Industrial Training

At

Magbro Healthcare Pvt. Ltd.

Master of Science

In

Biotechnology

BY

Neha Thakur (197814)

Under the Guidance of

Internship Guide- Mrs.Rishpa Sharma, Mr.Sanjay Gupta

Administrative Guide- Dr. Jitendraa Vashistt, Associate Professor

Jaypee University of Information Technology

Waknaghat, Himachal Pradesh

February-May 2021

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Declaration

I declare that the work in Industrial Report entitled “Industrial Report at Magbro Healthcare” presented in fulfilling part of the Master's of Biotechnology requirements at Jaypee University of Information Technology: Waknaghat is a true record of my work under the guidance of Mrs. Rishpa Sharma, [QC, QA Manager], and Mr. Sanjay Gupta [Production Manager] at Magbro Healthcare. This work has not been submitted to anywhere for the reward of any other degree / diploma. I am fully responsible for the content of this project report.

Date: 22 May,2021

Neha Thakur

Regd. No-197814

Msc. Biotechnology

Jaypee University of Information Technology

Supervisor's Certificate

This is to certify that the work reported in the Msc. The dissertation entitled," Industrial Report at Magbro Healthcare" submitted by Neha Thakur (197814) at Jaypee University of Information Technology, Waknaghat,Himachal Pradesh is a bonafide record of her original work carried out under my supervision. This work has not been submitted elsewhere for any other degree or diploma.

Signature of Supervisor

Date: 22/05/2021

Name of Supervisor: Dr. Jitendraa Vashistt

Designation- Associate Professor

Department of Biotechnology and Bioinformatics

Jaypee University of Information Technology, Waknaghat

Training Certification

MAGBRO

www.magbro.in

MHPL/2021-22 /01

08 May 2021

TO WHOM IT MAY CONCERN

This is to certify that Ms. Neha Thakur D/o Hansraj Roll No-197814 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.

MAGBRO HEALTHCARE PVT. LTD.

Authorized Signatory

Acknowledgement

Department of Biotechnology and Bioinformatics at Jaypee University of Information Technology, Waknaghat for providing an opportunity to work in a Pharmaceutical industry

I consider it a great privilege and honour to go for an Internship Programme under **Magbro Healthcare Pvt. Ltd**. Hence I would like to offer my heartiest thanks to **Mr. Sudhir Maingi** {Managing Director} of the Company.

I am greatly indebted to Dr.Sudhir Syal {Head of Department}, Dr. Anil Kant and Dr. Jitendraa Vashistt, Department of Biotechnology and Bioinformatics for giving me the chance to undergo an Internship programme which helped me carrying out my project work.

I would also like to thank my seniors at the company, colleagues, Manager- Ma'am Rishpa and Sir Sanjay for extending their constant cooperation which went a long way towards the completion of this training and report.

I am grateful to my parents for providing continuous support throughout my period of training. I want to thank all those who were involved directly or indirectly in the completion of the work.

Neha Thakur

Msc. Biotechnology (197814)

Jaypee University of Information Technology

Himachal Pradesh

Objective of Industrial Training

The main purpose of Industrial Training is to expose students to real work. This will help students gain knowledge, develop skills, improve communication and provide an opportunity to work with industry employees. In addition, it helps students to link between theoretical knowledge and practical application in the Industry.

Other objectives of Industrial Training are to-

- *It gives a clear idea of interest in a particular field.*
- *It helps me to take responsibility for my work.*
- *Training helps to closely study the global problem in terms of job profile.*

Organization Overview

Magbro Healthcare Pvt. Ltd has gained an immense expertise in supplying and trading of medications for various countries. This company is located in Nalagarh, Himachal Pradesh.

- Incorporated in **2003** with an Annual Turnover of **Rs.10 to 25 Crores**.
- They have made it through certification for India and other countries like Philippines, Cambodia, Sri-Lanka, Vietnam, Nigeria, Ukraine etc and in process to achieve other countries approvals.

MISSION- Magbro mission is to achieve heights in pharmaceutical industry by providing best quality products.

MOTTO- Customer satisfaction is our motto

CEO of the Company is – <u>Sudhir Maingi</u>

- **LOCATION**- Situated in Vill. - Mehsa Tibba, P.O- Manjholi, Tehsil- Nalagarh and district is Solan (Himachal Pradesh)
- **COPORATE OFFICE**- Om Shanti Complex, 218, Industrial Area Ludhiana, Punjab-141003
  Email: www.magbro.in

<u>Warehouse/ Dispensing Unit</u>

I have performed In-house training in Warehouse in these three Departments;

1. Purchase of Pharmaceutical Products
2. Storage of Ordered Products
3. Distribution of Stocked products

Layout Of Storage Area

Raw Material under testing is kept in the Yellow Area.	Raw material and API which are approved and passed through all the tests and sampling by QC are kept in a Green Area with a Label.	This area is kept for Liquid solutions and some Liquid related Raw Material. Approved Raw Materials and Product.	Rejected Raw Materials after the testing and analysis by QC are kept in Red Section with a Reject Label and informed to a QA Officer.

Labelling of tested materials-

1. Name of company
2. Condition of material (tested/non tested)
3. Name of item
4. Batch number
5. Manufacturing date
6. Expiry date
7. Quantity received
8. Analytical report number
9. Released/ rejected
10. Signature of store in charge

Production Section

Tablet category

A tablet is a combination of active ingredients and additives, usually in powder form, pressed or blended tightly. The ingredients include binders and lubricants to ensure granulation, dispersion to ensure the tablet is broken down in the digestive tract, and sweeteners or flavours are used to hide the unpleasant taste of active ingredients and pork used to make unmixed pills look.

There are three methods followed by the production phase-

- **Granulation**

Rapid Mass Granulator

- RMG is used for mixing pharmaceutical ingredients and making granules before compression and is also called A High Sheer Mixer. In this structure, the formation of granules occurs by ascending, rotating, and moving the object. RMG equipment capacity at Magbro is 30-60kg.

[Rapid Mass Granulator at Magbro Healthcare as shown in the figure.]

- **Compression**

Tablet Compression Machine

[Tablet Compression Machine at Magbro as shown in the figure.]

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

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

Basic Machine Parts-

• Hopper to hold and feed granulation to be pressed.

• Death defines the size and shape of the tablet.

• Top and bottom punches for compressing granules with dies.

• Cam Tracks tracking boxing.

• Method for transporting granulation from hopper to death.

• Hydraulic pressure adjusters.

• Tablet removal is done by

- Number of tool kits
- Number of compression stations
- Rotation speed of the press
- Recompression stations are used to help in comprising difficulty.

❑ Coating

[Tablet Coating Pan at Magbro as shown in the figure.]

Tablet Coating Pan

The tablet cover has 1 coating and the room is full of air through the central AC system. Tablet coating is the use of a cover-up compound on a mobile tablet with simultaneous use of hot air to facilitate the evaporation of the solvent. The distribution of the tablet cover is achieved by the movement of the tablet and can be understandable or direct in the application of the cover design.

COATING OF TABLET: -

Tablet coating, an additional step in the manufacturing process, increase to coat a tablet is usually based on one or more of the following objectives:-

(a) To mask the taste, odour or colour of the drug.

(b) To provide physical and chemical protection for the drug.

(c) To control the release of drug from the drug.

(d) To protect the drug from the gastric environment of the stomach with and acid resistant enteric coating.

TYPES OF TABLET COATING:-

1. Film coating
2. Enteric coating

- **Film Coating**: - This coating refers to the coating of tablets with a single compound or mixture of film-forming agents, such as polyethylene glycol, hydroxyl-propyl methyl cellulose, carbowax, etc. solvent and sprinkled on tablets around a cover pan. The process continues until the same fine film is formed on the tablets
- **Enteric Coating:** - The Enteric coating is given pills to protect the tablet from the breakdown of acid in the stomach but release the drug very quickly and completely when the tablet passes through the intestines or in an alkaline environment. The enteric insertion process consists of water-testing tablets by coating with shellac in a cover pan and enteric coating materials are added to the rotating tablet to form and form an enteric coating. The separation time for enteric tablets is directly proportional to the size of the coat. A thick coat means disintegration is required in the large intestine.

Place one tablet in six tube tubes and if the tablet has soluble outer layers, soak the basket in water at room temperature for 5 minutes. Use materials without adding dices,

use 0.1 N hydrochloric acid is an immersion liquid stored at 370 Celsius. At the end of two hours, remove the assembly from the liquid NO tablet showing signs of decay, except for pieces of cover, of cracks that may allow the contents to escape. Then insert the disk into each tube and apply the material using phosphate buffer pH 6.8 as a immersion liquid stored at 370 +/- 20C. At the end of 60 minutes remove the assembly from the liquid and check for pills.

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:

"Capsule is a robust measure in which a drug is treated in a gelatin capsule."

The capsule is used for oral drug treatment. Solid capsules are used to fill a solid object and soft capsules are used to fill liquids and semisolids.

Benefits: -

Capsules are tasteless, odourless and can be easily treated. They are attractive in appearance.

The drug has a foul odour and taste and is packaged in a tasteless shell. Easy to manage and manage.

Disadvantages: -

Hygroscopic drug is not suitable for filling capsules. A concentrated solution that requires pre-dilution is not suitable for the pills because if they are given in this way they lead to stomach upset.

Capsule Hand Filling Machine-300 Holes

[Capsule hand filling Machine at Magbro Healthcare]

The capsule hand filling machine is made of stainless steel. In this machine empty pills are filled into a loading tray and then placed on a bed. The carcasses of the pills are sealed using a cam handle and separate cakes on a loading tray. The powder tray is filled with the correct amount of the drug and distributes the drug through a dispenser to replenish the drug bodies evenly. Excess powder is collected in place of the powder platform. Lower the pin plate to press the powder against the body. After pressure, the pin plates are raised and the remaining powder is filled into the body of the pills. Press the caps with the help of a plate above the rubber and work and use a lever and open the cap and body of the pills. The loading tray is removed and the filled tablets are placed on the tray. With a 200-hole machine, about 5000 capsules can be filled in one hour and with 300 holes, about 7500 capsules can be filled in one hour.

COOLING TRINES- It has 4 rooms; the roof is non-existent and is covered with a fabric with some pressure in each room. Pills are moulded here. In rooms 1, 2 and 3 they are rubbed over the fabric with hairy towels so that all the particles attached to the capsule are drained. In the storage room the towel is sprayed with glycerine / paraffin which in rubbing on top of the capsule creates light on it.

STEPS Involved During the Process-

Finishing

Completed and sealed capsules require finishing work before testing or packaging in 7 labels; the following steps are involved in the termination process.

Cloth Dusting

This is usually done by hand in this process individual tablets are rubbed with a cloth that may or may not contain inert oil.

Inspection

This procedure is desirable to take an incomplete capsule and damage it. Currently the test is done manually.

Packaging

The finished product is allowed to pack very wide, packed either in strip packs or in blister packs.

Capsule Store with a temperature not exceeding 300C and the moisture content in the capsule is 12 to 15%. This level should be maintained during retention. Prolonged exposure to high and low humidity can cause distortion or brittleness. Capsule should be stored in humidity at 30 to 40 percent humidity and also stored in a cool, dry place.

Weight variation in Capsule: - Weight limit less than 300 mg +/- 10%, weight over 300 mg +/- 7.5%.

Liquid Filling Phase

It is a formulation of biphasic liquid formulations consisting of solid particles (continuous phase or distribution area). As doses form suspension there are many benefits. The suspension allows for the formation of very soluble drugs that have a very low solubility in pharmaceuticals.

In addition, the suspension of non-aqueous solvent provides a useful method of drug administration that rapidly reduces the aqueous solution.

Desirable aspects of drug suspension include.

• Pour capacity and easy volume removal.

• Dispersal ready for scheduled repairs.

• Good smooth look.

• Resistance to bacterial contamination.

• Suspensions are usually adjusted using distribution methods. Shear must be used during the distribution process. This is usually achieved on a large scale using a colloidal mill.

Ointment Manufacturing Machine

https://5.imimg.com/data5/CX/EI/MY-5660997/ointment-manufacturing-plant-500x500.jpg

[Same type Ointment Manufacturing Machine utilized at Magbro Healthcare]

Types of Rejections on Ointment Line

- Leakage due to Sealing Defects
- Deformed or dented tubes
- Cutting Defects
- Discoloured tubes
- Coding on tube crimp is not clear
- Smudging of printed text matter

Packing Section

Final product comes

In packing section

⇩

Packing with blister, strips,

Aluminium foil strips

& jar packing

⇩

Packing in to cartoons

⇩

Final packing in card

Board boxes

Equipments

[Blister Packing Machine at Magbro Healthcare]

[A]. Blister packing machine-

Uncoated and coated tablets full blister packaging is made by automatic machine. Tablets are fully machined between PVC 7 aluminium foil.

The machine has four basic units

1. Blister forming units

2. Batch coding units

3. Mark units

4. Unit cutting packs

[1]. Blister forming units

It has structural rollers to separate any type of roller required as per size and shape of the tablets / tablets to be packaged can be changed to the unit. The unit is also supplied with roller rollers & vacuum system. The PVC film is heated by heating the rollers and soaking them into the lower holes of the metal structure with a vacuum system attached to the moulding roller. These gaps created in PVC film are called blister and the process is called blister form.

[2]. Batch coding units

This part of the machine has multiple rollers and an inkpot and one of the rollers can be supplied with a number of rubber stamps at the price of batch coding, mfg. Expiration date. Date in aluminium foil.

[3]. Mark units

This section consists of two single-roller folders and other sealing rollers. When the PVC film with bubbles and aluminium foil is passed b / w these two, the sealant cover is placed in foil melt & stick on the PVC film & the tablets feeded in the blister are also packed pack / the PVC film & aluminium foil.

[4]. Package cutting units

This unit is provided with separate cutters and different types of cut can be attached to the unit as packet sizes are required.

[B]. Strip packing machine

[Strip Packing Machine at Magbro Healthcare]

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.

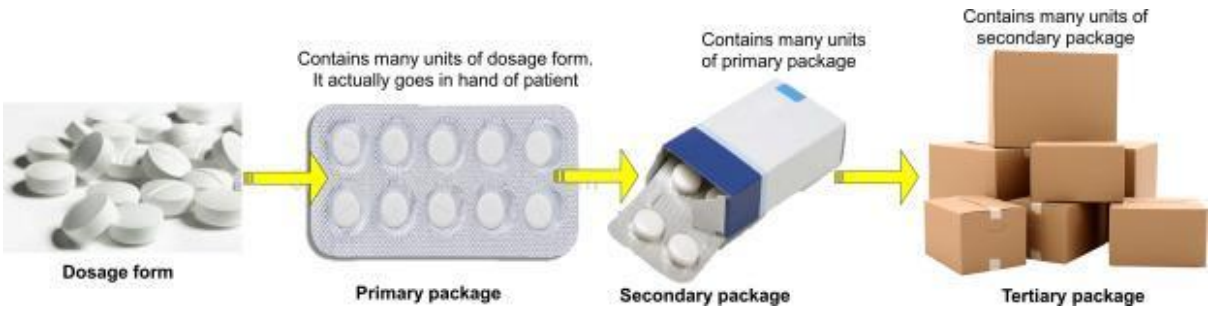
[3]. Alu- Alu Packing

Alu-Alu Packing is called as Aluminium-Aluminium Packing given to the pack of medicine with the help of heat and proper sealing at the temperature of 180-220 degree Celsius. Batch code printing, Lidding Foil, Perforation and Punching is done in next steps.

[Alu-Alu Packing Machine at Magbro Healthcare]

Packaging is mainly of two types-

Primary Packaging and Secondary Packaging



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Quality Control

Quality Control and Quality Assurance in Magbro Healthcare

Quality Control: It is the part of GMP concerned with sampling, specification and testing, documentation and release procedures which ensures that the necessary and relevant tests are performed and the product is released for use only after ascertaining its quality.

GMP: It is the part of Quality Assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use.

Quality Assurance: It is the sum total of the organized arrangements with the objective of ensuring that products will be of the quality required for their intended use.

Quality Assurance department is associated with the following responsibilities-

[1].Raw materials

Quality assurance should look at the actual content of the raw material used for cleanliness before it is taken to the production department.

The quality assurance person is responsible for the production of raw materials used in the construction of the valuation form. He checks the raw material and allows the order of the correct weight of the raw material.

Most of the raw materials are weighed in an environmentally controlled environment, where they are transferred to secondary containers that only rotate within the production department.

[2]. Manufacturing equipment

Personal quality assurance should ensure that the product is designed, stored and stored for easy cleaning should its intended use and minimize contamination during production, equipment and equipment should be thoroughly cleaned and maintained according to written instructions, adequate records of these processes and inspections should be considered is an individual in quality assurance.

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

Only raw materials with a green label are allowed in the repair area, depending on the type of product. Personal quality assurance should be checked and verified that the temperature and humidity in the area are within the required range of the product, if the temperature and humidity exceed the limits, the production pharmacist must be notified and remedial action taken.

The specific procedure must be evaluated at each step of the process in accordance with the written procedure of the certification process. Specific Samples Samples should be taken to a quality control laboratory for potency testing and any other tests required to ensure uniformity.

[4]. Compounding

The current best production methods require that the process be sufficiently validated at all production stages throughout the process of process-driven production is deleted and tested and the data is recorded in special forms as described in the monograph used products.

If deviations from the specified limits occur, the necessary corrective action is taken and assessed to determine whether the quality of the product is now within the limits.

[5].Packing material control

Quality assurance self-examination and verification of all packaging materials and equipment that will be used for packaging work to ensure that it has the correct identification using the parameter gram per square meter (GSM)

Inspection of packaging material is done by the quality assurance officer in the store who issued the need for packaging materials in the store.

[6] .Finished Product Control

The final test of the finished product was performed in a quality control laboratory. These tests are designed to determine compliance with specific details. Completion testing is therefore compliant with pre-determined standards prior to the release of the packaging product and subsequent distribution is a critical factor in quality assurance. This testing and process evaluation ensures that each unit contains the number of drugs included in the label, that each drug in each unit is available in full advertising, that the drug is stable in the formulation of its final container closure shelf life expectancy.

[7] Quality Assurance during packaging operation

If quality control laboratory analysis ensures that the product is compliant with quality and quality testing that ensures production operations.

Quality assurance personal should periodically inspect the packaging lines and should check filled and labelled containers for compliance with written specification.

Quality assurance should perform an independent inspection and select finished preservation samples should consists of at least twice the quality necessary to perform all tests required to determine whether the product meets its established specification. These preservation samples should be retained for at least one year after the expiration date and should be stored their original package under conditions consists with product labelling.

Quality Control Work (Summary)

Sampling of API's, Excipients, finished products and packing material etc.

- API Testing (Active Medicinal Ingredients)
- Recipient Testing
- Examination of the sample process
- Testing of Finished Products
- Packaging material testing
- Completion studies of finished products
- Storage and measurement of instruments
- Discovery of Chemicals and Glassware's
- Reference level detection
- Acquisition retention of microbiological test sets
- Doing a COA (Certificate of Analysis)
- Studying product complaints
- Destroy the control sample after six months of the Expiration Date

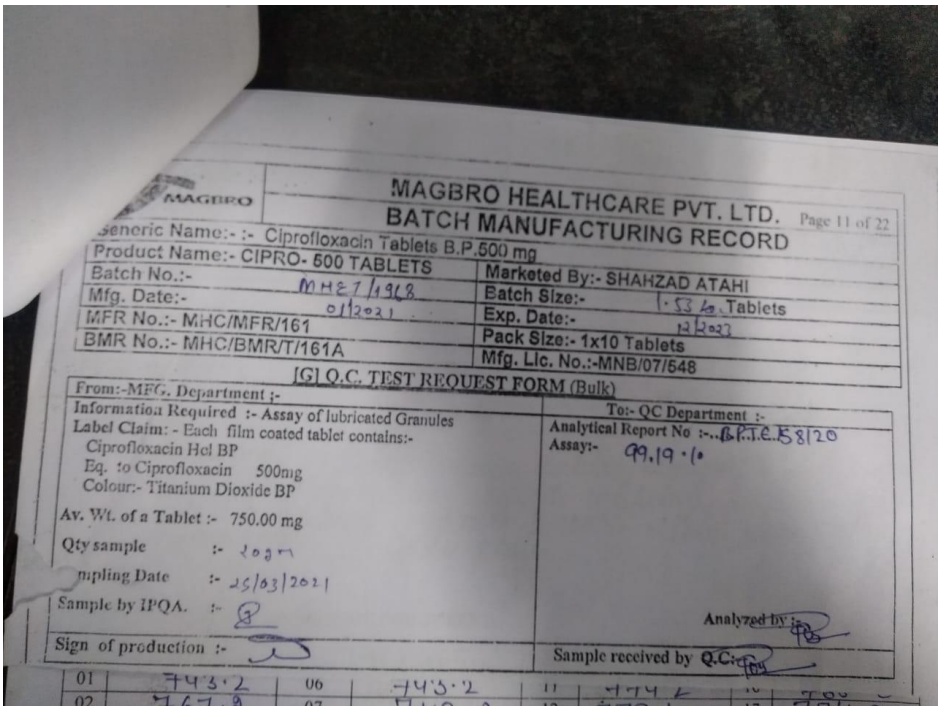
Quality Control Department

1. Quality Control Sampling Section

Responsibilities:-

- Drawing a Raw Material sample in the store
- Drawing samples of F.G. from the production stage
- Maintaining a control sample for indicators and learning intensity
- Final test for each collection
- Look at the physical parameters of the tablet or tablets

Example of Cipro -500 B.P. mg Physical Parameters



MAGBRO HEALTHCARE PVT. LTD. Page 11 of 22
BATCH MANUFACTURING RECORD

Generic Name:- :- Ciprofloxacin Tablets B.P.500 mg
Product Name:- CIPRO- 500 TABLETS
Batch No.:- MHC7/1963
Mfg. Date:- 01/2021
MFR No.:- MHC/MFR/161
BMR No.:- MHC/BMR/T/161A
Marketed By:- SHAHZAD ATAHI
Batch Size:- 1.53 Lac Tablets
Exp. Date:- 12/2023
Pack Size:- 1x10 Tablets
Mfg. Lic. No.:-MNB/07/548

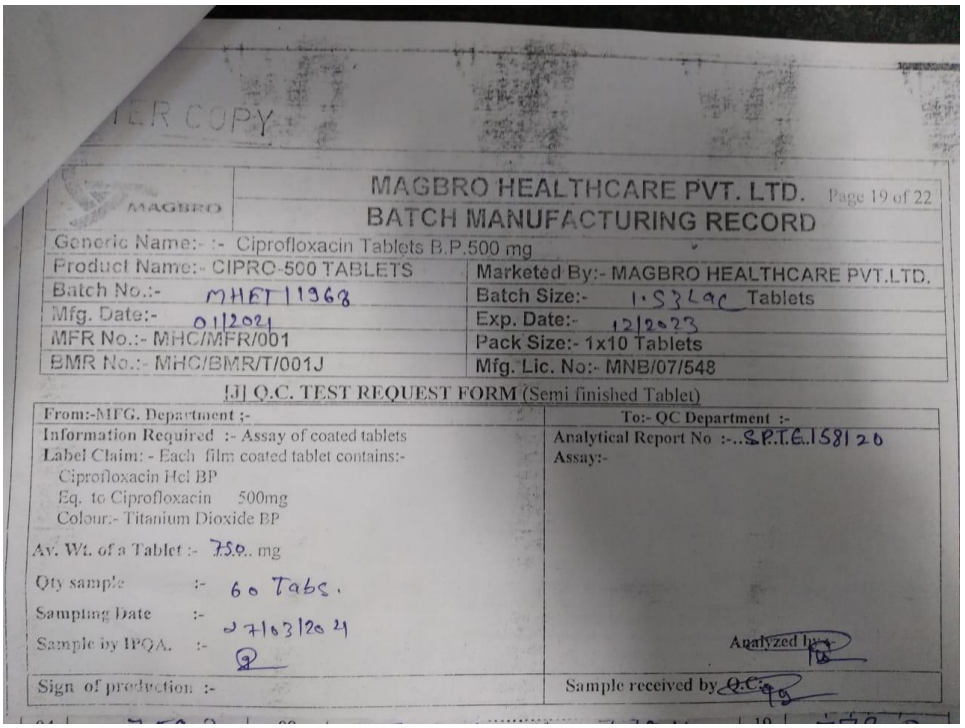
[G] Q.C. TEST REQUEST FORM (Bulk)

From:-MFG. Department :-
Information Required :- Assay of lubricated Granules
Label Claim: - Each film coated tablet contains:-
Ciprofloxacin Hcl BP
Eq. to Ciprofloxacin 500mg
Colour:- Titanium Dioxide BP
Av. Wt. of a Tablet :- 750.00 mg
Qty sample :- 100gm
mpling Date :- 25/03/2021
Sample by IPQA. :-
Sign of production :-

To:- QC Department :-
Analytical Report No :- B.P.C.58/20
Assay:- 99.19 %
Analyzed by :-
Sample received by Q.C:-

01 743.2 06 743.2 11 744

[redacted]



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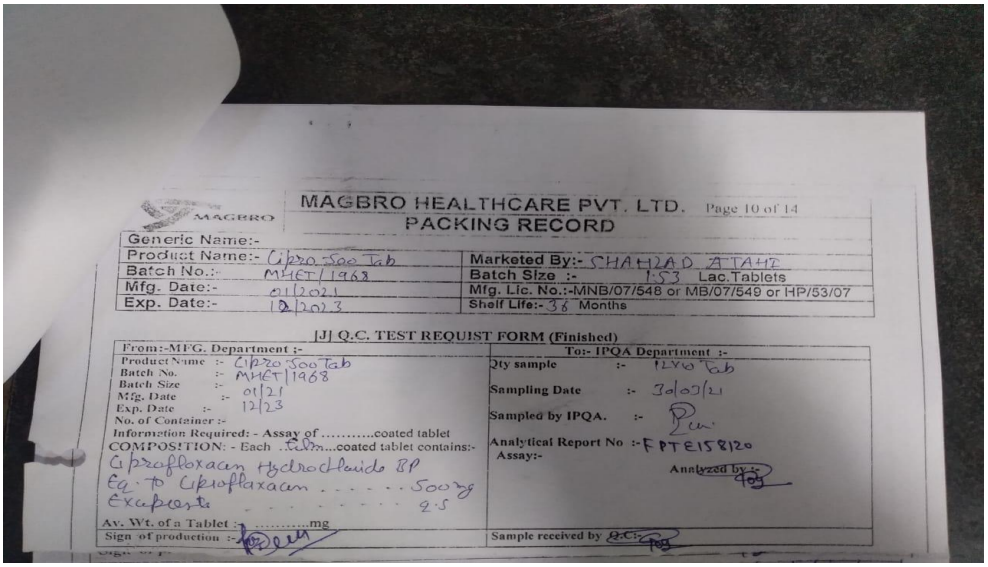
MAGBRO HEALTHCARE PVT. LTD. Page 19 of 22
BATCH MANUFACTURING RECORD

Generic Name:- :- Ciprofloxacin Tablets B.P.500 mg	
Product Name:- CIPRO-500 TABLETS	Marketed By:- MAGBRO HEALTHCARE PVT.LTD.
Batch No.:- MHET/1968	Batch Size:- 1.53 Lac Tablets
Mfg. Date:- 01/2021	Exp. Date:- 12/2023
MFR No.:- MHC/MFR/001	Pack Size:- 1x10 Tablets
BMR No.:- MHC/BMR/T/001J	Mfg. Lic. No:- MNB/07/548

JJ Q.C. TEST REQUEST FORM (Semi finished Tablet)

From:-MFG. Department ;-	To:- QC Department :-
Information Required :- Assay of coated tablets Label Claim: - Each film coated tablet contains:- Ciprofloxacin Hcl BP Eq. to Ciprofloxacin 500mg Colour:- Titanium Dioxide BP Av. Wt. of a Tablet :- 750.. mg Qty sample :- 60 Tabs. Sampling Date :- 27/03/2021 Sample by IPQA. :-	Analytical Report No :- SPTE158120 Assay:- Analyzed by:
Sign of production :-	Sample received by Q.C:

[redacted]



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MAGBRO HEALTHCARE PVT. LTD. Page 10 of 14
PACKING RECORD

Generic Name:-	
Product Name:- Cipro 500 Tab	Marketed By:- SHAHZAD ATAR
Batch No.:- MHET/1968	Batch Size :- 1.53 Lac.Tablets
Mfg. Date:- 01/2021	Mfg. Lic. No.:-MNB/07/548 or MB/07/549 or HP/53/07
Exp. Date:- 12/2023	Shelf Life:- 36 Months

JJ Q.C. TEST REQUIST FORM (Finished)

From:-MFG. Department ;-	To:- IPQA Department :-
Product Name :- Cipro 500 Tab Batch No. :- MHET/1968 Batch Size :- Mfg. Date :- 01/21 Exp. Date :- 12/23 No. of Container :- Information Required: - Assay of .....coated tablet COMPOSITION: - Each tablet contains:- Ciprofloxacin Hydrochloride BP Eq. to Ciprofloxacin ..... 500mg Excipients ..... q.s Av. Wt. of a Tablet :- .....mg	Qty sample :- 1210 Tab Sampling Date :- 30/03/21 Sampled by IPQA. :- Analytical Report No :- FPTE158120 Assay:- Analyzed by:
Sign of production :-	Sample received by Q.C:

[redacted]

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ISSUED BY

MAGBRO HEALTHCARE PVT. LTD. NALAGARH

CUMENT	TEST DATA SHEET (TABLET)
PRODUCT NAME	Cipro-500 Tablets

Generic Name	Ciprofloxacin Tablets B.P 500 mg.				
B. No.	MHET/1968	Mfg date		Exp date	
B.size	1.53 Lac	Stage	Finish	Qty. Sampled	
Sampled on		Date of Analysis		Date of Approval	

(1) DESCRIPTION: White colour tablet, elongated, Biconvex film coated tablets, having one side central break line and other side plain.

(2) IDENTIFICATION:

(3) UNIFORMITY OF WEIGHT FOR TABLET:

Limit (.....to.....)

S.No.	Wt. of tablet in mg	S.No.	Wt. of tablet in mg	S.No.	Wt. of tablet in mg	S.No.	Wt. of tablet in mg
01	743.2	06	743.2	11	774.2	16	768.0
02	767.2	07	743.2	12	773.4	17	774.2
03	759.2	08	768.6	13	760.3	18	779.4
04	759.2	09	768.0	14	779.4	19	773.0
05	773.4	10	773.4	15	773.4	20	743.2

Weight of 20 Tablets: 15202.8 mg

Avg wt of Tablet: 760.1 mg

Min 743.2 mg −2.22% Max 779.4mg 2.53%

Complies/ Does Not Complies

(4) HARDNESS:

Limit (.....)

Hardness of individual tablets Kg/ cm2									
01		02		03		04		05	
06		07		08		09		10	

Avg..... Min..... Max.....

Complies/ Does Not Complies

(5) THICKNESS:

Limit (.....to.....)

Thickness of individual tablets in mm									
01	5.35	02	5.34	03	5.36	04	5.34	05	5.36
06	5.36	07	5.34	08	5.34	09	5.34	10	5.35

Avg 5.35mm Min 5.34mm Max 5.39mm

Complies/ Does Not Complies

Form no.: QC0014-F02 -06

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MAGBRO

MAGBRO HEALTHCARE PVT. LTD. NALAGARH

ISSUED BY Q.A.

DOCUMENT	TEST DATA SHEET (TABLET)
PRODUCT NAME	Cipro - 500 Tablets

(6) DIAMETER / LENGTH :

Limit (.....to.....)

Diameter / Length of individual tablets in mm									
01	17.60	02	17.62	03	17.60	04	17.61	05	17.62
06	17.60	07	17.61	08	17.59	09	17.61	10	17.59

Avg. 17.60 mm Min. 17.59 mm Max. 17.62 mm.

Complies/ Does Not Complies

(7) WIDTH:

Limit (.....to.....)

Width of individual tablets in mm									
01	8.56	02	8.56	03	8.58	04	8.56	05	8.56
06	8.55	07	8.59	08	8.57	09	8.55	10	8.56

Avg. 8.56 mm Min. 8.55 mm Max. 8.59 mm.

Complies/ Does Not Complies

(8) DISINTEGRATION TEST :

Limit (NMT 2 min)

Observation.....05..min. 10 Sec.

Complies/ ~~Does Not Complies~~

(9) FRIABILITY TEST :

Wt. of 20 tablets before revolutions (W_1) :

Wt. of tablets after 100 revolutions (W_2) :

Friability : $\frac{W_1 - W_2}{W_1} \times 100$

Observation..... %.

Complies/ Does Not Complies

ANALYSED BY		**DATE**	
CHECKED BY		**DATE**	

2. Quality Control Chemical Section

Responsibilities:-

- Comprehensive analysis of the entire RM process to a set standard
- Posting a report to a manufacturer, store, QC Office
- Performing strength tests
- Metal storage and completing measurement records

3. Quality Control Microbiology Section

Responsibilities:-

- Microbiological analysis of RM process
- Posting a report on production
- Asset quality inspection quality control
- Performing strength tests

4. Quality Control Office

Responsibilities:-

1. To make Certificate of Analysis of Raw Material and of Finished Products
2. To maintain and keep records of analysis and Certificate of analysis

Example of COA of Cipro-500 mg Tablets-

MAGBRO HEALTHCARE PVT. LTD. NALAGARH

Vill- Mehsa Tibba, P.O- Manjholi, Teh – Nalagarh, Distt. Solan (H.P.)-174101

FINISH PRODUCT CERTIFICATE OF ANALYSIS

PRODUCT NAME	CIPRO-500 TABLETS	A.R.No.	FPTE158120
BATCH No.	MHET/1968	MFG. DATE	01/2021
BATCH SIZE	1,53,000 Tablets	EXP. DATE	12/2023
DATE OF SAMPLING	30/03/2021	DATE OF ANALYSIS	30/03/2021
SAMPLE QTY.	12X 10 Tablets	DATE OF RELEASE	31/03/2021

TEST	SPECIFICATION	RESULT
DESCRIPTION	White coloured, elongated shaped, biconvex film coated tablets having one side central breakline & other side plain.	White coloured, elongated shaped, biconvex film coated tablets having one side central breakline & other side plain.
IDENTIFICATION	Ciprofloxacin Hydrochloride BP	Complies
AVERAGE WEIGHT	767 mg ± 5 %	760.18 mg
HARDNESS	NLT 3.0 Kg/cm²	5.00 kg/cm²
UNIFORMITY OF WEIGHT	Avg. wt. ± 5 %	-2.22 % to +2.53 %
DISINTEGRATION TIME	NMT- 30 Min	05 min. 10 sec.
DISSOLUTION	NLT 80 %	90.65 %
RELEATED SUBSTANCES Impurity C Impurity E The area of any secondary Peak The sum of the areas of all the secondary peak Disregard Peak	 NMT 0.5 % NMT 0.3 % NMT 0.2 % NMT 0.5 % NMT 0.05 %	 0.16 % 0.081 % Not detected 0.22 % Not detected

ASSAY: (Each film coated tablet contains)	**Claim**	**Obtained**	**%**	**Limit**
Ciprofloxacin Hydrochloride BP Eq.to Ciprofloxacin	500 mg	495.95 mg	99.19 %	95 % - 105 %

REMARK: The finish product **complies/ ~~does not comply~~** as the prescribed standard quality as per **B.P** specifications.

	Prepared By	Checked By	Approved By
Name			
Signature			
Date	31/03/2021	31/03/2021	31/03/2021

Quality Control Instruments-

Test tubes, boiling tube, pipette, funnel, beaker, burette, funnel separating these are made of borosil glass. Pipes are available in a capacity of 1-50ml and are both standard and transferable. Ammonia cleaning tools for cleaning, boiling equipment are available. Dividing slums range from 250-500 ml. silica grease is applied to its dots before use.

[1]. P^H meter

The pH measurement is usually made with a suitable potentiometer known as a pH meter consisting of two single electrodes composed of glass and sensitive to the activity of hydrogen ion and the other electrode of the calomel reference. Determination is carried out at a temperature of 25 degree C, unless otherwise specified in each case.

- Use the pH meter by measuring the apparatus whose measurement is done using the pH 4 solutions for the first time as a primary level, adjusting the meter and reading the correct pH value.
- Use the second pH solution 9.2 to measure and measure the pH meter using the third pH solution at a level between 7 and adjust the meter reading by setting the scale.
- The above meter is rated where the reading should not exceed a pH unit of 0.05 than the value corresponding to each solution.
- Now remove the electrode from the solution to be tested and measure the pH at the same temperature after taking the study and wash the glass electrode with mineral water and rinse with tissue paper and put it in a container with mineral water.

[2]. Melting point apparatus

This apparatus is used for determination of melting range or temperature.

- These containers contain a suitable construction glass boat and a volume containing one in a simple liquid or other suitable liquid for a bath up to a height of not less than 14 cm.
- Proper range of silicon liquid at temperatures up to 300^{o}C (this liquid is already stored in XL-lab equipment).
- Liquid paraffin at a sufficient temperature of up to 250^{o}C.
- Glycerine heats up to 150^{o}C.

Procedure

Melt the equipment to be tested by keeping it in a tube and start the equipment by adjusting the temperature difference controller and shift switch and see the melting of the object or its decay in metal lenses or by directly adjusting the light intensity using a rigid handle and record reading.

[3] Polarimeter-

It is a trading tool designed to determine optical rotation with a defined optical solution for use with a sodium lamp and capable of providing readings of the nearest 0.02o suitable for many purposes.

Procedure

• First measure the resources using a previous dry sucrose solution and measure the apparent rotation on a 2-dm tube at 25^{o}c.

Concentration (G/l 100ml)	**Angle of rotation (+) at 25^{o}c**
10.0	13.33
20.0	26.61
50.0	66.23

- Accurately measure the value of the object being tested to provide a resolution of the energy specified in the monograph and then transfer to a volumetric film using water or another solvent if specified.
- When solvent is used only part of it is obtained to obtain a pure consistency.
- Make a volume and solvent at 25oc and mix well. Transfer the solution to a polarimeter tube within 30 minutes from the time the object is dissolved and during this interval keep the solution at 25oc.
- Find the zero point of the polarimeter and do at least five readings of the observed solution of the test solution at 25oc and then subtract the equivalent no. of learning in the same tube as the solvent (empty) instead of the test solution.
- Now empty reading has been removed from the standard resolution shown, this will provide the correct visual rotation.

[4].Ultra- Violet & visible spectrophotometer

This tool is used to analyze raw materials and finished products to calculate its percentage purity.

Description

This technique is based on the principle that when the radiation is transmitted by a layer of solution that contains and absorbs an object, part of the radiation is absorbed; the intensity of the radiation emanating from the solution is less than the intensity of the radiation entering it. This absorption magnitude is defined by extraction and is used to calculate the purity percentage of the sample product.

This extinction is based on the concern of the object absorbing solution and the size of the absorbing layer taken by the scale, usually for calculation purposes, the end of the 1% w / v solution is accepted over IP.

Procedure

- The instrument is usually calibrated by using Holmium per chlorate solution.
- The test substance is usually dissolved in the solvent and its mixing is done according to the required samples (usually 50mg) are taken and the mixing is done based on the desired mcg of solute.
- Now make an empty determination using the solvent where the solution is made.
- Adjust the duration of the energy can be UV or visually according to each monograph and record the test and standard detection readings and calculate its purity of%.

[5].Dissolution apparatus (USP standards)

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

[6].Disintegration test apparatus

[Disintegration Test Apparatus at Magbro Healthcare]

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

Type of tablets	Disintegration Time
Coated tablet	**30 Min.**
Uncoated tablet	**15 min.**
Dispersible tablet	**3 Min.**
Enteric Coated tablet	**2 hour**
Effervescent tablet	**30 Sec.**

[7].Hardness tester

Monsanto hardness tester is used to measure tablet hardness. Hardship is the main factor that creates separation and termination.

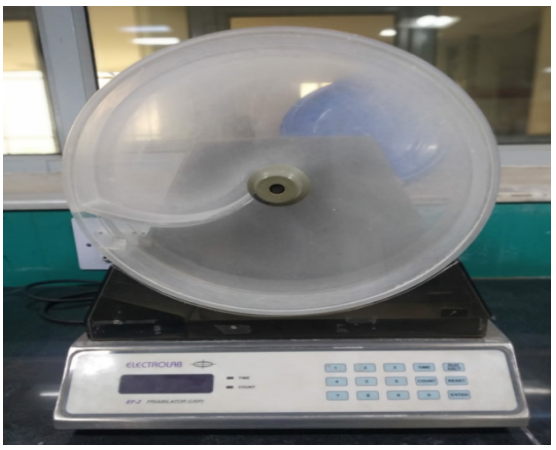
[8].Friability test apparatus (USP standard)

This tool is used to measure the softness of pressed tablets. This test is done by knowing the amount of loss of the tablet during the transport and packaging dispute or during the production process. This procedure is used to determine the body strength of a drug with a constant weight of 6.5g.

Maximum Loss of weight is not greater than 1% is acceptable.

The Friability of a tablet is not more or less than 10% of the actual weight.

$$\%\text{Weight Loss} = \frac{\text{Initial Weight of Medicine} - \text{Final Weight of Medicine}}{\text{Initial Weight of Medicine}} \times 100$$



[Friability Test Apparatus at Magbro Healthcare]

[9]. Electronic balance

It is most widely and accurate weighing instrument used for weighing of the materials.

[10].Magnetic stirrer

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

[12].Muffle furnace

It has a metal body where ¾ ft. Thickness tied with silica bricks and glass wool can heat up to 1000oc. it has room temperature and fine set and temperature increase control.

[13].Hot air oven

This apparatus is used for drying purposes and used for the sterilization purposes.

[14].Hot plate

This is used for the heating purposes.

[15].UV cabinet

This instrument is used for detection and observation of TLC plates at short (254mm), long (366mm) and ultra- violet wavelengths.

[16]. HPLC (High Performance Liquid Chromatography)

HPLC is used to identify and quantify the conc. of the compound, the more concentration it is the more signal it will give to the Detector.

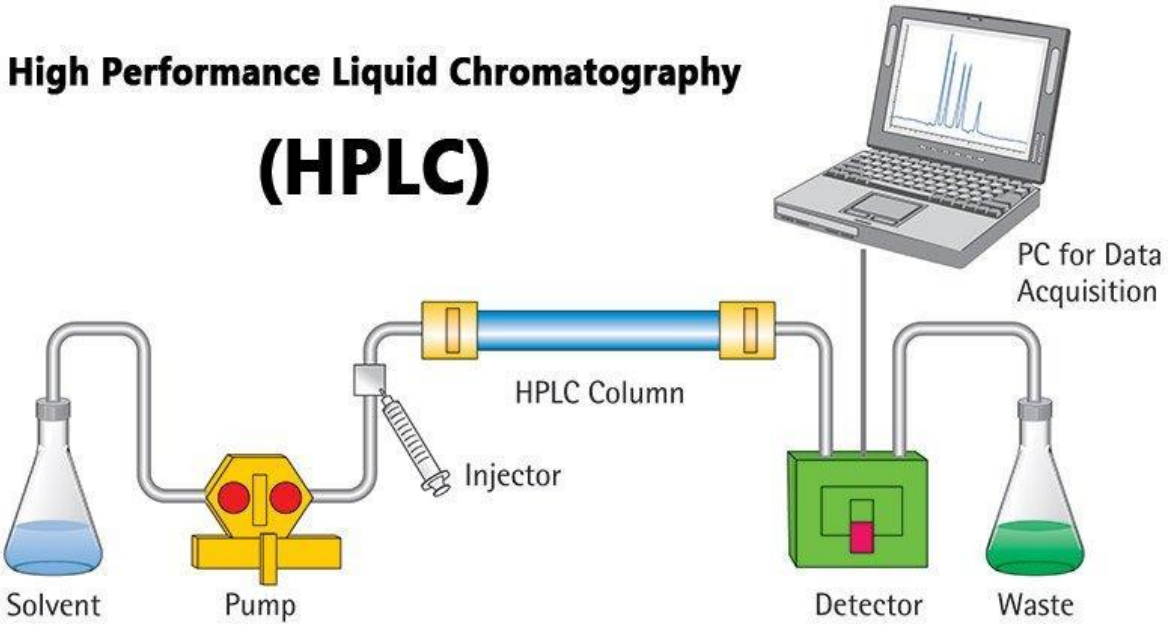
Working

1. The dam contains a cell / solvent cell.
2. A high pressure pump is used to produce the flow of solvent-millimetres.
3. An injection is used to inject a sample where the mobile section broadcasts and goes to the HPLC column.
4. A standing category exists in the HPLC column and a split occurs in that column.
5. After that, the detector is used or required to detect the combined strips as they come out of the HPLC column because most of the chemicals are naturally coloured.
6. Then the garbage of the mobile section enters the dump room and uses a separated clean mixture to read further by collecting the purified fraction of the compound. This is called preparatory chromatography,
7. A high pressure tube is used for communication between systems.
8. The computer data channel is then connected to the detector to record the electrical signal required to produce a chromatogram to identify the concert. Sample conc.
9. The flow remains from left to right in the HPLC.
10. Dye belts go differently so it is easy to separate them chromatographically.
11. Sensors are present to separate the compound.
12. Each height symbolizes a different compound detector response.
13. A chromatogram is organized by a computer data channel.
14. HPLC column platforms must be free of charge and must be made of stainless steel or Peek TM (technically crafted plastic), or glass.

Magbro Healthcare- 2 HPLC Systems are there

1 is Manual HPLC by Agilent Technology

2nd one is Automatic HPLC by Lab Solutions



https://microbenotes.com/wp-content/uploads/2018/10/High-Performance-Liquid-Chromatography-HPLC.jpg

Preparation of Volumetric Solutions

Some Examples-

1. **0.1M Sodium Thiosulfate**

25g Sodium Thiosulfate + 200mg mg Sodium Carbonate – Dissolve in 1000ml Distilled Water

Standardization-

200mg Potassium Bromate + 250ml Distilled Water – {Remove} 50ml Solution +add 2g Potassium Iodide + Add 3ml {2M} HCL+ Add Starch-Titration = Blue Colour Discharge

2. **0.1M Silver Nitrate**

100mg Sodium Chloride +5ml Water + 5ml Conc. Acetic Acid + 50ml methanol + Eosin Solution (indicator 1-2 Drops) –Titration = Pink Colour Discharge

3. **0.01M EDTA**

150mg Anhydrous Sodium Carbonate + 100ml Water + Methyl red Indicator= Faint Pink colour will produce

4. **1ml HCL**

1.5gm Anhydrous Sodium Carbonate + 100ml Water + Methyl Red Indicator= Pink Colour Discharge

5. **0.05M Iodine**

0.15g Arsenic trioxide + 20ml {1M} NaOH +40ml Water +Indicator (Methyl Orange Solution) +Add Drop wise HCL =Yellow colour Discharge

These are some examples of Volumetric Solutions, we prepare in the lab of Magbro Healthcare.

Conclusion

Magbro Healthcare helped me to imbibe the detailed information about the production section, packaging section, QA Section and the QC Section.

This industrial training provided a valuable learning experience in the carrier exploration process and gave us unexpected benefit. Now I have evaluated the class room taught facts and ideas and applied them to the real life situation. We came to know about many things such as the Good Manufacturing Process, the Current Good Manufacturing Process and the basic laboratory requirement of product validation, the variety of machine used in the large scale industries of medicine etc.

I would like to conclude by saying that these factors enhanced my knowledge and have created a lifelong interest to learning through an exposure to new educational experience.

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[3] A. G. Long and R. L. Williams, "The United States Pharmacopeia Senior Vice President, Global Alliances and Organizational Affairs INTERNATIONAL MEETING OF WORLD PHARMACOPOEIAS."