labelling means a display of written, printed or graphic matter upon immediate container or the wrapper of a drug package • The term “labeling” designates all labels and other written, printed, or graphic matter upon an immediate container of an article or upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container

• **Labeling in India** – All labels of a drug should conform as per the specifications under the Drugs and Cosmetics Rules 1945. – That no person sell or distribute any drug unless it is labeIed in accordance with the Rules (Rule 95 of D&C Act). • it includes information regarding – indications, effects, dosage form, frequency and duration of administration, warnings, hazards, contraindications, side effects, precautions and other relevant information.

• **For identification of the product** • Provide ingredients • Purpose /use of the product • Child safety • Other information like maximum retail price(MRP), Batch No., Shelf-life etc
The Food and Drug Administration (FDA) requires that drug labeling be balanced and not misleading. The label must be scientifically accurate and provide clear instruction to health care practitioners for prescription drugs and to consumers for over- the-counter drugs and supplements. Labeling regulations require that the statement of ingredients must include all ingredients, in the order in which they are used in the drug. 1. Brand identification Labeling helps in the identification and principal place of business of the person by or for whom the prepackaged product was manufactured, processed, produced or packaged for resale.

. **Description**
Labels provide the information regarding the pharmaceuticals.
It describes the composition, batch no., cost, manufacturing date, expiry date etc.
3. Promotion Finally labels helps in promoting the product through attractive and bright graphics replacing paper labels glued on bottles.
4. To differentiate Standard and Counterfeit drugs A counterfeit drug bears an unauthorized representation of a registered trademark on a product identical or similar to one for which the trademark is registered.
The use of scratch off label containing a unique code can be done which if texted to a free no. provides a response from company server, which will assure the authenticity of product. The use of unique holograms and designs in labels, which can not be easily copied.

• **The safe use of all medicines** depends on users reading the labeling and packaging carefully and accurately and being able to assimilate and act on the information presented.
• All labels must be clear and concise and must bear all necessary information regarding the safe use of a product.

• **Manufacturer label • Dispensing label**
. • A label which contain drug information for the use of medical practitioners, pharmacists, or nurses supplied by the manufacturer, packer, or distributor of the drug. • Rule 96 of the Drug and Cosmetic Rules (manner of labelling) mandates the minimum information which needs to be put on the label of all medicines.

Legal Requirements:

1. Proprietary name and established name
2. Strength and dosage form.
3. Quantity.
4. Instructions for the use.
5. Precautions & warnings.
6. Manufacturing license no.
7. Batch number.
8. Manufacturing & Expiry date .
9. The name and address of pharmaceutical industry for drugs included in the India Pharmacopoeia or t¬ Compendial Name: The name of an article for which a monograph is provided in an official compendia/pharmacopoeia. ¬ Established Name: The designated FDA Official name or the Compendial name. ¬ Proprietary Name: The exclusive name of a drug substance or drug product owned by a company under trademark law. ¬ Proprietary name/Generic name, Established name and Compendia name ϖ It is amount of active drug per unit dose.¬ Strength and dosage form ϖ Brand name which is used to market the drug. ¬he official pharmacopoeia and official compendia of drug standards prescribed in the rule 124, the name or synonym specified in the respective followed by letters 'I.P.'

. **Brand Name Generic Name Strength Dosage Form**

. **And it is legally required to mention that no. on the label.¬ Manufacturing Licences are issued By State Drug Authorities. ¬ In India, to manufacture any drug, it is required to get a Mfg. Lic. No. as per Drug and Cosmetic Act, 1945. ¬ Manufacturing license no. ϖ**

. **The container hold 20 tablets and each tablet has a dosage strength of 500 mg.¬Quantity/volume present per packaging unit. ¬Quantity ϖ**

Instructions, Precautions and warnings for their Use:ϖ

Keep out of the reach of children: All dispensed medicines should carry this information on label¬ Protect from light: necessary for light sensitive formulations.

Store in cool place: store under 0°c to 8°c ¬Storage conditions

. "A designation printed on label of a drug that identifies the batch and permits the production history of the batch including all stages of manufacturer and control to be traced and are viewed"¬Batch No./ Lot no.:

. **Manufacturingϖ & Date stated** on the label of a drug after which a drug is not expected to retain its claimed efficacy, safety, quantity, or potency or after which it is no permissible to sell the drug is called Expiry Date.¬ In compliance with Good Manufacturing Practices (GMP) regulations, the manufacture date printed on the label represents the date the product was produced. ¬Expiry date

Name and address of pharmaceutical industry

. All dispensed medicines should ideally be provided with a label, which clearly states:
(i) Name of the patient

(ii) Name, strength, batch number and expiry of the medicine, in case the medicine has been repacked or cut out from a larger pack
(iii) Dosage and usage instructions

(iv) Date of delivery

(v) Storage instructions

(vi) Name and address of the pharmacy

of the package inserts or leaflets is to provide information essential for the safe and effective use of the drugs, and hence reducing the number of adverse reactions resulting from medication errors. • In India, regulations for package insert are provided under 'Section 6.2' and 'Section 6.3' of 'Drugs and Cosmetics Act (1940) and Rules (1945). 1. Kalam A, Anwar S, Fatima A, "Drug Package Inserts In India: Current Scenario", World Journal Of Pharmacy And Pharmaceutical Sciences, Mar 2014, 3(4), 385-392

Shelf life in the medical product as packaged for sale. Incompatibilities List of excipients Antidote for overdosing Undesirable effects/side effects. Effects on ability to drive and use machines, if contra-indicated. Pregnancy and lactation, if contra- indicated. ⎪Interaction with other medicaments and other forms of interaction. Special warnings and special precautions for use, if any. Contra-indications. Posology and method of administration • Content of Packaging Insert [5]: Sec 6.2 Therapeutic Information Sec 6.3 Pharmaceutical Information Nature and specification of the container. Special precautions for storage. Shelf life after first opening the container. after dilution or reconstitution according to direction.

. [6] Labeling machines are machines that dispense, apply or print- and-apply labels to various items, products, containers, or packages
• Labeling equipment are various machines, including label printers, label applicators, printer-applicators, and labeling systems, that apply labels to various products and packages. Semi Automatic Labeling Machine Fully Automatic Labeling Machine

Types of Labeling machinery
1. Semi Automatic Labeling Machine
2. Fully Automatic Labeling Machine •
3. Fully Automatic Single Side Sticker Labeling Machine
4. Fully Automatic Double Side (front & back) Sticker Labeling Machines • Fully Automatic High Speed Sticker Labeling Machine
• Semi Automatic Labelling Machine are suitable for labelling on Round Vials, Bottles. • No change of parts is required for change in size of containers & labels suitable for Glass, Plastic, Composite Containers can be prepared. • Grooved and Brut Shaped Bottles can also be labeled. • The Semi Automatic Labelling Machine incorporates latest sophisticated. • Microprocessor Controlled Stepper Motor Drive, Fiber Optic Label and Container sensing system.

Fully Automatic Labelling machine is useful to place label accurately on round shape of product. • Full or partial wrap labeling can be possible. • A unique feature of machine is if the body diameters changes, than also machine operates without change in part. •

Products of different diameter like small size of vials and bottles upto containers can be accommodated in the same machine & Speed is depend on the length of label.

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Different types such as Alluminium, Glass, Plastic products can be accommodated on the machine. • Labeling speed is automatically synchronized with conveyor speed to ensure quality. • Push and press optional attachment is used to ensure smooth labeling without wrinkles or bubble.

pressure from consumers and regulatory bodies to prevent counterfeiting and improve safety. Manufacturers and packaging companies need to ensure products can be recognized and verified quickly and easily throughout the supply chain, communicating vital information to retailers and distributors. • Today's drug manufacturers can choose from a wide selection of : – Automatic Identification and Data Capture (AIDC) technologies – Radio Frequency Identification (RFID) tags

. • For instance, using AIDC technologies, manufacturers can include product or batch specific data in individual product labels. In the pharma industry, this could enable suppliers and retailers to verify a product quickly and accurately — in most cases using standard technology. • RFID tags can be read without the need for close contact or a direct line of sight, and offer read/write functionality, which makes them ideal for tracking products and monitoring processes. However, relatively high cost and complexity of implementing the technology has prevented its progress in many areas, including the pharma industry.

Furthermore, **2D barcodes** can also function as a database themselves, providing a portable information source on the labelled product.¬ This increased level of information can be held on a label the same size or smaller than a conventional barcode label, and the codes can, in most cases, be printed using the same technology, helping to minimize the cost of upgrading. ¬ 2D barcodes can hold considerably more information than standard barcodes (usually up to approximately 1000 characters of information on a single label) making them better suited to meet the requirements of today's manufacturers. ¬• 2D Barcodes: