected devices link the medication with a network of information:

- **Real-time data sharing:** Physicians can monitor patient compliance and adjust treatments based on adherence data.
- **Patient engagement:** Some smart packaging includes **QR codes** or links to mobile applications that provide patients with detailed

information on the drug, possible side effects, and instructions, improving patient education and safety.

5. Sustainability and Eco-friendly Smart Packaging

With growing awareness of environmental issues, smart packaging technologies are also incorporating sustainability. **Biodegradable materials** and **recyclable components** combined with advanced technologies help reduce the environmental footprint of pharmaceutical packaging.

6. Security and Tamper Evidence

Smart packaging includes features like:

- **Tamper-evident seals** that alert users if a product has been compromised.
- **Electronic seals** with built-in digital signatures that only authorized personnel can break, ensuring that the product has not been tampered with during shipping or storage.

Quality control and rule This guidance helps drug packaging material manufacturers set up a quality management system to ensure their products meet the required standards for use. It follows GMP and ISO 9001 principles and incorporates ISO 15378 specifics. Since there are differences between the quality systems used by pharmaceutical companies (GMP) and packaging manufacturers (ISO 15378), this guidance uses GMP terms to ensure both sides understand and follow the same rules. The goal is to standardize production, improve product quality, and encourage the use of Process Analytical Technologies to meet customer needs and boost satisfaction. The guidance applies to the design, manufacture, and supply of pharmaceutical packaging materials, including packaging systems, drug delivery devices, and printed materials that come into direct contact with drugs. It can be used for internal or external inspections, contract agreements with customers, and supplier audits. Regular type indicates basic requirements, while italics show additional practices for reference.

Key terms in this guidance include:

Batch: A defined quantity of packaging material with consistent characteristics.

Batch Record: Documentation tracking the batch's production and control.

Calibration: Ensuring a measuring instrument's accuracy.

Clean Room: A controlled environment that minimizes contamination.

Contamination: The introduction of unwanted material.

Finished Product: Packaging material that has completed production.

Intermediate Product: Packaging material in the middle of production.

Starting Material: Raw materials used to produce packaging.

Change Control: Documented management of changes in materials, processes, or equipment.

Deviation: Departure from approved procedures.

In-process Control: Testing during production to ensure the product meets specifications.

Out of Specification (OOS): Test results that do not meet set standards. The guidance defines the responsibilities of quality units, establishes controls for procurement, equipment, and facilities, and emphasizes the importance of validating and verifying production processes. It encourages collaboration between packaging manufacturers and pharmaceutical companies to ensure the quality and safety of drug packaging materials.

Recent Trends In Pharmaceutical Packaginge In Industry

The pharmaceutical packaging market is constantly advancing and has experienced annual growth of at least five per cent per annum in the past few years. The market is now reckoned to be worth over $20 billion a year. As with most other packaged goods pharmaceuticals need reliable and

speedy packaging solutions that deliver a combination of product protection, quality, tamper evidence, patient comfort and security needs. Constant innovations in the pharmaceuticals themselves (such as prefilled syringes, blow fill seal vials, powder applications and others) also have a direct impact on the packaging. Traditionally, the majority of medicines (51%) have been taken orally by tablets or capsules, which are either packed in blister packs (very common in Europe and Asia) or fed into plastic pharmaceutical bottles (especially in the USA). Powders, pastilles and liquids also make up part of the oral medicine intake. However, other methods for taking medicines are now becoming more widely used. These include parenteral or intravenous (29%), inhalation (17%), and transdermal (3%) methods. Oral tablets themselves are also now available in a wide range of different shapes and sizes. These changes have made a big impact on the packaging industry and there is an increasing need to provide tailored, individual packaging solutions, which guarantee the effectiveness of medicines. Due to degradation from environmental factors, such as light and humidity, there is often a direct link between packaging and a remedy's effectiveness. Packaging of oral medicines generally conforms to requirements for easy dispensing, child resistance but senior-friendliness, but packs must also be identifiable, functional and very often hermetically sealed. However, some innovations provide added benefits in one area but may not conform to the expected standards governing another. For instance, blister packs provide convenience and ensure hygiene. They are ideal for our fast-paced lifestyles and the need to take medication on the go and, as a result, there has been a large increase in their use. Indeed, blister packaging has provided the best worldwide growth among all pharmaceutical packaging products, with demand increasing 6.2 per cent annually to over $4 billion in 2006.Advances in the packaging machines themselves has seen the incorporation of precise filling mechanisms, as the wrong dosage of a medicine could be life threatening. Gentle handling is also essential and packs should be hermetically sealed for higher product safety A solution to achieve hermetically sealed packs for blister, blow fill-seal pouches, vials and other products is to overwrap them into a horizontal flow wrap. These flow wraps consist of a foil laminate that is able to increase the shelf life of the product as well as to ensure 100% tightness. Some packaging needs are not driven by the need for hygiene, safety or traceability. The increased focus on marketing of pharmaceutical products will become even more important in the future and will drive factors such as the need for flexibility in terms of various pack types and sizes. Other needs are simply driven by costs as pharmaceutical manufacturers face increased cost pressures throughout the entire production and packaging process. As a result, packaging machines have to become more efficient and user friendly, offering flexibility, easy operation, robustness, intelligence and protection from interference. It is a challenge to cover all aspects at once. The ongoing globalization trend with extended competitive landscape in the pharmaceutical industry will lead to smaller batch sizes. If existing packaging equipment is used, this will have a negative effect on productivity, as older machines are often not designed for quick changeovers and flexibility. New packaging lines will have to offer high flexibility while maintaining production levels. World demand for pharmaceutical packaging is forecast to rise 5.5 percent annually through 2015. The developed countries of Western Europe, the US and Japan will account for over 70 percent of the amount, although China will provide faster growth opportunities. India and Brazil will also evolve into fast-growing markets. This study analyses the $47.2 billion world drug packaging

industry. It presents historical demand data for the years 2000, 2005 and 2010, and forecasts for 2015 and 2020 by raw material (e.g., plastic resins, paper and paperboard, glass, aluminium foil), product group (e.g., primary containers, closures, labels, secondary containers, prescription containers, accessories), world region and for 14 countries7. Strong growth in emerging markets such as India and China have contributed to an increase in revenue optimism.

Global market trends

Report also reveals the trend of global packaging industry, which is as below: 2004:Total market value was 405 $US billion(approx.), 2005:The total market value was 425 $US billion(approx.) 2006:Total market value was 440 $US billion(approx.) 2007: Total market value expected to reach 465 $US billion (approx.) and in the year 2008, it may reach 480 $US billion(approx.) and by the end of the year 2014 it may touch 585 $US billion (approx.).Presently the average annual growth rate is nearly 3.5%, which is expected to touch US$597Bn by 2014 Pharmaceutical Packaging Industry - 2011 Yearbook provides insights into the global pharma packaging market, with coverage of the market landscape, key market trends, market drivers and restraints. The report provides market forecasts for the global pharma packaging industry until 2017. The geographical distribution of pharma packaging manufacturers across key geographies, such as the US, the top five countries in the European region, Japan and BRIC (Brazil, Russia, India and China) countries have been provided. Key cost and developmental issues have also been addressed. The report also provides an indepth analysis of the competitive landscape, including the benchmarking of top companies, key trends on mergers and acquisitions, and licensing agreements involving pharma packaging.10(fig1) The global pharma packaging market was valued at $47.8 billion in 2010. The market is forecast to grow at a compound annual growth rate (CAGR) of 7.3 per cent from 2010–2017, to reach a value of $78 billion by 2017. The global pharma industry is currently registering rapid expansion, with advances in manufacturing processes, and technology innovation and integration, which are the main factors behind the growth of the pharma packaging industry globally. This growth is expected to be highest in the emerging economies of India and China, primarily on account of increasing generics and contract manufacturing activities in these countries. The pharma packaging industry will continue to grow as drugs worth $142 billion go off patent in the next five years, expanding the generic market and the entire pharma packaging industry. The fastest growth in the pharma packaging market is expected to come from prefillable syringes and parenteral vials, which will continue to expand as advances in biotechnology lead to the introduction of new therapies that must be injected. The increasing demand for biologics will strengthen demand for innovative product packaging solutions in the global pharma packaging market. All these factors, along with the growing pharma industry, will continue to drive demand for packaging. However, the packaging industry will have to overcome challenges, such as the availability and price volatility of raw materials and changing health regulations, in order to meet increasing demand from the growing pharma industry.

Functions of Pharmaceutical Packaging

1. Containment - The containment of the product is the most fundamental function of packaging for medicinal products. The design of high-quality packaging must take into account both the needs of the product and of the manufacturing and distribution system. This requires the packaging: not to leak, nor allow diffusion and permeation of the product, to be strong enough to hold the contents when subjected to normal handling and not to be

altered by the ingredients of the formulation in its final dosage form.

2. Protection - The packaging must protect the product against all adverse external influences that may affect its quality or potency, such as light, moisture, oxygen, biological contamination, mechanical damage and counterfeiting/adulteration.
3. Presentation and information - Packaging is also an essential source of information on medicinal products. Such information is provided by labels and package inserts for patients.
4. Identification - The printed packs or its ancillary printed components serves the functions of providing both identity and information.
5. Convenience - The convenience is associated with product use or administration e.g., a unit dose eye drop which both eliminates the need for preservative and reduces risks associated with cross infection, by administering only a single dose.

Recent Packaging Technologies

Blow-fill-seal technology

Aseptic blow-fill-seal (BFS) technology is the process by which plastic containers are formed, filled with sterile filtered product and sealed in an uninterrupted sequence of operations within the controlled sterile environment of a single machine. The blow-fill-seal process is a robust, advanced aseptic processing technology, recognized by worldwide regulatory authorities for its inherent operational advantages over conventional aseptic production. Blow-fill-seal systems offer a unique combination of flexibility in packaging design, low operating cost and a high degree of sterility assurance. The machines require a minimum number of operating personnel and have a relatively small space requirement. A variety of polymers may be used in the process, low and high-density polyethylene and polypropylene being the most popular. The innate ability to form the container/closure during the actual aseptic packaging process allows for custom design of the container to meet the specific needs of the application. This flexibility not only improves container ease of use, but provides a means of interfacing with many of today's emerging drug delivery technologies, most notably in the field of respiratory therapy.

Blow-fill-seal process

Container moulding

Thermoplastic is continuously extruded in a tubular shape . When the tube reaches the correct length, the mold closes and the parison is cut . The bottom of the parison is pinched closed and the top is held in place with a set of holding jaws. The mold is then transferred to a position under the filling station.

Container filling

The nozzle assembly lowers into the parison until the nozzles form a seal with the neck of the mold . Container formation is completed by applying a vacuum on the mold-side of the container and blowing sterile filtered air into the interior of the container. The patented electronic fill system delivers a precise dosage of product into the container. The nozzles then retract into their original position**.**

Container sealing

Following completion of the filling process, the top of the container remains semi-molten. Separate seal molds close to form the top and hermetically seal the container. The mold opens and the container is then conveyed out of the machine . The cycle is then repeated produce another filled container. The filled containers are tested and checked to ensure that they meet the very strict specifications laid down for such products. The duration of the complete cycle is between 10-18 seconds, depending on the container design and the amount of liquid to be filled.

Advantage of BSF Tchnology

BFS technology offers considerable advantages over conventional aseptic filling of preformed (plastic or other) containers, which are described as follows:

1. BFS technology reduces personnel intervention making it a more robust method for the aseptic preparation of sterile pharmaceuticals.
2. There is no need to purchase and stock a range of prefabricated containers and their closures. Bulk containers of plastic are required.
3. Cleaning and sterilization of prefabricated containers and closures is not required. A clean, sterile container is made within the BFS machine as it is required for filling.
4. The cost of material transport, storage and inventory control is reduced.
5. Validation requirements are reduced.
6. The technology allows the design of high-quality, custom-designed containers with tamper-evident closures in a variety of shapes and sizes.
7. There is a large choice of neck and opening device shapes.
8. A single compact BFS machine takes the place of several conventional machines, saving floor space. In addition, zones for transport to successive filling and closing procedures are not required because these operations all take place in the BFS machine itself.
9. The operation of BFS machines is less labor intensive than conventional aseptic filling.
10. The code numbers and variable data such as batch number and expiry date can be molded into the container itself rather than being added at a subsequent stage.
11. The process lends itself to the production of single dose containers and therefore preservatives are not necessary as they are with multi-dose containers.

Blow-fill-seal technology has gained much market focus in recent years due to the increased focus on biologics, proteins and other complex solutions. These important products often cannot withstand exposure to high temperatures for extended periods of time without degradation of their active components. Conventional terminal sterilization, therefore, is not an acceptable method to produce a 'sterile' product. Bulk sterilization, sterilization by gamma irradiation or filter sterilization followed by direct packaging utilizing the blow-fill-seal process are often used successfully for these types of products.

Safty ampule beaker

Ampoules are small glass vessels in which liquids for injections are hermetically sealed. They are opened by snapping off the glass top at the neck. The scoring at the neck does not always break where it is intended. This is due to the glass re-melding to some degree at the score line. When the cap is snapped off, glass chips can fly off and a jagged or sharp edge can cut the hands of the healthcare worker. Safer products exist removes the risk of broken glass cuts when breaking off the glass top. Safe BreaK™ is a safety ampoule breaker and it avoids dangerous glass filing required during breaking the ampoule. No gauze pads necessary to protect hands. SafeBreaK™ prevents cross contamination. Snapit® invented by a Registered Nurse in Rockhampton, QLD, Australia. Most people who work with ampoules have suffered an injury from breaking an ampoule. Furthermore, the very sharp edge on both the ampoule and the ampoule lid when the neck of an ampoule is snapped off can cause serious cuts. Snapit® reduces the risk of sustaining a sharps injury by keeping hands out of harms away. Snap off Ampule Ampoules are small glass vessels in which liquids for injections are hermetically sealed. A typical pharmaceutical ampoule has a narrow neck between a cylindrical body and a conical tip. Ampoule is a small, hermetically sealed glass or plastic container, e.g., one containing medication for parenteral

administration. Snap off ampoule enables to break a piece from a whole ampoule. Hisafe™ ampoules are manufactured with pre-fragilized systems like Safe Cut™ OPC ampoules or Safe BreaK™ color ampoules for easy opening by doctors without cutter or filling. Safe Cut™ ampoules open safely by using a predetermined breaking point to give a clean cut. Safe Break™ ampoules come with color ring on its constriction which is used to open the ampoules easily by hand

Child Resistance Packagind

Child-resistant packaging (CRP) or C-R packaging is special packaging used to reduce the risk of children ingesting dangerous items. The CRP containers defy penetration by children but can be opened by adults. This is often accomplished by the use of a special safety cap with locking mechanism.

The U.S. Consumer Product Safety Commission has stated in a press release that "There is no such thing as child-proof packaging. So you should not think of packaging as your primary line of defense. Rather, you should think of packaging, even child-resistant packaging, as your last line of defense."

It is required by regulation for prescription drugs, over-the-counter medications, pesticides, and household chemicals. In some jurisdictions, unit packaging such as blister packs is also regulated for child safety. In developed countries like UK, it has been made compulsory to pack drugs like Aspirin, Paracetamol, Elemental iron, Contraceptives and many other drugs to be packed in CRP**.**

What's next?

Packaging and delivery systems as a differentiator for drug products will continue to become more important, especially in crowded therapeutic areas and for solving industry-wide problems such as drug-product counterfeiting. The market today is receptive to packaging systems that can provide track-and-trace capabilities and product authentication throughout the supply chain. Pharmaceutical seals are an ideal platform for these technologies. The wider use of technologies such as RFID tags embedded in the plastic button affixed to the seal, or ultraviolet inks applied to the seal, providing item-level security may be seen. The drive for cleanliness and purity will no doubt continue into the foreseeable future. With advances in material science, we can expect cleaner elastomeric formulations by utilizing BFS technology for manufacturing primary packaging and delivery-system components e.g., Respules™, Twist Tip™. The coatings with near-total barrier properties e.g., PICVD coatings may have a potential market. Although predicting the future is problematic, but one prediction with confidence can be made: as pharmaceutical research continues to develop advanced, life-saving therapies, the systems used to package and administer those therapies will keep pace through advances in material science and innovative design.

a] substance

There are variety of substrates used in the design of packages with intent to provide counterfeit and tamper evident features starting from litho paper, polystyrenes, destructive vinyl's, acetate films synthetic paper and coatings etc., There are many ways of incorporating covert markers within a substrate, such as visible or UV fluorescing fibers, or chemical reagents in carton board or paper. Watermarks can be embedded in leaflet paper, or metallic threads interwoven in the base material, possibly including an overt optically variable devices (OVD) feature. These require a dedicated supply source and large volume production, which, if affordable, results in a very effective option. Micro-encapsulated distinctive odors can be applied as an additive to an ink or coating to provide a novel covert or semi-overt feature, as well as sound chips creates special opportunities in the design.

b] Packaging designs

Packaging designs like sealed cartons, aerosol containers have inherent strength against counterfeiting

c] Sealing systems

Special caps such as the outer tamper evident system or the foil seal as an internal tamper evident feature are commonly used for pharmaceutical products. Sealing options are lever-lidded tins, secure packaging tapes, lined cartons and tear tapes/bands.

5. Security labels

Tamper evident and security labels play an important role in providing some relief to the consumers against fakes. In self adhesive labels the substrate mostly performs as a complimentary interaction of the substrate and the pressure sensitive adhesive. While passive security labels have been extensively used, today one can find a greater application of functional labels such as printing plus anti-theft. Some label options are:

a) Paper labels with security cuts

The substrate used for these labels is ordinary coated/uncoated paper. The security features are built in by the label printer at the converting stage. With the help of a special cutting die, the face material is given cuts at various angles so that by any ways one tries to remove these labels the paper will tear off. A general purpose permanent adhesive works fine with such labels. Care is taken to ensure that the adhesive will adhere well and firmly to the surface on which the label has to be applied.

b) Destructible labels

Needs a special substrate designed for the purpose. Most of the high-end applications use a specially made cellulose acetate film. The film is very intricately designed so that it has adequate strength to undergo conversion into label stocks in roll form. It is available both in clear and opaque formats and further converted into labels using aggressive pressure sensitive adhesives. The labels can be automatically dispensed on automatic label dispensers and when attempted to be removed, break-up into very small fragmented pieces. The cost effective vinyl have replaced acetate film. A combination of various synthetic polymers can be used to impart low inherent strength to the substrate.

c) Void labels and tapes

The most important of the tamper evident security labels and have text built into them. When as a self adhesive label they are removed, they exhibit the word VOID both in the removed film and the adhesive layer left behind. These substrates gain importance as there can be customization built into the labels produced with it. One can use polyester or biaxially-oriented polypropylene (BOPP) as face materials. Variety of colors, even metallization is possible. The text VOID could be replaced by the customers brand, emblem or a message, which would normally be invisible till the label is opened. Due to the versatility of things that can be done with the product, these label substrates have found widespread usage worldwide. The substrates can even be designed to work as tapes for the final outer corrugated cartons to prevent pilferage.

d) Self destructing paper label

The labels are very similar to destructible labels as mentioned earlier. In this case, the substrate used is of very weak strength paper of low grammage. The paper is also heavily loaded with fillers creating a weak and brittle paper. Labels made from such papers fragment into pieces when attempted to be removed. However, converting it is a very tricky issue when using these substrates due to the lack of strength. The papers are very difficult to source since most of the paper mills are trying to develop papers with very high strength.

e) Holographic labels

The labels form a very large and important part of the security label market and are an ideal choice for product authentication. The holographic foil that is an optically variable device is largely made

using a polyester film base. The optical interaction of the holographic image and the human eye makes it ideal for brand promotion and security. These products reveal the holographic image when tilted in light. The image so revealed can be customized to the need of the brand owners to make the maximum impact. The hologram production involves development of complex origination process and a lot of innovation to make it difficult for counterfeiters to duplicate. Many holograms are designed such that besides offering brand authentication they also have tamper evident properties. The top polyester layer has a special coating that if the hologram is attempted to be removed, the top layer peels off leaving the hologram behind on the product

f) Multi layered labels

The face stock of the labels is laminates of different substrates depending on the requirement of the security label, which can be film to a film or film to paper or other coatings. The layers are designed such that on separation they either exhibit tamper evidence by way of a one layer getting fiber tear or by complete separation and exhibiting a design or message. The various layers are bonded together by adhesive or heat seal coatings depending on the requirement of the design of the label. The segment of substrates can be vast and can be designed to the requirements of the user and offering variants as per the imagination of the designer or producer.

g) Transfer labels

The substrate consists of either polyester or BOPP. The film has a release coat over which the matter is printed and then adhesive coated. Such labels when applied and peeled off, the clear top layer comes off leaving the printed matter behind. This can also be designed such that some printing is subsurface and remains behind and some printed matter is on the top and comes off with the top layer.

h) UV fibers in paper

Here the substrate is paper and the security is built in at the paper mill during the paper making process. UV light sensitive fibers are incorporated into the pulp and evenly distributed in the paper. When labels made from such paper are exposed to UV light, the fibers glow indicating the genuineness of the labels. The volumes required for these substrates have to be large enough to allow the paper mill to produce a batch full of pulp that would eventually be converted into paper for security labels. The color of the fibers can be selected as per the wish or need.

i) Security threads

Thin micronic threads are introduced in the substrates either at the label stock making stage or they are separately built into two layers of paper laminated together. The threads can also be sensitive to UV light which will glow under UV light. e.g., currency notes.

j) Water mark

The mark that can be seen as an image in the paper when held against the light. The mark scan can also be built into the paper at the paper making stage in a paper mill. The volume has to be large enough to justify incorporating the markings in the paper making process. However, some converters do print these with inks where security requirements are not of a very strict nature.

6. Coding, printing and graphics

a) Coding and marking

For a long time, regulatory compliance drove the need for coding and marking on the packaged products starting with best before date. However, with an increasing awareness and greater printing and marking options like ink jet coding, laser coding and electrolytic etching for metal marking on can decide their use to evolve an overall anti-counterfeit feature. These provide the opportunities for online coding with flexibility, programmable options, time saving and low running costs. Depending on the exact requirements one can go for the touch dry contact

coding, non contact coding or the permanent laser coding etc. Traceability and counterfeiting measures can be improved by using a variable data on the labels i.e., to create unique marking of the packages, which can be made cost effective by using digital printing technology for producing on demand short run packed products.

b) Security graphics

Fine line color printing, similar to banknote printing, incorporating a range of overt and covert design elements such as guilloches, line modulation and line emboss. They may be used as background in a discrete zone such as an overprint area, or as complete pack graphics, and can be printed by normal offset lithography or for increased security by intaglio printing. Subtle use of pastel "spot" colors makes the design more difficult to scan and reproduce, and security is further enhanced by the incorporation of a range of covert design elements, such as micro-text and latent images.

7. Holograms

Holograms were used first for promotional purposes during 80's and exhibited a phenomenal growth by 1996. Probably the most familiar overt feature is the "dove" hologram which has been used to protect credit cards for many years. A hologram normally incorporates an image with some illusion of 3-dimensional construction, or of apparent depth and special separation. Holograms and similar optically variable devices (OVD) can be made more effective when incorporated in a tamper evident feature, or as an integral part of the primary pack (e.g., blister foil). They can be incorporated into tear bands in over wrap films, or as threads embedded into paper substrates and hence may be usefully employed on secondary/transport packs. Several processes can be used to incorporate holograms into packaging; flexible, folding cartons or bottles. Methods include pressure sensitive, shrink, or glue applied labels, hot stamping, web transfer and lamination. Essentially selection options for the hologram are the image and media. The right combination of the two components produces a successful anti-counterfeiting marking that meets the desired objective.

8. Forensic markers

There is a wide range of high-technology solutions which require laboratory testing or dedicated field test kits to scientifically prove authenticity. These are strictly a sub-set of covert technologies, but the difference lies in the scientific methodology required for authentication.

a) Chemical taggants

Trace chemicals which can only be detected by highly specific reagent systems, but not normally detectable by conventional analysis.

b) Biological taggants

A biological marker can be incorporated at extremely low levels (parts per million or lower) in product formulations or coatings, or invisibly applied to packaging components. At such low levels they are undetectable by normal analytical methods, and require highly specific "lock and key" reagent kits to authenticate.

c) DNA taggants

Highly specific DNA "lock and key" reagent systems can be applied to packaging by a variety of printing methods. They require a "mirror image" recombinant strand to effect the pairing, and this reaction is detectable by a dedicated device. Security is further assured by hiding the marker and reagent pair in a matrix of random DNA strands, but the test is tuned to work only with one recombinant pair.

d) Isotope ratios

Naturally occurring isotopes are highly characteristic of the source compound, and accurately be determined by laser fluorescence or magnetic resonance techniques. They can provide a "fingerprint" of one or more of the product constituents, or alternatively a specific marker

added with its own unique signature. Detection requires highly specialist laboratory equipment.

e) Micro-taggants

Micro-taggants are microscopic particles containing coded information to uniquely identify each variant by examination under a microscope. It may take the form of alphanumeric data depicted on small flakes or threads, or fragments of multicolored multilayered laminates with a signature color combination. These can be embedded into adhesives, or directly applied to packaging components as spots or threads.

f) Nano-Printing The technologies allow microscopic application onto individual tablets. UV inks allow invisible printing onto any substrate including glass vials and ampoules and provide an excellent security.

CONCLUSION

In today's globalized world, the packaging industry faces significant challenges. As international markets open up, meeting global standards and maintaining high quality becomes essential. To stay competitive, the packaging industry needs to invest more in research and adopt a holistic approach that goes beyond just the functional aspects of packaging. Currently, very few pharmaceutical companies dedicate time and resources to R&D in packaging. Many of the traditional packaging options available don't offer adequate protection against counterfeiting or ensure the quality needed. The industry has been slow to adopt new technologies, likely due to high costs. Since packaging plays a crucial role in the drug manufacturing process, it is ethically important for the industry to incorporate scientific methods into its practices. With a focus on product needs, security, cost-efficiency, and patient convenience, pharmaceutical packaging is poised for rapid and innovative growth, helping to build strong brand identities in the process.

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