|| jai sri gurudev ||

ADICHUNCHANAGIRI UNIVERSITY

Sri Adichunchanagiri College of Pharmacy

(Approved by PCI, New Delhi)

SACCP/554/2025-26

Date: 12.08.2025

INDUSTRIAL TRAINING LETTER

To,
HR MANAGER
Peenya Pharmaceuticals Pvt Ltd
3rd phase, NO 68, 6th Main Rd, Mec Layout, Phase 3, Peenya, Bengaluru, Karnataka 560058

SUBJECT: Request for Industrial Training – Reg.

Dear Sir,

Season's Greetings from Faculty of Pharmacy, Sri Adichunchanagiri College of Pharmacy, B G Nagara

I take this privilege to introduce our College, Sri Adichunchanagiri College of Pharmacy, BG Nagara, and situated 100 Km away from Bangalore. Our institute is a constituent college of Adichunchanagiri University. I am happy to share that our college ranks 83rd position by NIRF (National Institutional Ranking Framework) ranking, accredited by NBA (National Board of Accreditation), certified by ISO 9000-2015 and affiliated to NAAC A+ accredited university offering D Pharm, B Pharm, M Pharm (7 specializations), Pharm D and Ph. D programs.

As a part of curriculum, as per orders of Pharmacy Council of India, New Delhi, upcoming B Pharm Graduate shall undergo industrial practical training in an esteemed pharmaceutical industry for a period of **not less than 150 hours or 21 days** for the successful completion of the graduation course. Further, this training program enables the student to understand the pharmaceutical industrial process thoroughly.

In this regard, I request you to **provide an opportunity for our below mentioned B. Pharm students to get trained in your esteemed Pharmaceutical Industry for a period of not less than 150 hours or 21 days** preferably in the first week of August 2025.

List of students

NAME	REG NO.	COURSE	MOB NO.
Mr. Vishwas G N	22BP1098	6th Sem B. Pharm	9353060377
Mr. Harshith Kumar U N	22BP1028	6th Sem B. Pharm	7892073249
Mr. Harish B	22BP1026	6th Sem B. Pharm	6362477874

We will be pleased if you take the necessary steps and oblige us.
Thanking You,
With regards,

Principal
Principal
Faculty of Pharmacy -
Sri Adichunchanagiri College of Pharmacy
Adichunchanagiri University
NAAC A+ Accredited
B.G.Nagara - 571448

॥ jai sri gurudev ॥

ADICHUNCHANAGIRI UNIVERSITY

Sri Adichunchanagiri College of Pharmacy

(Approved by PCI, New Delhi)

SACCP/546/2025-26

Date:09/08/2025

INDUSTRIAL TRAINING LETTER

To,
Human Resource Manager
Madhur Pharma Research Laboratories Ltd
No. 292-294, 4th Phase
Peenya Industrial Area
Bangalore - 560058

SUBJECT: Request for Industrial Training – Reg.

Dear Sir,

Season's Greetings from Faculty of Pharmacy, Sri Adichunchanagiri College of Pharmacy, B G Nagara

I take this privilege to introduce our College, Sri Adichunchanagiri College of Pharmacy, BG Nagara, and situated 100 Km away from Bangalore. Our institute is a constituent college of Adichunchanagiri University. I am happy to share that our college ranks 83rd position by NIRF (National Institutional Ranking Framework) ranking, accredited by NBA (National Board of Accreditation), certified by ISO 9000-2015 and affiliated to NAAC A+ accredited university offering D Pharm, B Pharm, M Pharm (7 specializations), Pharm D and Ph. D programs.

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List of students

NAME	REG NO.	COURSE	MOB NO.
Mohammed Zain C A	22BP1059	6th Sem B. Pharm	9740845471

We will be pleased if you take the necessary steps and oblige us.
Thanking You,
With regards,

Principal

Principal
Faculty of Pharmacy -
Sri Adichunchanagiri College of Pharmacy
Adichunchanagiri University
NAAC A+ Accredited
B.G.Nagara - 571448

Faculty of Pharmacy
Sri Adichunchanagiri College of Pharmacy
B.G. Nagara - 571 448, Karnataka

ADICHUNCHANAGIRI UNIVERSITY

NAAC GRADE A+
ACCREDITED UNIVERSITY

PEENYA PHARMACEUTICALS PRIVATE LIMITED

BANGLORE, KARNATAKA

INTERNSHIP REPORT

Bachelor of Pharmacy (B. Pharm)

SUBMITTED BY:

VISHWAS GN [22BP1098]

HARSHITH KUMAR UN [22BP1028]

HARISH B [22BP1026]

ACKNOWLEDGMENT

I would like to express my sincere gratitude to Peenya Pharmaceuticals Company for providing us with the opportunity to intern in their company. Supervisor and staff of Peenya Pharmaceuticals for their guidance and support throughout the internship. I also extend my thanks to my teachers from Sri Adichunchanagiri College of Pharmacy for their continuous encouragement.

We would also like to express our appreciation to the staff at Peenya Pharmaceuticals Private limited for their warm welcome assistance during our internship.

INTRODUCTION

The report details of our internship experience at Peenya Pharmaceuticals Limited,Bangalore. They are innovative manufacturers of Sustained Release Formulations (Tablets , Syrups, capsules) they have a state- of-the-art CGMP compliant, WHO certified, dedicated facility to produce tablets,Syrups and capsules. They follow a validation and quality assurance protocol right from development of the product to the finished product stage.

Their adherence to standards ensures that the materials, equipment, process and technical personnel deliver the products as per exact specifications. Peenya Pharmaceuticals is a R & D customer-driven organization, committed to meeting stringent quality standards

COMPANY REVIEW

At Peenya Pharmaceuticals, we are constantly striving to provide high quality medicines that empower medical professionals and serve patients. Peenya Pharmaceuticals focuses to ensure production of Tablets. Each Tablet contains uniform drug content.

The layering or coating is done in a scientific manner and process for each and every product to ensure that there isn't any entrapped moisture and the surface of the Tablets is even. Further, uniform film coating ensures the required release pattern and a seal coat so that the release pattern of the product does not change until expiry.

INTERNSHIP ACTIVITIES

During our internship, we were observed and involved in various activities , including

1. Storage department
2. Production department
3. .Manufacture department
4. Quality assurance
5. Quality control

STORES

Stores in the Pharmaceutical Industry

The stores (or store department) in a pharmaceutical company is a vital section that dealswith receipt, storage, control, and issue of materials required for manufacturing, testing, and distribution of medicines.

1. Types of Stores Raw Material Storeo Stores APIs (Active Pharmaceutical Ingredients) and excipients. o Materials must be stored in controlled conditions (temperature, humidity).

Packaging Material Storeo Stores primary (blisters, bottles, strips) and secondary (cartons, labels, leaflets) packaging materials.

Finished Goods Storeo Stores manufactured products ready for dispatch.

Requires proper labeling, quarantine, and release by QA.

Engineering Storeo Keeps spare parts, lubricants, tools, and maintenance materials. General Storeo Stationery, housekeeping, safety equipment, etc.

2. Functions of Store Department1. Receipt of Materialso Verify supplier documents (invoice, COA, challan). o Check material quantity and quality before acceptance.

3. Storageo Maintain proper environmental conditions (temperature, humidity, segregation). o Separate quarantine, approved, rejected, returned, and recalled materials.

4. Inventory Controlo Use systems like FIFO (First In First Out) or FEFO (First Expiry FirstOut). o Maintain minimum, maximum, and reorder levels.

4. Issuance of Materialso Provide materials only against authorized requisitions. o Record all transactions for traceability.

5. Documentationo Stock registers, bin cards, electronic ERP/SAP systems. o Compliance with GMP (Good ManufacturingPractices).

Production department

AUTOMATIC CAPSULE FILLING MACHINE

Verify the cleanliness of the area and the equipment.

Do not operate the machine in automatic mode without all the protective guards in the proper closed position.

Powder filling: The powder is loaded into the drug filling hopper and transferred to the powder tub by s stirrer.

The stroke of the tamping device ejects the slug into the body of the capsules

Capsule closing and ejection: The capsules are closed and locked by means of closing pins.

Filled and closed capsules are ejected by ejection pins and come out through the exit.

Operation: switch on the mains run the machine for at least one complete rotation.

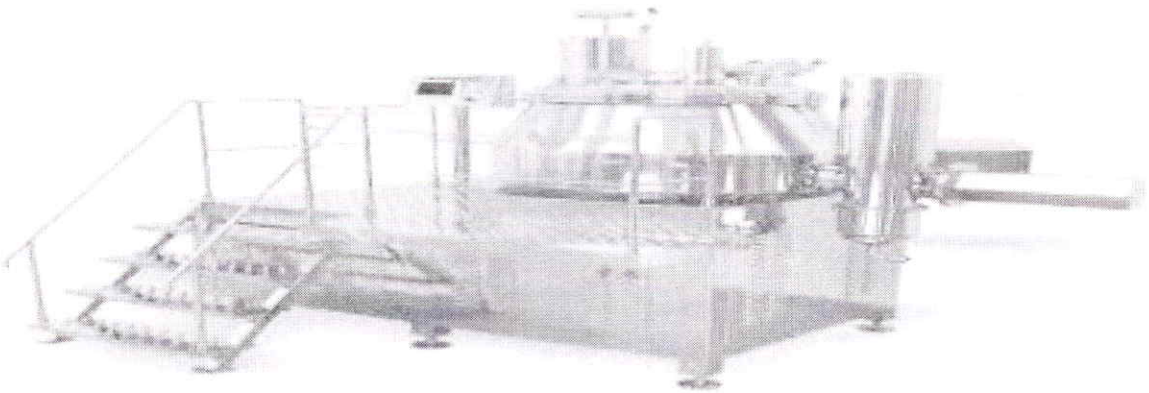
Start on pressing this key machine starts in auto mode.

In the main screen of the control panel the following options are selected auto alarm, product select and sample

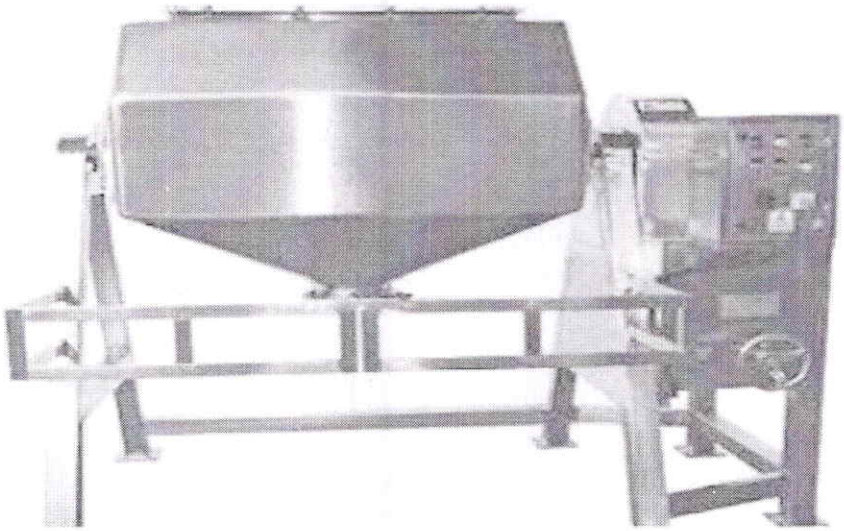
In the auto function screen it involves the start, stop, time reset, alarm status, sample setting are selected as per the batch requirement.

EQUIPMENTS INVOLVED IN GRANULATION

Rapid mixture granulator works on agitation and tumbling. The impeller isresponsible for uniformly mixing wet granules, and the chopper helps inbreaking or reducing particle size. At the starting process or during binderaddition, the impeller and chopper generally operate at low speed. Then afterthe formation of wet mass, they are operated at high speed to make the Desired granules



Octagonal blender



An Octagonal Blender is a slow-speed, tumbling-type blender used foruniform mixing of dry powders and granules in the pharmaceutical industry. ? Features Octagonal shape (8-sided) for efficient tumbling. Works on the principle of diffusion blending. Gentle mixing – prevents granule breakage. Capacity: few kg to hundreds of kg (batch processing). Simple design, easy to clean (cGMP compliant).

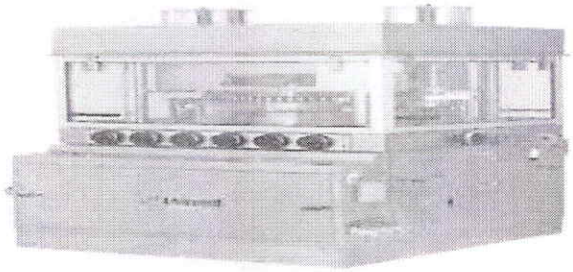
COMPRESSION

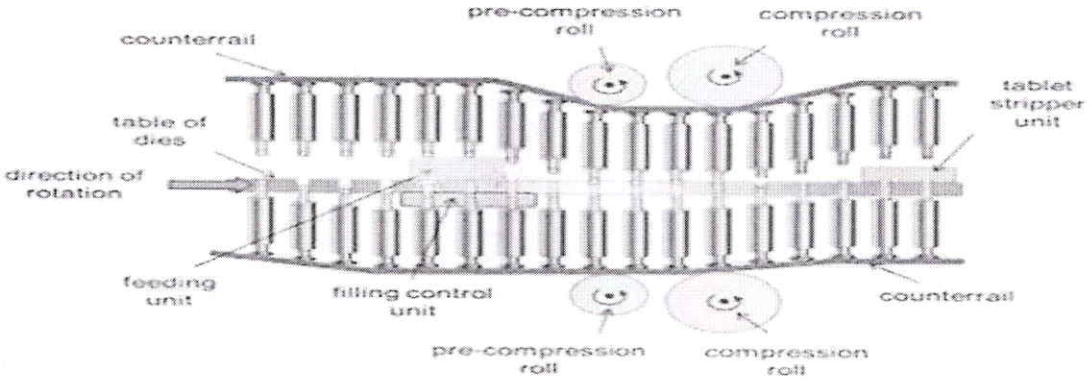
Compression in Pharmaceutical Industry?

Definition

Compression is the process of compacting powder or granules into tabletsusing a tablet press machine. It is a critical step in tablet manufacturing.

MACHINE IN COMRESSION





Manufacturing Department

The manufacturing area in the pharmacy industry focuses on the industrial-scale production of medicinal drugs by transforming raw materials into finished products, adhering to stringent Good Manufacturing Practices (GMP) for safety and quality. This process involves two main stages: primary manufacturing, which produces Active Pharmaceutical Ingredients (APIs), and secondary manufacturing (or formulation), where APIs are combined with excipients and converted into final dosage forms like tablets or capsules. Key aspects of this area include quality control, innovative production methods such as continuous manufacturing, and navigating complex regulatory requirements to ensure safe and effective medicines for humans and animals.

Primary Manufacturing (API Production):

This stage involves the synthesis, extraction, and purification of active compounds that provide the therapeutic effects of a drug.

Secondary Manufacturing (Formulation):

This process transforms the APIs into stable, effective, and administrable forms, such as tablets, capsules, injections, or creams, through various unit operations like granulation, milling, and coating.

QUALITY ASSURANCE

Sustained release formulations are designed to deliver the correct amount of drug at the right time, at the required site in the body to ensure onset of therapeutic action and to maintain the same over a period of time, providing continuous relief to the patient. Stringent in process quality control procedure at each and every stage of manufacturing .The pellets and the blend undergo various tests and invitro analysis for uniformity of drug content, size, release pattern to ensure zero defects.

Quality is assured through

- Validation techniques: equipment ,facility, processes, analytical methods and technical personnel, strict adherence to sops
- Audits and compliance to the observations
- Stability studies as per ICH guidelines :long term and accelerated studies
- Shelf life studies
- Degradation studies
- Controlling levels of impurities

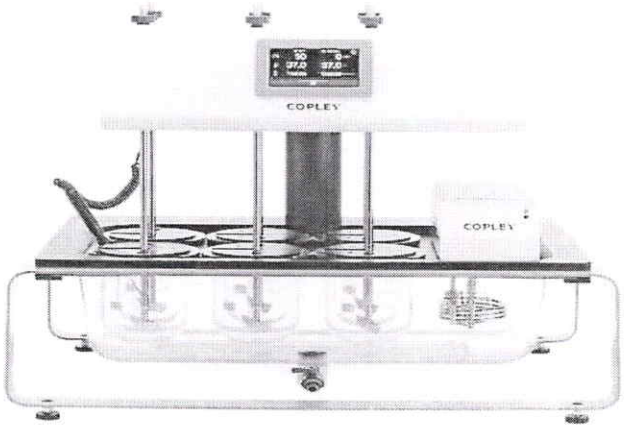
QUALITY CONTROL

Introduction

Quality Control (QC) in the Sterile Product Division ensures that all raw materials, in-process samples, and finished sterile products meet pharmacopoeia standards (USP, EP, JP, IP) and regulatory guidelines (FDA, WHO, EU GMP). The main objective is to verify the sterility, purity, potency, and safety of sterile pharmaceutical products through chemical, physical, and microbiological testing using advanced analytical instruments.

1)Dissolution test

In industrial pharmacy, a dissolution test apparatus measures how quickly a drug from a solid dosage form (like a tablet or capsule) dissolves in a liquid medium, ensuring consistent product quality and predicting in vivo bioavailability. Apparatus I is the USP Basket Method (also known as Apparatus 1), which uses a cylindrical wire-mesh basket to hold the dosage form, immersing it in a dissolution medium within a water bath. The basket is rotated by a motor to simulate physiological conditions and help release the drug.



2)Disintegration Test

Disintegration Test is a solid state instrument designed for the accurate estimation of disintegration time of tablets as per IP/USP standards. The instrument is designed to test two batches of six tablets, simultaneously. The unit is extremely useful for pharmaceutical industries. It is used in quality control and R & D to determine compliance with the disintegration requirement of the tablet and capsule as per USP/BP/IP standards.

Instrument uses the latest microprocessor technology and advanced engineering techniques so as to give enhanced accuracy and reproducibility. The system has user friendly prompts, which guide you throughout the measurement process.

Specifications

Number of Baskets	2
Stroke Length	55 mm ± 2 strokes / minute
No. of Timers	2 Timers
Timer Display	5 Digit LED Display for each Timer
Timer Range	1Sec. To 9 Hrs. 59 Min 59 Sec.

3)Leakage Test

Leak Test Apparatus is a solid state instrument designed for the leakage testing of food, drug and other industrial chemical products. The instrument is used to test the quality of packing processes in strips, blisters and sachets containing tablets, granulates and liquids. They are also used to check that the seals enclosing the product are perfectly intact.

The Instrument is equipped with microcontroller based 4 digit seven segment bright red LED display. Soft touch keys provides a convenient user interface.

The unit contains a polycarbonate desiccator housing to sustain the vacuum for long time. A compact vacuum pump for creating high vacuum level in short time period is used. A vacuum gauge on the front panel of the instrument indicates the vacuum level. The vacuum gauge is connected to a control valve that isolates the vacuum inside desiccator from the vacuum source.

Test samples to be analyzed are placed into the polycarbonate desiccator housing. A vacuum pump generates vacuum inside the desiccator. The vacuum generated is held for a pre-set time, and then released manually.

4)PH Meter

Industrial pharmacy, a pH meter is a precise scientific instrument that measures the acidity or alkalinity (pH) of liquid solutions by detecting hydrogen ion concentration, enabling quality control in drug formulation and manufacturing. It operates on potentiometry, measuring the voltage difference between a glass electrode and a reference electrode to determine pH, and requires regular calibration with buffer solutions for accurate, reliable results. Key components include the glass electrode, reference electrode, and a digital display, with robust, corrosion-resistant models ideal for pharmaceutical environments.

A pH meter works on the principle of potentiometry, measuring the voltage difference between a reference electrode and a glass electrode that is sensitive to hydrogen ion (H^+) concentration in the solution. This voltage, proportional to the pH, is measured and converted into a readable pH value using the Nernst equation. This allows industrial applications to accurately determine the acidity or alkalinity of solutions, ensuring product quality and process control in pharmaceutical manufacturing.

5)Hardness Test

Tablet Hardness Tester is Important in the Pharmaceutical ...In industrial pharmacy, a tablet hardness apparatus, also known as a tablet hardness tester or tablet breaking force tester, is a device that measures the force required to break a tablet. This measurement ensures tablet integrity during handling, packaging, and transport, and influences the tablet's disintegration, dissolution, and drug release properties. The apparatus works by applying force to the tablet using a probe or indenter until it fractures, measuring the force at the point of breakage, and displaying the value on a digital or mechanical screen.

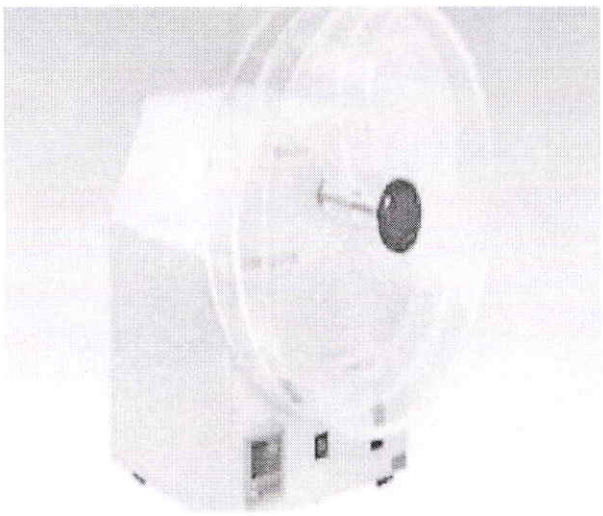
In industrial pharmacy, a hardness apparatus measures a tablet's resistance to fracture by applying increasing pressure between two jaws until the tablet breaks. The principle involves a motorized or manual mechanism that compresses the tablet, and a load cell or spring-based system records the force required to cause the tablet's fracture. This force, expressed in units like Newtons (N) or kilograms-force (kgf), indicates the tablet's mechanical strength, which is crucial for ensuring durability during handling, packaging, and transportation, and ultimately for consistent drug release and patient safety.

6) Friability Apparatus Test

Friability apparatus tests the tendency of pharmaceutical tablets to break, chip, or crumble during handling and transportation by subjecting them to a standardized tumbling action in a rotating drum. The apparatus features a motor that spins acrylic drums at a controlled speed, typically 25 RPM, causing tablets to tumble and fall, simulating mechanical stress.

After a set number of rotations, the tablets are weighed to determine the percentage of weight loss, which indicates their friability and ability to withstand physical stress.

Friability apparatus is to determine a tablet's resistance to mechanical stress by simulating handling and transportation. A set of tablets is placed in a rotating drum with baffles, where they undergo a controlled tumbling motion, falling onto each other and the drum wall. The percentage of weight loss after this standardized test indicates the tablet's friability, with an acceptable loss of less than 1% generally considered robust.



Madhur Pharma & Research Laboratories (P) LTD

INTERNSHIP REPORT Bachelor of Pharmacy (B. Pharm)

(From 11th Aug 2025 to 4th Sep 2025)

SUBMITTED BY

Mohammed Zain C A 22BP1059

Sri Adichunchanagiri College of Pharmacy, B G Nagara.

NBA NATIONAL BOARD OF ACCREDITATION

NAAC A+ GRADE

ACKNOWLEDGMENT

We would like to express our sincere gratitude to madhur pharma and research laboratories private limited company for providing us with the opportunity to intern in their bangalore unit.I also extend my thanks to my teachers from Sri Adichunchanagiri College of Pharmacy for their continuous encouragement.

We would also like to express my appreciation to the staff at madhur pharma LTD. for their warm welcome and assistance during our internship

VISION - The vision of a research scientist and a passionate entrepreneur takes on social and commercial expressions." This, in short, explains the genesis and growth of SamiSabinsa Group.

OBJECTIVES

The primary objectives of my internship were:

To gain practical knowledge and experience in the pharmaceutical industry.

To understand the manufacturing processes of sterile product injectables.

To learn about quality control and assurance practices.

To develop skills in documentation and regulatory compliance.

INTERNSHIP ACTIVITIES

During our internship, we were observed and involved in various activities, including

1. Warehouse department
2. Production departments

- ABC Block
- G Block
- DIOL Block
- HVD Block
- SPD Block
- Extraction Block
- Formulation And Finishing Dept.

3. Quality assurance
4. Quality control
5. Microbiology
6. Safety & EHS department

Production Department

ABC block

Synthetic extractions in SSR & GLR done in this block

Like : -

- Boswellia Serrata extract (AKBBA >60%)
- PiPerine 1950%
- Thymoquinone
- Centella Asciteca extract
- Colleul forskohlis extract
- Rebersa Sulphate
- Resveratrol 95%

General Process

Equipment Cleaning

↓

Charging of Solute + Solvent

↓

Maintaining the const temp

↓

Filtration

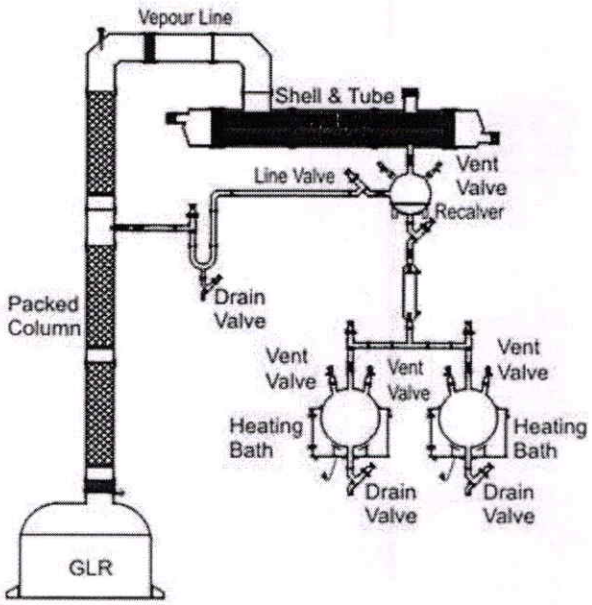
↓

Water washing

↓

End Product will be sent to QC for assay verification

Glass reacter



Stainless Steel Reacter

Material charged thorough manual Temperature gauge Maintains the temp.

Reactor Status board contains the info about

-Previous Product
-Present Product
-Batch no
-Date
-Status: like processing or not

Motor garebox (distillation process) -

Vapour column.

- Condensor
- Reciever
- Steam

Operating System

- Cooling water : room temperature
- Chilled water : 15-20°C
- Braile water : less than 0°C

Jaket
Vessel
Lighter

Storae tank

Excess slovent from recever with be Stored here.

Scrubber

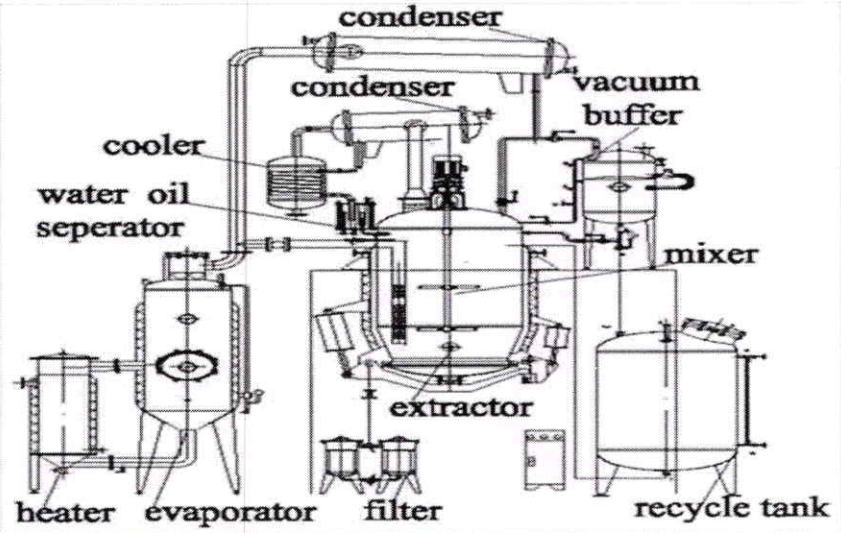
- Suckes the fumes & dilutes before relese

Crystalizer

- Less quantity products are produced here

Filter press

- Used in filtration process



DIOL Block

- In Diol Department mainly Curcumin extraction will be prossed

Curcumin C3 Complex 95% { by the Hexane + isopropyl Alcohol } process

Curcumin
↓
Oleo resin + Solvent
↓
Aging [2-4days)
↓
Filter process feed
↓
Wet cake formation
↓
Centrifuge or spin dried
↓
Changed to RVPD
↓
Dried end product after aproved by QC

Verification tests :

LOD :- Loss on drying

Assay :- purity of material

Other Methods

- Isopropyl Alcohol Process
- Ethyl acetate + Hexane process
- Hexane + isopropyl Alcohol process

High Vacuum Distillation Block

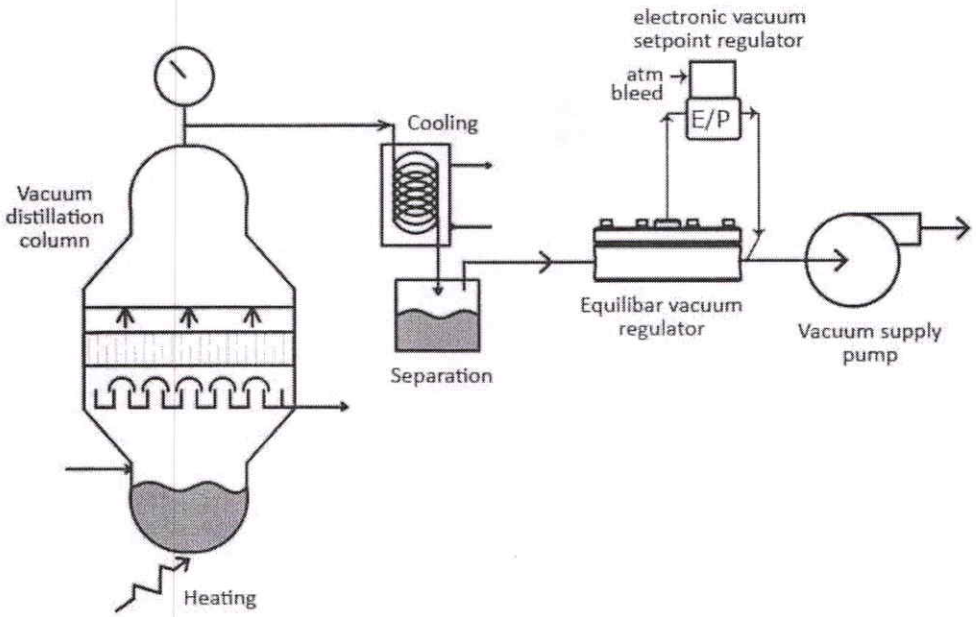
•Normally, liquids boil at high temperatures.But many herbal compounds (essential oils, phytochemicals) are heat-sensitive — they get destroyed or lose aroma at high temperatures.
•In high vacuum distillation, pressure inside the apparatus is reduced (vacuum created).
•Lower pressure = lower boiling point → the herbal extract distills at a much lower temperature.
•This protects delicate compounds and allows pure extraction without decomposition.

General Procedure

•Preparation of Raw Material
Dry the plant material (leaves, roots, flowers,seeds) and make it coarse/fine powder.
•Applying Heat under Vacuum
Heat the flask gently. Apply high vacuum (using vacuum pump) to lower boiling points.
•Condensation
Vapors pass through a condenser (cooled tube) and turn back into liquid.
•Collection
Collect the condensed herbal extract (oil, essence, or fraction) in a receiver flask.
•Separation & Storage

Separate layers (oil/water if present). Store in dark

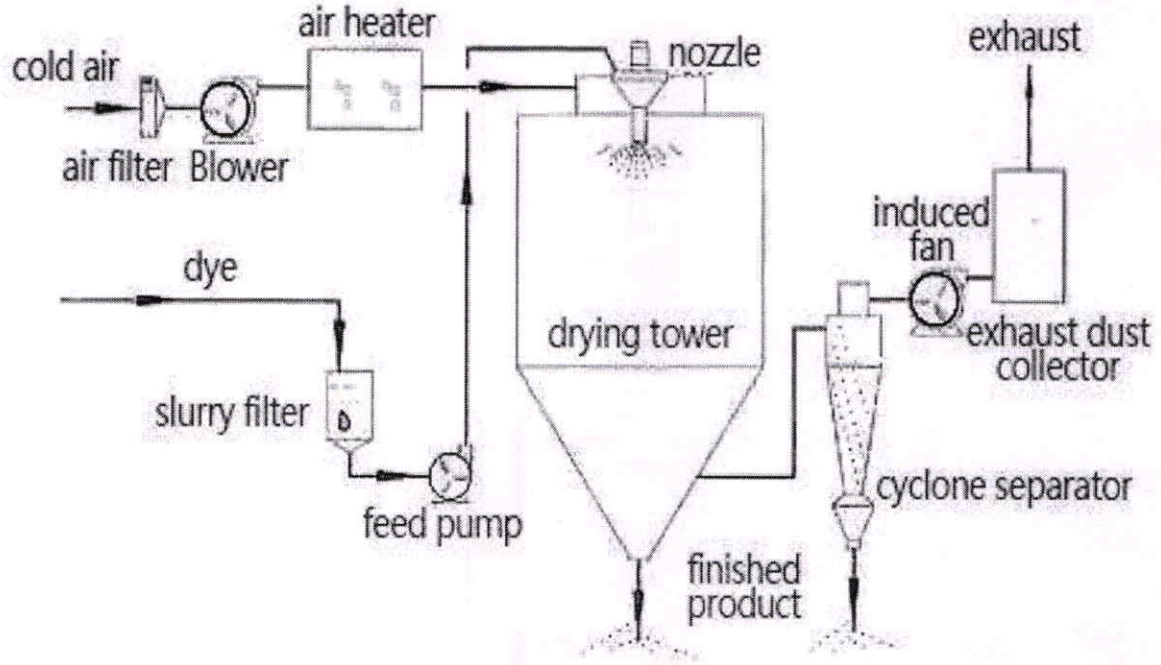
glass bottles to preserve activity.



SPD Block

Spray drying works on a simple idea:
A liquid (like herbal extract) is turned into a fine mist.
Hot air quickly dries these tiny droplets.
The water (or solvent) evaporates, leaving behind a dry powder. So,
liquid in → fine dry powder out.

General Procedure
•Prepare the herbal extract
First, the herbs are boiled or extracted with water/alcohol to pull out the useful compounds.
•Feed into spray dryer
The clean liquid extract is pumped into the spray dryer.
•Atomization (making fine mist)
A nozzle or rotating disk breaks the liquid into very tiny droplets (like a fog).
•Drying with hot air
Hot air is blown inside.The droplets meet this hot air, water evaporates almost instantly.
•Collecting the powder
The dried particles fall down as a fine herbal powder.
Powder is collected at the bottom or through a cyclone separator.



Formulation & Finishing Department

1 Tray Drier

Works on hot air circulation.

Heated air passes over herbs placed on trays.

Moisture from herbs evaporates → hot air carries it away.

This reduces the moisture content and preserves the extract.

General Procedure

1. Loading: Spread the herbal material evenly on trays (thin layers).

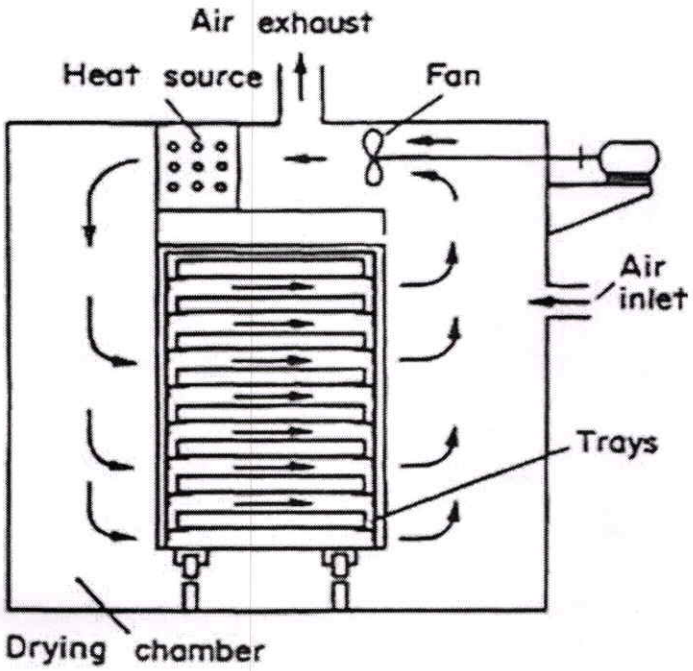
2. Air Flow: Close the chamber; hot air is blown in and circulated.

3. Drying: Maintain proper temperature & airflow (too high can destroy active compounds).

4. Moisture Removal: Moisture from herbs evaporates and exits through exhaust.

5. Completion: When herbs reach the required dryness, switch off heating.

6. Unloading: Take out the dried herbs and pack/store properly.



Fluidized Bed Dryer (FBD)

Hot air is passed through a bed of moist granules or herbal extract powder.
The air velocity is high enough to lift and suspend the particles (like boiling liquid → "fluidized state").
Because of this fluidization, each particle is surrounded by hot air → fast and uniform drying.

General Procedure

1. Load the Wet Material
Herbal extract (usually in granules or concentrated powder form) is placed in the drying bowl.

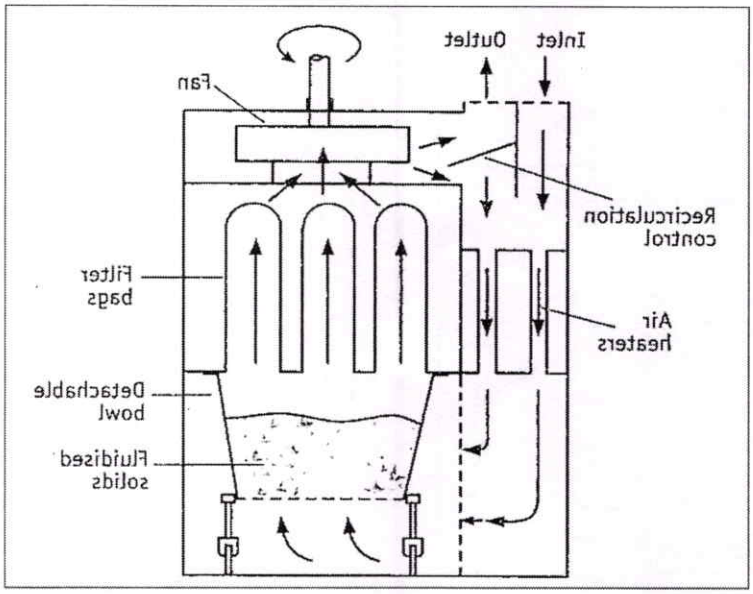
2. Start the Blower
Hot filtered air is introduced from the bottom.
Air speed is adjusted so the material lifts and moves in a fluidized state.

3. Drying Process
The hot air removes surface and internal moisture.
Continuous mixing prevents clumps and ensures uniform drying.

4. Monitor Conditions

Air temperature, humidity, and drying time are controlled depending on the herb's heat sensitivity. Usually 40–60°C for herbal extracts (to protect active compounds).

5. Discharge
Once the desired moisture content is reached, the dried herbal powder is discharged.



Pulveriser

A pulveriser is a machine used to grind dry herbs into fine powder.
Principle:
It works on the mechanical principle of impact, shear, and friction.
Herbs are crushed between moving blades or hammers.
Continuous grinding reduces particle size.
The fine powder increases surface area, which helps in better solvent penetration and extraction of active compounds.

General Procedure

1. Collection & Cleaning – Collect the required plant part (leaves, roots, bark, seeds, etc.), clean to remove dirt.

2. Drying – Shade-dry (or oven-dry at controlled temperature) to remove moisture.

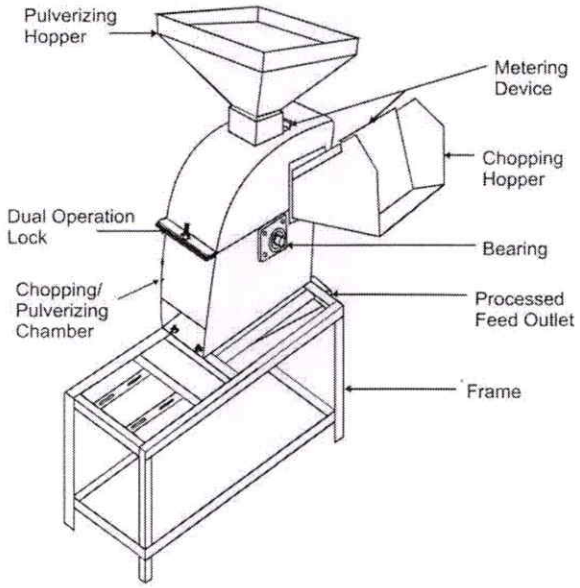
3. Pulverisation – Grind the dried material into coarse or fine powder using the pulveriser.

4. Sieving – Pass the powder through a sieve for uniform particle size.

5. Extraction –
Take the powdered drug.
Add a suitable solvent (like water, alcohol, hydroalcohol).
Use methods like maceration, percolation, or Soxhlet extraction depending on the compound.

6. Filtration & Concentration – Filter to remove solid particles, then concentrate the extract under reduced temperature.

7. Drying & Storage – Dry the final extract and store in airtight container.



Polygonal Blender

A polygonal blender (also called a multi-faceted or double-cone blender) is a machine used to mix powders and plant materials evenly.
The polygonal (many-sided) shape helps materials tumble, rotate, and cascade from different angles. This ensures uniform mixing without dead spots (no part left unmixed).

General Procedure

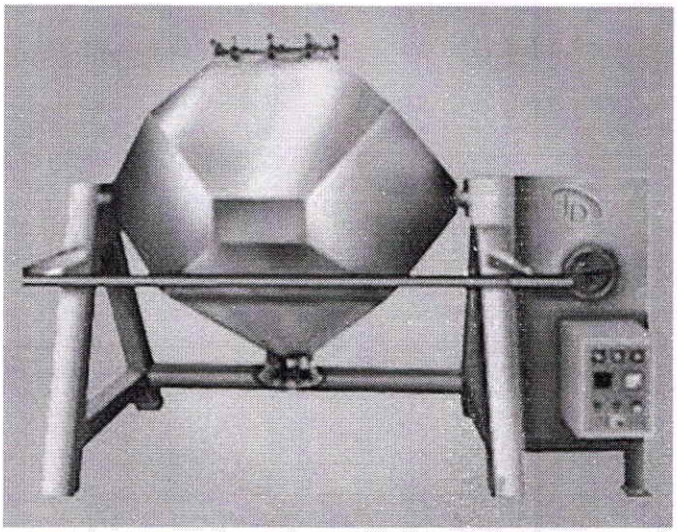
1. Raw material preparation
Collect herbal plant parts (leaves, roots, seeds, etc.). Clean, dry, and grind into fine powder.

2. Blending
Place the herbal powders (or powder + excipients/solvents if needed) into the polygonal blender. The polygonal motion ensures homogeneous mixing.

3. Extraction
After blending, subject the mixture to an extraction process (like maceration, percolation, Soxhlet, etc.) with a suitable solvent (water, ethanol, etc.).
This pulls out the active phytochemicals.

4. Filtration & Concentration
Filter the solvent-herb mixture.
Evaporate or concentrate the extract.

5. Drying & Storage
Dry the extract (spray drying/freeze drying).
Store in airtight containers for use in medicines, supplements, or cosmetics.



Warehouse department

The warehouse plays a vital role in ensuring the quality, safety, and compliance of materials used in the production. It is responsible for the receiving, storage, handling, and distribution of raw materials, excipients, primary packaging materials, and finished products while adhering to Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP).

1. Raw Materials and Primary Packaging Materials Receiving

Process:

- Pre-Receipt Documentation Check: Verify supplier documents (Certificate of Analysis, Material Safety Data Sheet, Packing List, etc.).
- Physical Inspection: Check the condition of materials (e.g., integrity of packaging, labelling, quantity verification).
- Quarantine: Materials are labelled and placed in the quarantine area until quality control (QC) approval.
- Sampling: Quality control takes samples for analysis as per SOPs and pharmacopoeia standards.
- Approval & Rejection:
    - If materials pass QC tests → Moved to the approved storage area. ○ If materials fail QC tests → Transferred to the rejected materials storage area.

2. Storage of Raw Materials and Primary Packaging Materials

Storage Conditions:

- Raw Materials: Stored under controlled conditions (e.g., temperature, humidity) based on product requirements.
- Cold Storage: Certain materials require refrigeration (2-8°C) or deep-freezing conditions.
- Humidity-Controlled Storage: For moisture-sensitive materials, desiccants and dehumidifiers are used.
- FIFO & FEFO Principles: Materials are dispensed based on First-In-First-Out (FIFO) or First-Expiry-First-Out (FEFO) to prevent expiry issues.

Storage Segregation:

- Quarantine Area: Temporary holding until QC approval.
- Approved Storage: Materials that have passed QC testing.
- Rejected Storage: Separated and labelled area for non-conforming materials.
- Returned Goods Area: For materials returned from production or suppliers.
- Highly Potent or Hazardous Material Storage: Special containment for controlled drugs or toxic substances.

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3. Picking Process

Picking refers to selecting the required materials for production.

Picking Workflow:

1. Material Request from Production: Production issues a Material Requisition Form.
2. Verification of Batch & Expiry: Warehouse staff ensures correct batch numbers and expiry dates are picked.
3. Material Dispensing: Materials are dispensed as per SOPs in a controlled area, ensuring no cross-contamination.
4. Weighing & Labelling: Some raw materials are weighed before dispensing and labelled with usage details.
5. Transfer to Manufacturing Area: Picked materials are sent to production through pass boxes or controlled transfer areas to maintain sterility.

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4. Shipping & Dispatching (Finished Products & Materials)

Shipping of Finished Products:

- QC Approval: Products are released for dispatch only after passing QC testing.
- Packaging: Sterile products are packed as per regulatory guidelines (e.g., cold chain logistics for temperature-sensitive products).
- Labelling & Documentation: Batch numbers, expiry dates, and regulatory documents (CoA, packing list, bill of lading) are prepared.

- Cold Chain Monitoring: If required, temperature loggers or data monitoring devices are used to maintain storage conditions during transit.

Shipping of Raw Materials & Packaging Materials:

- Inter-Site Transfers: If raw materials or packaging components are sent to another facility, they are packed and transported under validated conditions.

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5. Rejected Materials Storage & Disposal

Rejected materials must be stored and disposed of in compliance with GMP & regulatory guidelines to prevent contamination and unauthorized use.

Rejected Materials Handling:

- Clear Labelling: All rejected items are tagged with a "Rejected" label and stored separately.
- Reasons for Rejection: May include non-conformance to specifications, damage, contamination, or expired stock.
- Disposal Methods:
    - Incineration: For hazardous waste materials. ○ Destruction by Authorized Vendors: Third-party disposal services may be used.
    - Return to Supplier: If applicable, rejected batches may be returned to the vendor with proper documentation.
- Record Maintenance: Logs are maintained for traceability, including rejection reasons and disposal records.

Quality Assurance (QA) department

1. Introduction

Quality Assurance (QA ensures that products are manufactured and controlled according to Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), and regulatory guidelines (FDA, WHO, EU GMP, MHRA, etc.). QA plays a vital role in preventing contamination, ensuring sterility, and maintaining product quality and safety.

Role of QA Ensuring Sterility Assurance: Validating aseptic processing, environmental monitoring, and sterility testing.

- Regulatory Compliance: Maintaining adherence to cGMP, ICH Q10, and pharmacopoeia standards (USP, EP, JP, IP).
- Training & Qualification: Conducting Good Documentation Practices (GDP), aseptic technique, and contamination control training.
- Batch Record Review & Release: Verifying all quality control (QC) tests, in-process checks, and sterility test results.

- Audits & Inspections: Conducting internal audits, vendor audits, and preparing for regulatory inspections.

QA ensures compliance through a Quality Management System (QMS), which includes:

- Change Control
- Deviation Management
- Corrective and Preventive Action (CAPA)
- Market Compliance

Quality Control (QC) department

Introduction

Quality Control (QC) ensures that all raw materials, in-process samples, and finished sterile products meet pharmacopoeia standards (USP, EP, JP, IP) and regulatory guidelines (FDA, WHO, EU GMP). The main objective is to verify the sterility, purity, potency, and safety of sterile pharmaceutical products through chemical, physical, and microbiological testing using advanced analytical instruments.

Key Functions of QC in the Sterile Product Division

2.1 Raw Material Testing

- Ensures all incoming raw materials (API, excipients, solvents, and primary packaging materials) meet specifications before use.

2.2 In-Process Quality Control (IPQC)

- Conducts real-time monitoring of critical parameters during manufacturing, such as pH, Assay.

2.3 Finished Product Testing

- Evaluates sterility, endotoxins, assay, and physical characteristics of the final product.

Analytical Instruments for Chemical Testing

1. High-Performance Liquid Chromatography (HPLC)

   - Principle: Separation of compounds based on polarity using high-pressure liquid flow through a column.
   - Purpose: Assay, impurity profiling, degradation studies.
   - Application: Ensures the purity and potency of raw materials, in-process, and finished sterile products.

2. Gas Chromatography (GC)

   - Principle: Separation of volatile compounds via a carrier gas through a stationary phase.

- Purpose: Residual solvent and volatile impurity analysis.
- Application: Identifies organic solvents used in the formulation of sterile injectables.

3. UV-Visible Spectrophotometer (UV-VIS)

- Principle: Absorption of UV-Vis light by molecules at specific wavelengths.
- Purpose: Quantitative analysis of drug concentration.
- Application: Used for the assay of APIs in sterile solutions.

4. pH Meter

- Principle: Measures hydrogen ion concentration in a solution.
- Purpose: Ensures pH compliance with specifications.
- Application: Used to check the pH of sterile formulations such as injectables and ophthalmic solutions.

5. Dissolution Tester

- Principle: Measures drug release from solid dosage forms over time.
- Purpose: Evaluates drug dissolution profile.

Hot Air Oven

- Principle: Uses dry heat sterilization to kill microbes and remove moisture. ○ Purpose: Ensures sterilization and drying of glassware and heat-resistant materials. ○ Application:
- Used for dry heat sterilization of glass syringes, vials, ampoules, and pipettes in the QC lab.
- Removes moisture from hygroscopic materials before testing. ○ Ensures proper drying of desiccants, powders, and culture media.
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6. Polarimeter

- Principle: Measures the optical rotation of chiral compounds in a solution.
- Purpose: Identifies and quantifies optically active substances.
- Application:
- Used in the identification and purity testing of chiral APIs such as antibiotics, vitamins, and amino acids.
- Ensures compliance with pharmacopeial optical rotation specifications.
- Checks stability and degradation of optically active drug substances in sterile formulations.
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7. BOD Incubator (Biochemical Oxygen Demand Incubator)

- Principle: Maintains controlled temperature for microbial and biochemical studies.
- Purpose: Supports growth of microorganisms for testing.
- Application:
- Used in microbial limit testing and environmental monitoring.

- Maintains samples at controlled temperatures (20°C - 37°C) for water and wastewater analysis.ication: Used for sterile ophthalmic suspensions and extended-release injectables.

Microbiology Department

The Microbiology Department in the Sterile Product Division (SPD) plays a crucial role in ensuring that sterile pharmaceutical products are free from microbial contamination. The department is responsible for sterility assurance, environmental monitoring, and compliance with regulatory guidelines to maintain the highest standards of product quality and patient safety.

Key Areas of the Microbiology Department in SPD

1. Environmental Monitoring (EM)

Environmental monitoring ensures that cleanrooms and controlled areas meet microbiological safety requirements. It involves:

- Air Sampling:
  - Active air sampling (e.g., RCS sampler, SAS sampler) ○ Passive air sampling (Settle plates)
- Surface Monitoring: ○ Contact plates (RODAC) for equipment and surface swabbing
- Personnel Monitoring:
  - Glove and gown swabs to check operator hygiene
- Water and Utility System Monitoring:
  - Testing of Water for Injection (WFI), Purified Water (PW), and Clean Steam ○ Compressed air and gas monitoring

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2. Sterility Testing

Sterility testing ensures that sterile products are free from viable microorganisms. The methods include:

- Direct Inoculation Method:
  - The test product is added directly to a growth medium and incubated to check for microbial growth.
- Membrane Filtration Method:
  - The product is filtered using a 0.45µm or 0.22µm filter, then placed in a culture medium for incubation.
- Growth Media Used:
  - Fluid Thioglycolate Medium (FTM) – for anaerobic and facultative bacteria ○ Soybean Casein Digest Medium (SCDM) – for fungi and aerobic bacteria

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3. Aseptic Process Validation (APV) / Media Fill Trials

Media fill trials simulate aseptic manufacturing processes to validate sterility assurance.

- Method: ○ A sterile growth medium (e.g., SCDM) is used instead of the drug product. ○ If microbial growth occurs, the process fails validation.

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4. Validation of Sterilization Processes

Ensures that sterilization methods effectively eliminate microorganisms. Includes:

- Autoclave Sterilization (Moist Heat) ○ Uses saturated steam at 121°C for 15 minutes or 134°C for 3 minutes.
  - Biological Indicators (BIs): Geobacillus stearothermophilus spores.
- Dry Heat Sterilization ○ 160-180°C for 2 hours to sterilize glassware and metal tools.
  - BIs: Bacillus atrophaeus spores.
- Gamma Radiation Sterilization
- Ethylene Oxide (ETO) Sterilization ○ Used for heat-sensitive materials, requires aeration to remove toxic residues.
- Filter Integrity Testing (for aseptic filtration) ○ Bubble Point Test – Measures pressure required for air to pass through a wetted membrane. ○ Forward Flow Test – Detects filter leaks based on air diffusion rate. ○ Pressure Hold Test – Ensures filter integrity under pressure.

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5. Microbiological Method Validation

Ensures microbiological test methods are accurate and reliable. Includes:

- Suitability Testing: ○ Confirms the growth promotion ability of culture media.
- Recovery Studies:
  - Ensures microorganisms can be detected in different sample types.
- Method Precision, Accuracy, and Robustness Tests.
- Regulatory Reference: USP <1227>, ICH Q2(R1)

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6. Cleanroom Qualification & HVAC Monitoring

Ensures cleanroom air quality meets ISO classification standards:

- Particle Count Testing: Checks airborne particulates using laser particle counters.
- HEPA Filter Integrity Testing: Ensures proper air filtration.
- Differential Pressure Monitoring: Prevents contamination by maintaining proper air pressure gradients

Environmental, Health & Safety (EHS) Department

The Environmental, Health, and Safety (EHS) is to ensuring compliance with Good Manufacturing Practices (GMP), Occupational Safety and Health Administration (OSHA) regulations, Environmental Protection Agency (EPA) guidelines, and local regulatory requirements.

This document outlines EHS considerations facility design, process safety, waste management, personnel safety, and compliance monitoring.

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1. EHS Objectives

The primary goals of EHS in sterile product facilities are:

✓ Ensuring Sterility & Contamination Control – Prevent microbial contamination in cleanrooms.

✓ Protecting Employee Health & Safety – Minimize exposure to hazardous chemicals, biological agents, and high-risk operations.

✓ Environmental Protection & Sustainability – Control emissions, reduce waste, and optimize resource utilization.

✓ Regulatory Compliance & Risk Management – Adhere to international guidelines (OSHA, GMP, FDA, EPA, ISO 14001, etc.).

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2 Pure Steam & Sterilization Systems:

- Autoclaves, dry heat sterilizers, and vapor-phase hydrogen peroxide (VPHP) systems ensure aseptic conditions.

2. Waste Management & Environmental Compliance

1. Biomedical & Hazardous Waste Disposal:
   - Autoclaving, incineration, or chemical neutralization of biohazardous waste.
   - Safe disposal of culture media and contaminated materials.
2. Effluent Treatment & Water Disposal:
   - Effluent Treatment Plants (ETP) to neutralize hazardous waste.
   - Zero Liquid Discharge (ZLD) systems in compliance with EPA & GMP.
3. Air Emissions Control:
   - HEPA & activated carbon filters for cleanroom exhaust.
   - VOC (Volatile Organic Compound) scrubbers for solvent emissions.

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3. Emergency Preparedness & Risk Management

1. Fire Safety & Explosion Prevention:
   - Automatic Fire Suppression Systems (FM-200, CO_2, Water Mist).
   - Explosion-proof electrical systems in sterile solvent areas.
2. Spill Management & Chemical Leak Control:

- Emergency Spill Kits for cytotoxic and hazardous drugs.
- Secondary Containment Systems for bulk liquid storage.

3. Personnel Training & EHS Audits:

o Annual GMP & EHS training for all employees. o Regular risk assessments & compliance audits. o Chemical sterilization safety measures to protect workers.

CONCLUSION

Our internship at Madhur Pharma and research laboratories private limited company has been an invaluable experience, providing us with practical knowledge and skills that will be beneficial in our future career as a pharmacist. We are grateful for the opportunity to work with a team of dedicated professionals and to contribute to the production of lifesaving medications.