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ADVANCE TRENDS IN PHARMACEUTICAL PACKAGING

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ABSTRACT

Packaging is a important factor. It is a art and science of enclosing the product for distribution, storage, sale and use. Pharma markets absorb the major portion of the overall drug market. Recently, it focus on the preservation and quality of the enclosed product. Pharmaceutical packaging is a multiphase board process the class of this process is primary, secondary and tertiary. Recently numerous advancement and changes are taken into consideration for product safety, patient compliance and stability. Keep drug secure from young children is one of the main objective of the pharmaceutical companies. The pharmaceutical packaging market is constantly advancing. Therefore the review shows that conventional pharmaceutical packaging and recent advancement have been delineated.

INTRODUCTION:-

Packing is the science, are and technology of the enclosing orbit protecting products for distribution, storage, sale and use. Packaging also reference to the process of design, evaluation and production of packages. Pharmaceutical packaging can be define as the convential mean of providing presentation, protection, identification, information, compliance, integrity and stability of the product.[1]

Pharmaceutical packaging is more important for the all type of dosages forms like solid, semisolid, liquid, powder, suspension, poultice etc. The material of packaging is more important for storage, protection, preservation, distribution and sale etc.

Pharmaceutical packaging is highly regulated but with some variations in the details, depending on the country of origin or the reason several factors can be include : assurance of the patient safety, assurance of the efficacy of the drug through the intended self life, uniformity of the drug through different production lots through documentation of all the materials and processes, control of possible migration of packaging components into the drug, control of degradation of the drug by oxygen, moisture, heat etc. Packaging is also involved in dispensing, closing and use of the pharma products , communication of proper use and cautionary label are also regulated. Packaging is an integral part of pharma products.[2]

Package should provide adequate information like – rout of administration, storage condition, batch number, manufacture date, expiry date, manufacture's name, address and product license number.

New ideas of dynamic packaging, intelligent packaging and nanotechnology offers arrangement which play a vital part to improve or observing food quality and security and amplifying time span of usability.

IDEAL REQUIREMENT/DELECTION OF PACKAGING:-

- It must protect the preparation from environmental conditions.
- It must be non-reactive with the product and so does not alter the identity of the product.
- It must not impart tastes or odors to the product.
- It should be non-toxic.
- It must be FAD approved.
- It must protect dosage form from damage or breakage.
- It must meet tamper-resistance requirements, wherever applicable.
- It should be adaptable to commonly employed high-speed packaging equipments.[3]

FUCTIONS OF PHARMACEUTICAL PACKAGING:-

1.PROTECTION:-Packaging must be protect the pharmaceutical product against all the adverse external influence of the environment such as light, moisture, heat, oxygen, biological contamination, mechanical damage and other factors that may affect of the potency and quality of the pharmaceutical product .

2.PRESENTATION AND INFORMATION:-Presentation and information is also essential factor for the packaging of the medicinal product. Labels and package provide information to the patients.

3.IDENTIFICATION:- The printed packs provide the identification of the pharmaceutical product. It shows the information and contain of the particular product. It's help to identify the product easily.

4.CONTAINTMENT:- 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, not allow diffusion and permeation of the product, to be strong enough to hold the content 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.[4]

5.MARKETING:-It use often used as marketing tool to differentiate a product and to convey a certain message or brand image to highlight the pharmaceutical aspects for consumers.

The kind of packaging and the materials used must be chosen in such a way that:

- Packaging itself does not produce any adverse effect on the quality of the pharmaceutical product though chemical reactions, leaching of packaging materials or absorption.
- Product does not produce any adverse effect on the quality of pharmaceutical packaging by changing is properties or affecting its protective functions.
- Packaging as well as the product itself should not have any adverse effect on the environment.
- Another important factor considered must be its low cost, edge of fabrication, availability and regulatory acceptance of the material as well as the final product used.

The key philosophy of packaging is that it must be gentle to the environment and thus, most of the pharmaceutical companies are willing to accept this as their prime responsibility. As a result pharmaceutical companies have also started the use of recycled resources for packaging and made their packaging easier to recycle.[4]

6.CONVENIENCE:-Packaging must be convenient enough to increase consumer access to products and improve distribution, handling, selling and using such products.

TYPES OF PACKAGING SYSTEMS:-

Pharmaceutical packaging is classified into 3 types.

Primary packaging system

Secondary packaging system

Tertiary packaging system

1.PRIMERY PACKAGE SYSTEM:-It is made up of those package components and subcomponents that come into direct contact with the product or those that may have a direct effect on the product shelf life. Example:- IV containers, Ampoules.

2.SECONDARY PACKAGE SYSTEM:- It protect to the product as well as the primary packaging. It also hold the individual goods. It is outside to the primary packaging I t include carton, corrugated shipper and pallets.

3.TERTIARY PACKAGE SYSTEM:-It is use to protect not only the pharmaceutical product but also the primary and secondary packaging. It used to handling and shifting of the pharmaceutical packages from one place to another places. Examples: Containers, barrels, cardboard boxes etc.

Table1:TYPES OF PRIMARY AND SECONDARY PACKAGING MATERIALS

Material	Type	Example of use
Plastic	Primary	Vials, ampoules, dropper bottle etc.
Glass	Primary	Vials, ampoules etc.
Metal	Primary	Tin plated steel
Cardboard	Secondary	Carton box
Paper	Secondary	Labels, patients information leaflet.

CONTAINERS USED IN PRIMARY PACKAGING:-

Primary package for solid dosage forms:-

1) **Blister packaging:-** Blister packaging is the packaging of the plastic material. In this type the each dose of medication is placed in small plastic bubble and backed by a sheet of foil. This is not a complicated packaging and cost is also slightly low. This packaging protect the product from other external environmental factors such as humidity and contamination. It is usually used as unit dose packaging for tablet, capsule or lozenges.[6]

Fig.1: Blister Package

2) Strip package:- Strip package is the package for the unit dosage form. It is the method of enclosing the dose in between two film of material so that each is contained between separate compartment. In strip package unit dose protect individually.[6]

Fig.2: Strip Package

Primary packaging for semisolid dosage form:-

1) Semi solid dosage form include ointment, cream and pastes. The containers used for semisolid dosage for is tubes and plastic containers. Other type of products also available in market for e.g. Pressurized products. For these type of products the package made up of stainless steel. The package used must be strong to control pressure built up in the container.

Fig.3: Semisolid Dosage(Cream)

Primary package for oral liquids:-

1.Well closed containers:-This type of container protect the liquids from dust, moisture, microorganism etc. They prevent the loss of liquid and other volatile substances. Well close containers are easy to handling, storage and distribution.

Fig.4: Well Closed Containers

2.Air tight containers:-

This type of container protect the drug from the environment, physical and the chemical factors. It also prevent the rancid odors that are often caused by presence of bacteria or any another foreign substance.

Fig.5: Air Tight Containers

3.Single dose container:-Single dose container contain enough drug/medication for one patient's immediate need. That containers should not be reused or refilled.

Fig.6: Single Dose Containers

4.Multi dose container:-This type of container contain multiple doses are withdrawn at various intervals e.g. vials.

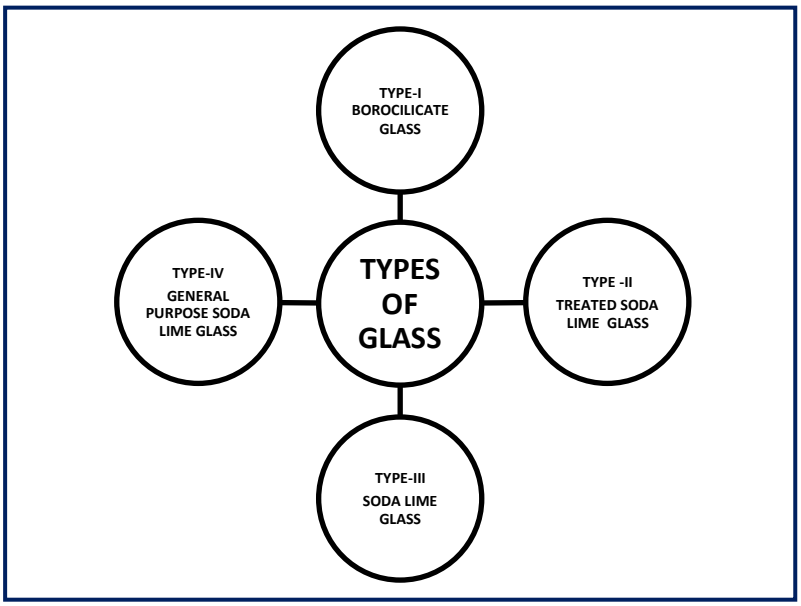
Fig.7: Multi Dose Containers

5.Light resistance containers:-

These containers protect the pharmaceutical product from light. These containers are made up from the light resistance substance. E.g. Amber colored glass containers.

Fig.8: Light Resistance Containers

CLASSIFIACTIONOF GLASS USED IN PHARMACEUTICAL PACKAGING:-



- **TYPE-I:BOROCSILICATE GLASS:-**Highly resistance glass, substantial part of the alkali and earth cations are replaced by boron or aluminum and zinc. The addition of about 6% boron to form borosilicate glass reduces the leaching action, so that only 0.5 ppm is dissolved in a year. This glass is suitable for parental usages.

Fig.9: Borosilicate Glass

TYPE II: TREATED SODA LIME GLASS:- This type ofglass is formed by removal of surface alkali by treatment with sulfur dioxide, ammonium sulfate or ammonium chloride to prevent " weathering" or blooming". The glass is treated with the above said chemicals at an elevated temperature. This glass makes the surface resistant and the alkali removed appears on surface as blooms.

Fig.10: Treated Soda lime Glass

- **TYPE III: REGULAR SODA LIME GLASS:-** The containers are made up of untreated commercial soda-lime glass. Chemical resistance is better than average. It is suitable of storage of anhydrous parentral products.

Fig.11: Regular Soda lime Glass

- **TYPE IV: GENERAL PURPOSE SODA-LIME GLASS:-** These containers are made up of the plane soda-lime. This is use to storage of oral and topical preparation.[5]

Fig.12: General Purpose Soda-lime Glass

ADVANCE TRENDS IN PHARMACEUTICAL PACKAGING:-

1)CHILDREN RESISTANCE:- It refers to as 'special packaging'. Keeping The drugs secure from children while insuring user friendliness to seniors is one of the main objective of pharmaceutical packaging. More advanced CR packaging such as special blister packs and cardboard packaging has only released into the market in the last decade and looks set to continue its growth in the future as its popularity increases. So, we should think the CR packaging is our last line of defense. Burgopak's sliding CR blister pack can only be opened by applying pressure at two separate points on the packaging. The blister pack and information leaflets are integrated with the outer box which ensures the product is never separated from its packaging. Burgopak healthcare won the award for the " most innovative Child Resistant packaging Design.[7][8]

Fig.13: Children Resistance Package

2)THE TALKING PACKAGING "SELF TALK":- This packaging is from Germany. It is audiovisual events that adds value to our package. Self-talk is the 1st talking package. WIPAC is a special pen-shaped reader is used to identification of the information of the product like manufacturer, brand, self-life or other information. Also a VTT Technical Research center:-It shows the information by NFC tags. It provide spoken dosage instruction. It is to much helpful for the blind person.[9]

Fig.14: Self Talk Package

3)RADIO FREQUENCY IDENTIFICATION (RFID):- RFID is a part of the Automatic identification and data capture technology that include barcodes. It uses an electronic chip and it is easy to read the information of the content. The RFID is helpful for the carry and collect the data needed to track and trace product through the supply chain. It having less cost than traditional devices for temperature monitoring.[4][8]

Fig.15: Radio Frequency Identification

4)DISPENSING CAPS:- The dispensing cap is suitable for liquid additives as well as granules, beverages. They also use for the sensitive vitamins and supplements. Shinsen caps: it is also a type of dispensing cap. This design only by plastic part doesn't have aluminium parts.[4]

Some types of dispensing caps:

- Threaded screw cap
- Lug cap
- Crown Cap
- Roll-On Cap
- Pilfer proof Cap

Fig.16: Dispensing Caps

5)BLOW-FILL SEAL PACKAGING TECHNOLOGY:- The glass is most widely used packaging material and other materials also used they are aluminium foil, plastic etc. Recently

biodegradable polymers are used as the packaging material. This packaging is useful for the storage of sterile products or the liquid parental drug.

It is develop in Europe in 1930s and introduce in the 1960s. It is use for the ophthalmic and Respiratory drug and also use for the parental and veterinary products. It is suitable for unit dosage form. i) Micro dose package ii) The twist Tip vial. These are the two Types of the Blow-Fill Seal Packaging Technology.[10]

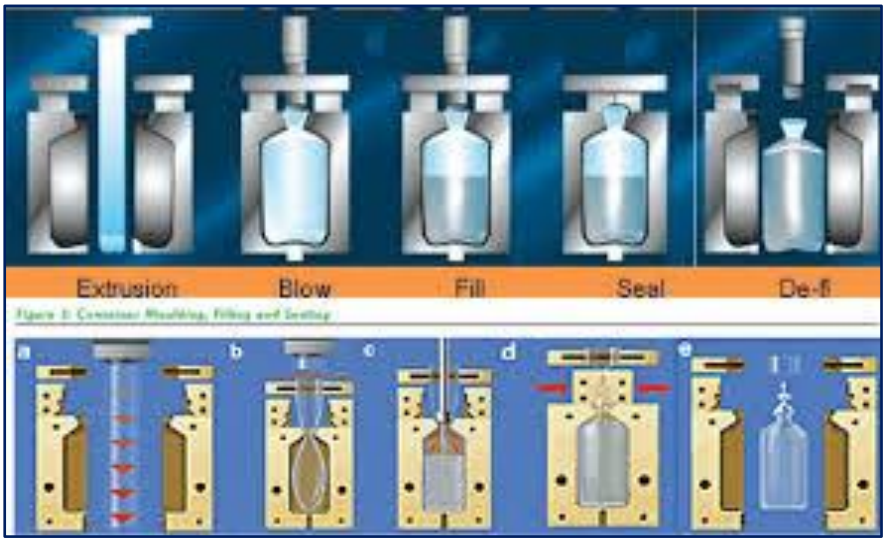


Fig.17: Blow-Fill Seal Package

6)BUBBLE PACK:-The Bubble pack can be made in several ways but is usually formed by sandwiching the products between a thermo formable, extensible, or heat-shrinkable plastic film and a rigid backing material. This is generally accomplished by heat-softning the plastic film and vacuum-drawing a pocket into the film in a manner similar to the formation of ablister in a blister package. The product is dropped into the pocket, which is then sealed to a rigid material such as heat-seal-coated paperboard. If a heat-shrinkable material is used, the package is passed through a heatedtunnel, which shrink the film into a bubble or skin over the product, firmly attaching it to the backing card[11]

Fig.18: Bubble Pack

7)ROBOTICS IN PHARMA PACKAGING:- In the pharmaceutical packaging robots plays a vital role as they use for the identification as well as the accuracy, precision and hygiene. The improve worker's safety to improve quality. Also use in the complicated process, researches and development, production and packaging.

In many instance, robotics are utilized to automate the subsisting manual process such as loading cartons, horizontal form fill seal machines or blister machines. In these cases, the advantages include incremented celerity, efficiency and as increase to overall equipment efficacy(OEE), other advantage may lead to reduced cost, reduced injury and eliminating rework.

Robotic cells typically offer a minutely diminutive foot print. Concurrently, these cells offer a benevolent work envelope, sanctioning the installed equipment to handle multiple packaging lines. A typical robotics lading assembly, or collating system utilizes a footprint less than 3' X 3'. Even a dual cell palletizer, typically an immensely colossal robotics packaging machine, only occupies less than 12' X10' of floor space. In integration to minute footprint, robotic packaging lines can preserve space by utilizing a single robotic cell for multiple functions, eliminating the desideratum for adscititious equipment. For example, a robotic code packing and palletizing cell can be engendered that both loads products into cases but additionally places the filled cases on a pallet, reducing the equipment and space required.

ROBOTIC DISPENSING – It is machine have been accessible for over 10 years as an option stockpiling framework to routine haul out drawers in group drugs stores. This framework is an electronically controlled computerized stockpiling that offers the limit of an unmistakably bigger, routine stockpiling, while taking up just at least space. Robotics dispensing is the only solution that brings the benefits of consummate prescription fulfillment. The latest generation of robotics prescription dispensing systems transcends pristine counting to introduce consummate prescription processing, form vial cull and labeling to counting, capping and sorting, alleviating the desideratum for direct human intervention with every prescription.[11][4]

Fig.19: Robotics Dispensing

8)PREFILLED SYRINGES:- Syringe is a simple reciprocation pump , the modern syringes consisting a piston(plunger) that fits tightly within the cylindrical tube called barrel. It is generally used in clinical medicine to administer injections, infuse intravenous therapy into bloodstream.

Environmental awareness is even starting to extend to the syringe market. It replace the 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 packing materials like cardboard.[4]

Fig.20: Prefilled Syringes

Advantages of prefilled syringes: There is many advantages of these syringes like sterility, convenience, safety, affordability and accuracy.

- Sterility: It is the advantage of the prefilled syringes once a standard syringes is loaded with a drug then it will remain ideally sterile for around 12 hours. When we want to check the sterility of the syringes then put the solution in a prefilled syringe cartridge stay sterile for roughly a few years (this is referred to as a self life of 2-3 years).
- Convenience: During an emergency (an allergic reaction), filling of standard syringes can be a time consuming and perplexed process, so that requires an expeditious injection syringes. Prefilled cartridges sanction injections to be administered more expeditiously especially in a diligent hospital. They can lessen stuffing in emergency rooms and other treatment regions.(4)
- Safety: It is the very important for the drug , it have caliber of the precision, which make the drug safer to utilize. Some injections are reach the opportune depth and that dosages ate administered smoothly due to the cartridges designed to fit into the self-aspirating syringes. It is useful for inject medications without having to push on a plunger.

- Affordability: Standard syringes highlight tube shaped glass barrels and firmly fitting glass poles, which area a great deal mote costly to produce in contrast with plastic base prefilled cartridges and their relating syringes. Moreover, prefilled cartridges are a great deal less inclined to split or break in contrast with their standard glass partners.
- Accuracy:- It is very important factor of the precise dosage of prefilled syringes. This is very useful for the patients who need to self-infuse medicine but have no medical training. As indicated by boschpackaging.com, with standard syringes it is conceivable to stuff (or under fill) the barrel, which could contrarily affect the viability of the treatment.
- **Marketing Advantage:-** The prefilled syringes have the traditional packaging in vials include ease of use. It help to eliminate the dosing error because prefilled syringes actually contain the exact dose. Not only do healthcare providers prefer prefills, but healthcare products are withal accepted and prominent ecumenically. Products can be found in virtually every hospital in the US and overseas. This authentic-time exposure gives us a unique opportunity to develop products for customers that will be well accepted by their ultimate recipients -end-users, medicos and other healthcare professionals.
- **Manufacturing Advantages:-** During the manufacturing the prefilled syringes require the less overfill. For example, for a 0.5ml vial, the USP recommends 20-25% overfill. In contrast, for a 0.5ml, required overfills is less than 2%. As a result, potentially 18-23% more doses can be engendered. Simple and flexible processing formats make prefills more facile to incorporate into a pharmaceutical company manufacturing.
- **Medical advantages:-** The prefilled syringe have the more medical advantages. They also have the more professional benefits from precise, pre-quantified dose, reduced dosing and medication errors and reduced risk of microbial contamination. Prefills are convenient for emergency use and have potential for duplicate peel-off labels which facilitate patient charting. Single use prefilled syringes do not require preservatives. Actually we conclude that the 9 out of 10 healthcare professionals preferred prifills to conventional needles and syringes.

9) TWO-IN-ONE PREFILLED VIALS:-Tamper-evidence design of vials dispenser enables consumers to determine the authenticity of the product. At the 22nd DuPont Awards for Packaging, Innovations. It have the EZ fusion it contains the following components-top and bottom chambers made up of polypropylene and have the stopper and tin cap. Fusion Two-In-One vials take the guesswork of the mixing drugs, so there is less waste. There is less chance of contamination and it provides a cost- effective solution versus traditional glass vials.Fusion Two-In-One was launched at Interphex New York. These vials are the multi-chamber dispenser, which

provides a closure solution for filling and separately packing in sterile vial. They explains "The mixture forms with a simple twist after removing the safety ring and flip-flopping the insulation spacer them gently shaking the vial prior to usage." " It takes a long period of pharmaceutical firms to validate a new packing material." They also explain adding that plastic application are the trend in parenteral design, " Innovation of parenteral packaging is rising in its importance, especially with the rising in its importance, with biotech drug product and consider their product quality control by including the final packing design.[12]

Fig.21: Two on one Prefilled vials

10)ECO-FRIENDALY PHARMA PACKAGING:-The pressure to develop sustainable, eco-friendly products is pressurizing packaging industry and has even begun to affect pharmaceutical packaging. The development of sustainable packaging is difficult task. Environmental considerations must not lead to any compromise on a package's safety or accessibility. This Packaging is useful for the mono-materials instead of a material mix, for the optimized labeling solution for the package concerned and for the separtability of components in the recycling process.

Fig.22: Eco- Friendly Package

11)IMPROVING PATIENT COMPLIENCE:-Incidence of Alzheimer's and other age related disorders are going to be a major cause of worry in near future. By 2020 14.2% of above 60 age population will be In India only. This led us to work out with packaging in such a way that it will provide patient compliance with its own ease. Walmart's new compliance pack launch is one of its kinds to help patient compliance the portable, calendar-style prescription packs are aimed to increase patient adherence to drug regimens. Pack provides a physical a physical printed reminder and an opportunity for consumers to see whether a dose for a certain day has been taken or not. Greater adherence improves patient compliance/ outcomes and ultimately reduces healthcare costs across the supply chain.

The market today is equipped with packaging systems that can provide packing features and product authentication throughout the supply chain. The wider use of technologies against counterfeiting will develop in near future, such as RFID tags affixed to the seal; use of UV inks for seals may be seen. The coatings with near-total barrier properties e.g., PICVD, PET-EVOH-PET, PP-EVOH-PP coatings may capture a potential market in future. The global pharmaceutical 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% from 2010-2017. The global pharmaceutical industry is currently registering rapid expansion with advances in manufacturing processes and technology innovation and integration which are the main factors behind the growth f the pharmaceutical packaging industry globally. This growth is expected to be highest in the emerging economies of India and China, primarily on account of countries, Pharmaceutical Packaging Industry- 2011 Yearbook.[13]Although on efforts, one can definitely predict that as pharmaceutical research will continue to develop life-saving therapies, therapies for develop life-saving therapies, therapies for advanced life the packages required to carry and administer those therapies will also maintain its pace by advancement in design innovations and discovery through material sciences.[10]

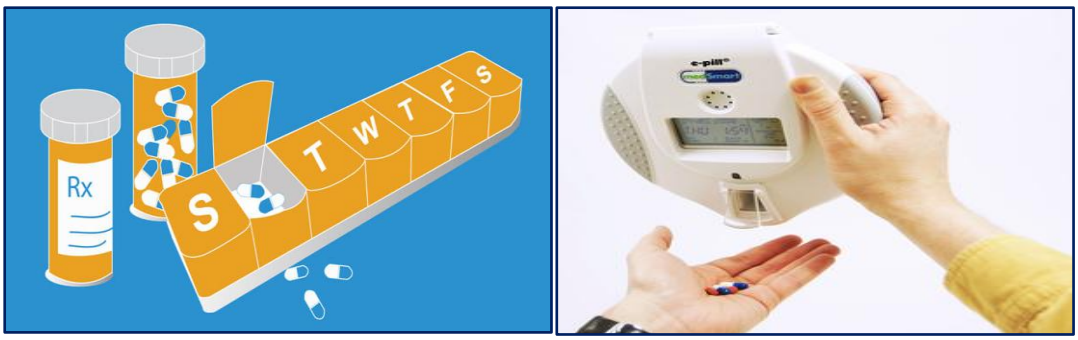


Fig.23: Patient Compliance

12)AUTO IDENTIFICATION SYSTEM:- Auto identification system is use for the identification of the product information. It recognize the ingredient, mfg. date, exp., date, category and identification of the barcode of the label. It is for easy identification of the pharmaceutical products.

Fig. 24: Auto Identification Package

CONCLUSION:- As the pharmaceutical packaging of the pharma products is very important with the regards to its stability, safety, acceptance to patient, transport, use etc. In the Pharmaceutical Packaging there is always a huge scope for advancement and the improvement of product packaging. Therefore the new techniques like Cypak advance medication, Prefilled syringes design, auto identification system Robotics etc. seems to be promising in pharmaceutical products packaging.

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