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Pharmaceutical Sciences **REVIEW ARTICLE ……!!!**

TYPES OF PACKAGING MATERIALS USED IN PHARMACEUTICALS: A REVIEW

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ABSTRACT

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 life saving 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.

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 life saving 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.[1,2]

Pharmaceutical 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.

Types of packaging:[3]

- **Primary Packaging:** This is the first packaging envelope which is in touch with the dosage form or equipment. The packaging needs to be such that there is no interaction with the drug and will provide proper containment of pharmaceuticals. E.g. Blister packages, Strip packages, etc.
- **Secondary Packaging**: This is consecutive covering or package which stores pharmaceuticals packages in it for their grouping. E.g. Cartons, boxes, etc.
- **Tertiary packaging**: This is to provide bulk handling and shipping of pharmaceuticals from one place to another. E.g. Containers, barrels, etc.

Two types of containers are used for packaging: [3,4]

1. Glass Containers
2. Plastic Containers

Glass Containers: These need to be chemically inert, impermeable, strong and rigid proving FDA clearance.

Types of Glass for pharmaceutical industry:[4]

Type I-Borosilicate glass: Highly resistant and chemically inert glass. Alkali's and earth cations of glass are replaced by boron and/or aluminum and zinc. These are used to contain strong acids and alkalis.

Type II-Treated soda-lime glass: These are more chemically inert than Type I glass. The glass surface is de-alkalized by "Sulfur treatment" which prevents blooming/weathering from bottles.

Type III- Regular soda lime glass: Untreated soda lime glass with average chemical resistance.

Type IV- General Purpose soda lime glass: Glass is not used for parenterals, used only for products intended to be used orally or topically. Colored glass is used to screen out Ultraviolet rays and is thus effective for protecting contents from light. Amber glass and red colored glass is used for this purpose.

Major disadvantage of glass as a packaging material is its fragility and weight.

Plastic Containers: Plastic containers of high quality can be easily formed with different designs. These packages are extremely resistant to breakage and leakage. Primarily plastic containers are made from the following polymer[5,6]

1. **Polyethylene (PE): Provides good barrier against moisture, relatively poor one against** oxygen and other gases. High density polyethylene is used with density ranging from 0.91-0.96 leading to four basic characteristics of container, (1) Stiffness, (2) Moisture-vapor transmission, (3)stress cracking and(4)clarity or translucency based on polymer density used.
2. **Polypropylene (PP):** Polypropylene has features of polyethylene in addition it does not stress-crack in any condition. Hot aromatic or halogenated solvents soften the package. It has high melting point making it suitable for boilable packages and products needed to be sterilized. Brittleness at low temperature is its major disadvantages.
3. **Polyvinyl Chloride (PVC)**: Can be produced with crystal clear clarity, will provide good gaseous barrier and stiffness. Reduction in residual vinyl chloride monomers had further enhanced PVC quality. PVC is used as coating on glass bottles providing shatter resistant coating.
4. **Polystyrene**: Rigid and crystal clear plastic. Not useful for liquid products. Polystyrene has high water and gaseous permeability also these are easily stretchable and breakable. To increase their

strength and quality for permeability polystyrene is combined with rubber and acrylic compounds.Based on the composition these are classified as intermediate impact, high impact and super impact packages.

5. **Nylon (polyamide)**: Many dibasic acids and amines combine to provide numerous varieties of nylon. Nylon is extremely strong and is quite difficult to be destroyed by mechanical means. Nylon provides resistance to wide range of acids and alkali only disadvantage of it is being permeable to water vapor for some amount this can also be dealt with coating of PE over the container. Not used for long term storage of products.
6. **Polycarbonate**: Has an ability to be sterilized repeatedly. It has immense rigidity and is a possible replacement for glass, vials and syringes. It has qualities like high dimensional stability, high impact strength, resistance to strain, low water absorption, transparency, and resistance to heat and flame. Polycarbonates have impact strength five times greater than any other common packaging plastics.
7. **Acrylic multipolymers (Nitrile Polymers)**: These are polymers of acrylonitrile or methacrylonitrile monomers. These provide for packaging of those products which are not packed in usual packages as they provide for high gas barrier, good chemical resistance. [7]

IDEAL PROPERTIES OF PACKAGING MATERIALS:[7,8]

The packaging materials used should possess the ideal characteristics such as

1. Protection from environmental conditions such as humidity, temperature etc.
2. The product packed in the container must be non-reactive to the container enclosing it.
3. The odor and the taste of the product must not be altered.
4. The packaging material must be non-toxic.
5. FDA approved packaging materials must be used.
6. Requirements such as tamper-resistance must be maintained.

OBJECTIVE OF PACKAGED PACKAGING[8]

Packaging and package labeling have several objectives:

- Package should provide adequate information regarding the contents, route of administration, batch number, expiry date, storage condition and manufacturer name and address.

- Package should have acceptable design and assist patient compliance.

The drugs which are enclosed in the package requires protection from shocks, temperatures, vibrations, compression which are generally caused by improper transportation and handling. So it is necessary to have a package that can resistthese problems.

NOVEL PHARMACEUTICAL PACKAGING SYSTEMS:[9]

Constant innovations in the pharmaceuticals like prefilled syringes, blow fill seal vials, powder applications have led to a direct impact on the packaging industry. Traditionally, the majority of medicines have been taken orally by tablets or capsules, which are either packed in blister packs or fed into plastic pharmaceutical.

However, other methods for taking medicines are now becoming more widely used. These include parenteral or intravenous (31%), inhalation (16%), and transdermal (4%) 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. For this reason, one of the packaging that has been introduced in the pharmaceutical industry is intelligent packaging. At present, this packaging system is growing rapidly. In pharmacy, intelligent packaging is designed to facilitate communication within the whole medicinal product chain, as well as to ensure its better quality and safety. The role of the intelligent drug packaging is also to increase the effectiveness of the taken drug, which has a direct effect on the improvement of the patients' health and brings considerable savings. An example of this type of packaging is system based on conductive ink on a carton board based blister inlay, which is connected to a cellular module embedded in the package. This enables the tracking of one pill at the time on removal from the blister, whereby data is sent to the cellular module and then forwarded wirelessly, even instantaneously if required, using GSM or GPRS cellular networks, to electronic health record systems. This allows real-time tracking and intervention by a physician and also enables physicians to make timely changes to patients' medication. The principal benefits derive from the numerous possibilities that this solution provides to healthcare service providers: sending voice-call reminders or text messages (SMS) to patients, or making personal visits when important prescribed medication has not been taken in time.

In the pharmaceutical market there is also the "talking packaging". There are for patients who have problems with regularity in the use of drugs. System the "TalkPack" can be invisibly integrated into any printed image on any packaging material. This technology needs a special scanning pen. The method used by "TalkPack" is not limited to the packaging material but can be used by any printed material. No other composite elements are used which could influence the recycling qualities. A special pen-shaped reader is used to retrieve the stored information and to replay it as audio files. 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.

The huge changes relate to aerosols. In the pharmaceutical market there are systems of aerosols with indicators of dose. One example is nebulizer designed to operate in-line with standard ventilator circuits and mechanical ventilators. This system is operated without changing patient ventilator parameters. Besides, this nebulizer is refilled without interrupting ventilation. In order to remind the patient about the dose or to take the drug, special packaging was introduced to the market. It has a special closing equipped with electronic microcircuits, which strictly monitors the date and time of each opening and closing of the packaging. The packaging closing is equipped with an LCD screen, which shows the number of the drug doses administered within 24 hours, as well as the time that has elapsed since the last pill was taken.

As the pre-filled syringes become more popular on the pharmaceutical market, the packaging with a security mechanism has been introduced. The mechanism prevents injuries, and it is integrated with the safety label. It is related to the fact that the pre-filled syringe contains a needle, which poses the risk of an accidental prick with an already contaminated needle.

Child resistance packaging[10]

Child resistant packaging is essential criterion for highly potent pharmaceuticals. New child-resistant (CR) blister are designed to offer improved peel ability and printability while establishing protective qualities that prevent children from accessing pharmaceutically potent contents. Sliding CR blister pack by UK packaging producer “Burgopak” presents an example by introducing a blister pack that can only be opened by applying pressure at two separate points on the packaging. The blister pack and information leaflets are placed with the outer box ensuring that the product is never separated from its packaging.

A CR peel–push lid stock was formulated to eliminate the frustration linked with hard-to-peel CR, paper-based lid stock. The lid stock can be printed in seven colors to maximize brand identity on packages. The absence of a paper layer diminishes the issue related with moisture absorption and increases the time the material can be stored while awaiting conversion.

A CR folding carton has die-cut slots on the one end flap that align with die cut tabs present on the inner wall of the carton to lock the flap in proper place. Opening of carton requires a die-cut key to be removed from the carton's external panel. The key slides into the slots and pushes down the tabs to free the end flap.

Eco-friendly pharma packaging:[8,9]

The pressure to develop sustainable, eco-friendly products is pressurizing packaging industry and has even begun to affect pharmaceutical packaging, one of the industry's most complex sectors. The development of sustainable packaging is a difficult task for companies serving the pharmaceutical industry - environmental considerations must not lead to any compromise on a package's safety or accessibility.

Future prospects:

Pharmaceutical industry, research and manufacturing technologies are continuously evolving with demands of environmental ethics, patient compliance and novel medicaments this had driven significant developments in packaging and delivery systems. Increased investment in R&D sector had lead to formulation of large- molecule biopharmaceutical drugs some are still in development pipelines this has led to an increase in the need for injectable packaging and self administration systems. The earlier used old glass and elastomeric closure systems may not provide the effective barrier properties much needed for high-value, life saving therapies. Packaging R&D provided us with new materials and technologies that ensure extended drug-product shelf-life. Lyophilization had led to the formulation of liposome's and further the pro-liposome's, the therapies which are unstable in liquid form are lyophilized or converted to dry powder dosage forms. Lyophilized drugs need special care for storage and administration for the optimal performance by products. Lyophilization chambers with proper, non sticky stoppers are used for dose accuracy. Advancement in research of pharmaceuticals development had always

being dependent on the development in packaging technology. To maintain integrity of pharmaceuticals during storage, shipment, and delivery, quality of packaging provides assurance for all these.

Increase in self-administered therapies forces pharmacy research to formulate packages for self administration rather than for healthcare revolving around hospital care. In present healthcare often starts at hospitals/clinics but maintenance therapy revolves around the home. For treating chronic conditions such as arthritis, cancer, multiple sclerosis, Alzheimer's and other diseases that require frequent medication, self administration had led packaging to be evolved in such a way to provide compliance for therapy. Usually maintenance therapies are delivered by injection, demanding a need for patient-friendly administration systems.

Packaging systems is required to ensure that the potency of the drug must be preserved and it should promote compliance with a dosing regimen, ensuring dosing accuracy, and be as safe, easy to use and painless as possible for patients. Manufacturers involved in packaging for the self drug administration process need to provide delivery systems that will simplify drug reconstitution before use, especially for nonprofessional caregivers.

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