

New Methods and Technology of Pharmaceutical Packaging in the Future

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Abstract

Pharmaceutical packaging may be defined as the science, art and technology of enclosing or protecting products from distribution, storage, sale and usage including printed material employed in the finishing of a pharmaceutical product. We conducted this research paper by observing the different types of reviews, as well as conducting and evaluating literature review papers. The packaging can be defined as an economical means of providing presentation, protection, identification information, containment, convenience and compliance for a product during storage, carriage, display and until the product is consumed. Packaging must provide protection against climatic conditions biological, physical and chemical hazards and must be economical. The packaging of pharmaceutical a product is very important with regard to its stability, acceptance of the patient, transport, etc. There will always scope for advancement and improvement of pharmaceutical packaging.

Key words: pharmaceutical packaging; materials; recent advances; food products; methods; technology

Introduction

Pharmaceutical packaging may be defined as the science, art and technology of enclosing or protecting products from distribution, storage, sale and usage including printed material employed in the finishing of a pharmaceutical product. It's absolutely necessary to select the right package for a product; because the container or the package forms an integral part of the product. This is true not only for pharmaceutical products, but also for food products, consumer durables or electronic devices. The basic purpose of packaging is to protect the integrity, purity, potency and quality of the product. Packaging is, therefore, a technology and a science, which deals with the study of materials and methods used to pack the product; and also the knowledge of the machinery used for packing the product. In the manufacture, storage, and marketing of pharmaceutical products, package design and packaging are of paramount importance. This is so, because a faulty or defective packaging system can lead to destabilization of a drug, causing serious, untoward or toxic manifestation in the patient. Packaging is important in material handling, storage and transportation. A drug may become totally useless or even toxic, if the container reacts with the contents, regardless of how well the product is formulated.

Packaging must provide protection against climatic conditions biological, physical and chemical hazards and must be economical. Stability of the product throughout the shelf life. Package should provide adequate information related to the contents including legal requirements, route of administration, storage conditions, batch number, expiry date, and manufacturers name and address and product license number. Package should assist in patient compliance. Package should preferably have an aesthetically acceptable design. The primary packaging consist of those packaging components which have a direct contact with the product (i.e. bottle, cap, cap liner, label etc.) The main functions of the primary package are to contain and to restrict any chemical, climatic or biological

or occasionally mechanical hazards that may cause or lead to product deterioration. Packaging must also function as a means of drug administrations. The packaging external to the primary package is known as the secondary packaging. The secondary packaging mainly provides the additional physical protection necessary to endure the safe warehousing and for refill packaging.

Ideal qualities of a pharmaceutical packaging

1. It should have sufficient mechanical strength so as to withstand handling, filling, closing and transportation.
2. It should not react with the contents stored in it.
3. It should be of such shape that can be elegant and also the contents can be easily drawn from it.
4. It should not leach alkali in the contents.
5. The container should not support mould growth.
6. The container must bear the heat when it is to be sterilized.
7. The contents of container should not be absorbed by the container.
8. The material used for making the container should be neutral or inert.
9. Any part of the container or closure should not react with each other.
10. Closure should be of non-toxic nature and chemically stable with container contents.

Types of packaging materials

The following materials are used for the construction of containers and closures.

1. Paper and board
2. Rubber
3. Glass

4. Plastic
5. Metal

Advances in pharmaceutical packaging

Cypak's advanced medication monitoring and report card systems

This is an advanced packaging technology can enable to patients to communicate with healthcare professionals through printed technology. This record the time and data that a pill was taken based on when it is

removed from its blister pack. This allows the patients to log their feedback on side effects and treatment efficacy and upload it. This technology holds significant potential for new levels of patient-doctor interface to workout best treatment plan. Sensor-based packaging concepts are best applied in clinical trials. This helps in drug development to establish whether a drug is ineffective or simply not being taken properly.

Cypak's advanced medication technology is used in targeting clinical trials market, as poor date resulting from non-compliance can be financially devastating in this context [1].



Figure 1: Cypak's advanced medication monitoring and report card systems.

Burgopak's sliding cr blister pack

Burgopak healthcare and technology- won the award for the “Most Innovative Child Resistant Packaging Design” at the Pharmapack Paris

exhibition. The Burgopak's sliding CR blister pack can only be opened by applying force at two different points on the packaging.

The blister pack and leaflets are coordinated with the outer box, which insures the product is never separated from its packaging [2].



Figure 2: Burgopak's Sliding CR Blister Pack.

Pharma small hands resistant (shr): a re-closed and tear resistant carton

A reclosable and tear-resistant carton is ideal for highly toxic drugs. Stora Enso and Bosch launched Pharma small hands resistant (SHR). Stora

Enso Pharma SHR is a child restraint reclosable carton. It is ideal for highly toxic drugs and it is easy to use for senior adults. It is tested with the highest F=1 rating in the US. It is an innovative paperboard package system it only requires simple squeeze and pull manoeuvre [3].



Figure 3: Pharma Small Hands Resistant (SHR): A re-closed and tear Resistant Carton.

The Silenor® Patient Starter Kit features

The Silenor® Patient Starter Kit features a novel carton design that when opened resemble a bedroom complete with bed and nightstand. Contained within the design is a seven count unit dose carded blister, removable from the design to enable portability and convenience. To support patient

compliance and adherence, the bed carton design contains a literature pocket, housing the medication guide, the Sleep -Saver™ Program prescription discount card, and a multi-panel color leaflet complete with instructions on taking Silenor®, description of side effects, guides to enrolling in the Sleep -Saver™ program including website and tollfree number, as well as additional information on insomnia treatment. (Compliance Prompting, 2010)



Figure 4: The Silenor® Patient Starter Kit features

Eco-Friendly Pharma Packaging

Environmental considerations must not lead to any compromise on a package's safety or accessibility. New pharmaceutical packaging concepts are beginning to emerge that address environmental concerns without sacrificing packaging advances made in the last decade

Ecoslide-RX sustainable compliance packaging

Folding Box Company and Legacy Pharmaceutical Packaging launched their Ecoslide - RX sustainable compliance packaging.

The pack is made from 100% recycled material, using unbleached paperboard and a clay-coated surface designed to house blister packaging with a minimum of unsustainable film and foil.

The slide package meets all the modern expectations for child-resistance and accessibility for seniors, but doesn't require heat sealing in the manufacturing process, reducing both costs and energy usage [4].



Figure 5: Ecoslide -RX sustainable compliance packaging

Prefilled syringes

Advantages and driving factors of prefilled syringes

Self-filling a syringe can be a cumbersome process, which is not only slow but can also result in incorrect dosages and spillages. The availability of prefilled syringes introduced both convenience and accuracy to self-administered drugs. The increased use of prefilled syringes is not only following the general consumer trend of a growing demand for convenient and easy-to-use products – it is also driven by the pharmaceutical producers as a consequence of improved safety and the reduction in drug overfills [5].

Packaging against counterfeiting

AS per FDA - counterfeit drugs account for 10% of all medication in the US. EU believes between 1% and 3% of medicines. Latest developments are fluorescent labels, packaging with laser surface authentication, which can be identified through a unique code, and near field communication (NFC) tags [6].

In India for instance, drug companies have been sending their medicines to overseas markets including an obligatory sport barcode on their outermost packaging, started in October 2011.

These are distinct aspects to deciphering and de-complexifying the counterfeit pharmaceutical supply chain. One that is probably more in use today by almost all pharmaceutical companies worldwide is the Product-Based tracking methodology which incorporates the use of high technology system to identify counterfeit products in the market.

These technologies include Tamper-evident packaging, holographic, bar codes and the more recent RFID.

It is true that a security device on packaging components provides no assurance as to authenticity of the contents, which may have been substituted or adulterated.

Security device alone do not reduce counterfeits, but are designed to make them easier to detect.

Classification of Anti-Counterfeit Technologies Overt (Visible) Features:

Overt features are intended to enable end users to verify authenticity of a pack. Such features will normally be prominently visible, and difficult or expensive to reproduce.

The lists of overt features are follows:

Holograms:

Optically Variable Devices (OVD):

Colour Shifting Security Inks and Films

Security Graphics

Sequential Product Numbering

On-Product Marking



Figure 6: Overt (Visible) Features

Covert (Hidden) Features

The purpose of a covert feature is to enable the brand owner to identify counterfeited product. The general public will not be aware of its presence nor have the means to verify it. If compromised or publicized, more covert features will lose some security value. The list of Covert features includes:

- Invisible Printing

- Embedded Image
- Digital Watermarks
- Hidden marks and printing
- Laser coding
- Substrates
- Anti-copy and Anti-scan design
- Odour



Figure 7: Covert (Hidden) Features

Forensic markers:

There is a wide range of high technology solutions which require laboratory testing or dedicated filed test kits to scientifically prove authenticity of the products. The list includes:

- Chemical Taggants
- Biological Taggants
- DNA Taggants

- Isotope ratios
- Micro-taggants [7]

Serialization/Track and Trace technologies

A number of Track and Trace applications are under development for the pharmaceutical sector. These involve assigning a unique identity to each stock unit during manufacture, which then remains with it through the supply chain until its consumption [7].

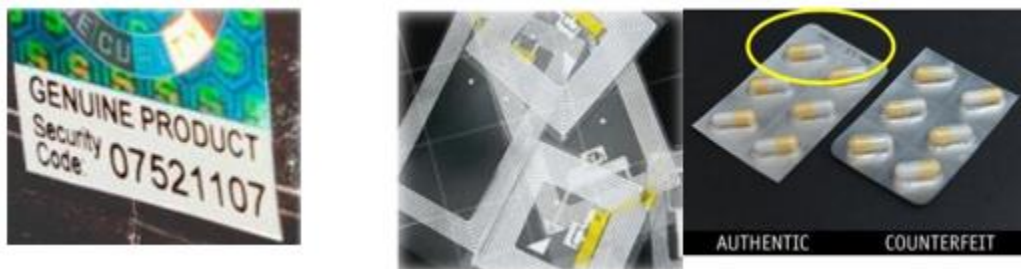


Figure 8: Serialization Track/trace Technology, RFID, Topography - Authentic & Counterfeit product

Tamper Resistant Packaging

The requirement for tamper resistant packaging is now one of the major considerations in the development of packaging for pharmaceutical products. Tamper resistant package is one having an indicator to entry in which, if missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. FDA approves the following configurations as tamperresistant packaging: Film wrappers, Blister package, Strip package, Bubble pack, Shrink seals, and bands Oil, paper, plastic pouches, Bottle seals, Tape seals, Breakable caps, and Aerosol containers.

Advancement in Pharmaceutical Packaging The Talking Packaging

There are two developments in talking packaging at this moment. The "TalkPack" from Wipak Walsrode GmbH in Germany, a system, which can be invisibly integrated into any printed image on any packaging material, but needs a special scanning pen. A recent development by VTT Technical Research Centre of Finland using tags with NFC (Near Field Communication) based technology connected to NFC-enabled mobile phones to download text, audio or web page product information, which can be played back on their handset [8].



Figure 9: Talk Pack-Wipac

A special pen-shaped reader is used to retrieve the stored information and to replay it as audio files and render speech, music or sounds audible and thus the consumer can obtain information on the manufacturer, brand, shelf-life or other information. Talk Pack does not require any RFID or microchips. The dot code is simply printed on top of images and texts using a special varnish. This technology can be used with all printing technologies and package types. Dispensing caps or Functional caps - store dry or liquid supplements separately from the water-released by the consumer they form energy or vitamin drink or sometimes a medicinal drink. Everything from pharmaceuticals to nutraceuticals, can be packed and properly dosed by a dispensed cap [9].

Recent changes and development in Inhalers (MID, pMID, DPI, nebulizers)

Hydrofluoroalkane (HFA) propellant replacing the chlorofluorocarbon (CFC) due to concerns about the latter's damaging effect on the ozone layer. The US Food and Drug Administration (FDA) have ruled that no CFC MDIs will be sold in the US after 2008. As a result of the requirement to use HFA propellants, challenges arose with respect to re-designing formulation, valves, and actuators and conducting clinical trials. The elastomeric components in existing metering valves are generally incompatible with HFA propellants, and some surfactant.

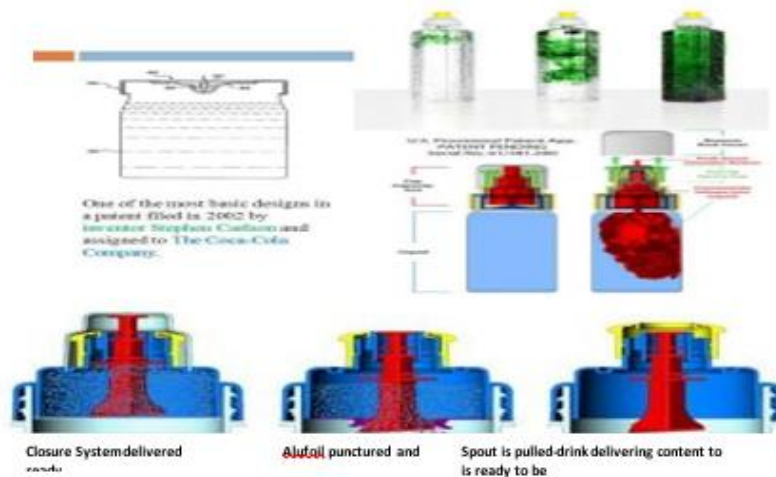


Figure 10: Dispensing cap

DPI devices are categorized as Single-unit dose inhalers in which each dose is loaded into the device before use (Aerolizer™, Novartis; Handihaler™, Boehringer Ingelheim) and Multidose reservoir inhalers in which a large supply of drug is pre-loaded into the device (Turbuhaler™ or Flexhaler™, AstraZeneca; Twisthaler™, Schering-Plough). Multiunit dose inhalers in which several single doses are individually sealed and discharged each time the device is actuated (Diskus™, GlaxoSmithKline). The Aerolizer uses separate single-dose capsules while the Flexhaler, Diskus, and Twisthaler all have dose indicators. In contrast, pMDIs do not have an independent means by which to monitor the number of doses remaining in the device, the FDA issued guidelines that recommended manufacturers integrate.

Diskus Inhaler Technique

Device innovators and manufacturers were honored as AANMA's first innovative technology award at the 15th annual Allergy & Asthma Day Capitol Hill on Thurs., A DISKUS® is a dry-powder inhaler that holds 60 doses. It features a built-in counter, so that you always know how many doses you have left in it. First dry powder inhaler that simplifies asthma care by combining an inhaled corticosteroid with a long-acting bronchodilator in one device [10].



Figure 11: Diskus Inhaler

Recent Technical Advancements in Parenteral packaging Blow-Fill-Seal Technology

It is developed in Europe in the 1930s and introduced in the US in the 1960s, has emerged as a preferred method for aseptic packaging of

pharmaceutical and healthcare products due to unrivalled flexibility in container design, overall product quality, product output and low operational costs.



Figure 12: Blow fills seal process

Blow-Fill-Seal Vs. Conventional Aseptic Processing Uninterrupted sequence

- Reduction in the number of parts required to assemble the package
- Blow-fill-seal offers a cost advantage over conventional aseptic processing
- It produces a one-piece, aseptically filled container with a built-in safety seal

Applications

Blow-fill-seal technology is commonly used for ophthalmic and respiratory drugs, and it is also being employed for Parenteral and dental and veterinary products. Since blow-fill-seal technology is suitable for unit dose, its use is increasing as more and more companies move to single-use packages. Process operates at low temperatures and incorporates several fill systems, allowing flexibility in terms of the volatility and viscosity of products that can be packaged.

There are two types of blow-fill-seal packaging:

- 1] The Micro Dose package
- 2] The Twist-Tip vial



Figure 13: (a) Micro Dose Package (b) The Twist Tip Vial

These packages are made using a modified blow-fill-seal process. One of the more recent advancements in blow-fill-seal technology is the ability to insert sterile packaging components into the container to make it a multi-use container [11].

Syreen Prefilled Syringe Design

Environmental awareness is even starting to extend to the syringe market. It replaces glass with cyclic olefin polymer (COP). This material has allowed secondary packaging altogether as the COP design forms its own outer shell. The ability of packed syringes to clip into place eliminates the need for packaging materials like cardboard.



Figure 14: Syreen Prefilled Syringe Design.

Stora Enso – PHARMA Ddsi Wireless

This technology is based on conductive ink on a carton board-based blister inlay, which is connected to a cellular module embedded in the package.

- The removal of pills is tracked and the information can be sent to an electronic database automatically via GSM or GPRS cellular networks.

- A doctor can simply use the packaging data to track a patient's medication intake.
- The system can also issue phone calls and text messages to the patient, healthcare professionals and even relatives. Even voice and sound-based packaging system have been developed to help blind and illiterate patients take their medicines safely.



Figure 15: Stora Enso- Pharma DDSI Wireless.

Robotics in Pharmaceutical Packaging:

In many instances robotics are utilized to automate the existing manual process such as loading a carton, horizontal form fill seal machines or blister machines. In these cases, the advantages include increased speed, efficiency and an increase in overall equipment effectiveness (OEE). Other advantages may lead to reduced cost, reduced injury and eliminating re-work. Robots are extremely accurate and repeatable. They operate 24/7 and, with options like vision and line tracking, can verify placement of product and track movement of continuous motion machines to keep up with production speed.

Robotic cells typically offer a very small foot print compared with other type of packaging equipment. At the same time, these cells offer a generous work envelope, allowing the installed equipment to handle multiple packaging lines. A typical robotic loading assembly, or collating system uses a foot print less than 3' x 3'. Even a dual cell palletizer, typically a large robotic packaging machine, only occupies less than 12' x 10' of floor space. In addition to small foot print, robotic packaging lines can save space by using a single robotic cell for multiple functions, eliminating the need for additional equipment. For example, a robotic case packing and palletizing cell can be created that both loads products into cases but also places the filled cases on a pallet, reducing the equipment and space required.

Material & Methods

We conducted this research paper by observing the different types of reviews, as well as conducting and evaluating literature review papers.

Result & discussion

The packaging can be defined as an economical means of providing presentation, protection, identification information, containment, convenience and compliance for a product during storage, carriage, display and until the product is consumed. Packaging must provide protection against climatic conditions biological, physical and chemical hazards and must be economical. Pharmaceutical packaging is a multiphase broad process which is classified into primary, secondary and tertiary level. Presently, numerous advancements and changes are taken into consideration for product safety, stability and patient's compliances. An important role of pharmaceutical packaging is to transform the formulation into an attractive and marketable product. So many issues regarding the pharmaceutical product like stability, sale, patient compliance etc are related with the packaging and in regard to this; present review is done on the various advancements in the packaging techniques and selection of packaging material. The review details several

of the recent pharmaceutical packaging trends that are impacting packaging industry, and offers some predictions for the future.

Packaging should provide protection, identification, information, convenience and compliance for a product during storage, carriage, display and until such time the product is consumed. A thorough background about the product, the market, the distribution system and other facilities available has to be considered while selecting a packaging material. Pharmaceutical packaging should look into concerned issues like child safety, patient compliance, patient traceability, tampering and diversion of pharmaceutical products. Now, major additional concerns of drug counterfeiting. Considerable steps have to be taken to ensure packaging traceability. Some manufacturers have affixed the use of barcodes to pharmaceutical products. Tracing pharmaceuticals right from their origin at a chemical plant to the patient beside may be attainable when Radio Frequency Identification (RFID) is embedded throughout the pharmaceutical packaging and makes it easier to ensure that the product is authentic and thereby improves the efficiency of drug supply chain. Advanced integrated robotic systems are becoming more and more common in packaging lines for a wide variety of applications and at the same time it lowers costs, reduces risks, and shortens times.

Conclusion

The packaging of pharmaceutical products is very important with regard to its stability, acceptance of the patient, transport, etc. There will always scope for advancement and improvement of pharmaceutical packaging. Therefore, new techniques like Cypak's advanced medication, Syreen prefilled syringe design, etc. Seems to be promising in pharmaceutical product packaging. In recent decades, pharmaceutical packaging technology has been an important technique in the pharmaceutical industry. After formulation, the next step is packaging. It is an important process in pharmaceuticals because it provides protection for products, identification & protection against physical damage and also gives compliance with the products & improves patient compliance. Some other better research will go into packaging for better results and pharmaceutical companies are increasingly working to improve productivity and reduce costs in their manufacturing and packaging operations. It gives good quality packs & good sales & also economical results. Expanding markets and innovative marketing strategies have led to an increased demand for packaging products. Pharmaceutical packaging will be a multiphase broad process which is classified into primary, secondary and tertiary levels. Presently, numerous advancements and changes will take into consideration product safety, stability and patient compliance. An important role of pharmaceutical

packaging is to transform the formulation into an attractive and marketable product.

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Authors' Contribution

The first authors developed the proposal, undertook the literature search and review, and then collect and analyse the data under supervision of my respective advisers. The second author gives constructive comments and guidance and work with the main author with respect to the research objective.

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