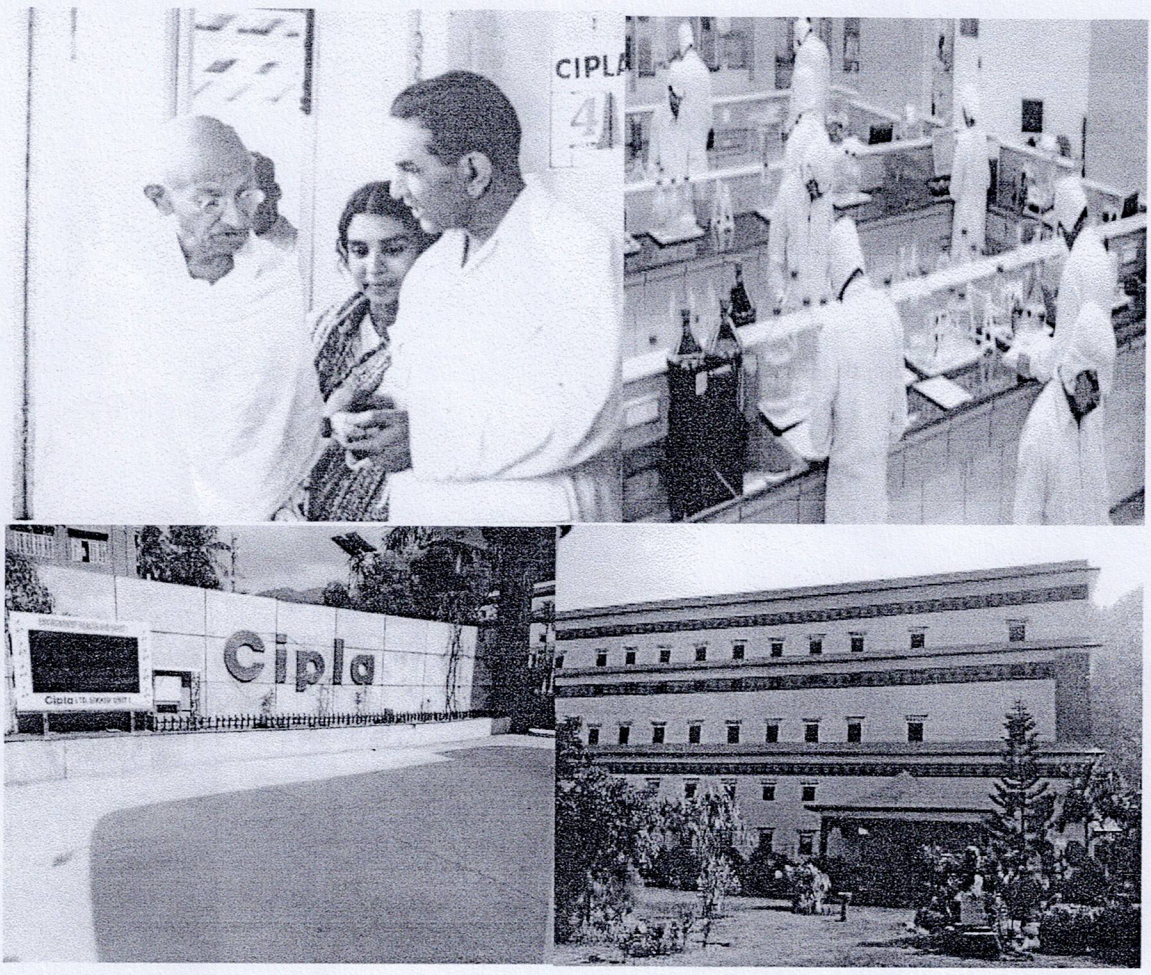
Cipla

INDUSTRIAL TRAINING REPORT OF CIPLA UNIT 1, SIKKIM



- *NAME: 1. MAHIMA CHOWDHURY (University Roll Number: - 18901920015)*
  2. VANSHIKA AGARWAL (University Roll Number: - 18901920084)
  3. SINCHAN KUMAR ROY (University Roll Number: - 18901920101)
  4. SAYAK MONDAL (University Roll Number: - 18901921112)
- *INSTITUTE: DR. B. C. ROY COLLEGE OF PHARMACY AND ALLIED HEALTH SCIENCES, DURGAPUR*
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Dr. B. C. Roy College of Pharmacy & AHS Durgapur

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal 713206

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INTRODUCTION

In 1935 CIPLA was founded by **KHWAJA ABDUL HAMIED** as the chemical industrial & pharmaceutical laboratories in Mumbai. In July 1984, the name of the company was changed to 'CIPLA LIMITED'. In 2015, CIPLA stood third in the India's Most Reputed Brands list, in a study conducted by Blue Bytes, a leading Media Analytics firm in association with TRA research, a brand insights organization. Cipla primarily develops medicines to treat respiratory, cardiovascular disease, arthritis and depression; other medical conditions. Essentially, the company has earned a name for itself by adhering to the best quality standards and hence getting approvals from the ministries of health of various nations as well as international agencies.

Company's Own Words

- **Slogan:** Caring for life.
- **Vision:** To be the first global biotech company to provide high-quality products at affordable prices that will enable access for millions of patients worldwide by the year 2025.
- **Mission:** Cipla's mission is to be a leading global healthcare company which uses technology and innovation to meet the everyday needs of all the patients
- It is the world's largest manufacturer of anti-retroviral drugs. Cipla also cooperates with other enterprises in areas such as consulting, commissioning, engineering, project appraisal, quality control, know-how transfer, support, and plant supply
- Cipla Inhaler is a medicine used to treat various heart conditions such as hypertension, angina (heart-related chest pain), arrhythmia, migraine, and tremor. It lowers blood pressure, thus decreasing the risk of future heart attack.

Dr. B. C. Roy College of Pharmacy & AHS Durgapur

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

ADMINISTRATION

A business administrator focuses on the work being done and the results that work is producing. Monitoring productivity and accounting are cornerstone responsibilities of a business administrator.

Managers supervise the clerical and administrative personnel in an organization or department. They can recommend and implement changes in policies and procedures so that goals are met more quickly with better results.

The job role of an administrator involves the following duties:

- Preparing, organising and storing information in paper and digital form
- Dealing with queries on the phone and by email
- Greeting visitors at reception
- Managing diaries, scheduling meetings and booking rooms
- Arranging travel and accommodation
- Arranging post and deliveries
- Taking minutes at meetings
- Updating computer records using a database
- Printing and photocopying
- Ordering office supplies
- Maintaining office systems
- Liaising with suppliers and contractors
- Liaising with staff in other departments, e.g. finance, HR

Dr. B. C. Roy College of Pharmacy & AHS Durgapur

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

GMP & cGMP

GMP refers to the Good Manufacturing Practice regulations promulgated by the US Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act. GMP regulations address issues including record keeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling. Most GMP requirements are very general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls.

Key Principles of GMP:

- Creation and enforcement of Standard Operating Procedures (SOPs).
- Comprehensive documentation of all procedures and processes.
- Validation of SOP effectiveness.
- Development and implementation of efficient working systems.
- Development of employee competencies.

cGMP: Accordingly, the "C" in cGMP stands for "current," requiring companies to use technologies and systems that are up-to-date in order to comply with the regulations. Systems and equipment that may have been "top-of-the-line" to prevent contamination, mix-ups, and errors 10 or 20 years ago may be less than adequate by today's standards.

So cGMP refers to the Current Good Manufacturing Practice regulations enforced by the FDA. cGMP provides for systems that assure proper design, monitoring, and control of manufacturing processes and facilities.

Dr. B. C. Roy College of Pharmacy & AHS
Durgapur

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

Areas under cGMP:

- Quality assurance
- Facility design
- Control systems and procedures for maintaining facilities
- Environmental and personnel monitoring
- Equipment
- Containers and closures
- Components
- Production and process controls
- Release testing
- Laboratory controls
- Stability and expiration dating (for compound drug products)
- Packaging and labels
- Reserve samples

DIFFERENCE BETWEEN GMP AND cGMP:

There are two primary differences between the two.

Quality/Rigor — With a focus on using the most current and improved standards, cGMP is more rigorous and results in higher-quality drug components and manufacturing. Beyond the manufacturing process, cGMP also extends into intended drug use to watch and make sure pharmaceuticals are not being misused. CDMOs and drug manufacturers adhering to cGMP standards also often have a digital Quality Management System, which makes sure standard processes and approvals are followed with digital steps and signatures that cannot be skipped or tampered with.

Cost — With more current and innovative technologies in use, cGMP is typically more expensive than GMP. More extensive and a higher quantity of testing done in cGMP also adds to the costs.

Dr. B. C. Roy College of Pharmacy & A.H.S. Durgapur

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

SOP OF GMP & cGMP

SOP stands for standard operating procedure. SOPs are more than simply a written set of work instructions. A standard operating procedure is a document containing step-by-step instructions to guide employees on how to perform a technical, repetitive process within an organization.

The SOP for GMP and cGMP would typically cover the following areas:

•***RESPONSIBILITIES***: Clearly define the roles and responsibilities of personnel involved in the manufacturing process, including management, quality control, and production teams.

• ***DOCUMENTATION***: Explain the requirements for documentation, record-keeping, and data management, including guidelines for creating, reviewing, updating, and archiving documents.

• ***TRAINING:*** Outline the training requirements for personnel involved in manufacturing activities, emphasizing the need for ongoing training and competency assessments.

• ***FACILITIES AND EQUIPMENTS***: Describe the requirements for maintaining an appropriate manufacturing facility, including cleanliness, environmental controls, and equipment calibration, qualification, and maintenance procedures.

• ***MATERIALS AND MANAGEMENTS***: Cover the procedures for ensuring the proper handling, storage, and labelling of raw materials, intermediates, and finished products, including documentation of batch records, traceability, and inventory control.

• ***MANUFACTURING OPERATIONS:*** Define the procedures for each step of the manufacturing process, including batch reconciliation, weighing, mixing, filling, packaging, and labelling, highlighting any specific considerations for cGMP compliance.

• ***QUALITY CONTROL(QC)***: Detail the requirements for in-process and finished product testing, including specifications, sampling plans, testing methods, and documentation of results.

• ***DEVIATION, CHANGE CONTROL, AND CAPA:*** Provide guidance on reporting and investigating deviations from established procedures,

implementing changes, and managing Corrective and Preventive Actions (CAPA).

• ***AUDITS AND INSPECTIONS***: Describe the procedures for conducting internal and external audits and inspections, including preparation, record review, and response to observations or non-compliances.

• ***COMPLAINTS AND RECALLS:*** Explain the procedures for handling customer complaints, evaluating product quality issues, initiating recalls if necessary, and conducting root cause analyses.

• ***CONTINUOS IMPROVEMENT:*** Emphasize the importance of ongoing monitoring, analysis, and improvement of the manufacturing processes to maintain compliance with GMP and cGMP requirements

Dr. B. C. Roy College of Pharmacy & AHS
Durgapur

9/12/24
Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

PERSONAL HEALTH AND HYGIENE

Good personal hygiene is required in pharmaceutical industries to safeguard the product and avoid any type of contamination that effects quality of medicinal product. Individual persons are responsible for quality of a medicinal product and hence collectively can be termed as "personnel".

In the pharmaceutical industry, hygiene holds the utmost importance to ensure the safety of both end consumers and employees.

There are four key areas to focus on:

1. production hygiene 2. personnel hygiene 3. plant and surface disinfection 4.and performance monitoring.

1. Check the premises carefully to identify hard-to-clean surfaces, and clean these areas with disinfectants that are lab-tested for efficacy and compliant with industry safety standards. Cement the storage areas and walkways to minimise the risk of spreading impurities. The flow of components, drug product containers, closures, labelling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination.

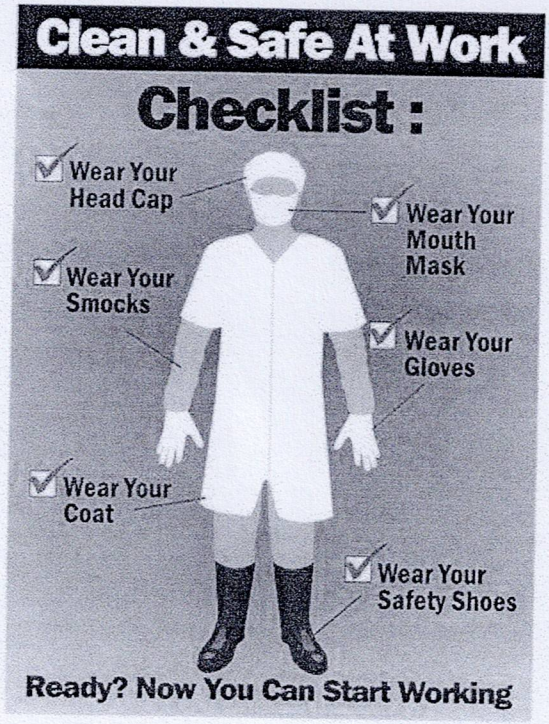
2. The garments prevent contamination from particles generated by, and microorganisms shed from, the body; Gowns are sterilised and non-shedding, and cover the skin and hair (e.g., caps, snoods for must aches and beards, protective goggles). All overlapping gown components have an adequate barrier between them (e.g., gloves overlapping sleeves). Make sure there's the right kind of hygienic specialised garments available in sufficient numbers at all times so that all personnel accessing the aseptic manufacturing are appropriately gowned.

3. Use high-quality, industry-approved sterilisation products that are tested for efficacy, user-friendliness, and occupational safety. Ensure the walls, ceilings and floors are washable and have no crevices; regular cleaning, scrubbing & disinfection are important to avoid impurity accumulation and the spread of contaminants.

Roy College of Pharmacy
Durgapur

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

4. Identify problem areas and take necessary measures to eliminate the bottlenecks and improve the processes. Monitor hygiene performance with digital tools that give you an up-to-date view of the entire manufacturing, storage, workwear, and cleaning process. Utilise data to make sure the processes run smoothly and to avoid bottlenecks in the process.



Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

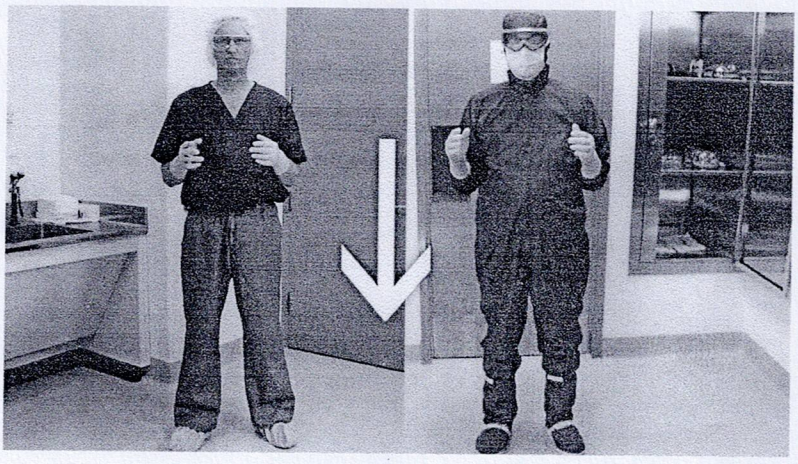
CHANGING ROOM PROCEDURE

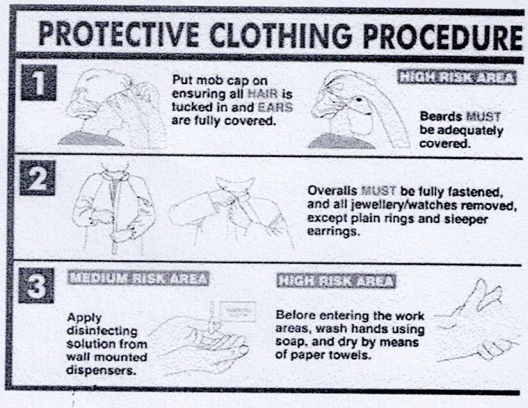
Entry procedure:

- Enter to change room from the outer corridor.
- Remove street footwear in the designated area, if applicable.
- Remove personnel belonging like wrist watches, jewellery, other ornaments, etc, and keep them in the lockers provided.
- Collect Apron /Coat/ Linen from the locker and wear
- Wear the clean cap
- Crossover the bench and wear the factory footwear, if applicable, or wear the shoe cover one by one and cross the cross over bench
- Look attire into the mirror for proper gowning
- Disinfect your hands with 70 % IPA provided in the change room.

Exit procedure:

- Enter the change room
- Remove the factory footwear and keep it in the cabinet of the crossover bench then cross the crossover bench. If the shoe cover is worn then directly cross the cross over bench
- Remove the primary gown (shirt, trousers, and cap) and put it in the "Used Garment Bin"
- Remove the shoe cover and put it in the "Waste Bin"
- Take your belongings from the locker
- Wear street footwear as applicable and exit from the change room
- During lunch/break if one needs to come out from the production area, keep shirt, trousers, and cap under the lockers provided in the change room before crossover the bench



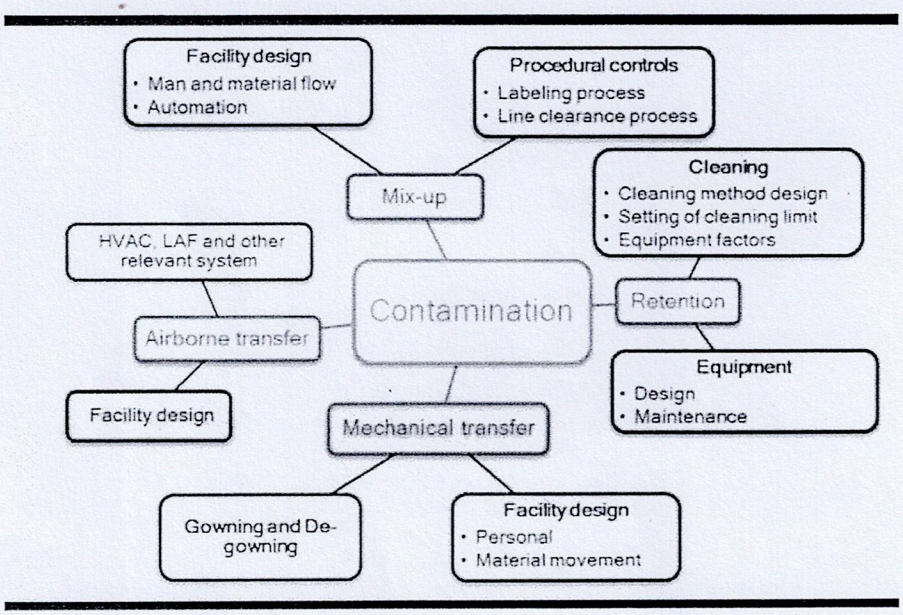


Dr. B. C. Roy College of Pharmacy & A.H.S. Durgapur

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

PREVENTION OF CROSS CONTAMINATION

To prevent cross contamination, pharmaceutical companies implement strict hygiene and sanitation procedures, robust cleaning programs, use dedicated equipment & facilities, perform regular quality control tests and QA release activities throughout the supply chain.



1. **Personnel training**: Personnel responsible for line-clearance procedures must be specially trained and authorised for this task
2. **External visitors:** Do not allow external visitors to enter production areas. If this is unavoi-dable, they should be given information in advance not to touch materials or products and stay within assigned areas.
3. **Personnel clothing**: All personnel in areas where single units of products are handled must wear protective clothing without pockets.
4. **Regular Audits and Inspections**: Conduct routine internal and external audits to assess adherence to established procedures and identify areas for improvement in preventing cross-contamination.

5. **Production Area:** Premises should be laid out in such a way as to allow the production to take place in a logical order to minimise intermediate storage of unlabelled products. The adequacy of the working and in-process storage space must permit the orderly and logical positioning of products and materials to avoid cross contaminations.

6. **Storage Areas:** Quarantine areas must be clearly marked, and their access should be restricted to authorised personnel. Any system replacing the physical quarantine must give equivalent security. Keep only one material or required

materials issued for one batch on one pallet unless clear physical partitioning exists.

7. **Design and Construction**: Equipment which is difficult to clean or has space where products can be concealed, can increase cross contamination risks. Consider any risk of potential cross contamination during design and construction of equipment.

8. **Special requirements for printed secondary Packaging materials:** Cartons and boxes should be code-read on the packaging line. Verification by manual means requires a duplicate inspection. An edge code may be used as an alternative for inserts and leaflets. Personnel must be trained in correct use of edge-code identification.

9.**Monitoring and record-keeping**: Implement a robust monitoring system to track the movement of materials, inspections, and testing processes. Maintaining detailed records allows for traceability and facilitates identification of potential sources of cross-contamination.

Dr. B. C. Roy College of Pharmacy & AHS * Durgapur

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

OHC (OCCUPATIONAL HEALTH CENTRE)

OHC stands for Occupational Health Centre, which is a specialized medical facility that focuses on providing healthcare services to workers in various industries. OHCs play a crucial role in maintaining the health and well-being of employees, as well as promoting a safe working environment. Its primary goal is to prevent work-related injuries, illnesses, and accidents, as well as to provide comprehensive healthcare services and support to employees.

Aspects: **Preventative Care**: Conducting regular health check-ups and monitoring of employees to identify any work-related health issues

- **Occupational Injury and Illness Treatment**: They have expertise in diagnosing and managing occupational diseases like occupational lung diseases, noise-induced hearing loss, repetitive strain injuries, and chemical exposure-related illnesses.
- **Occupational Rehabilitation**: They aim to facilitate the worker's safe and timely return to work, often collaborating with occupational therapists and other healthcare professionals.
- **Employee Assistance Programs (EAPs):** Offering counselling, mental health support, and resources to assist employees in dealing with personal and work related challenges, stress, and mental health issues
- **Worksite Evaluations**: Organizing health awareness programs, workshops, and training sessions to educate employees about healthy lifestyle choices
- **Compliance with Regulations**: Ensuring compliance with occupational health and safety regulations, standards, and guidelines set forth by local, national, or international regulatory bodies.
- **First Aid and Emergency Response**: Providing immediate medical assistance and first aid in case of injuries or medical emergencies within the workplace.

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

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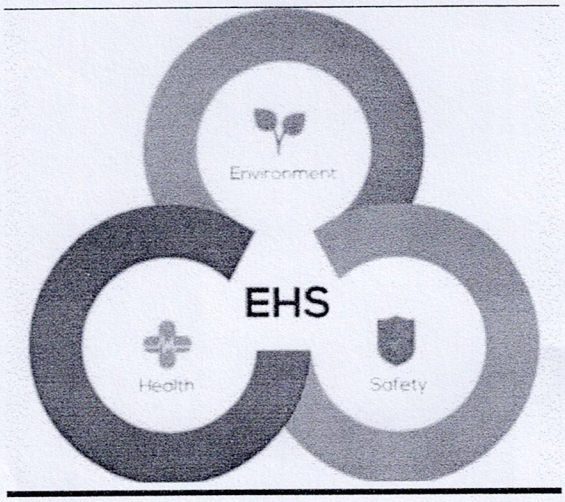
EHS (ENVIRONMENTAL, HEALTH AND SAFETY)



EHS stands for Environment, Health, and Safety. EHS management is critical for preventing accidents, reducing environmental impact, complying with regulations, and fostering sustainable practices.

Environmental Protection:

- Pollution Prevention: Implementing measures to reduce pollution of air, water, and soil, such as emission controls and wastewater treatment.
- Sustainable Practices: Promoting sustainability through energy efficiency, resource conservation, and adoption of renewable energy sources.

Occupational Health and Safety:

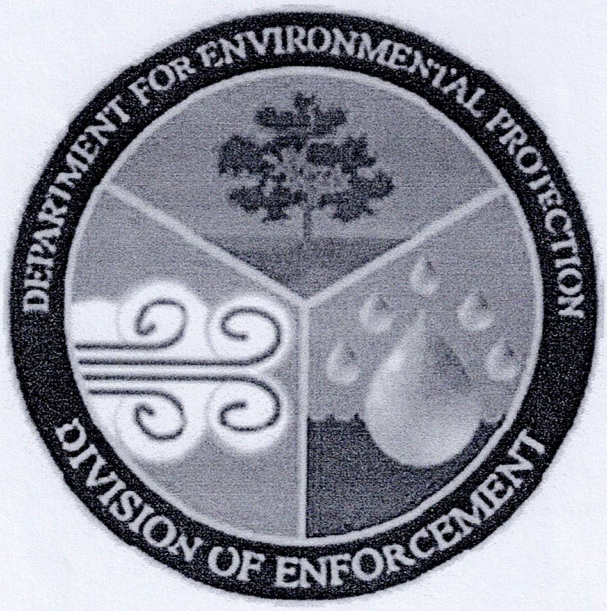
- Workplace Safety: Ensuring a safe work environment by identifying and mitigating potential hazards, providing safety equipment, and conducting regular safety training.
- Risk Assessment and Management: Identifying, assessing, and managing risks associated with workplace activities to prevent accidents and injuries
- Emergency Response Planning: Developing plans and protocols to respond effectively to emergencies such as fires, chemical spills, or natural disasters.

Health and Well-being:

• Employee Health Programs: Implementing wellness programs to promote healthy lifestyles, mental health support, and preventive healthcare for employees.

• Occupational Health Services: Providing medical surveillance, health screenings, and occupational health assessments to monitor and maintain the health of workers.

WATER SYSTEM IN EHS: The water system in EHS refers to the infrastructure and resources used to supply and distribute water within the Environmental Health and Safety (EHS) department.



Prof. (Dr.) Samir Kumar Samanta
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Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

QUALITY CONTROL

Quality control is essential in the pharmaceutical industry because it ensures that medications are safe and effective for their intended uses. This involves testing samples of drugs to ensure that they meet the required standards for strength, purity, and accuracy.

HPLC: High-performance liquid chromatography (HPLC) is a type of liquid chromatography used to separate and quantify com- pounds that have been dissolved in solution. HPLC is used to determine the amount of a specific compound in a solution.

HARDNESS TEST: This test is also known as "Crushing Strength Test". Tablets require a certain amount of strength, or hardness to withstand mechanical shocks of handling in manufacture, packaging and shipping. Tablet hardness has been defined as the force required to break a tablet in a diametric compression test.

Disintegration test in quality control: The disintegration test is an important quality control (QC) test conducted on pharmaceutical tablets or capsules to ensure their proper disintegration or dissolution in the body. The test helps to determine if the tablet or capsule will release the active pharmaceutical ingredient (API) properly so that it can be absorbed by the body.

Drug Dissolution Test: In the pharmaceutical industry, drug dissolution testing is routinely used to provide critical in vitro drug release information for both quality control purposes, i.e., to assess batch-to-batch consistency of solid oral dosage forms such as tablets, and drug development, i.e., to predict in vivo drug release profiles

Friability Test: Friability is defined as the percentage of weight loss of powder from the surface of the tablets due to mechanical action and the test is performed to measure the weight loss during transportation.

Quality Control mainly follows the "**ALCOA**" system, which means-

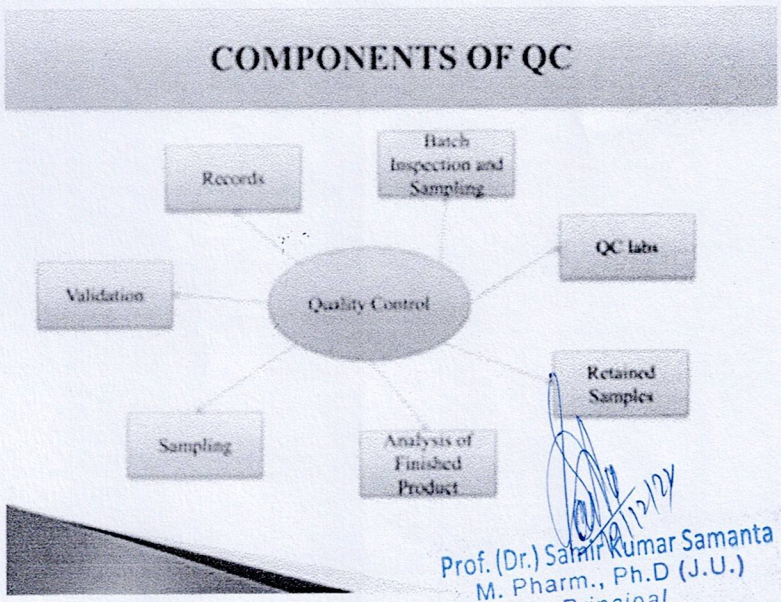
A= Attributable

L= Legible

C= Contemporaneous

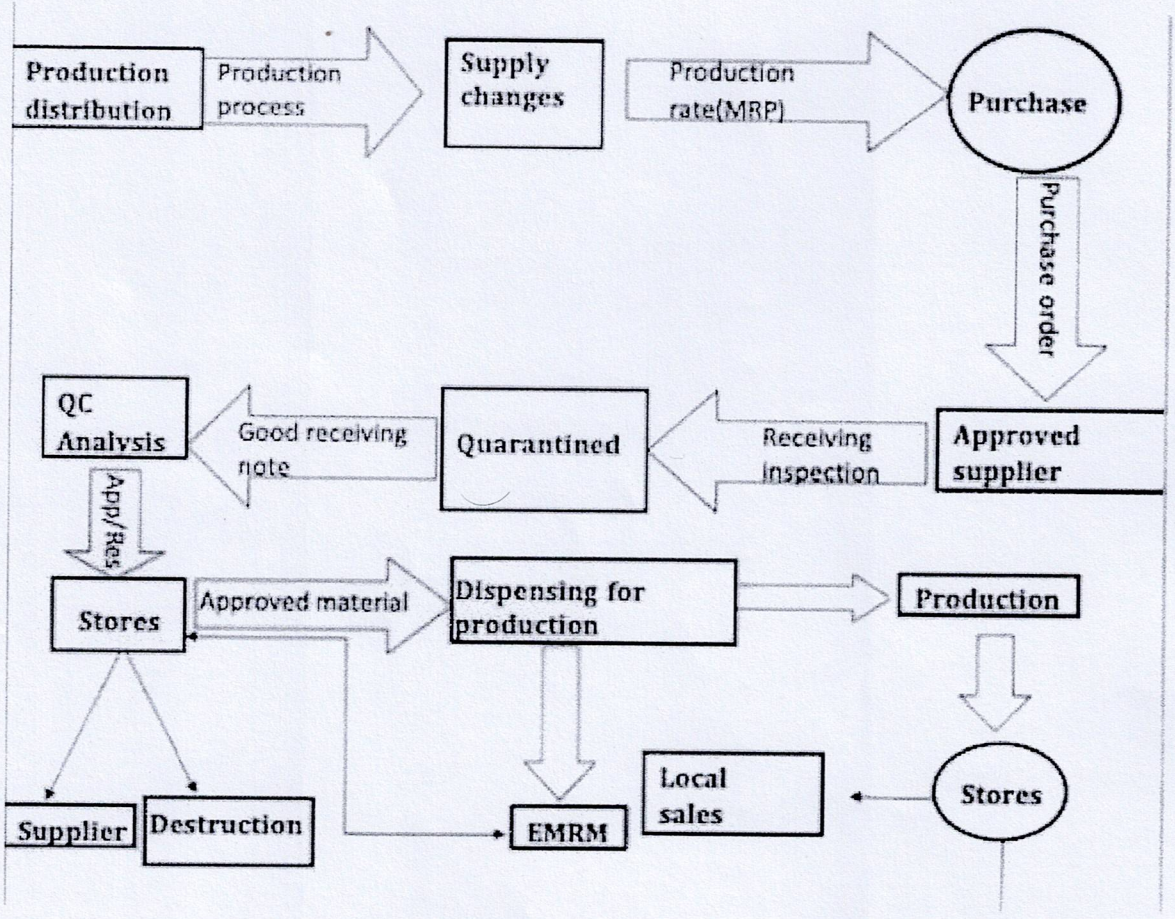
O= Original

A= Accurate



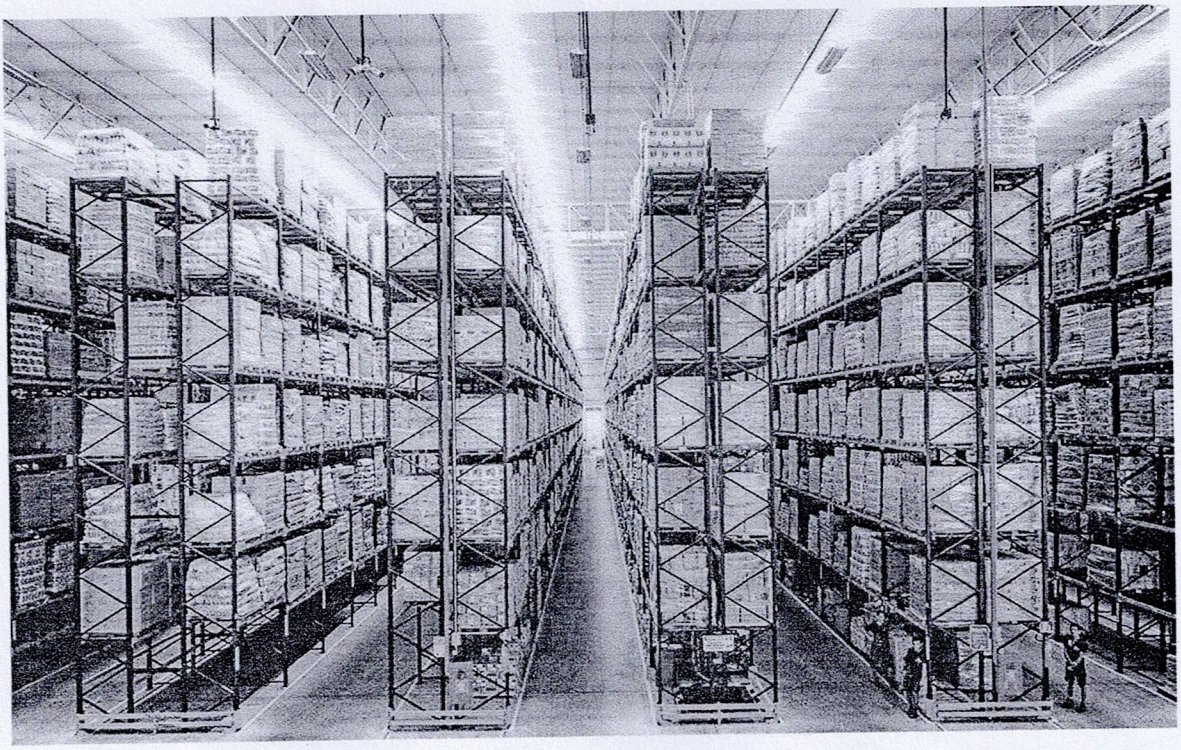
STORE

A "store" in the pharmaceutical sector is often referred to as a location or area within a pharmaceutical manufacturing or distribution setup where pharmaceutical goods, raw materials, equipment, and other supplies are arranged and systematically stored



Here are key aspects of a store within the pharmaceutical industry:

- Storage Conditions and Compliance
- Temperature-Controlled Storage
- Inventory Management
- Warehousing Solutions
- Material Handling and Safety
- Labelling and Identification
- Good Storage Practices (GSP)
- Rotation and First-In-First-Out (FIFO) Principle
- Hazardous Materials Storage



TABLET MANUFACTURING

Tablets are commonly manufactured by wet granulation, dry granulation or direct compression. These methods may be considered to consist of a series of steps (unit processes) – weighing, milling, mixing, granulation, drying, compaction, (frequently) coating and packaging. Regardless of the method used the unit processes – weighing, milling and mixing, are the same; subsequent steps differ.

Formulation and Product Development: The process starts with formulation development, where the drug's active and inactive ingredients are selected and combined in specific proportions to create the tablet formulation. This step involves selecting suitable excipients, binders, disintegrants, lubricants, and other additives

Size Reduction Equipment: Common size reduction equipment used in tablet manufacturing includes a variety of milling equipment like hammer mills, vibration mills, pin mills, end-runner mills, edge-runner mills, cutter mills, and ball mills

Weighing Balance Machinery: Weighing balance equipment used in tablet manufacturing is used to get the precise weight of your tablets and is available in bulk and electronic weighing balance system

Granulation: Granulators are used in tablet manufacturing to create wet or dry tablet granules. Granulator machines commonly used today include rotating shape granulators, mechanical agitator granulators, high-shear granulators, fluidized-bed granulators, and dry granulators

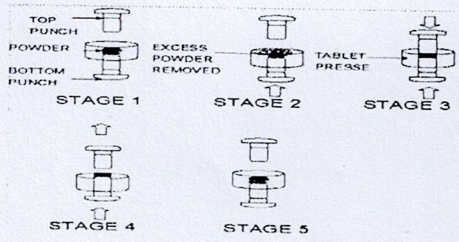
Blending: A wide range of mixing equipment is used in tablet manufacturing to mix powders and ingredients accurately. The most common machinery available includes pneumatic mixers, diffusion mixers, convective mixers, ribbon blenders, orbiting screw mixers, horizontal blenders, and planetary blenders

Sifting: The dried granules may be milled or sieved to obtain the desired particle size for compression. This step improves uniformity and aids in achieving the desired tablet weight and quality.

Drying: In wet granulation, the granules are dried to remove excess moisture and achieve the desired moisture content for tablet compression. Proper drying is crucial to prevent tablet defects and ensure the flow and

compressibility of granules. Dry mixing and wet granulation are performed by using RMG & FBE.

Compression: The blended granules are compressed into tablets using a tablet press machine. The machine exerts pressure to compact the granules into tablet form using a set of punches and dies. Various tablet shapes, sizes, and designs can be achieved using different tooling.



Coating and Polishing Machines: In the pharmaceutical industry, tablet coating systems and polishing machines cover tablet surfaces with a thin coating solution. Using a tablet coating machine has a variety of benefits, like masking the odor and taste and prolonging shelf life.

Quality Control: Quality control checks are performed at various stages of the manufacturing process, including testing the raw materials, in-process testing during granulation and compression, and final product testing. Tests include hardness, thickness, weight variation, friability, disintegration, and dissolution testing

Packaging: The final tablets are packaged into blister packs, bottles, or other suitable packaging materials. Proper labelling and compliance with regulatory requirements are essential.

Storage and Distribution: Packaged tablets are stored under appropriate conditions to maintain their stability and efficacy. They are then distributed to wholesalers, pharmacies, or directly to consumers.

Throughout the entire manufacturing process, adherence to Good Manufacturing Practice (GMP) guidelines and other relevant regulatory standards is paramount to ensure the quality, safety, and efficacy of the produced tablets. Each step involves careful consideration and control to produce high-quality tablets for patient use.

B. C. Roy College of Pharmacy Durgapur

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

CAPSULE

It is solid pharmaceutical dosage forms in which the drug or a mixture of drugs is enclosed in a Gelatin Shell or any other suitable material to form various shapes.

Capsules are classified into two categories based on the amount of gelatin present.

Hard Gelatin Capsule

Soft Gelatin Capsule

The fundamental difference between the two is that hard gelatin capsules are less plasticised than soft gelatin capsules. In addition, hard gelatin capsules have two parts, the "cap" and "body". Hard gelatin is widely used and filled with powder drugs or medicine pellets.

The Dipping Method used to manufacture hard gelatin capsules involves steps like Dipping, Rotation, Drying, Striping, Trimming, and Joining

Developing the formulation: I

In developing a capsule formulation, the goal is to prepare a capsule with accurate dosage, good bioavailability, ease of filling and production, stability, and elegance. In dry formulations, the active and inactive components must be blended thoroughly to ensure a uniform powder mix for the fill. Care in blending is especially important for low-dose drugs, since lack of homogeneity in blending may result in significant therapeutic consequence

Selection of Capsule Type:

Choose the appropriate type of capsules: typically, hard gelatine capsules (HGC) or vegetarian capsules (made of hydroxypropyl methylcellulose or other plant-based materials). Selection depends on the product, target market, and any specific dietary or cultural considerations

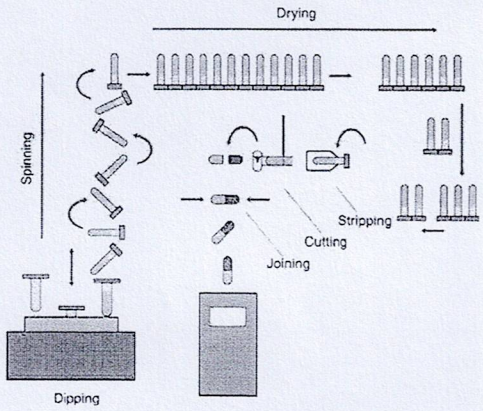
Capsule Filling:

Filling the capsules involves dosing the appropriate amount of the fill material into the capsule shells. This is done using capsule filling machines, which can be manual, semi-automatic, or fully automatic

Capsule Sealing:

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

As mentioned previously, some manufacturers make tamper-evident capsules by sealing the joint between the two capsule parts. One manufacturer makes distinctive-looking capsules by sealing them with a coloured band of gelatin.



Capsule cleaning and polishing:

Small amounts of powder may adhere to the outside of capsules after filling. The powder may be bitter or otherwise unpalatable and should be removed before packaging or dispensing. On a small scale, capsules may be cleaned individually or in small numbers by rubbing them with a clean gauze or cloth. On a large scale, many capsule- filling machines are affixed with a cleaning vacuum that removes any extraneous material from the capsules as they exit the equipment.

Printing:

Printing company labels are significant for product identification. The required graphic is imprinted on the capsules using the company's ink and stamping equipment.

Testing:

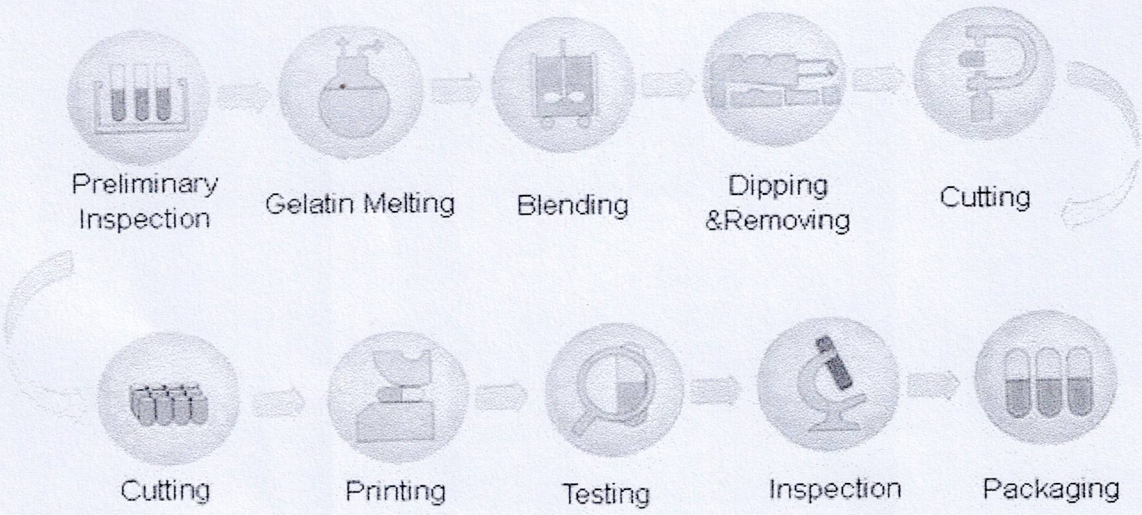
After the printing phase is completed, the quality testing phase begins. An automatic capsule inspection system detects faults in capsules. The machine can identify faults like inadequate filling, perforations, internal chips, splits, grooves, short bodies, multiple caps, curved caps, brittle produce, short and long caps, bubbles, black spots/heterochromatic spots, and many others.

Packaging:

Package the capsules into appropriate blister packs, bottles, or other packaging materials. Proper labelling is crucial, including dosage information, expiry date, and any other necessary information.

Shipping:

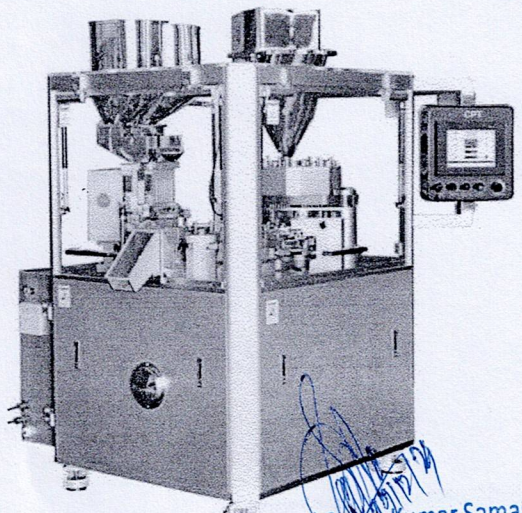
Packed capsules are kept in a temperature and humidity-controlled facility until shipping.



Working Principle of A Capsule Filling Machine

Every machine has its own working method. The capsule filling machine works in a step-by-step process that is as mentioned below.

- The positioning of colourless & translucent capsules in the capsule filling tray.
- Division of capsule caps from their bodies.
- Filling up the capsule body with pharmaceutical ingredients
- Rearrange the caps and bodies
- Expulsion of filled capsules from the machine



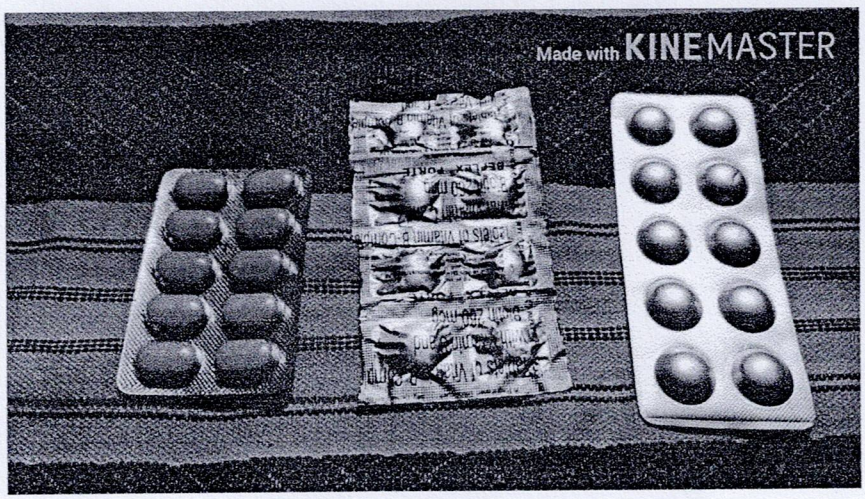
GENERAL PACKAGING

There are three types of packing in the pharma industry - primary, secondary, and tertiary.

The primary packaging consists of packaging material that is in direct contact with the drugs. The different types of primary packaging for pharmaceutical products are as follows:

Blister Packs: Blister pack is the most common pharmaceutical packaging used to hold solid medicines in place. These are pre-formed foil, paper, or plastic packs. Blister packs have a pocket or cavity made from thermoformed plastic. At its backside, there is a paperboard, aluminium foil, or plastic film seal that can be easily punctured by hand. Notably, this seal includes all the important information related to the drug.

Strip Packaging: It is a unit packing dosage and is specifically used to increase the dosage life as it protects the content individually. The most significant difference between blister and strip packaging is that strip doesn't have thermo-formed cavities. Instead, the packaging is formed around the tablet.



Vials: Vials are plastic, or glass containers specifically used to hold solid, powder, and liquid drugs. They are bigger in size and capacity compared to ampoules. The vials are closed with crimp vials (rubber stopper or metal cap), screw vials (screw cap or dropper), or lip vials (plastic stopper or cork). However, plastic vials have different closure systems - hinge caps - which can be easily closed when pressed. The bottoms of the vials are mostly flat.

Bottles: Most frequently used to carry liquid drugs as well as capsules and formed tablets. Because of excellent properties, glass bottles are most commonly used for liquid doses. And plastic bottles are used for tablets and

capsules. Although they come in different colours, the most common is brown and orange as they can prevent ultraviolet light from harming photosensitive contents.

Secondary Packaging

Once the primary packaging is done, it is the time for the packaging that is called secondary packaging. It is just another layer of packaging which can be any printed material, like boxes.

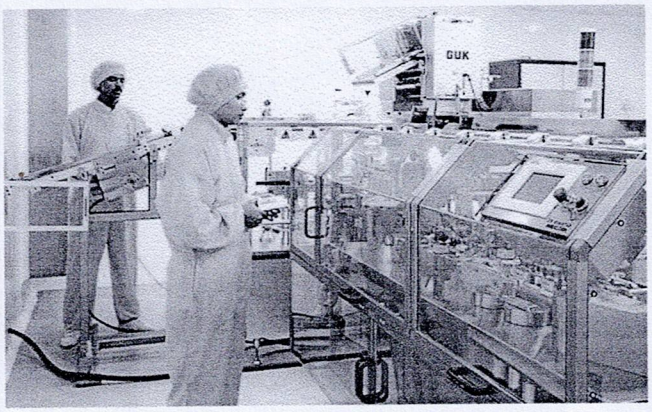
All the important information is printed on these boxes, like ingredients, manufacturer's name, address, warning, and type of medicine. The printed information helps the manufacturer to distinguish between different boxes with different drugs easily. The secondary packaging essentially gives the drugs a brand image at the same time, further protects them during transportation.

Tertiary Packaging

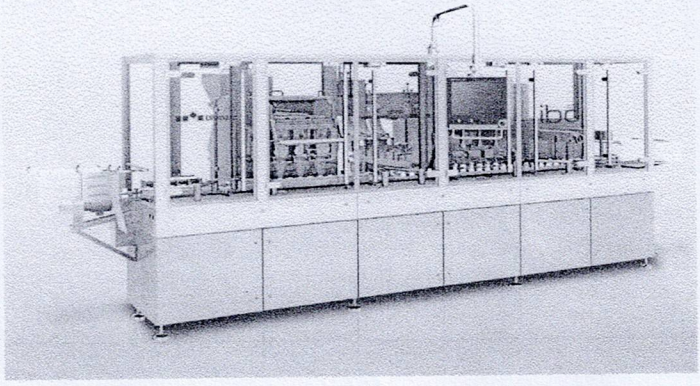
The last type of packaging, i.e. tertiary packaging, is important for the shipping process. The end consumers don't see this packaging. The retailers often remove them before they showcase the medicines in their shops or clinics.

FFS AND NASAL

FFS: Form fill seal (FFS) technology is an automated computer operated technology, to prepare sterile products. Mostly it is applicable for I.V. infusion bottles. The form-fill-seal process involves the use of a single piece of equipment to form a plastic container, fill the container with the parenteral drug product and then hermetically seal the container.



NASAL: Nasal administration, popularly known as snorting, is a route of administration in which drugs are insufflated through the nose. It can be a form of either topical administration or systemic administration, as the drugs thus locally delivered can go on to have either purely local or systemic effects. Nasal preparations are usually solutions or suspensions administered by drops or as a fine mist from a nasal spray container, which could include an aerosol with a metered valve



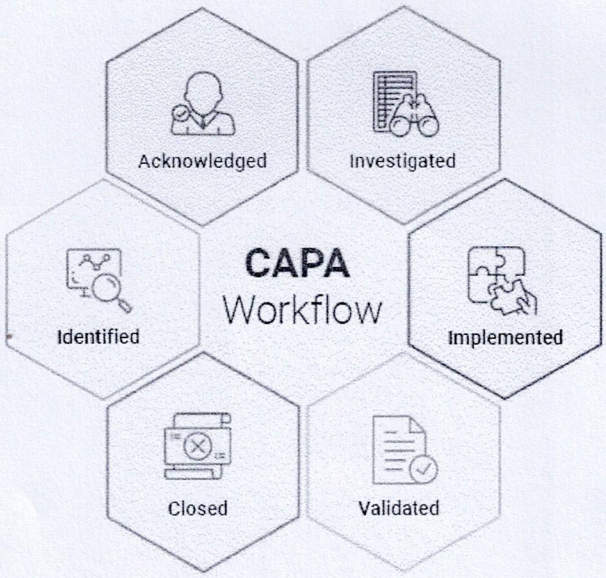
QUALITY ASSURANCE

Quality Assurance (QA) activities include a planned system of review procedures conducted by personnel not directly involved in the inventory compilation/development process. Reviews, preferably by independent third parties, should be performed upon a finalised inventory following the implementation of QC procedures. Reviews verify that data quality objectives were met, ensure that the inventory represents the best possible estimates of emissions and sinks given the current state of scientific knowledge and data available, and support the effectiveness of the QC programme. Pharmaceutical Quality Assurance is the assurance of quality requirements for a product or service in the pharmaceutical industry.

Duties and Responsibilities of QA in pharmaceutical industry

- **Review of Manufacturing Processes**: The QA person ensures that manufacturing processes meet the required quality standards by reviewing the manufacturing procedures, batch records, and testing protocols.
- **Product Release**: A QA person ensures that products are released only after they have met the required specifications and are deemed safe and effective.
- **Quality Control:** A QA person collaborates with the Quality control (QC) team to ensure that laboratory testing is conducted appropriately and meets the required specifications.
- **Audit:** The QA person conducts regular internal audits of the manufacturing facility to ensure that the facility meets the required quality standards.
- **Documentation:** A QA person is responsible for ensuring that all necessary documentation is completed accurately, in a timely manner, and in compliance with regulatory requirements.
- **Deviation Management:** The QA person is responsible for reviewing and approving deviation reports and ensuring that corrective and preventive actions (CAPA) are implemented.
- **Complaint Handling**: The QA person is responsible for reviewing and investigating product complaints to ensure implementation of corrective and preventive actions (CAPA).
- **Product recall**: The QA person is responsible for reviewing and investigating product which are called back due to some defects in the products and ensure corrective and preventive actions (CAPA)

CAPA stands for Corrective Action and Preventive Action, a system for analysing, correcting, and preventing issues. It outlines procedures to solve the issue, it also analyses the cause of the problem to prevent its recurrence.



Dr. B. C. Roy College of Pharmacy & AHS
Durgapur

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206

ENGINEERING

Engineering plays a crucial role in CIPLA by designing and developing the equipment, systems, and processes required for the production and manufacturing of pharmaceutical products. Here are some key areas where engineering is involved in the pharmaceutical industry:

- Pharmaceutical Process Engineering: To ensure high-quality goods and regulatory compliance, engineers build effective production processes for pharmaceutical products that are both efficient and affordable. When a method is being validated, they optimize the process parameters, scale up laboratory procedures to levels of commercial production, and guarantee effective technology transfer.
- Equipment Design and Development: Engineers create specialized machinery for the pharmaceutical business, including mixing tanks, bioreactors, filtration systems, and packaging machines. They make sure the machinery complies with stringent hygienic, safety, and legal standards and enhance its performance for effective output.
- Engineers create and put into place automation and control systems to watch over and manage pharmaceutical manufacturing operations. To increase process effectiveness, precision, and dependability, this includes designing and integrating robotic systems, data collection systems, and supervisory control and data acquisition (SCADA) systems.
- Engineers are in charge of planning and building pharmaceutical manufacturing facilities, making sure they adhere to Good Manufacturing Practices (GMP) and regulatory standards. For the production of pharmaceuticals, they design cleanrooms, HVAC systems, and utility systems like those for producing compressed air, steam, and purified water.
- Engineers collaborate with quality assurance teams to develop and put into practice validation protocols for the machinery, procedures, and systems utilized in the production of pharmaceuticals. They carry out validation testing and analyses to make sure that systems are in conformity with the necessary quality and regulatory standards.
- Packaging and Serialization: Engineers create and develop pharmaceutical product packaging systems, taking into mind elements like product protection, security, usability, and legal requirements. In order to maintain traceability and anti-counterfeiting measures.

The Equipment and Their Capacities are listed below

EQUIPMENT	CAPACITY
STEAM PRESSURE	4.5 – 9.5 Kg/cm2
STEAM TEMP	180°c
FUEL PUMP PRESURE	18 – 22 kg/cm2
FUEL TEMP	Ambient temperature
STACK TEMP	280 ° c
WATER PUMP	11 kg/cm2
FEED WATER TANK LEVEL	Above 60 cm
FUEL TANK LEVEL	60 cm

OVERVIEW

Our 15-day industrial training program at CIPLA has finally come to a close.

During our entire training period we came close to all the aspects and analysis which are carried out to the industry and at the same time we have learned about how to follow the rules and regulation according to cGMP & GMP.

On the exposer of working with CIPLA we have come to know about the 5 years goal that is:

- Zero Harm
- 100% compliance
- Carbon (+ve)
- Water (+ve)
- Zero waste to landfill

Also, we learned new things along this journey, not just about the industry but also about environment, togetherness, collaboration, dedication, discipline, and the realities of life.

Cipla

Caring for

Dr. B. C. Roy College of Pharmacy & AHS Durgapur

Prof. (Dr.) Samir Kumar Samanta
M. Pharm., Ph.D (J.U.)
Principal
Dr. B. C. Roy College of Pharmacy & AHS
Durgapur, West Bengal-713206