Industrial Training at Magbro Healthcare Pvt. Ltd.

Report submitted for the partial fulfillment of the degree of

MASTER OF SCIENCE

IN

BIOTECHNOLOGY

Submitted By

RISHU KUMARI

197820

Under the guidance of

Internship Guide: - Miss Rishpa Sharma (QA/QC Manager)

Administrative Guide: - Dr. Jata Shankar (Associate Professor)

Faculty of bioinformatics and biotechnology

Jaypee University of Information Technology

Wakhnaghat,
Solan, H.P.

February-May 2021

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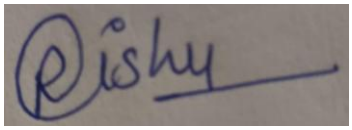
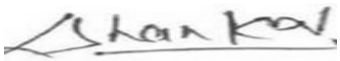
STUDENTS DECLARATION

I hereby declare that the report entitles **"Industrial training at Magbro Healthcare"** submitted in partial fulfillment for the award of degree of Master of Science in Biotechnology to Jaypee University of Information Technology, Wakhnaghat, Solan (H.P) is original report work carried out by me under the guidance and supervision of Miss Rishpa sharma. No part of this report has been submitted for any other degree or diploma to this or any other university.



Rishu kumari

This is to certify that the above statement made by the candidate is correct to the best of my knowledge.



Jata Shankar

Administrative Guide

Dr. Jata Shankar (Associate Professor)

Department of Biotechnology and Bioinformatics

Date: 20-05-2021

CERTIFICATE-I

MAGBRO

www.magbro.in

MHPL/2021-22 /02 **08 May 2021**

TO WHOM IT MAY CONCERN

This is to certify that Ms. Rishu Kumari D/o Kehar Singh Roll No-197820 student of M.Sc Biotechnology, Jaypee University of Information Technology Waknaghat Distt, Soaln (H.P) **has successfully completed her Industrial Training under the supervision of Miss. Rishpa Sharma, Manager Q.C./ Q.A. & Mr. Sanjay Gupta, Manager Production from 08.02.2021 to 08.05.2021 in this organization.**

We wish her all the best in her future endeavors.

For Magbro Healthcare Pvt. Ltd.

Authorized Signatory

MAGBRO HEALTHCARE PVT. LTD.
(A WHO, GMP & ISO 9001:2008 Certified Co.)
Regd. Office: Om Shanti Complex, 218, Industrial Area-A, Ludhiana-141003 (Pb.) Tel: +91-161-2223063 Fax: +91-161-2221247
Works: Village Mehsa Tibba, P.O. Manjholi, Tehsil Nalagarh, Distt. Solan-174 101 (H.P.) Tel: +91- 01795-265378-79-80
CIN:-U24230 PB 2006 PTC 30212

CERTIFICATE- II

The report entitles **"Industrial training at Magbro Healthcare"** submitted by Rishu kumari (197820) to Jaypee University of Information Technology, Wakhnaghat, Solan (H.P.), in partial fulfillment for the award of degree of Master of Science in Biotechnology in the Faculty of Bioinformatics and Biotechnology has been approved by the student's Research Guiding Committee after an oral examination of the same.

Name & Signature of Chairperson

Name & Signatures of Research Guiding Committee Members

Head, Dept. of Bioinformatics & Biotechnology

Dean of Faculty

ACKNOWLEDGEMENT

I consider it a great honour to have had the opportunity to undergo the industrial training work in Magbro healthcare. I would seize the opportunity to acknowledge my deep sense of gratitude towards all those who extended their kind help in fulfilling this endeavor.

I avail this opportunity to acknowledge my sincere and humble indebtedness and I convey my heartiest thanks to ***Mr. Sudhir Maingi (****Managing Director****)*** ***Miss Rishpa Sharma (*** *Quality Control Manager****), Sanjay Gupta (Production Manager)*** *my guide* ***Dr. Jata Shankar*** *(Associate Professor),* ***Dr. Sudhir Syal (****HOD),* ***Dr. Anil Kant Thakur*** *(Associate Professor & Coordinator of M.Sc. Biotechnology), Department of Bioinformatics and Biotechnology, Jaypee University, who conceived and shaped the research problem and provided adept guidance.*

At last, I am greatly thankful to all staff members and colleagues of Magbro Healthcare for their most valuable suggestions, constant encouragement, and affectionate guidance during the period of this training, which went a long way towards the completion of this Training and Report.

PREFACE

This is my great experience in industry as a trainee and unforgettable moments share with respectable staff of MAGBRO HEALTH CARE Pvt. Ltd**.** I have learnt various techniques and discipline under the kind management of executive of different departments.

It is my attempt to express in this report that what I get from my training from a simplified face of anti- Infectives, Introduction to the plant, and the various requisite Techniques Which was observed during the traning program.

INTRODUCTION

Pharmaceutical industry is a **"**Life Saving Industry**".** It provides the platform for the conversion of drugs in suitable doses form and medicinal articles, which have a significant role in treatment, mitigation, prevention and cure of varies diseases.

Science is evidence just as houses are made of so as science made of facts but a pile of stones and not a house and a group of facts is not necessarily science.

A pharmaceutical manufacturing unit is a premise where a group of skilled & non skilled person work under the supervision of an experienced directorate so that efficient therapeutically effective least toxic formulation of the drugs may get prepared to serve the community in a sense to make it healthy and growing and hence to make this beautiful world persistent forever.

MAGBRO HEALTH CARE Pvt. Ltd is one of the pharmaceutical manufacturing units which have owed to carry over the above responsibilities with complete awareness and honesty. Main products of Magbro Healthcare Pharmaceutical in their Solid & Liquid Department are-Tablet, Capsule, syrup, Ointment, Shampoo etc.

LOCATION- Situated in Vill. - Mehsa Tibba, P.O- Manjholi, Tehsil- Nalagarh and district is Solan (HP)

COPORATE OFFICE- Om Shanti Complex, 218, Industrial Area Ludhiana, Punjab-141003

Email: www.magbro.in

Objective of Training

- Training is a practically concerned with procedure in which a person is able to learn practically from his theoretical knowledge.
- Training offers practical information to the students.
- Training supports to study closely the ground level problem regarding their job profile.
- Training eliminates the hesitation of the student about their working skill and personality development.

SOME PRODUCTS OF MAGBRO HEALTHCARE

Brand	Generic Name
MELOFAR-15 TABLET	MELOXICAM TABLETS USP
LIPID DROP-FN TABLETS	ATORVASTATIN &FENOFIBRATE TABLETS
PREGNAMOM TABLETS	VITAMIN&MINERALS TABLETS
CIPRO-500 TABLETS	CIPROFLOXACIN TABLETS B.P
CITISAR TABLETS	CITICOLINE TABLETS
ETORIFAR TABLETS	STOXICOXIB TABLETS
CIPMAG TABLETS	CIPROFLOXACIN TABLETS
DUOTRAM TABLETS	TRAMADOL HYDROCHLORIDE AND PARACETAMOL
MURATAC CAPSULES	RABEPRAZOLE SODIUM CAPSULES
RAMIPRIL-H TABLETS	RAMIPRIL& HYDROCHLORIDE TABLETS
LOVOCIN TABLETS	LEVOFLOXACIN HEMIHYDRATE IP TABLETS
EASELAC SOLUTION	LACTULOSE SOLUTION USP
REDFOL	FERROUS FUMARATEORAL SUSPENSION BP
ULSOL-O GEL	ANESTHETIC ANTACID GEL

SAFETY HEALTH AND ENVIRONMENT

MAGBRO HEALTHCARE has a clear safety policy and takes safety measures as importantly as production, cost and quality.

Objectives: -

The safety and health of all employees is first priority. The only acceptable level of safety and performance is one that prevents injuries and accidents. The following objectives have been laid down in line with the above.

- To create and maintain a safe, injury free and accident-free work place.
- To create clean surroundings and environment acceptable to all employees, the customers and the public.

Safety Rules: -

- No smoking is in the plants/factory.
- Rough housing of any type is prohibited in the factory.
- The employees shall have the adequate knowledge of the adverse effects (if any) of the chemicals being used by them.
- Proper protective equipment's shall be provided to the employees and they shall be given training for the use of these equipment's.
- Preventive maintenance and checks shall be made to avoid the probability of a failure or an accident.
- The speed limit of the vehicles inside the factory shall be 20kms/hr.

PHILOSOPHY: -

- All injuries can be prevented.
- All working exposures can be safe guarded.

- Prevention of the personal injuries is good business.
- Employee involvement is essential.
- Accidents don't happen but they are caused.
- Safety is everyone's responsibility.

DEPARTMENTS OF INDUSTRY:

The Company is complex in the manufacturing of almost all segments of products having its self-regulating manufacturing sections which are precise with centrally air-handling system. There are Division of departments in Magbro Pharmaceutical industry [1].

1. Ware house
2. Production department
3. Quality control department
4. Packing department

WARE HOUSE

It receives raw material. Until this material not tested according to guidelines, it is remains there. Temperature and humidity are kept under control.

- Manager store & distribution
- Distribution in charge
- System operator
- Raw material operator
- Finish Good operator

RAW MATERIAL STORE:

Raw material store was Divided into following sections:

- Quarantine area
- Finish product quarantine area.
- Active material quarantine area.
- Chiller area

Quarantine:

All raw materials, workings, packaging, and labeling materials are held in our "quarantine" area until they are sampled, tested, and unrestricted for use by our "quality control laboratory". Sampling of the products through Quality control officer [10].

Finish product quarantine area

Finish products are stored in controlled atmosphere according to their salt property. Different quarantine sections for liquid and tablet storage.

Active material quarantine area.

In this section raw material is kept under normal conditions active pharmaceutical ingredients is kept in 15-25 C, excipients are kept at 25 C in subsection of this area

Chiller area

This area used for sensitive products to prevent from damage and sensitive products are kept in separate area with proper conditions. the process of dispensing according to SOP [9].

Duties of Store Manager: -

- Store Manager obtains the raw materials and transfers it to the quarantine with the label "Quarantined" before receiving it transfer to the bulk after clearance from QCD. The QCD accumulates the sample and reports for its release, it is according to the specifications or rejection if not.
- After refusal from Quality Control Department, red "Rejected" slip is fixed on each of the Quarantined material and the "Quarantined" slip is removed.
- After unrestricting by the Quality Control Department, green "Released "Slip is fixed on each of the Quarantined material and the "Quarantined" slip is removed.
- The material release information's is entered in the material log sheet. The Store Keeper manages to handover the RM to the bulk with required information fixed on it. Two copies of GRN after issue of Raw Material from QC are propose released [1].

Documentation work: -

Following documentations work done in ware house for various processes.

- Humidity log book.

- Dispensing log book.
- Raw material requisition.
- Raw material analysis report.
- Request for retest of the Raw material.
- Certificate of analysis.
- Verification slips of Material
- Identification of material (pink slip)
- Sampled at Q.C (yellow slip)
- Pass result from Q.C(Green Slip)

PRODUCTION DEPARTMENT

In production department these things are mandatory to wear,

- Cap.
- Lab coat.
- Production shoes or cover.

In Magbro pharmaceutical Division of Production department in following section:

a) Tablet Section
b) Capsule Section
c) Liquids Section

Tablet Section

Tablets are solid forms that containing drug substance with solid diluents and solid form of tablets form with compression methods [1].

Why tablets are Manufactured?

- Tablet manufacturing that are proper uniform in weight and drug content
- Tablet manufacturing physically and chemically for long storage
- Cost of oral products are cheap.
- Oral products are easy for shipping and lightest or cheapest to packaging [2].
- Product Identification simplest and cheapest method for other additional process.

- Better for large scale products from other forms of medicine.
- Best property physically and chemically for manufacturing, sampling and packaging.

Unit Operations: -

a) Granulation

- Shifter
- Paste cattle
- Rapid mass granulation
- Fluid bed dryer
- Multi miller
- Blending (Mixing)

b) Direct compression.

c) Coating

Equipment's-

1) RMG (rapid mass granulation)

- Produce precise blend
- Break down of agglomerates very rapidly
- Mechanical heat builds up with in powder and high-power requirement drawbacks.
- Capacity is 30-60kg. Horse power is &with shorter time interval given to reduce heat formulation [3].

2) **Fluidized Bed Dryer (vertical)**

- Fluidized used to reduce moisture content from powder and granules mixture, solid bed looks like boiling liquid and called fluidized if hot air is used to fluidize the bed, drying of solid will take place very rapidly [8].
- Efficient heat & mass transfer. Dryer capacity is 30kg. & overage drying time is 30min. High drying capacity of fluid bed dryer so that static times are shorter than static bed convection dryers. Heating time of thermo labile materials is minimized. Produce free flowing product.

Free movement of granules particle eliminate the risk of soluble material that occur in static bed [8].

- Short drying times mean that the unit has a high output from a small floor space. Attrition due to turbulence, five particles become entrained and generation of charges of static electricity due to vigorous movement.

3) Multi mill-

- Multi miller part of granulation section for bulk material and widely used to require size reduction of large granules, multi miller break large granules into smaller granules.

4) Shifter-

- Shifter works on separation of particle, separation of the particle on the basis of size and sieving of granules.

5) Double cone Blender-

- Double cone blender used to mix powder and granules properly, It mix granules and material constantly being intermixed as the blender rotates.

Tablet Compression Machine-

Compression machine provide shape to powder and granules with the help punches and die**.**

Stages of compression machine during process: -

- Filling
- Metering
- Compression
- Ejection

Compression Machine-1(27 *stations, Tooling-D)*

- In MAGBRO HEALTH CARE Pvt. Ltdlimited two machine are present having 27 stations & output are 48000 tablets per hours.

Compression Machine-2(37 *stations, Tooling-B)*

- In MAGBRO HEALTH CARE Pvt. Ltd limited one machine is present having 37 stations & output are 54000 tablets per hours.

BASIC PARTS OF MACHINE-

- Hopper located upper side for holding and feeding granulation to be compressed.
- Different dies are used to provide shape of tablets and define size.
- Upper and lower punches for compression of granules with in dies.
- Cam for guiding movement of upper punch and lower punch.
- Hydraulic pressure adjusters.

- Tablet machine's output is affected by-

1. Number of tooling sets
2. Number of compression stations
3. Rotation speed of the press
4. Recompression stations are used to help in comprising difficulty.

TABLET DISINTEGRATION TEST APPRATUS: -

Disintegration apparatus is used to check the disintegration time of the tablets as per IP/USP standards. This test commonly used in quality control and R&D to determine the disintegration time of the tablet and capsules. TWO BEAKERS Capacity of 1000ml, it moves UP and DOWN. Setting of the instrument manually Disintegration test occur in 37.2 Temperature of the water bath maintained using accurate sensors, Speed of the basket as per specification of IP/BP/ USP Specification [5].

Type of tablets	**Disintegration Time**

Coated tablet	**30 Minute.**
Uncoated tablet	**15 min.**
Dispersible tablet	**3 Min.**
Enteric Coated tablet	**2 hour**

LEAK TEST APPARATUS: -

leak test is solid state instrument used to check leak property of the products; leak test applies after packing. It checks the seals enclosing of the product, leak test used for tablets, capsules, liquid, ointments [8].

TABLET COATING PAN

Tablet coating section has 1 coating machines and chamber is fully air condition by centralized AC system.

COATING OF TABLET

Tablet coating, an additional step in the manufacturing process, that based on following objectives:

- Coating is used to reduce the bitterness of the tablet
- Coating depends on salt property of the Tablets
- To control the release of the drug
- Protect drug from environment and specific release condition of drug in the stomach.

COATING PROCESS: -

Coating process of the tablet require coating material that depends on the film coating and enteric coated tablets. Coating material applied on the surface of the tablets, pallets etc. Heating air is introduced with Coating pan that evaporates the solvent. Distribution of the coating tablets by the movement of the coating pan vertical [3].

TYPES OF TABLET COATING: -

1. Film coating
2. Enteric coating

Film Coating: - It is referring to the coating of tablets by a single or mixture of film forming agents, such as, polyethylene glycol, **hydroxyl-propyl methyl cellulose**, carbowax, etc. These

film forming agents are dissolved in a volatile solvent and sprayed to the tablets rotating in a coating pan. The process is continued until a uniform good film is formed over the tablets [9].

Enteric Coating: - Enteric coated tablet contains 8-10% Coating material. The Enteric coating is given to tablets to protect the tablet from disintegration in the acidic medium in stomach but release the drug rapidly and completely when the tablet passes in the intestine or alkaline medium. The enteric coating process consists of water proofing tablets by coating with shellac in coating pan and then enteric coating material is added to the rotating tablet to form and enteric coat. The time of disintegration of enteric coated tablets is directly proportional to the thickness of coat. The thick coat means the disintegration is required in large intestine [3].

CAPSULE SECTION

This section has three cabins with four semi-automatic capsule filling machines, all cabins are fully centrally air conditioned with one entry & one exit.

"Capsule is a solid dosage form in which the medicinal agent is dosed in the gelatin capsule."

Capsule is used for the oral administration of drug. Hard geletin capsules are used for poweder, pallets and soft capsules are used ti fill liquid Example: -Vitamin E capsules [6]

Advantages: -

Capsules are tasteless and odor less from other medicine.

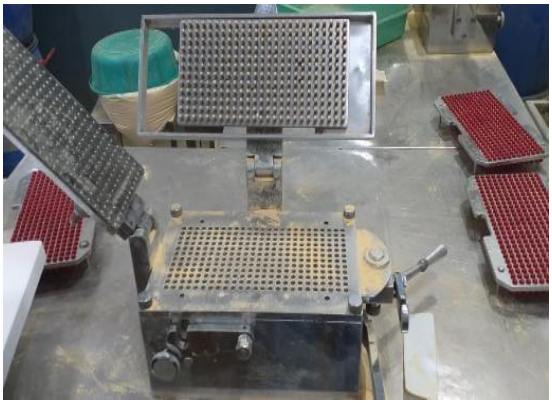
Capsules enclosed in tasteless shell without any fragrance.

Disadvantage: -

Hygroscopic drug is not appropriate for filling in capsules. The concentrated solution which involves in previous dilution, which are unsuitable for capsules because that lead irritation in the stomach.

CAPSULE FILLING EQUIPMENT

Capsule hand filling machine. (300 holes)



Working: -The capsule hand filling machine is made up of stainless steel. In Capsule filling machine the unfilled capsules are filled in the loading tray which is then placed over the bed. The bodies of the capsules are locked by using cam handle and caps are separated in the loading tray. The powder tray is filled with an accurate quantity of drug and spread the drug with a help of spreader that fill the bodies of capsules uniformly. With 200 holes machine, about 5000 capsules can be filled in one hour and with 300 holes, about 7500 capsules can be filled in one hour [9].

STEPS INVOLVE IN DURING PROCESS

FINISHING: -

The filled and sealed capsules necessitate a finishing operation before inspection or packing in strips 7 labeling; the following steps are involved in the finishing process [9].

CLOTH DUSTING: -

This is generally done manually in this process individual capsules are rubbed with cloths which may or may not contain inert oil [9].

INSPECTION: -

This process is desirable to pick up imperfect and damage capsules. As yet inspection is manually.

PACKING: -

The finished product is allowed for packing most widely, they are packed either in strip packaging or in blister packaging [7].

Capsule Store at temperature not exceeding 30^0C and moisture content in capsule are 12 to 15%. This level should be maintained during storage. Storage during high and low humidity condition for extended period can cause deformation or become brittle. Capsule should be store in the areas with relative humidity is around 30 to 40 percent and also stored in cool and dry places.

Weight Variation in Capsule: - The weight limit less than 300 mg +/- 10%, weight greater than 300 mg +/- 7.5%.

ORAL LIQUID SECTION

SUSPENSION: -

Pharmaceutical suspension consists of solid particle in liquid medium. The diameter of the particle present in suspension 0.5um. In addition, a suspension in non-aqueous solvent offers a useful form of administration for drugs that reduce rapidly in aqueous solution [3].

The desirable properties of a pharmaceutical suspension include.

- Pour ability and the easy removal of dose.
- Ready re dispersion of a settled preparation.
- Elegant smooth appearance.
- Resistance to microbial contamination.
- Suspensions are normally prepared using dispersion techniques. Shear must be applied during the dispersion process. This is often achieved on a large scale by using a colloidal mill [2].

FORMULATION-

[1]. VEHICLE- Sorbitol, Propylene glycol, Water etc.

[2]. ADDITIVES

(A). COLOURING AGENTS- sunset yellow, erythrosine, tartrazine etc.

(B). FLAVOURING AGENTS –pineapple, mixed fruit

(C). SWEETENING AGENTS-, saccharin, aspartame etc.

(D). PRESERVATIVES- propyl paraben, methyl paraben. Dim benzoate etc.

EQUIPMENTS

[1]. SUGAR SYRUP TANK: -

This is a big size tank made by generally stainless steel and other suitable matter and used to dissolve sugar in water with or without application of heat and make a viscous sugar solution.

[2]. BATCH PREPARATION TANK: -

Batch preparation tank polished with stainless steel and allow for heating and cooling of the content. Whole preparation process occurs in tank.

This tank is big size tank with a stirrer rotated by a motor in which batch are prepared. Sugar solutions are made in sugar syrup tank and transfer in this tank and all active ingredients as per formula are mixed and stir properly. This tank is usually made up of 300 lit. Of capacity [3].

[3]. HOMOCOLLOID MILL: -

It is very important in formulation of suspension. It is used to reduce the particle size 5- 10 microns.

[4]. FILTER PRESS: -

It is also an important machine used for filtration of liquid oral syrup. The multistage filtration makes the filtrate sparking clear. It is most versatile of filters since the no. & type of filter sheets can be varied to suit a particular requirement. It can be used for course to fine filtrations and

provides multistage filtration with in a single press. The normal range of flow is three gallons per minutes per squire fit of filter surface at a pressure of up to 25 psi [3].

It is having two main components

(A). centrifugal pump & electric motor

(B). filter supporting frame work enclosed in a pressure tank, six filters are supported on six stainless steel support screens of eight diameter. The frame is bottled of the filter (woven) & adjusted in the pressure tank syrup holding tank is connected to the pump with pipe, operate the pump to push the liquid in to the liquid passes through the filters and come out being clear liquid [5].

[5]. BOTTLE WASHING MACHINE-

This machine is used for washing of bottle which is operated by an electric motor. This machine is provided with 96 washing cavities used for washing of bottles.

[6]. BOTTLE INSPECTION MACHINE-

This machine is consisting of a tube light which is used for the inspection of empty bottle.

[7]. SEMIAUTOMATIC VOLUMETRIC FILLING MACHINE-

This machine is used for filling the measured volume of liquids into the bottle. This machine is provided with a piston that attached to the other side with a tank. It is a double head or four head machine consists of two/four filling syrups [5].

QUALITY ASSURANCE AND QUALITY CONTROL

Quality assurance: -

The system of quality assurance shall accomplish manufacturing of pharmaceutical products insure that-

- The pharmaceutical products are designed and developed to [preventing the mistakes and defect during manufacturing and avoids various problem during delivering to customer.
- All manufacturing, packing, dispensing records are recorded in Quality assurance proper manner and limited period of time
- All documents of the checked in quality assurance [10].
- The finished product is correctly checked according to data, calculations, sampling etc.
- The pharmaceutical products are not release for sale or supplied before authorized person have certified that each production batch has been product and control in accordance with requirements of the labels, claims and any other provisions relevant to the production control [10].

Quality assurance department is associated with fallowing responsibility

[1]. Raw materials: -

The quality assurance responsible for issuing of raw material which is used for the formulation of dosage form. He inspects the raw material and allows the order for the correct weighting of the raw material [10].

Most raw materials are weighted in an environmental control weighting area, where they are transferred in secondary containers that circulates only inside the production department [10].

[2]. Manufacturing equipment: -

Quality assurance should ensure that manufacturing equipment is designed, located and maintained so that it facilitates through cleaning is suitable for use and minimizes probable for contamination during manufacturing, manufacturing equipment's and utensils should be thoroughly cleansed and maintained in accordance with specific written direction, adequate records of such procedures and tests if appropriate should be monitored by quality assurance.

[3] Quality assurance at start-up raw material processing: -

Properly Labeled raw materials are allow in the processing area, depending upon the nature of the product. Quality assurance officer check and verify that the temperature and humidity, specified under limits required for the product, if the temperature and humidity is beyond the specified limits, production chemist must be informed for further action [1].

Quality assurance officer check each step in the process according to written in process qualify assurance procedure. At certain points Samples are taken to the quality control laboratory for potency assay and any other testing that is necessary to be ensure uniformly and purity.

[4]. Compounding: -

Current good manufacturing practices required the process of quality assurance documented all records of manufacturing in production run in process sample are removed and tested and data are recorded on special forms.

If results of tests and data not under limits, its necessary corrective action is taken and re-tested to determine the quality of the products is now under limits.

[5]. packing material control: -

Quality assurance personal inspect and verify all packaging components and equipment's to be used for the packaging operation to ensure that it has the proper identification by using the parameter gram per square meter (GSM)

The evaluation of packing material by quality assurance personal the store person issued the requisition of packing material from store [10].

[6]. Finished product control: -

Final testing of the finished product in quality control laboratory. These tests are designed to determine the product physical and chemical property. Final product pass by quality control through various specification. Finished product testing require to check claim of the product. Product sample compare with Active material of the product according to IP/BP/USP specification [1].

[7]. Quality assurance during packaging operation; -

Quality control laboratory analysis pass the products according to specification and quality assurance inform packing department for further process. Quality assurance officer inspect the packaging lines and should check filled and labeled containers for compliance with written specification [4].

Quality assurance should execute an independent inspection during packing of the products. Quality assurance officer stops the line in any contamination, improper packing occurs. Quality assurance preserved control sample in control sampling room, that sample should retained for at least one year before expiration date and product properly stored in their original packing with proper labeling [4].

Role of quality assurance: -

- Temperature check
- Humidity checking
- Line clearance (at different stages, in line clearance IPQA Officer focus on cleanliness proper, identification of product, batch No. record, packing product, product labeling)
- Stability testing
- Maintain record

- Dispatch testing
- Handling of market complains
- Dispensing checking
- In-process testing
- SOP designing
- Workers training
- Validation
- Self-inspection / internal audit
- Art work
- Market return

Duty of IPQA officer in production and packing department

Record Previous product details: -

- In process Line Clearance:
- Product:
- Batch No.:
- Batch Size:
- Status: Compression.
- Machine Name:

QUALITY CONTROL SECTION

Quality control is the part of GMP, all sampling testing, specifications, documentation comes under GMP. Which certify that required and relevant tests are accepted. Products are not released for sale or supply until quality control laboratory tests the products according to specification.

Quality control laboratory evaluate product at each stage that eliminated error of the production. The sampling of Raw material is done by the QC department and After that raw material enters into store and 'UNDER TEST' label is pasted on it by the officials in the raw. For Active Pharmaceutical Ingredient (API), 100% sampling must be done [5].

Quality Control laboratory, confirms that the products are pure, safe and effective and unrestricted only after thorough analysis as per stringent specifications, methods and procedures developed according to international guidelines viz. EU, cGMP, MHRA, WHO, TGA, etc.

The quality control performs activities during sampling

Analysis of Raw material and packaging material: -

Raw material/ packaging material

↓

Receipt

↓

Verification

↓

Sampling

↓

Under test

↓

QC test

↓

Approved and Rejected

Approved -for Manufacturing

Rejected -Return to supplier

Analysis of Finish Product

Completion of batch product

↓

Analyzed by QA

↓

Under test

↓

QC test

↓

Preparation of Report and Checking

↓

Approved / Rejected

Approved -for Manufacturing

Rejected- Return to supplier

In Process Checks

Received In process requistion along with sample

↓

Testing as per requistion

↓

Results conveyed to production.

Role of quality control officers: -

- Detailed instruction in writing for carrying out each test and analysis
- Proper record of rejected and release each batch raw material.
- Record of semifinished and finished product in proper format
- Release and rejected final packing material record [8].

- Store finished product with proper documentation.
- Proper entry of raw material, semi-finished, finished product.

In-process test for Tablets, capsule, Liquid

QC perform following test

- Appearance (color, size, shape)
- Average weight.
- Disintegration Test
- Hardness Test
- Thickness
- Diameter
- Dissolution Test
- Friability test

In-process test for Capsule

- Physical appearance
- Disintegration test
- Average weight.
- Weight variation

In-process test for Liquid

- pH
- Viscosity of the sample
- Weight per ml
- Deliverable Final volume

INSTRUMENT ROOM

Test tubes, boiling tube, pipette, funnel, beaker, burette, separating funnel these are made up of borosil glass. Pipettes are available from 1-50ml capacity and are both of graduated and transfer type. Ammonia distillation test apparatus, boiling point apparatus are also available. Separating funnels are from 250-500 ml. silica grease is applied on their dots before use.

1) P^H meter: -

pH meter is used to determine various solutions, buffers in pharmaceutical industry. pH meter contain probe that pass electrical signal to pH meter and display result. Different chemicals are required to increase and decrease the pH according to sample specification.

Procedure: -

- Operate the p^H meter by calibrating the apparatus its calibration is done by using a buffer solution of p^H 4 firstly as a primary standard, adjusting the meter and read the appropriate p^H value [8].
- Use a second reference buffer solution of p^H 9.2 for calibration and again calibrate the p^H meter using a third reference buffer solution of intermediate pH of 7 & adjust the meter reading by setting the scale.
- Now emerge the electrode in the solution to be examined and measure the p^H at the same temperature after taking the reading wash the glass electrode with de mineralized water and cleaned with tissue paper and immersed it in to a beaker containing de mineralized water.

2) Ultra- violet & visible spectrophotometer: -

This instrument is used to analyze the raw material and finished products for calculating its percentage purity. This instrument is based on the principle intensity of light passes through sample solution at specific wavelength [6].

Procedure

- The instrument is usually calibrated by using Holmium per chlorate solution.
- The substance being examined is generally dissolved in a solvent and its dilution is perform according to required monograph (usually 50mg) samples are taken and its dilution is performed based on desired mcg of solute.
- Now perform the blank determination using the solvent in which solution is made.
- Adjust the wavelength either UV or visible according to individual monograph and noted down the reading of absorbency of test and standard and calculate its % purity.

3) Dissolution apparatus (USP standards)

A dissolution test uses an apparatus and uses as specific test condition and specific criteria according to product condition. It evaluates the performance of the product in buffer or HCL.

Dissolution test contain four standardized apparatus according to IP, BP, USP: - Basket, paddle, Reciprocating cylinder, and flow through cell.

This apparatus is used to estimate the dissolution rate of the tablets and capsules.

4) Disintegration test apparatus: -

Disintegration test measures the ability of the tablet break down into smaller particles and and check the active drug absorbed into the body under various conditions.

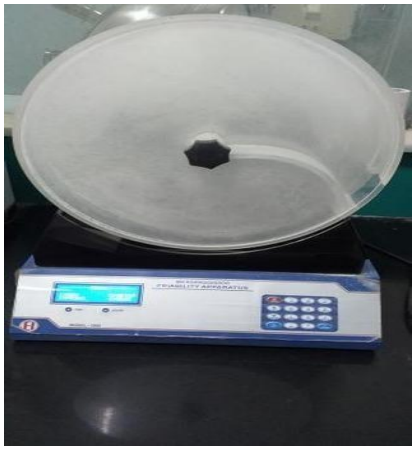
This apparatus is used to estimate the disintegration time of tablets and capsules.

5) Hardness test: -

Hardness test used to determine the breaking point and structural integrity of a tablet. The breaking point of the tablet based on shape of the tablet and hardness test similar to friability test of tablet.

Monsanto hardness tester is used to estimate the hardness of the tablets.

6) Friability test apparatus (USP standard)



This instrument is used to estimate the friability of the compressed tablets.

This test is also known as “abrasion test”. This test is performed to check the ability of the tablet during transportation and handling. Friability test limit between 0.5 to 1 Percent The result obtained from sample that complies with limits.

The instrument used for friability test is known as friabilator test apparatus.
All the tablets of a particular batch should be uniform in weight, if a small variation in weight is there, that should fall within the prescribed pharmacopeial limits as follows:

Uniformity of contents: - The test for tablet is performed by assaying the particular drug, according to the Pharmacopoeia method. The variation in Friability test percentage Due to following reasons:

- **Variation in the weight of an individual tablets.**
- **Purity of medicament.**
- **During the process of granulation.**

7) Magnetic stirrer: -

Use to dissolve the sample; they have also temperature control along with stirrer speed set up.

8) Electrical water bath: -

For gradual heating from 30^{o} - 100^{o}c.

9) Hot air oven: -

Hot air oven used to sterilize the laboratory apparatus. This apparatus is used for drying purposes

10) Hot plate: -

Hot plate used for mixing and heating chemicals samples**.**

11) Electronic balance: -

Electronic balance use to check unknown mass. It is most widely and accurate weighing instrument used for weighing of the materials.

12) Polarimeter: -

Polarimeter is used for liquid sample, it measures the angle of rotation caused by passing polarized light through active substance

13) Moisture balance: -

This instrument used to estimate the percentage of moisture content present in the sample at a particular temperature.

14) HPLC Test: -

It is used for distribution of the analyte between mobile phase and stationary phase and it separate the components of a mixed drug substance.

Detectors are used to determine the separate compounds by ultraviolet absorption. The absorption depends on the concentration. Response of the sample recorded by the computer software in the form of peak [6].

PACKAGING SCTION

A pharmaceutical packaging material are selected adequately to preserve the integrity of product material selected must have following factors: -

- Packaging material not reactive with products

- They do not impact the product taste and odor.
- Packaging of products nontoxic.
- They must be FDA approved.
- They must be temperature resistance requirement.

Uses of packaging: -

Physical protection

Information transmission

Marketing

Convenience

Types of packing

Primary packing: -

Envelop the material firstly and hold. this is the smallest unit of distribution.

Primary packing occurs through packing machine [8].

Eg: - blister packs, strip packing, bottle.

Secondary packing: -

It occurs outside the primary packing and used group of primary packages together.

Eg: - printed cartons etc.

Tertiary packing: -

It contains group of secondary packing and used for shipping purpose and handling.

Eg: - Containers and edge protectors [8].

Equipment's

Two type of packing was done: -

1. Blister Machine
2. Strip Machine

1. **Blister packing machine-**

The uncoated and coated tablets are packed in blister packing is performed by an automatic machine. Tablets are packed by machine between PVC 7 aluminium foil.

Machine has four basic units

1. blister forming units
2. batch coding units
3. sealing units
4. pack cutting units

Blister forming units

It is having detachable formation rollers any type of roller required as per size & shape of tablets/capsules to be packed, can be replaced in the unit. The unit is also provided with a heating rollers & vacuum system. The PVC film is heated by heating rollers & then sucked in to the cooled cavities of the formation roller by the vacuum system attached to the formation roller. These cavities formed in the PVC film are called blister & the process called blister formation [9].

Batch coding units

This part of the machine has a number of rollers and an inkpot and one of the rollers can be provided with number of rubber stereos for batch coding price, mfg. Date exp. Date on the aluminum foil.

Sealing units

This part has two rollers one folder and other sealing roller. When PVC film with blisters & aluminium foil are passed b/w these two, the sealant coating applied to the foil melt & stick on the PVC film & the tablets feeded in the blister are also got packed b/w the PVC film & aluminum foil [9].

Pack cutting units

This unit is provided with detachable cutters different types of cutter can be attached to the unit as per required of the pack size.

2.Strip packing machine

It is also a packing machine & used when a product is to be protected from moisture efficiently, strip packing is to be used. Most widely capsules &few tablets are main dosage form to be packed by this machine. Here the product is to be packed between two aluminium foils which are packed by polythene film. This machine has low heat-sealing rollers, cutters batch coding rollers, hopper, vibrator etc. the maximum packing speed of this machine is 85 strips per second [9].

WORKDONE & RESULT

Physical parameters: -

Vernier Caliper used to check Physical parameters.

- Weight variation
- Thickness
- Diameter
- Width
- Friability

Testing Uniformity of Tablet on the basis of physical appearance: -

Serial Number	Weight(mg)
1.	525.8
2.	517.8
3.	520.1
4.	520.8
5.	522.0
6.	520.7
7.	517.0
8.	525.8
9.	525.7
10.	520.3

Average weight

= 5213.5/10

= 521.3 mg

Minimum weight

= 517.0mg

So, minimum variation

= Minimum-Average weight /Average weight x100

517.0-521.3/ 521.3 x100

= -0.8%

Maximum weight

=525.8mg

So, maximum variation

Minimum-Average weight /Average weight x100

525.8-521.3/521.3 x100

= +0.8%

a) Thickness of the tablets

Serial No.	Thickness(mm)
1.	5.0
2.	5.1
3.	5.0
4.	5.2
5.	5.0
6.	5.1
7.	5.1
8.	5.0
9.	5.0
10.	5.0

Average =5.0

b) Diameter of the tablets

Serial No.	Diameter(mm)
1.	17.42
2.	17.40
3.	17.41
4.	17.42
5.	17.43
6.	17.42
7.	17.41
8.	17.44
9.	17.42

10.	17.41

Average = 17.4mm

INSTRUMENT USED

FRIBILITY TEST: -

- To determine the friability: -
- The average weight of tablets for friability test 6.5gm.
- Carefully deducts the tablets from weighing machine and Note down initial weight of the tablets.
- Set the time duration for 4min in friability test.
- Set Number of counts to 100.
- Friability test drum cleaned with no contamination and add initial weight tablets and close lid.
- After 4 min duration it automatically stops and take out the tablets.
- Take After weight of the tablets.

FORMULAE: -

$$= \frac{\text{Before weight- After weight}}{\text{Before weight}} \times 100$$

- ✓ Friability should be less than 1%

Sample: -

$$= \frac{6.243-6.228}{6.228} \times 100$$

= 0.02%

Result= PASS

Dissolution test

Sample- Y

Semifinished sample

Buffer preparation

- 40gm potassium hydrogen phosphate Dissolve in 6L water and adjust pH 6.8.
- Apparatus Basket used in Dissolution test According to IP and 900ml buffer
- Added in each bowl and set rpm, time according to IP/BP.

Sample tested in UV-spectrophotometer

HPLC Test

Assay of Z Tablets: -

Buffer

1ml of Triethylamine dissolve in 1000ml of water and set 3.0pH with OPA.

Preparation of Mobile phase: -

700ml buffer makeup with 300ml methanol and prepare 1000ml volume of Mobile phase.

UV-VIS Spectrophotometer. (Ultra -Violet Visible)

Assay of X Tablets:

Sampling of the tablets and Assay used to check the amount of active material and compared with the claim given.

Preparation of Standard:

According to I.P, B.P instructions.

- Weight of the 50 mg Linezolid into the 50ml volumetric flask.
- Dissolve with methanol and sonicate.
- Make up volume up to 50ml with methanol.

Test preparation:

- **Sample weight=**Equivalent weight X Average weight/Claim

  50 X 750/600

  =62.5mg
- Weighing of linezolid sample 62.5 mg.
- Add sample into volumetric flask.
- Mix with methanol and sonicate.
- Make up volume upto50ml.
- Filter the sample with Whatman filter paper.

- Dilute sample 1ml above to 50ml with methanol.
- Mark as TEST.

Procedure:

a. Measure the absorbance of blank solution.
b. Measure the absorbance of standard solution.
c. Measure absorbance of sample at 357nm.
d. calculate the sample percentage.

Preparation of volumetric solutions

- **0.05M EDTA**

18.6gm EDTA dissolve in 1000ml of distilled water.

Standardization: -

- 250mg calcium carbonate added in flask with 10ml HCl (1M), 15mlNaOH (1M),50ml water.
- Sonicate properly and after that Indicator -hydroxy naphthol added in flask.

- **0.1M EDTA**

37.2gm EDTA dissolve in 1000ml of distilled water.

Standardization: -

- 250mg calcium carbonate added in flask with 10ml HCl (1M),15mlNaOH (1M),50ml water
- Sonicate properly and after that Indicator -hydroxy naphthol added in flask.

- **0.1M HCl**

8.5 HCl dissolve in 1000ml of distilled water.

standardization: -

- 150mg Anhydrous sodium carbonate dissolve in 100ml of water.
- Methyl red indicator added into flask.

- **1M HCl**

- 85HCl dissolve in 1000ml of distilled water.

standardization: -

- 1.5mg Anhydrous sodium carbonate dissolve in 100ml of water.
- Methyl red indicator added into flask.

- **0.1M NaOH**

- 4gmNaOH dissolve in 1000ml of distilled water.

Standardization: -

- 500mg potassium hydrogen phthalate added in 75ml of water and addition of phenolphthalein indicator.

- **1M NaOH**

- 40gm NaOH dissolve in 1000ml of distilled water.

Standardization: -

- 5g potassium hydrogen phthalate added in 75ml of water and phenolphthalein added as indicator.

- **0.05M Iodine**

- 14gm Iodine and 36gm Potassium Iodine into the flask.
- 100ml water added into the flask and 3 drops of HCl added.
- Make volume up to 1000ml.

Standardization: -

- 0.15gm arsenic trioxide,20ml 1M NaOH, 40ml water, 0.1ml Methyl orange solution and drop wise add HCl.
- Color change yellow to pink.
- After that 2gm Sodium carbonate and 50ml water,3ml starch solution added.

- **0.1M Ammonium Thiocyanate**

16.98gm Ammonium thiocyanate dissolve in 1000ml of water.

Standardization: -

- 30ml 0.1M Silver nitrate,50mlwater,2ml Nitric acid,2mlferric ammonium sulphate added into flask.
- Titrate with 0.1M Ammonium Thiocyanate solution.
- Color change red to brown.

Sampling through Titration: -

Sample: - Calcium citrate malate

- 250mg sample (Calcium citrate) added in conical flask with 10ml HCl.
- Heat the sample and then cool.
- 50ml distilled water and 15ml NaOH (1M).
- Hydroxy Naphthol Blue used as Indicator.
- Titration of calcium citrate with 0.05M EDTA.

CONCLUSION: -

During three-month traning period, a lot of experience, knowledge that I have learned in MAGBRO HEALTHCARE. Hands-on is complement to the science or theory learned.

During the my industrial traning period, there are several changes from the opinion of learning environments and discussion among colleagues. It directly increases the devotion and rational attitude toward myself.

Therefore, I conclude that the industrial traning program has providing many benefits to students and lot of exposure in industrial area.

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