Glenmark

A new way for a new world

# Industrial Training Report

At

## Glenmark Pharmaceuticals LTD

Ranipool , East Sikkim

Submitted to fulfill the requirements of certification for

Bachelor Of Pharmacy

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

MAKAUT, WB.


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## ✦ *About Glenmark Pharmaceuticals Industry :-*

Glenmark was founded with a vision to emerge as a leading integrated research-based, global pharmaceutical company. Our branded generics business has a significant presence in markets across emerging economies including India.

The generics business services the requirements of developed markets like US and Western Europe. Our API business sells products in over 65 countries including the US, various countries in the EU, South America and India.

With 14 manufacturing facilities and 4 R&D centers spanning across GPL and GLS, dedicated to the goal of enriching lives across the globe we believe that the real force behind our continued successes are dedicated employees from across 60 nationalities, committed to creating 'A new way for a new world'.

•The first day was about the general introduction of operations & Quality work process, safety concerns –

• Natural Hazards:→

I. Fire
II. Landslide.
III. Earthquake.

❖ Systemic Hazards →

I) Mechanical.

ii) chemical

❖ Safety concerns :-

1) Emergency exits
2) Assembly points
3) Helpline number - 8500


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❖ Personal Hygiene :

i) Maintaining nails & beard

ii) Proper sanitization to avoid any type of contamination

iii) Wearing PPE (Personal Protective Equipment) kit.

❖ Precautions about various hazards :-

i)Chemical substances must contain Sop to be purchased.

ii) Avoiding instruments with mechanical errors.

iii) Substitution of hazardous instrument.

iv) Modification of hazardous instrument.

v) Safety guidelines to avoid self harm.

vi) Informing the respective authority about

near miss hazards.

The second day was about the processing of ETP (Effluent treatment plant) and (Environment, Health & Safety system)

ETP Effluent treatment plant. It is one kind of process plant.

Domestic + Drug extract→ Pipe → Equalization Tank(capacity 25 kl) → Polymer (catch)Ph maintain by adding NaOH Granulations (neutral PH) → Flocculator (capacity 1-6Kl) → Aeration tank (Aerobic bacteria) (presence of jaggery) → Chemical treatment → Biological treatment → Secondary settler tank →Activated Carbon filter [for separation of TSS (Total suspended solids) and TDS (Total dissolved solids)] → Sampling point → Final tank → ROI (capacity 50kl) → Filter →ROII →Treatment → Evaporation.

**EHS controlling room :-**

*Equipment:-*

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- OCM (Online Monitoring System).
- BOD (Biological Oxygen Demand) incubator useful for determining levels of organic matter and nitrogen in waste water samples. It provides the required temperature for the growth of micro organisms and allows to perform the BOD testing .
- Hot Air Oven.
- Water Bath.
- COD digester used to determine chemical oxygen Demand in effluents like waste water, industrial water, Sewage water which are discarded after processing.
- Desiccator used both for the cooling of heated objects and for the storage of day objects that must not be exposed to the moisture.

- **ETP Turbidity Check Point:-**

Inlet effluent (Yesterday) → Inlet Effluent (today) → After primary treatment →

↓

After Biological treatment

↓

After Secondary treatment

↓

Final treatment water(Today )

↓

RO Final Treatment Water

- **Engineering HVAC :-**


HVAC - Heating Ventilation & Air conditioning The systems are equipped with filters that capture airborne particles, such as dust, bacteria, and other contaminants. This helps maintain a clean and sterile environment, preventing contamination of pharmaceutical Products & ensuring compliance with stringent regulatory requirements for cleanliness.

Flowchart of HVAC working system :-)

Room air Intake→ First Chamber of HU→ Pre. filter [Secondchamber](10 micron) →
↙ ↘

Hot water ← Chilled water coil ← Return to air HVAC Third chamber

↓

Fine filter → HEPA filter (3 micron) → Outlet.

From outlet the air goes back to the respective room. The room air comes to the first chamber of AHU through the intake pipe. Here 10% fresh air from HVAC room is mixed to maintain the oxygen level. The mixed air passes through the pre filter. The pre filter has the pore size of 10 micron. The air goes to the blower which is powered by the motor. Some of the air is exhausted to the HVAC filter. Rest of the

air room through the HEPA passes through the chiller water Coil. To lower the temperature. Here the water. molecules of the air get condensed I they are collected in a draining tray.

Now the air passes through the hot water coil. It lowers the moisture content maintaining the RH level less than 55%, and maintaining the temperature at 25°C. Then, the air passes through the fine filter & goes to the fourth chamber. At last, the air passes through the HEPA filter & goes back to the respective rooms through the outlet pipe.

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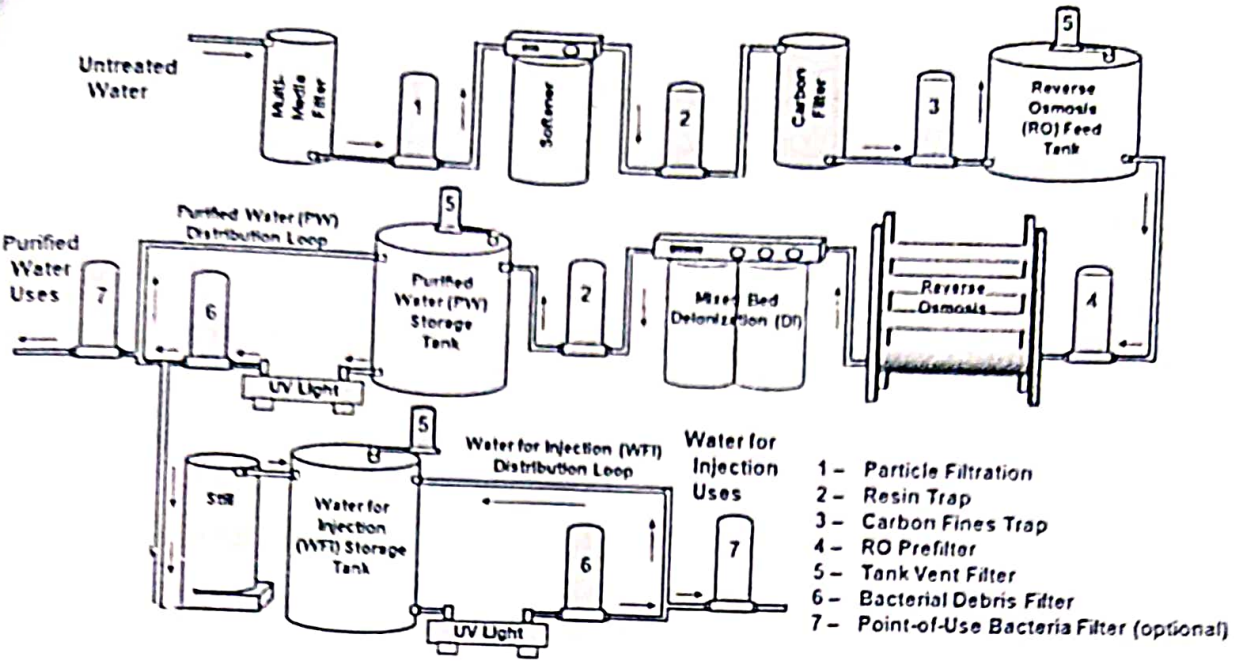


## UPS Room :-

UPS -> Uninterrupted Power Supply, comes in action when the power goes off. To avoid complete black out it is used. It also provides the necessary power supply to the computers to prevent data loss.

## UTILITY ROOM

Heart of pharmaceutical engineering. The utility room contains the boiler, water chiller (two types), transformer and Diesel generator.Boiler the boiler supplies the steam to heat the water for the hot water coil, the boiler uses diesel two types (High speed diesel) & (Low density oil), to vaporize the water. Vaporizing capacity of the boiler is 1.12 tones/hour.

**Water cool chiller:** It removes head from the process waters Water and transfers it to air via a heat exchange process water chillers are able to cool the water to below ambient temperature. These are two types (closed & Open).

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**Air cooled chiller:** It is used to utilize the power of Outside air and water to maintain the target temperature at a It uses water. constant level. It is generally closed system. Compressor, Condenser, radiator to cool the

**Transformer:** It is used to maintain the voltage. Generally the power supply is of 11KV. But the required voltage is 440, 240, 110 volt. Transformer, steps down the voltage from 11KV to the respective voltages.

**DG →Diesel Generator**

There are two diesel generators (750 KVA & 500 KVA), In the working day the 750 KVA generator is used, and in off days the 500 KVA generator is used. During the operation, if any power cut happens, the DG is started and the power goes to the DG Pannel Now, the Dot Pannel changes and supplies powers within three minutes.

Air Compressor → Generally two types (Reciprocation & Screw types) with 61, 135, 337 cubic feet per minutes. (cfm). It is used in pharmaceutical machinery and also for cleaning purposes (6kg pressure).

## Pharma Engineering :-

It involves the research, development, creation, and manufacturing of medicinal drugs. The engineering process. starts by identifying a specific condition on ailment and researching the effects of past and current drugs used to treat it.

After research phase, new pharmaceuticals are developed by synthesizing chemical compounds in a laboratory.

After development comes testing, in this phase the drugs are through tested for their effectiveness, safety Side effects and chemical reactions. One the new drug is reviewed & approved by the FDA, it can be manufactured & distributed to the public.

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- Pharma engineering has 3 sections.

I) utility is the heart of engineering, for the Supply of power

II) HVAC Air maintenance

iii) Pharma → Maintenance of work machine.

- **Planner** → Preventive maintenance with precautions,

  ↳ quarterly or half yearly

Equipment like RMG (Rapid Mixture Granulator) FBD (Fused Bred Dryer) are maintained of a duration of 3 months. On the other hand Desk, portable things are maintain within 6 months.

- **Granulation**→ a technique of particle enlargement -

by agglomeration, is one of the most significant unit operation, in which small fine particles are converted into large agglomerates called granules. Movable bowel FBD- Steam coil (Powder mixing & drying)

RMG Rapid Mixture Granulator:- used to mix the pharmaceutical ingredients & make the granules before compression and also called a high shear mixer.

- Shifter →Shifting of powder.

- Multi Mill→ long particle breaking. After processing Blender (lubrication) Coating 7 (compression) [Monolayer, Bilayer]

- D tooling large tablets

- B tooling small tablets.

Tablet Size depends on Dyes.

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**BBS (Blister Quickly Through Servo) :-**

Machine is a part of pharmaceutical packaging, where it helps to aggregate unit doses into a "blister form, as primary Packaging.

**90° angle** →Good blister, 45° angle Reject blister.

**Manual packing :-** is the manual process of packing your folded and glued boxes and placing them into cases.

**Pharma Engineers work : -**

I)Conceptualizing & designing product

II) Synthesizing & testing compound

III) Manufacturing, labeling, Packaging to optimize their distribution.

- **Warehouse** → It is the systematic storage of medicine and related goods. The pharmaceutical industry handles active ingredients and volatile substances that require controlled Storage environments to remain safe and viable.

Three parts →I) Raw material → Starch, Color, Solvent

II)Packing material→ Primary packing, Secondary packing, Tertiary packing

- Miscellaneous store.

**warehouse area :-**

- Warehouse entrance.
- Repackaging area.
- Quarantine area
- Storage area

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- Order preparation area
- Area for dispatch
- Warehouse technical area
- Administrative area

**Labeling of Cartoons:-**

- Batch Number
- Product Name
- Manufacturing date
- Expiry date
- Format Number
- Shipper Number
- Gross weight
- Quantity

Steps in warehousing

Purchase Weighing (100% weight) → Resting. (Yellow sticker) Quarantine → Clean → Store →QC Testing → (Green sticker) Approved

↘

Rejected (Red sticker)

- Hazard in Solvent area → Isopropyl alcohol
- Rejected Raw materials back to the provider.
- Rejected packing materials are destroyed.
- Quarantine Sampling → Dispensing (Block & bomb from sap) (one by one material inside for dispensing) [1 scope for 1 material] .
- **Log book information :-**
  - Temperature -25°c
  - Pressure difference (5-10) Pascal
  - Balance
  - Cleaning procedure
  - Relative humidity < 55%.

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•**Hygrometer→** A hygrometer is an instrument which measures the humidity of air or some other gas or air. amount of water vapor in the air .Materials should be calibrated before use.

• **Cleaning types →** Type A for same product (Drying).

Type B for different product (Cleaning everything).

**↓ Quality Assurance :-**

Pharmaceutical quality assurance is the assurance quality requirements for a product or service f in the pharmaceutical industry. Quality assurance aims to create and maintain customer confidence in the product, and the goal is to detect defects early or to prevent them.

• Scope → R&D activities, manufacture, Packaging, distribution.

• Vision→ leading integrated research bared global Pharma company.

• Mission→ Discovering, Developing & providing innovative healthcare.

• Values → Achievement, Respect, knowledge.

**↓ Quality Policy :-**

I)Patient centricity ,II) Adherence to regulation .III)quality focus ,

IV) Management oversight ,V)Continuous improvement ,vi)Innovation,

VII) Management & Commitment .

**↓ Organization structure :-**

*Managing Director* → Head of Global Quality → Head Quality Function

↙ ↘

Head Cluster Quality Head of Regional Quality

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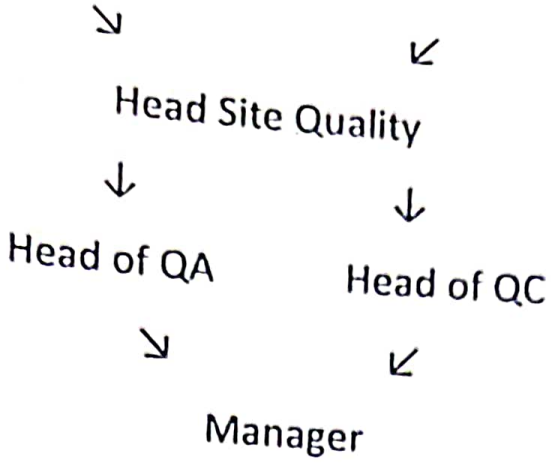


- **CQA:-** ***Corporate Quality Assurance:-***

It is a global Harmonization of BMS, qualification of contract testing lab (CTL), Contract manufact audits, wide information of IT & (R&D) assure that our products. robustly developed to support are timely .

- **Quality system :-**

•Service satisfy the expectation of patients. Customers & Public health needs.

• Implemented for the combine product that include compliance both drug and CGMP. Design is based on device by demonstrating a 6 quality system depicted.

1 Facility & Equipment system.

2 Production.

3.packaging & Labeling.

4.Material system.

5.Lab Control system.

6.Quality management system.

- **Vendor management :-**

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Each vendor is evaluated & qualified to supping to Glenmark before sourcing for commercial supplies begin.

**Departments of QA:-**

There are four departments of QA .IPQA → In process quality assurance.

- Validation & Qualification.
- Quality Management System & documentation
- Analytical Quality Assurance / Lab Quality Assure .

**BMS** → Quality Management system, This is the system like change management System, documents. incidences OOS, OOT, & investigation of deviation. implementation Corrective Preventive action, investigating market complaint validation, qualification raw material packaging. (finished products), risk management & risk assessment .

**CAPA** - Corrective action & Preventive action is tracked for its implementation. CAPA are checked as per the methodology.

- Described under CAPA procedure.
- **Quality System Enablers:** There are 6 systems in Quality system enables

I)Personnel training & Qualification

II)Service providers, Suppliers & Subcontractor

III) Management of Computerized system.

IV)Quality Risk management.

**Document Hierarchy :-**

GXP laws in pharmaceutical industries

Level 1 :Quality Manual.

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Level 2 : policies → Glenmark approach on implementation of particular process Company Quality Policy (Functional Quality Policy).

Level 3:Global Sop.

Level 4: Functional / Regional sop

Level 5 : Site Sop / Protocol.

Level 6:Records.

- **Abbreviation of some:-**

GBU→ Global business unit.

GCP →Good Clinical Practices.

GDP →Good Distribution practices.

GLP →Good Lab

GMP →Good Manufacturing

GVP →Pharmacovigilance.

GXP→ GLP + GDP + GILP + GMP + GVP

ICH→ International conference for harmonization

QMS →Quality Management System.

SOP →Standard Operation Procedure.

R&D →Research & Development

CDSCO →Central Drugs standard control Organization

CFR →Code of federal regulation.

- **Packaging :-**

Manufacturing & Packaging plays a vital role in in pharmaceutical industry-

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The packaging of medicine is vital to protect. The medicine from damage, germs, outer atmosphere, and bacteria have to take care and at the same time, of child I old age safety Concerns. Packaging in the pharmaceutical industry varies from medicine to medicine. Different packaging materials are used for various packaging purposes .

**1)Primary Packaging system:** Is the most crucial part of packaging a pharmaceutical product. Usually, blister strips & PET bottles are commonly used in primary packaging are as they made up of non-reactive substances Like PVC & aluminum. Some of the popular types of plastics used. used in packaging tablets and pills are:

i) Polyethylene (PE)

ii) PVC

ii) Nylon (Polyamide).

**2 .Secondary packaging system:-**

Once primary packaging is done, the next step is called "Secondary Packaging". It is. another layer of packaging that will most Likely by material like boxes and carton information such as active ingredients, manufacturer's. name medicine, warning address, type of precautions to those boxes. So that people are printed can easily distinguish them between two separate box filled with different pharmaceutical products .

**3. Tertiary packaging system:-**

lastly comes tertiary packaging, which is essential for shipping & transportation Purposes. Typically, consumers do not see tertiary packaging as the retailer removes the packaging material before showcasing the products in pharmacies clinics and hospital.

**•Automatic Packaging machine :-**

Flowchart :

Forming Film Reels → Forming Filum Preheating→ Pocket formation→ Auto feeding option (option)→Alu foil→ Sealing station→

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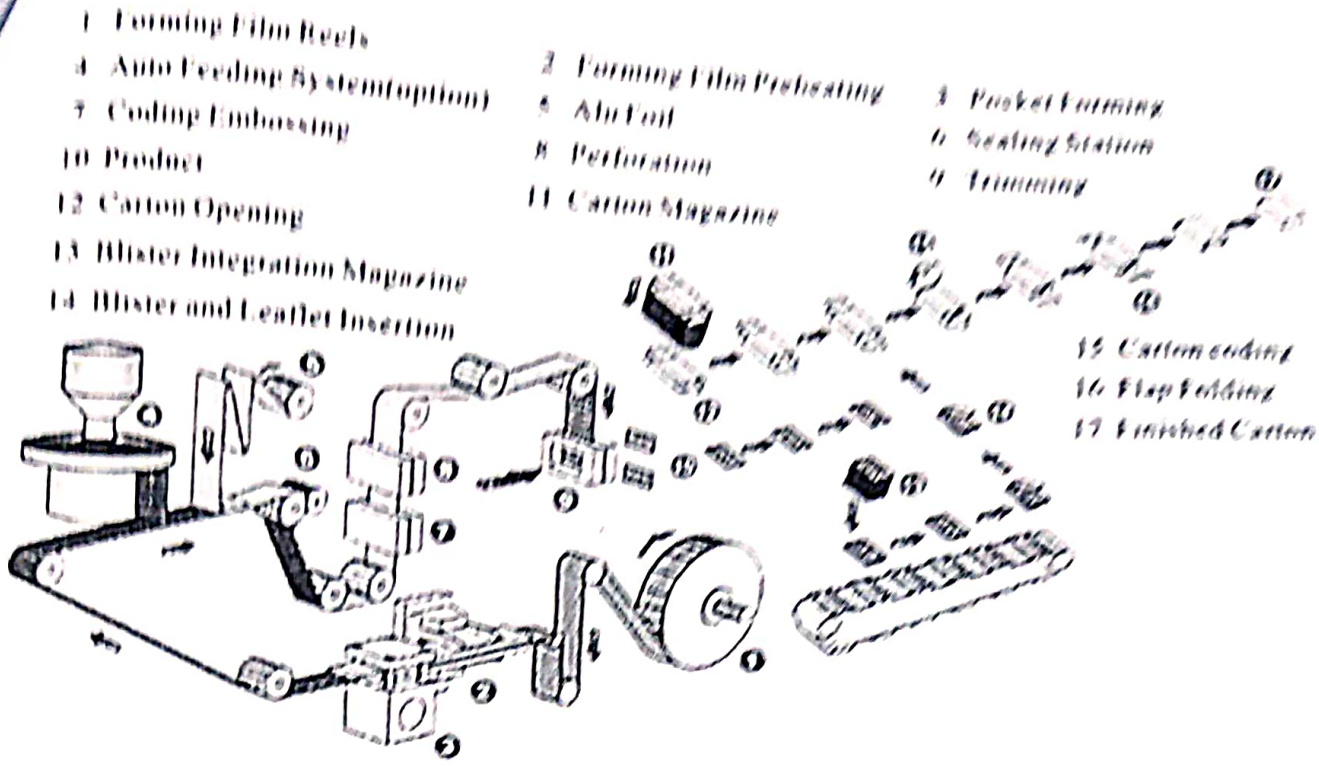


## Production :-

Production deals with Product manufacture all stages of pharmaceutical from producing active ingredients, through to Products f work in this involve the even area completion of finished packaging, Due to this diversity -take many forms use of specialist machinery.

- **Manufacturing process:**

PPIC department - (process of planning the PPICH company)

PPIC - Production Planning & Inventory Control) →pick from warehouse → Batch (dispensing) → Quarantine → Clean & Ready→ Critical point checking→ Production → IPQA→ Process Shifting →Binding →Dry Mixing→ Wet mixing → Final drying

- **Production area in Glenmark pharmaceutical :-**

1)Dispensed material store

2)Quarantine I, II, III, IV, V

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3)Granulation I, II, III, IV, V

4)Compression I, II, III

5)Coating area

6)Production office I, II

7)IPQA

8)Cleaned equipment area.

9)Used Equipment area.

10) Material & personal airlock.

- **Working principle of some equipment uses Production:→**

**FBD→** Fluid Bed dryer

**Construction →** A Bowel has with -to a perforated bottom a wire mesh support for placing materials be dried A fam is mounted in the upper part for circulating hot air Fresh air inlet, prefilter & to heat exchanger are connected serially to heat the air to the required temperature.

**Working:** A FBD works on a principle of fluidization of the materials. In this Process hot air or gas flow is introduced through the Bed of solid particulates. This gas air will upwards through the spaces between the particles.

- **Working principle of AMG (Rapid Mixture Granulation) :-**

In RMG, the formation of granules occurs by rising, whirling & tumbling motion of the material. Dry mixing is. done by adding all ingredients into the RMG by rotation of impellers & chopper at high speed. During the addition of binder solutions to the powder impeller fell chopper are operated at low speed. After the formation of welt mass impeller and chopper are operated at high speed to form the granules of the required size.

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Dry mixing takes about (3-5) minutes to mix. the ingredients, wet mixing takes (5-10) minutes to make the wet mass of material while the granulation process takes (5-10) minutes to make 0.5 mm time Consumed to 1.5 mm sized granules. Mixing in processing to depends upon -the ingredients quantity of their particle size.

**•Principle of Tablet compression machine :-**

The basic principle behind working with the Tablet compression pressure. The Machine is the hydraulic pressure is been transmitted via static fluid to all directions in the proportion. Multiple force is also been applied if needed.

•Four steps are required in tablet compression.

1)Filling → Transfer of granules into position for tablet compression. The ultimate product is the blended into. the homogeneous blend.n

2)Metering →This Process involves removal of excess granules from the compression machine. At this stage the to be compressed required weight of granules into tablets is controlled lower punch in by the height of the die & the height of the lower punch is controlled by the metering cam.

3) Compression → During this stage, the top and bottom Punch the die to enter come together by form the tablet, As the punches into the pressure with compression stage the top & bottom punches moves between two large wheels called compression rolls. These compression rolls push the punches to words the die to form the Product.

4) Ejection→ This procedure for the Process involves the lower tablet compression removal of the tablet from Punch-die Station. In this stage, the upper punch retracts from the die rises above the Cavity f turret table. Then the lower. punch rises in the die, which in turn pushes the

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tablet upward to the top surface of the die tablet & out of the die cavity. Then by scrapper, tablet are collected in the container.

•**Principle & mechanism of multi-mill:-**The principle involves variable force, rotating blades having both knife & sharp edges with Validated a Screen size to reduce particles in controlled manner. The mechanism involves the pulverization process (pulverization is the grinding, douching of materials into small particles). Knife blades are used to cut the large particles into are Small size particles that generated during the FBD drying process).

• **Colloidal mill:-** It is a machine that is to used reduce the particle size of a solid in suspension in droplet work a liquid, or to reduce the size in emulsions Colloidal mills: on a rotor- stator principle.

**Principle of Auto coater:-** The tablet to be coated make continuous Complicated Orbital motion the closed rotating Drum under the action of a streamline of Baffles. During the motion Coating medium automatically sprays according to the technological Process at the f rotational technological parameters, same time. hot filtered air supplied un des a negative pressure, the hot air penetrates through the tablets core layers & is discharged. from the bottom of the layers. so that the coating medium sprayed on the surface of the tablet cores will dry rapidly & evenly, thus forming a solid & smooth surface film on tablet .

•**Analytical Balance** → Mettler Toledo company.

•**Disintegration apparatus** → Disintegration where no occurs In this apparatus which define a state residue of the tablet & capsule remains on the screen of the apparatus.

•**Hardness tester**→ ERWEKA Company

•**Friability test** →apparatus Friability describes the tendency of a solid substance to break into Smaller Pieces especially by rubbing. In this

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Temp Controller→ Company: Electro-lab.

Dissolution tester → Company: Electro-lab

Sample collector → Company: Electro-lab

Syringe pump → Company: Electro-lab

Disintegration Tester → Company: Electro-lab

Refractometer Instrument → RUDOLPH

Melting Point Apparatus → Labindia.

***Some Basic Principles and Applications of Quality Control Instruments :***

**HPLC :-**

•Principle → Sample components separate from one another by a process of differential migration as they flow through -the column

HPLC Solvent → Pump → Injector (Sample ) → HPLC column → Detector

Detector →Data acquisition

↓

Waste

**•USES :-**

i)Purification of H2O

ii)Protein chromatography via ion exchange.

iii)Carbohydrate oligosaccharide anion- exchange chromatography at high PH.

**•Application :-**

→ Synthetic polymer analysis.

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→ Isolation of high value goods

→ Pollution analysis environment in analytics.

**Liquid chromatograph :-**

•) Company (Brand name) Shimadzu.

•) Model name →LC20 AD

•) Working principle → Liquid chromatography is an analytical technique in which the mobile phase is a liquid.

•) It is carried out either in a column or a plane

•) Sample with the mobile phase is passed through a column or plane, accompanied by the stationary phase.

•) Due to difference in adsorption, size, Partitioning d a ion exchange, different solutes Interact with the different extend. Stationary phase

•Application of liquid chromatography →

1. Liquid chromatography is used in environmental analysis & cleanliness testing .

2. It is used Control. in food analysis & quality.

3. It is used in forensic science & Hospitals.

UV Spectrophotometer :- The Principle of UV-Visible Spectroscopy is based on the absorption of ultraviolet light or visible light by chemical compounds, which results in the production of distinct spectra. Spectroscopy is based on the interaction between light and matter. When the matter absorbs the light, it undergoes excitation and de-excitation, resulting in the production of a spectrum.

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closer than 2.5 cm from the bottom of the beaker in their downward movement. Move the basket containing the tablets up and down through a distance of 5-6 cm at a frequency of 28 to 32 cycles per minute. Floating of the tablets can be prevented by placing perforated plastic discs on each tablet.

● Application of disintegration test in pharmaceutical industry:-

Disintegration testing measures the ability of a tablet to break down into smaller particles or granules to allow the active drug to be absorbed into the body.

**↓ Principles of pH meter :-**

The ability of a solution to conduct a current is called electric potential. Electric potential is key in understanding pH meter principles and applications.

A pH meter measures electric potential using 2 electrodes inserted into the liquid to create an electrical circuit. One of these electrodes, called the reference electrode, will contain a substance with a known electric potential. The other electrode, known as the sensor electrode, will be inserted into the solution being tested. The electric potential is the difference that results from comparing the reference electrode to the sensor electrode.

● Applications of pH meter :-

pH meters are used for soil measurements in agriculture, water quality for municipal water supplies, swimming pools, environmental remediation; brewing of wine or beer.

**↓ Polarimetry :-**

The principle of polarimetry or optical rotation depends upon various factors such as the number of molecules in the path of electromagnetic

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viscosity of the fluid and the length of the tube. Also, the viscous resistance value is inversely related to the fourth power of the radius of the tube.

**Applications of viscometer :-**

There are many types of viscometer available in the market. You buy Brookfield viscometer with an advance technology, which is very famous for measuring viscosity of material. However, there are several types of viscometers are available in the market and it really depends upon the user that which viscometer he wants to use for his research.

**Sonication :-**

Sonication is defined as the process in which sound waves are used for the lysis of the cell to disrupt them. While homogenization is defined as the process of cell lysis using physical force to break the cells. Sonication utilizes sound energy whereas homogenization utilizes mechanical energy.

**Uses of Sonication :-**

The sonication mechanism is used in ultrasonic cleaning which includes cleaning of particles that adhere to the surfaces.

It is used in laboratories for cleaning fragile objects such as spectacles and jewels. The artificial ageing of liquors and other alcoholic beverages is done by the process of sonication. Other applications of sonication in food industries include dispersions of emulgator and speeding the filtration process.

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**Conclusion:-** Through this Industrial Training I gained lots of knowledge about Pharmaceutical Industry and its inevitable role in the society. This one month, helps me to understand the provisions to manufacture the various solid doses forms (Tablets, Capsules), e. g. Telma AM, Telma H, Bilastine, Remogliflozin Etabonate etc. Its analysis and all about the production to a certain extent within this short period. Also helps me to understand the GMP requirements that should comply by the pharmaceutical Industry and its significance for the maintenance of quality of the formulations. These 30 days (150 Hours) gave me lots of field work experiences in the industry.

*Thank You...*

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