#### A STUDY ON THE MANUFACTURING OF INJECTABLES

Report on Internship Training submitted to Periyar University, Salem in partial fulfilment of requirement for the award of the degree of

#### **BACHELOR OF CHEMISTRY**

Submitted by

NAME: BHAVATARINI.R

**REG.NO: C21UG152CHE007** 

Under the Supervision of

Mr.Manjunath

Mylan Laboratories Limited, Hosur.



# DEPARTMENT OF CHEMISTRY ST. JOSEPH'S COLLEGE OF ARTS AND SCIENCE FOR WOMEN, HOSUR (Affliated to Periyar University, Salem)



### PERIYAR UNIVERSITY

#### INTERNSHIP TRAINING REPORT

1.	Name of the Candidate	Bhavatarini.R
2.	University Examination Registration Number	C21UG152CHE007
3.	Name of the college	St.Joseph's College Of Arts And Science for Women, Hosur
4.	Name of the Department/Degree	Chemistry/B.sc.,Chemistry
5.	Name of the industry/ Institute in which for internship Training Undergone	Mylan Laboratories Limited, Hosur
6.	Guide / Supervisor under whom the training undertaken	Mr.Manjunath (Department of Human Resources)
7.	Title of the Training	Manufacturing of Injectables
8.	Brief output training (not more than 2 Pages)	Annexure Enclosed
9.	Conclusion	The Production of Injectable drugs and sterility of the product
10	. Outcome of the training	To ensure that the product manufactured

Submitted for B.Sc., Internship Examination held on 14:11:2023. at the Department of Chemistry, St.Joseph's College Of Arts And Science for Women, Hosur.

Signature of the Student

Signature of the Guide

Head of the Department

PRINCIPAL ST. JOSEPH'S COLLEGE OF AF -3 & SCIENCE FOR WOMEN

Mookandapalli, Sipcot, HOSUR: 635 126, Krishnagiri-Dist.

#### Examiner:

1.

2.



Ref: Project//HR/006

Date: 04th February 2023

#### CERTIFICATE

This is to certify that Ms. BHAVATARINI R (Reg.C21UG152CHE007), a student pursuing B.Sc - Chemistry at St. Joseph's College of Arts and Science for women, Hosur has undergone Internship Training in "Functional Departments" from 23<sup>rd</sup> January 2023 to 04<sup>th</sup> February 2023 in our organization under the guidance of Mr. Manjunathan Sundaramoorthy.

We wish all the very best for her future endeavors.

For Mylan Laboratories Limited, Hosur

Palanikumar P

DGM - Human Relations

# INTRODUCTION:-

During the duration of January , I had a privilege of embarking on an enriching journey as an Intern at MYLAN Laboratories Limited. This Internship served as a pivotal opportunity for me to bridge the academic knowledge, as well as to gain valuable insights into the MYLAN sector. I have learned about the Production of Injectable manufacturing process and Vial fillings. MYLAN, a new global healthcare company committed to empowering people to live healthier at every stage of life. MYLAN was the first company to receive FDA approval of Ogivri , a bio similar to herceptin (trastuzumab), in late 2017 and has continued to obtain regulatory approvals for bio similar trastuzumab in nearly 30 additional countries around the world.

## ABSTRACT:-

The various pharmaceutics and medical related products are being produced in the company. I have learned about the Injectable manufacturing process and Vial fillings, which is to be their main Production. The staffs working there were entirely altruistic and they don't hesitate to teach us about the company.

- I had given an Internship program for 15 days. They have given the demonstration on the Production of Injectable manufacturing and Vial fillings. They have elucidated us very well.
- Each and every stage of manufacturing process and Vial fillings process explained in a proper manner.

#### **METHODOLOGY:-**

#### **PRODUCTION**

The visitors are not allowed, only highly sanitized and accessed people are allowed inside the aseptic area with safety suits. The Aseptic Area temperature is -16 degree Celsius.

The process of Vial, the first step is to wash the Vial and step up to drying, then move on to hot zone and cool zone. The product used in Vial washing is **TRIAMCINALONE ACETONIDE IYECTABLE**, the suspension USP is about (40mg/ml) 10ml. Vials are inspected by **ILLUMINATING LIGHT** to check whether there is a breakage or micro organisms present. If there is a breakage the vials are rejected and send to destruction area. To shift the bottles they use pass box in that there is a disinfectant namely NOVASAE. Terminal sterilization is used to avoid contaminated organisms.

TERMINAL STERILIZATION: Contamination, Burning Bacteria with full heat (Steam). Terminal sterilization (TS)- Yellow Label. Inspection – Blue Label.

#### DISCUSSION:-

# **QUALITY ASSURANCE (QA):**

Quality Assurance is an important part of Pharmaceutical manufacturing. It assures the quality of the products those are manufactured in manufacturing facility. Final release or

rejection of every batch of Drug products for distribution and sale. Stability testing and evaluation of shelf-life of products.

# QUALITY CONTROL (QC):

The main responsibility of this department is to ensure the quality of the product which is the Degree of Excellence for Use.Qc in which they prepare chemicals for drugs.bulk orders are made in this department. documentation are maintained in QC.verification of micro organisms.

Particulate matter is defined as unwanted mobile insoluble matter other than gas bubble present in the product. If the particle size of foreign matter is larger than the size of R.B.C. It can block the blood vessel.

## WARE HOUSE:

The department where the raw materials and finished products are kept safely. Vails, steel, ampoules, filters, sanitizer, cleaning agents, gloves, metals, etc. Hel are kept in Consumable room. Then the department of QC will analysis. After the analyzation of QC department the products are send to Quarantine Area. After Qurantine the products are send to Approved area. Finished Goods are in White colour.

Yellow colour – Under Quarantined Green colour – Approved. Cold room approved 2 degree Celsius to 8 degree Celsius Hot Spot – CABINET

#### PACKING AND LABELLING:

LABELLING: The label should state: Name of the preparation- Quantity of the preparation Manufacturing licensing number-Batch number-Date of manufacturing- Date of expiry-Storage condition-Retail price-Manufacturing address-Printed label storage room. To label locker and print labels (for product labeling. Some materials should be maintained in the cool temperatures . Maintained -5 degree Celsius.

PACKING: Packing is enclosing or protecting products for distribution, storage, sale, and use. After that completion of labeling the secondary packing is carried by respective department. After packing the products are stored in the warchousing for sale.

# **CONCLUSION:-**

Through internship training at MYLAN Hosur a clear knowledge has been obtained about the various stages involved in the manufacturing types of injectable and drugs filling. It was indeed a very exciting and a interesting training to attend. I have developed a lot of practical knowledge during the process of training which would definitely help me in the future aspects and my career.

# A STUDY ON THE MANUFACTURING OF INJEC TABLES

Report on internship training submitted to periyar uiversity,salem in partial ful fillment of requirements for the award of the degree of

#### BACHELOR OF CHEMISTRY

Submitted by

NAME: BRINDHA.M

REG.NO:C21UG152CHE008

Under the supervision of

Mr.MANJUNATH

**MYLAN, HOSUR** 



#### **DEPARTMENT OF CHEMISTRY**

ST.JOSEPH'S COLLEGE OF ARTS AND SCIENCE FOR WOMEN, HOSUR

(Affliated to periyar university, Salem)

# PERIYAR UNIVERSITY

## INTERNSHIP TRAINING REPORT

1.	Name of the Candidate	Brindha M
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4.	Name of the Department/Degree	Chemistry/ B.Sc., chemistry
5.	Name of the industry/ Institute in which for internship Training Undergone	Mylan, Hosur
6.	Guide / Supervisor under whom the training undertaken	Mr.Manjunath
7.	Title of the Training	Manufacturing Of Injectables
8.	Brief output training (not more than 2 Pages)	Annexure Enclosed
9.	Conclusion	Enclosed
10	Outcome of the training	To ensure that a product manufactured met the specification

Submitted for B.Sc., Internship Examination held on !!!!!! at the Department of chemistry, St. Joseph's College Of Arts and Science for Women, Hosur

Brindha M Signature of the Student Examiner

Signature of the Guide

Head of the

Department

PRINCIPAL ST. JOSEPH'S COLLEGE OF ARTS & SCIENCE FOR WOMEN Mookandapalli, Sipcot,

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Ref Project HR 009 Date 04th February 2023

#### CERTIFICATE

This is to certify that Ms. BRINDHA M (Reg.C21UG152CHF008), a student pursuing B Se. Chemistry at St. Joseph's College of Arts and Science for women. Hosur has undergone Internship Training in "Functional Departments" from 23<sup>rd</sup> January 2023 to 04th February 2023 in our organization under the guidance of Mi Manjunathan Sundaramoorthy.

We wish all the very best for her future endeavors

For Mylan Laboratories Limited, Hosur

Palanikumar P

DGM - Human Relations

Prindle M

# Manufacturing of Injectables

# INTRODUCTION :-

There I have learned the manufacturing process of injectables and vial fillings.mylan has a growing commercial presence domestically the current franchise includes critical.hepto,HIV,onco care and women's health care.

# ABSTRACT

MYLAN is now the part of VIATRIS, a new global healthcare company committed to empowering people to live healthier at every stage of life.

VIATRIS:VIA - to three,TRIS - Critical goals

- 1. Expanding access to Medicines.
- 2. Leading by innovating to meet patient needs.
- 3. Being trusted partner for the healthcare community Worldwide.
  - The manufacturing unit and other places were maintained with good care. The
    faculties and staffs working there were so kind and they teach us when asked
    about their process and products and other information regarding the production
    and the company
  - We were undergone internship program for 2 weeks they give a detailed information about vial fillings and injectables.

## METHODOLOGY

## PRODUCTION:

ASEPTIC AREA: The visitors are not allowed, only highly sanitized and accessed people are allowed inside the aseptic area with safety suits. The Aseptic Area temperature is -16 degree Celsius.

AUTO CLAVE AREA: Machine Parts, Vessels, Garments, Primary Dress – White Dress, Secondary Dress vial bottle fillings -washing the vial in filter water and dry the bottle.ss trays which they collect the vial bottle and sent to washing area. In washing area there are 2 zones hot and cool zone which they maintain temperature for Vials bottel washing. Vials are inspected by ILLUMINATING LIGHT to check whether there is a breakage or micro organisms. If there is a breakage the vials are rejected and send to destruction area. To shift the bottles they use pass box in that there is a disinfectant namely NOVASAE. Terrminal sterilization is used to avoid contaminated organisms TERMINAL STERILIZATION: Contamination, Burning Bacteria with full heat (Steam).

Terminal sterilization (TS)- Yellow Label, Inspection-Blue label.

# DISCUSSION

QUALITY ASSURANCE (QA): Quality Assurance is an important part of Pharmaceutical manufacturing. It assures the quality of the products those are manufactured in manufacturing facility. Final release or rejection of every batch of Drug products for distribution and sale. Stability testing and evaluation of shelf-life of products.

QUALITY CONTROL (QC): The main responsibility of this department is to ensure the quality of the product which is the Degree of Excellence for Use.Qc in which they prepare chemicals for drugs.bulk orders are made in this department . documentation are maintained in QC.verification of micro organisms.

WARE HOUSE: The department where the raw materials and finished products are kept safely. Vails, steel, ampoules, filters, sanitizer, cleaning agents, gloves, metals, etc Hcl are kept in Consumable room. Then the department of QC will analysis. After the analyzation of QC department the products are send to Quarantine Area. After Quarantine the products are send to Approved area. Finished Goods are in White colour.

ENGINEERING DEPARTMENT: TNEB – Tamil Nadu Electricity Board supplies the current to the process held inside the company. Engineering department produces the WFI (Water For Injection) which is used for washing the vials and ampoules. There are alarms of 3 Gates to Assemble in case of a Fire accident or Emergency (Main gate, Gate 2, Gate 3). Nitrogen is filled inside the vial where the drugs are inside because the Nitrogen Gas does not react with any drugs placed in the vial.

LABELLING: The label should state:Name of the preparation- Quantity of the preparationManufacturing licensing number-Batch number-Date of manufacturing- Date of expiry-Storage condition-Retail price-Manufacturing address-Printed label storage room. To label locker and print labels (for product labeling.Some materials should be maintained in the cool temperatures. Maintance – 5 degree Celsius.

PACKING: Packing is enclosing or protecting products for distribution, storage, sale, and use. After that completion of labeling the secondary packing is carried by respective department. After packing the products are stored in the warehousing for sale.

## CONCLUSION

Through internship training at MYLAN, Hosur a clear knowledge has been obtained about the various stages involved in the manufacturing types of injectables and drugs filling. It was indeed a very exciting and a intresting training to attend. I have developed a lot of practical knowledge during the process of training which would definitely help me in the future aspects and my career.

# A STUDY ON THE MANUFACTURING OF DRUGS

Report on Internship Training submitted to Periyar University, Salem in partial fulfilment of requirement for the award of the degree of

# **BACHELOR OF CHEMISTRY**

Submitted by

NAME: NINIDHAR

REG.NO: C21UG152CHE026

Under the Supervision of

# Mr. MANJUNATHAN SUNDARAMOORTHY

Mylan Laboratories Limited, Hosur.



#### DEPARTMENT OF CHEMISTRY

ST. JOSEPH'S COLLEGE OF ARTS AND SCIENCE FOR WOMEN, HOSUR

(Affiliated to Periyar University, Salem)



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Ref: Project//HR/007

Date: 04th February 2023

## CERTIFICATE

This is to certify that Ms. NINIDHA R (Reg.C21UG152CHE026), a student pursuing B.Sc - Chemistry at St. Joseph's College of Arts and Science for women, Hosur has undergone Internship Training in "Functional Departments" from 23<sup>rd</sup> January 2023 to 04<sup>th</sup> February 2023 in our organization under the guidance of Mr. Manjunathan Sundaramoorthy.

We wish all the very best for her future endeavors.

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HOSUR 635130

For Mylan Laboratories Limited, Hosur

Palanikumar P

DGM - Human Relations



# PERIYAR UNIVERSITY

# INTERNSHIP TRAINING REPORT

1.	Name of the Candidate	Ninidha.R
2.	University Examination Registration Number	C21UG152CHE026
3.	Name of the college	St. Joseph college of arts and science for women, Hosur
4.	Name of the Department/Degree	B.sc chemistry
5.	Name of the industry/ Institute in which for internship Training Undergone	Mylanpharmaceutical industry
6.	Guide / Supervisor under whom the training undertaken	Mr.manjunathansundaramoorthy
7.	Title of the Training	manufacturing of drugs
8.	Brief output training (not more than 2 Pages)	Annexure Enclosed
9.	Conclusion	The production of injectable drugs and sterility of the product.
10	Outcome of the training	To ensure that the product manufactured

Submitted for B.Sc., Internship Examination held on 14/11/2023. at the department of chemistry ,St. Joseph college of arts and science for women phose 15109.

Signature of the Student

Signature of the Guide

Head of the

Department

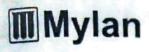
\$T. JOSEPH'S COLLEGE OF ARTS

Mookandapalli, Sipcot, HOSUR - 635 126, Krishnagiri - Dist. **Principal** 

Examiner:

1.

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Ref: Project//HR/007

Date: 04th February 2023

## CERTIFICATE

This is to certify that Ms. NINIDHA R (Reg.C21UG152CHE026), a student pursuing B.Sc - Chemistry at St. Joseph's College of Arts and Science for women, Hosur has undergone Internship Training in "Functional Departments" from 23<sup>rd</sup> January 2023 to 04<sup>th</sup> February 2023 in our organization under the guidance of Mr. Manjunathan Sundaramoorthy.

We wish all the very best for her future endeavors.

poratorio

HOSUR 635130

For Mylan Laboratories Limited, Hosur

Rahanikumar P

DGM - Human Relations

# THE PRODUCTION OF INJECTABLE DRUGS AND STERILITY OF THE PRODUCT

## INTRODUCTION

MYLAN PHARMACEUTICAL INDUSTRY was found in 1961 as milan pharmaceuticals by "MILAN PUSKAR AND DON PANOZ." HEATHER BRESCH is an american business executive .she was the CEO of netherland .it was a global generic and specialty pharmaceutical company. In November 2020, Mylan merged with VIATRIS and also defined as the discovers, develops, produces and market drugs for use of medications to be administered to patients with the aim of cure them .they are variety of laws and regulations that govern the patenting ,testing,safety, efficacy using drug testing and marketing of drugs.

## ABOUT THE COMPANY

MYLAN is now the part of "VIATRIS" a new global healthcare company committed to empowering people to live healthier at every stage of life.

MYLAN was the first company to receive FDA approval of OGIVRI, a bio similar to HERCEPTIN[trastuzumab], in late 2017 and has continued to obtain regulatory approvals for bio similar trastuzumab in nearly 30 additional countries around the world.

#### **HUMAN RESOURCES [HR]**

A human resources [HR] department performs human resources management functions, such as finding, hiring, training, and supporting new employees, one of the most important HR skills required is the ability to explore and find new ways to handle people and their concerns.

#### WARE HOUSE

A ware house is a building for storing goods. ware houses are used by manufactures, importers, exporters, wholesalers, transport businesses, customs, etc... and also ware house workers is responsible for varied daily tasks such as restocking, shelves, accepting incoming orders, processing and packing orders, conting inventory and ensuring orders are shipped in a timely manner.

IN ware house were the products are collected and after the analyzation of [QC] department the products will be organized in three ways

- QUARANTINE AREA [YELLOW LABEL]
- APPROVED AREA [BLUE LABEL]
- FINISHED AREA

## PRODUCTION

After the analyse of QC the products will be collected by production department through pass box with the LAF[ LAMINAR AIR FLOW], and then it will be disturbed properly for the production team members . it has many process team which work on it .

# VIAL WASHING

After the damage checking these will be collected for washing through passbox for autoclear and to avoid micro organisms "NOVASADE", this sanitizer spray on the material to avoid micro organisms.

# PACKING AND LABELLING

After the evaluation of the parenteral preparation, the ampoules, vials are properly packed and labelled and once again it will qualified with QC members and it will be shifted to finished area whereas the products will be shipped.

#### FLACULATION - ICII72

NAOH - sodium hydroxide [anioic poly] negative charge makes small particles into bundles.

# AREATION TANK

- · COD chemical oxygen demand
- . BOD biology oxygen demand
- . to live the micro organisms -COD
- to make feed the micro organisms -BOD

### MBR TANK

200 fliter sheets were used 0.1mn

## REVERSE OSMOSIS [RO]

No chemicals oxygen demand COD and chloride is used 90kl

less hardness - below 5

TDS - TOTAL DISSOLVED SOLID

hardnesss- below 200

#### EHS MAINTANCE

- RO [reverse osmosis] is used reduce the ph levels, hardness, density, bacterial membrance[0.001 micron]
- · HCL is used to reduce the Ph level
- ANTISCALART310 Is used to reduce or not scale formation.
- permit collected by pressure
- · FORCED EVAPORATION REACTANT to separate salts from the water
- · capacity 5kl
- TDS-30 ONLY
- · FEED 90 percentage required

## CONCLUSION

Injectables processing involes number of interesting challenges including

- Development of the experience and technical knowledge to trouble shoot issues as they occur.
- There are also significant benefits related to successful injectables drugs production including.
- protecting the sterility of the products as it moves through several phases of formulation, filling, packing.

# REFFERNCE

DRUG AND COSMETIC ACT IN 1940. WHO- GOOD MANUFACTURING PRACTICE FOR STERILE INDUSTRY

#### A STUDY ON THE MANUFACTURING OF TABLETS

Report on Internship Training submitted to Periyar university, Salem in partial fulfilment of requirement for the award of the degree of

#### **BACHELOR OF CHEMISTRY**

Submitted by

NAME : ELAKIYA. P

**REG.NO: C21UG152CHE012** 

Under the Supervision of

Mr. SHIVA KUMAR

Micro labs, Sipcot



## DEPARTMENT OF CHEMISTRY

ST. JOSEPH'S COLLEGE OF ARTS AND SCIENCE FOR WOMEN, HOSUR

(Affliated to Perlyar University, Salem)

# PERIYAR UNIVERSITY

#### INTERNSHIP TRAINING REPORT

1.	Name of the Candidate	Elakiya. P
2.	University Examination Registration Number	C21UG152CHE012
3.	Name of the college	St. Joseph's College of Arts and science for women , Hosur
4.	Name of the Department/Degree	Chemistry/B.sc Chemistry
5.	Name of the industry/ Institute in which for internship Training Undergone	Micro labs, Sipcot
6.	Guide / Supervisor under whom the training undertaken	Mr. Shiva Kumar
7.	Title of the Training	Packing and Raw Materials
8.	Brief output training (not more than 2 Pages)	Annexure Enclosed
9.	Conclusion	To know about various Products
10	Outcome of the training	To ensure the quality of the product in a good manner

Submitted for B.Sc., Internship Examination held on 14.21.23 at the Designment of chemistry, St.Joseph's college of Arts and science for women, Hosur 635 PERINCIPAL

P. Elakiya. Signature of the Student

Signature of the Guide

Department

ST. JOSEPH'S COLLEGE OF ARTS & SCIENCE FOR WOMEN Mookandapalli, Sipcot, HOSUK - 635 126, Krishnagiri - Dist. **Principal** 

Examiner:

1.

2..

Date: Sleaves

# STUDENT INTERNSHIP COMPLETION CERTIFICATE

This is to certify that Mr./Ms. ELAKIYA.P. (C210G152CIEC12).
Chemistry/ Bio Technology / Micro Biology / MBA/MSW from St. Joseph's  Chemistry/ Bio Technology / Micro Biology / MBA/MSW from St. Joseph's  College of Arts And Science for works  College Affiliated to Perugas University has/have successfully  completed Internship Training / Project work from 27/01/2023 to 10/02/2023.
We wish him/her/them all success in their future endeavours.
For MICRO LABS LIMITED
Authorised Signatory World

# Production of Packing and Raw Materials

# Introduction:

I had attended my internship Training in micro labs. There I have learned the working in the Production of packing and Raw Materials.

# Abstract:

The various industries are producing many Products. In that I have seen the packing of tablets in the Production of packing and Raw Materials in that company.

 The Staff members helped us in showing various departments. And they guided us in teaching the manufacture of tablets and they packed the tablets in different foils.

## Quality control:

They involve a set of process by which quality of all factors involved in the Production are analysed.

Quality control is checked in three different stages:

- 1. Raw Materials analysis
- 2. In process sample analysis
- 3. Finished Products.

## Packing:

- Analysis of every Materials used in packing.
- Packing can be classified into three categories :
  - 1. Primary (foils)
  - 2. Secondary (cotton box, Leaflets)
  - 3. Tertiary (shippers).

# Analysis of foil:

- Blister: soak in ethyl acetate for half an hour and check its weight whether it pass the range of pass limit description (PLD)
- 2. Strip foil: soak in acetic acid for 2 hours and check their weights whether it passes the range of pass limit description (PLD). Strip foil and blister can either be plain foil or printed foil after soaking in respective time limits and medium.
- 3. Form pack: soak in acetic acid for 24 hours and check their weights whether it passes the range of pass limit description (PLD). It will be plain foil after soaking.

# Gelatinous test (form pack):

0.25 of foil + 6 chemicals HCL 10 ml, sodium hydroxide 5g,  $_{1M}$  sodium hydroxide 4.3g solution, ammonium chloride 5.3g glycerol 85 ml)  $_{\rm gives}$  white precipitate.

# Test for Gram (for cotton and Leaflets):

Gram= ( weight of cut piece in gram / area of cut piece in square centimeter ) • 10000.

## Conclusion:

My experience in Micro labs was useful and I developed more skills in it. It helped to gain more knowledge about that packing Materials of tablets in the foils. Foils are different for each tablets and Raw Materials. This was new experience in company and it will be useful for our future development in our career.

### A Study on the quality control section

Report on Internship Training submitted to Periyar university, Salem in partial fulfilment of requirement for the award of the degree of

#### **BACHELOR OF CHEMISTRY**

Submitted by

NAME : INDHU.A

REG.NO: C21UG152CHE014

Under the Supervision of Dr.Sivakumar.

Microlabs Pvt Ltd, Hosur.



# DEPARTMENT OF CHEMISTRY ST. JOSEPH'S COLLEGE OF ARTS AND SCIENCE FOR WOMEN, HOSUR (Affliated to Periyar University , Salem)



# **PERIYAR UNIVERSITY**

#### INTERNSHIP TRAINING REPORT

1.	Name of the Candidate	Indhu.A
2.	University Examination Registration Number	C21UG152CHE014
3.	Name of the college	St.Joseph's College of Arts and Science for Women, Hosur
4.	Name of the Department/Degree	Chemistry/Bsc.Chemistry,
5.	Name of the industry/ Institute in which for internship Training Undergone	Microlabs private limited.
6.	Guide / Supervisor under whom the training undertaken	Sivakumar sir and Prabhakaran sir(Head of Quality control department)
7.	Title of the Training	Quality control section
8.	Brief output training (not more than 2 Pages)	Annexure Enclosed
9.	Conclusion	Enclosed
10	Outcome of the training	To ensure that the service provided met the specifications

Submitted for B.Sc., Internship Examination held on14:11:23at the Department of chemistry, St Joseph's College of arts and science for women, Hosting

A Indhu

Signature of the Student Examiner Signature of the Guide S.V. Hh

Head of the Department PRINCIPAL
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Date 10/02/207

# STUDENT INTERNSHIP COMPLETION CERTIFICATE

This is to certify that Mr./Ms. INDHU.A. (C21UG152CHEO14)
1 / III / III / IV year student/students of B. Pharm. / M. Pharm. / B. Sc., / M.Sc., Chemistry / Bio
Chemistry/ Bio Technology / Micro Biology / MBA/MSW from St. Joseph's College of Ants And Science for women
college / PSfiliated to Pering Tuniversity has/have successfully completed internship Training / Project work from 27/01/2023 to 10/02/2023
We wish him/her/them all success in their future endeavours.
FOR MICRO LABS LIMITED
Authorised Signatory

# Quality control of raw materials

## Introduction:

I attended my internship program in Microlabs private limited. There I learned the working and production of their products in large industrial scale.

## Abstract:

The various pharmaceutical and medical relate products are being produced in the company. Most of the products are related to tablets, capsules, ointments etc., which makes them one of the largest manufacturer in it. I have learned about the various packing methods, few steps in Quality control. The manufacturing unit was maintained with good condition.

- The faculties and the staffs working there were Kind and didn't hesitate when asked about their products and other information regarding their production
- We were given internship program for two weeks.
   They gave demonstration on the working of instruments used for sampling.

# Methodology:

They first equipped us with safety equipment and then allowed into the package area. They explained about

various packing methods like strip packing, bulk packing, Alu alu packing. It involves 3 stages like primary, secondary and tertiary. They used plastics like pvc, PE, PET.

In case of quality control ,the uv spectroscopy Which measures and interprets the electromagnetic spectra that result from the interaction between Electromagnetic radiation and matter. It consists of a light source, dispersion element, sample and a detector to analyze the sample.

# Discussion:

I have learned about the primary sampling of compounds and it's bulk production. Various instruments like Uv spectrometer and primary, secondary and tertiary sectors had their own machineries to pack the products.

## Conclusion:

My overall experience in the internship program in Micro labs private limited helped me to gain new experience and gain more knowledge about the testing and manufacturing of pharmaceutical products. The staffs were so helpful and taught us about the overall industrial and have an idea on how Pharma companies function ,produce their products and quality control sections.

# A STUDY ON THE MANUFACTURING OF TABLETS

Report on Internship Training submitted to Periyar university, Salem in partial fulfilment of requirement for the award of the degree of

## **BACHELOR OF CHEMISTRY**

Submitted by

NAME: JAYAPRIYA. Y

**REG.NO: C21UG152CHE016** 

Under the Supervision of

Mr. Sivakumar

MICROLABS LIMITED, HOSUR. .



# DEPARTMENT OF CHEMISTRY ST. JOSEPH'S COLLEGE OF ARTS AND SCIENCE FOR WOMEN, HOSUR (Affiliated to Periyar University, Salem)



# PERIYAR UNIVERSITY

### INTERNSHIP TRAINING REPORT

1.	Name of the Candidate	Jayapriya. Y
2.	University Examination Registration Number	C21UG152CHE016
3.	Name of the college	St. Joseph College of Arts and Science for Women
4.	Name of the Department/Degree	B. SC Chemistry
5.	Name of the industry/ Institute in which for internship Training Undergone	Microlabs Limited - Hosur
6.	Guide / Supervisor under whom the training undertaken	Mr. Sivakumar
7.	Title of the Training	Manufacturing of Tablets
8.	Brief output training (not more than 2 Pages)	Annexure Enclosed
9.	Conclusion	Production of Tablet
10.	Outcome of the training	To ensure that a product manufactured (or) service provided met the specification

Submitted for B.Sc., Internship Examination held on 14.11.12023 at the bepartment of sc chemistry, Hosur.

gnature of the

Student

Guide

Head of the Department

PRINCIPAL ST. JOSEPH'S COLLEGE OF ARTS & SCIENCE FOR WOMEN Mookandapalli, Sipcot, HOSUR - 635 126, Krishnagiri - Dist.

Principal

miner:



## MICRO LABS LIMITED

92, SIPCOT INDUSTRIAL COMPLEX, HOSUR - 635-126 (T.N.) Tel: +91-4344-276618, 277937 Fax: +91-4344-277261

Date: 06/02/2023

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1/II/IV year student/students of B. Pharm. / M. Pharm. / B. Sc., / M.Sc., Chemistry / Bio
Chemistry/ Bio Technology / Micro Biology / MBA/MSW from St. Joseph's College of Arts And Science For women college / Affiliated to Perugatuniversity has/have successfully completed Internship Training / Project work from 24/01/2023 to 06/02/2023
We wish him/her/them all success in their future endeavours.
For MICRO LABS LIMITED
Authorised Signatory  HOSUR

#### ABOUT THE COMPANY

Vicro Labs Limited is a multi-faceted healthcare organization established in 1973 by G.C.Surana. The company is a front runner in the pharmaceutical industry with

- Proficient marketing team,
- State-of-the-art manufacturing facilities
- International standards R&D center

## **MICROBIOLOGY**

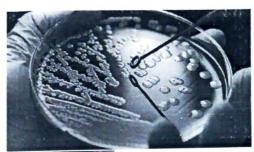
The Role of the Microbiologist is to ensure the quality of raw materials before they are processed in the The Kole of the microbiological quality of raw materials before they are processed in the moduction area, monitor the microbiological quality of Environment (air monitoring) and water, and validate production area and water, and validate he test methods used in testing finished products, and test finished products from microbiological prospective.

# The Growth Promotion test

The growth promotion test is an important quality control function in the pharmaceutical industry. It is The growth property of any media used to support growth when the mperative for establishing the ability and nutritive property of any media used to support growth when the noculum contains a small number of microorganisms.

# Microbial Limits Test

This test is used to estimate the total number of viable microorganisms or specific pathogens present in harmaceutical products as tablets, capsules, oral suspensions, injectable, ophthalmic and nasal solutions and ther medical devices. It is based on the principle that any viable microbial cell present in a sample will produce single colony when provided with a growth medium and favourable growth conditions.



#### **Enumeration test**

The finished products and raw materials Which is referred as TAMC (Total Aerobic Microbial Count) and IYMC (total combined yeast and Mould), the purpose of these tests is to find the number of bacteria and fungi found in the tested material and whether it is in the limit or not, the limit is defined from USP (United States Pharmacopeia), EP (European pharmacopeia), BP (British Pharmacopeia) or the pharmacopeia used in the country of the lab.

The enumeration of these colony-forming units (CFU) gives an estimate of the microbial population of the product. The microbial content of the product includes the total bacterial 15 I P a g e count (TBC), total yeast and mould count (TYMC). These tests are mandatory for the release of drug products.

#### Water Testing

Water is one of the major commodities consumed by the pharmaceutical industry. Total viable count is studied to rule out microbial contamination. Tests for presence of coliforms, E.coli and any other pathogens as Pseudomonas sp. Clostridia, Salmonella, Staphylococcus et c. are performed.

Membrane filtration technique: Collect the sample and make any necessary dilutions.

- Collect the appropriate nutrient or culture medium. Dispense the broth into a sterile Petri dish, evenly Scienting the absorbent pad.
- salurating the design of the forceps, and remove the membrane from the sterile package. Place the membrane filter into the funnel assembly.
  - the funner asserting lip of the sample container and pour the sample into the funnel.
- Turn on the vacuum and allow the sample to draw completely through the filter.
- Turn on the with sterile buffered water. Turn on the vacuum and allow the liquid to draw completely through the filter. through the filter.
- Flame the forceps and remove the membrane filter from the funnel.
- place the membrane filter into the prepared Petri dish.
- place the modern the proper temperature and for the appropriate time period.
  - Count and confirm the colonies and report the results

# Settle plate Method

settle plate sampling is a direct method of assessing the likely number of microorganisms depositing onto the settle plate same in a given time. It is based on the fact that, in the absence of any kind of influence, airborne report surface of the string particles deposited onto the agar surface of the string particles. The number of particles deposited onto the agar surface of the plate over the period of exposure is ascertained incubation of the plate and counting the number of microbial colonies, more commonly known as colony winds (CFU). The microbial deposition rate may be reported as the number depositing in a given area wit time.



## CLUSION

at the Micro Labs was very useful to us; we had good exposure over the pharmacy related side and experience too. This internship helped us to define what skills and knowledge we have to improve in becoming time.

### A Study on the Quality Control Section

Report on Internship Training submitted to Periyar university, Salem in partial fulfilment of requirement for the award of the degree of

#### **BACHELOR OF CHEMISTRY**

Submitted by

NAME: JEEVITHA.S REG.NO: C21UG152CHE017

Under the Supervision of

Mr.Vijayakumar sir.

Micro labs Private Limited, Hosur



# DEPARTMENT OF CHEMISTRY ST. JOSEPH'S COLLEGE OF ARTS AND SCIENCE FOR WOMEN, HOSUR

(Affliated to Periyar University, Salem)

## PERIYAR UNIVERSITY

#### INTERNSHIP TRAINING REPORT

_		
1.	Name of the Candidate	Jeevitha.S
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3.	Name of the college	St.Joseph's college of Arts and Science for Women, Hosur - 635126
4.	Name of the Department/Degree	Chemistry/ Bsc.Chemistry.,
5.	Name of the industry/Institute in which for internship Training Undergone	Microlabs private limited, Hosur.
6.	Guide / Supervisor under whom the training undertaken	Sivakumar sir and Prabhakaran sir ( Head of Quality control department)
7.	Title of the Training	Examining the quality of the raw materials.
8.	Brief output training (not more than 2 Pages)	Annexure Enclosed
9.	Conclusion	To determine the quality of the raw materials.
10.	Outcome of the training	To ensure the product manufacturing and packing met the specifications.

Submitted for B.Sc., Internship Examination held on 14:11:2023 at the Department of Chemistry, St.Joseph's College of Arts and Science for Wome - 635126

S. Jeevetha Signature of the Student

Examiner:

Guide

Head of the

Department

PRINCIPAL ST. JOSEPH'S COLLEGE OF ARTS & SCIENCE FOR WOMEN Mookandapalli, Sipcot,

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# MICRO LABS LIMITED

92, SIPCOT INDUSTRIAL COMPLEX, HOSUR - 635 126 (T.N.) - Tel - +91- 4344-278618, 277937 Fax : +91- 4344-277261

Date: 10/02/2023

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Chemistry/Bio Technology/Micro Biology/MBA/MSW from St. Joseph's College of Arts And Science for women college/Affiliated to Periyar University has/have successfully completed Internship Training/Project work from 27/01/2023 to 10/02/2023.
We wish him/her/them all success in their future endeavours.
FOR MICRO LABS LIMITED
Authorised Signatory

# Quality control of raw materials

#### Introduction:

I attended my internship program in Microlabs private limited. There I learned the working and production of their products in large industrial scale.

#### Abstract:

The various pharmaceutical and medical relate products are being produced in the company. Most of the products are related to tablets, capsules, ointments etc., which makes them one of the largest manufacturer in it. I have learned about the various packing methods, few steps in Quality control. The manufacturing unit was maintained with good condition.

- The faculties and the staffs working there were Kind and didn't hesitate when asked about their products and other information regarding their production
- We were given internship program for two weeks. They gave demonstration on the working of instruments used for sampling.

## Methodology:

They first equipped us with safety equipment and then allowed into the package area. They explained about various packing methods like strip packing, bulk packing, Alu alu packing. It involves 3 stages like primary, secondary and tertiary. They used plastics like pvc, PE, PET.

In case of quality control, the uv spectroscopy Which measures and interprets the electromagnetic spectra that result from the interaction between Electromagnetic radiation and matter. It consists of a light source, dispersion element, sample and a detector to analyze the sample.

### Discussion:

I have learned about the primary sampling of compounds and it's bulk production. Various instruments like Uv spectrometer and primary, secondary and tertiary sectors had their own machineries to pack the products.

### **Conclusion:**

My overall experience in the internship program in Micro labs private limited helped me to gain new experience and gain more knowledge about the testing and manufacturing of pharmaceutical products. The staffs were so helpful and taught us about the overall industrial and have an idea on how Pharma companies function and produce their products.

#### A STUDY ON THE MANUFACTURING OF TABLETS

Report on Internship Training submitted to Periyar university, Salem in partial fulfilment of requirement for the award of the degree of

#### **BACHELOR OF CHEMISTRY**

Submitted by

NAME: KAVYA. M

**REG.NO: C21UG152CHE019** 

Under the Supervision of

Mr. SIVAKUMAR

Microlab Pvt Ltd, Hosur.



#### DEPARTMENT OF CHEMISTRY

ST. JOSEPH'S COLLEGE OF ARTS AND SCIENCE FOR WOMEN, HOSUR

(Affliated to Periyar University, Salem)



## PERIYAR UNIVERSITY

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4.	Name of the Department/Degree	Chemistry/B. Sc., Chemistry	
5.	Name of the industry/ Institute in which for internship Training Undergone	Microlab Pvt Ltd, Hosur	
6.	Guide / Supervisor under whom the training undertaken	Sivakumar	
7.	Title of the Training	Manufacturing of tabletes	
8.	Brief output training (not more than 2 Pages)	Annexure enclosed	
9.	Conclusion	Production of medicines	
10	. Outcome of the training	To ensure that the products was manufactured	

Submitted for B.Sc., Internship Examination held on Atlanta at the Department of Chemistry St. Joseph's College of Arts and Science for Women, Hosur.

Signature of the Student

Signature of the Guide

Head of the Department Principal

ST. JOSEPH'S COLLEGE C

Examiner:

1.

2.



## MICRO LABS LIMITED

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Date:06/02/2023.

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Chemistry/ Bio Technology / Micro Biology / MBA/MSW from St. Joseph's College of Arts And Science for women college / Affiliated to Periyal University has/have successfully completed Internship Training / Project work from 24/01/2023 to 96/02/2023
We wish him/her/them all success in their future endeavours.
For MICRO LABS LIMITED
Authorised Signatory

## ABOUT THE COMPANY

Micro Labs Limited is a multi-faceted healthcare organization established in 1973 by G.C.Surana. The company is ranked 19<sup>th</sup> among all Pharmaceutical companies in India. They export their Products to over 68 countries across the world.

The company is a front runner in the pharmaceutical industry With

- · Proficient marketing team,
- · State-of-the-art manufacturing
- facilitiesInternational standards R&D centers

### Major Products:

Dolo-650, Amlong, Lubrex, Diapride, Vildapride, Olmat, Avas,

Tripride, Bactoclav, Tenepride-M & Arbitel, Esomeprazole,

Azithromycin, Simvastatin, Azelaic acid cream, etc...

#### **RAW MATERIAL SECTION**

### Basic terminology used:

API (Active pharmaceutical ingredient) – biologically active Component of a drug product [E.g.: Paracetamol]

- Excipient acts as the binding agent [E.g.: lactose, Succinate, citrate]
- Solvents E.g.: chloroform, methylene dichloride]
- Flavours E.g.: peppermint, banana, vanilla
- Colours E.g.: carnation pink, coated white
- Capsules a solid oral dosage form [ hard or soft gelatine]
- Pellets granules of drug substances [E.g:Lansoprazole]

#### Receiving samples:

Generally, all the samples are imported by containers and for analyses it is made into the polybags [Individual samples, sub pooled samples, composite samples] and reaches the labs.

#### Analysing parameters:

All the parameters for a particular drug should be followed By the specification mentioned on:

- BP-British pharmacopeia
- IP-Indian pharmacopeia
- EP-European pharmacopeia
- USP-united states pharmacopeia

### STABILTY:

Stability of the product is checked from raw material till the finished product. Shelf life of the product is also checked.

## Analysis of

- Appearance ( colour, shape, coating of tablet)
- Average weight
- Assay by HPLC
- Dissolution by HPLC
- Assay by UV
- Dissolution by UV

## HPLC(High performance liquid chromatography):

- The separation principle of HPLC is based on the distribution of the analyte (sample) between a mobile phase (eluent) and a stationary phase (packing material of the column.
- Depending on the chemical structure of the analyte, the Molecules are retarded while passing the stationary phase.



#### PACKING:

Analysis of every materials used in packaging Packing can be classified into 3 categories:

- Primaary (Foils)
- > Secondary (cotton box, leaflets)
- > Tertiary (Shippers)

### **CONCLUSION**

My overall experience in internship program in microlab helped me to gain new things knowledge about the testing and manufacturing of the pharmaceutical products. The staffs were so helpful and thought about their overall working in the industrial gave an idea about how pharma related companies function and produce their product.

### A STUDY ON THE MANUFACTURING OF TABLETS

Report on Internship Training submitted to Periyar university, Salem in partial fulfilment of requirement for the award of the degree of

#### **BACHELOR OF CHEMISTRY**

Submitted by

NAME: NATHIYA. K

REG.NO: C21UG152CHE024

Under the Supervision of

Mr.SIVAKUMAR

Microlab Pvt Ltd, Hosur.



# DEPARTMENT OF CHEMISTRY ST. JOSEPH'S COLLEGE OF ARTS AND SCIENCE FOR WOMEN, HOSUR

(Affliated to Periyar University, Salem)



## PERIYAR UNIVERSITY

### INTERNSHIP TRAINING REPORT

١.	Name of the Candidate	Nathiya. K
2.	University Examination Registration Number	C21UG152CHE024
3.	Name of the college	St. Joseph's College of Arts and Science for Women, Hosur
4.	Name of the Department/Degree	Chemistry/ B.Sc Chemistry
5.	Name of the industry/ Institute in which for internship Training Undergone	Microlab Pvt Ltd, Hosur
6.	Guide / Supervisor under whom the training undertaken	Mr. Sivakumar
7.	Title of the Training	Manufacturing of tablets
8.	Brief output training (not more than 2 Pages)	Annexure Enclosed
9.	Conclusion	Production of medicines
10.	Outcome of the training	To ensure that the product is manufactured
		1 (

Submitted for B.Sc., Internship Examination held on JH.J.J. 3 at the Department of Chemistry, St.Josephs's College of Arts and Science for Women Hosur

Signature of the

Signature of the Student Signature of the Guide

Head of the Department ST. JOSEPH'S COLLEGE OF ARTS
& SCIENCE FOR WOMEN

Mookandapalli, Sipcot,
 HOSUR - 635 126, Krishnagiri - Dist.
 Principal

Examiner:

,



## MICRO LABS LIMITED

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Date: 06/02/2023

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College of Arts And Science for women.  College / Affiliated to Polityal University has/have successfully completed Internship Training / Project work from 24/01/2023 to 06/02/202
We wish him/her/them all success in their future endeavours.
For MICRO LABS LIMITED
Authorised Signatory  Authorised Signatory

### ABOUT THE COMPANY

Labs in 1973, he put in his whole hearted efforts towards ensuring its unprecedented growth, and following his footsteps, the organization has never looked back.

#### VISION

Our vision is to built around a desire to being not just the best, but a leader in the development, manufacture and sales of premium pharmaceutical products. We wish to raise the flag of Micro Labs in India as well as abroad. Micro Labs is dedicated to manufacturing medicine of the highest standard and market it at affordable prices across the globe.

#### ASPIRATION

To become an organization answering to the highest standards of professionalism, Micro Labs aspires to deliver value through high quality pharmaceutical products and build strong brands across therapy segments. This can be achieved through our scientifically supported segments and processes, with strong implementation capabilities.

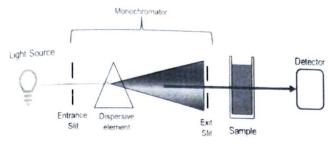
#### **RAW MATERIALS**

A raw material, also known as a feedstock, unprocessed material, or primary commodity, is a basic material that is used to produce goods, finished goods, energy, or intermediate materials that are feedstock for future finished products.

#### **PARAMETERS**

#### Identification:

- ➤ IR [infrared]
- > NIR
- > UV
- > HPLC
- CHEMICAL TEST
- ➢ GC
- 1) Spectroscopy:
- > Measures and interprets the electromagnetic spectra that
- > result from the interaction between electromagnetic
- radiation and matter as a function of the wavelength



### 2) Chromatography:

Chromatography, technique for separating the components, or solutes, of a mixture on the basis of the relative amounts of each solute distributed between a moving fluid stream, called the mobile phase, and a contiguous stationary phase.

#### API

Micro Lab's API (Active Pharmaceutical Ingredient) Unit produces cutting-edge pharmaceutical products that adhere to global quality standards. APIs involving complex chemistries and innovative non-infringing processes are produced cost-effectively, enabling the organization to have competitive edge in the global market. This unit facilitates the robust production of APIs in therapeutic areas such as anti-hypertensive, diuretic, anti-malarial, anti-inflammatory and ophthalmology. The division has developed strong skills in identification of non-infringing routes backed with IPR [Intellectual Property Rights] cell and is supported by a well-equipped analytical department, thereby creating an 'IP capital' for the company.

#### **DISINDISINTEGRATION TEST**

It involves the time required to break tablet components into Particles. It also involves 10 mesh and 40 mesh screen and time is measured while disintegrated particles pass through mesh Screen. There are two baskets A and B where basket A is below 18.5 Mm in length and basket B is above 18.5 mm in length.

#### FINISHED PRODUCT ANALYSIS

Finished products are those which have passed the different stages of testing and have completed all the manufacturing processes, they are divided into two parts depending on when they are sampled. They are: 1. Coated Uncoated 2. Powder Tablets, Capsules etc...

#### CONCLUSION

The internship in Microlab for 2 weeks went so good and valuable, I learnt about some of the pharmaceutical methods which will be a path way for my future studies in pharma field. Though the staffs were busy they clear the doubt whenever we raised questions. We Learned the different facets of working within the labs. I would like to thank the saffs and the HR of the department who is the path for our allowence for the internship.

## A Study on the Manufacturing of TABLETS

Reports on Internship Training submitted to Periyar university, Salem in partial fulfilment

Of requirement for the award of the degree of

#### **BACHELOR OF CHEMISTRY**

Submitted by

NAME: ROSHINI.M

**REG NO: C21UG152CHE030** 

Under the Supervision of

Mr.Sivakumar

Micro Labs Ltd, Hosur.



DEPARTMENT OF CHEMISTRY

ST.JOSEPH'S COLLEGE OF ARTS AND SCIENCE FOR WOMEN, HOSUR

(Affliated to Periyar University, Salem)



## **PERIYAR UNIVERSITY**

#### **INTERNSHIP TRAINING REPORT**

Name of the candidate	Roshini.M
University Examination Registration Number	C21UG152CHE030
Name of the college	St.Joseph's college of arts and science for women, Hosur
Name of the Department / Degree	B.sc., Chemistry
Name of the Industry / Institute in which for internship Training Undergone	Micro Labs Ltd, Hosur
Guide / Supervisor under whom the training undertaken	Mr. Sivakumar
Title of Training	Manufacturing of Tablets
Brief output training (Not more than 2 pages)	Annexure encolsed
Conclusion	Production of Medicine
Outcome of the training	To ensure that the product is manufactured
	University Examination Registration Number  Name of the college  Name of the Department / Degree  Name of the Industry / Institute in which for internship Training Undergone  Guide / Supervisor under whom the training undertaken  Title of Training  Brief output training (Not more than 2 pages)  Conclusion

Submitted for B.Sc., Internship Examination held on 14-11 2023 at the Department of ST. JOSEPH'S COLLEGE OF ARTS Chemistry, St.Joseph's college of arts and science for Women, Hosur. Roshini M

Singnature of the Student

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Head of the Department & SCIENCE FOR WOMEN

Mackandapalli, Sipcot, HOSUR - 635 126, Krishnagiri - Dist.

Examiner:

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## MICRO LABS LIMITED

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Chemistry/ Bio Technology / Micro Biology / MBA/MSW from St. Joseph's
College of Arts And Science for women.
College / ASSiliated to Periyas University has/have successfully
completed Internship Training / Project work from 24/01/2023 to 06/02/2023
We wish him/her/them all success in their future endeavours.
For MICRO LABS LIMITED
Authorised Signatory  HOSUN

## ABOUT THE COMPANY

Alicro Labs Limited is a multi-faceted healthcare organization established in 1973 by G.C.Surana. Micro Labs addicated to manufacturing of Tablets, Capsules, Ointments and API's (Active Product Ingredients) at the highest standard and marketing it at affordable prices across the globe.

## ISION OF THE COMPANY

To become a leader in the development, manufacture and sales of premium pharmaceutical products and come under top 10 pharmaceutical companies.

## QUALITY CONTROL

Quality control is checked in three different stages :

- · Raw material analysis
- · In process sample analysis
- · Finished product

QC deals with the system which accepts or rejects any activities or parameters which affects the quality of the nedicines and thus ensures good quality of the products.

Quality control has various division namely;

Microbio Lab, Raw material section, Stability lab,

Process validation, Packing material analysis.

#### PROCESS EVALUATION

There are certain process physical parameters should be evaluated and optimized such as appearance test, average weight test, uniformity test etc...

#### DEFINITION OF IPOC

PQC stands for In process Quality control. These are checks that are carried out the manufacturing process is completed. The function of the in process controls is monitoring. In process materials should be tested for identity, strength, quality, and purity as appropriate and approved or rejected by the quality control unit during the production process. While the Rejection in-process materials should be identified and controlled under quarantine system.

#### PURPOSE

- To ensure detectable and significant human errors.
- Abnormal interpretation
- Adoption of given procedures

### IPOC TEST

These are tests performed between QA and Qc and provides for the authorization of approved raw materials for manufacturing based on laboratory testing generally called as IPQCs such as Physical, Chemical, Microbiologic and Biologic tests

#### PROCESS VALIDATION

"Process validation is a documented program which provides a higher degree of assurance that a specific process will produce a product meeting its predetermined specifications & quality attributes. "The basic principles of quality assurance have as their goal the production of products that are fit for their intended use".

# Approach to Process Validation

There are three stages of processes validation

- Stage 1 Process Design: The commercial manufacturing process is defined during this stage based on knowledge gained through development and scale-up activities.
- Stage 2 Process Qualification: During this stage, the process design is evaluated to determine if the process is capable of reproducible commercial manufacturing.
- 1 Stage 3 Continued Process Verification: Ongoing assurance is gained during routine production that the process remains in a state of control.

## TYPES OF VALIDATION

- Prospective Validation
- Concurrent Validation
- Revalidation
- Retrospective Validation

## PHASES OF VALIDATION

- Design Qualification (DQ)
- Documented verification of the design of equipment and manufacturing facilities. Operational
  Qualification (OQ) documented verification of equipment or system performance in the target operating
  range.
- Process Performance Qualification (PQ) Documented verification that equipment or systems operate as
  expected under routine production conditions. The operation is reproducible, reliable and in a state of
  control.

#### CONCLUSION

It was really a good and learnable experience as a intern on microlab. They were many mentors to guide and to teach us and with the help of them I can learn some knowledge. I hope it will help with my future works. As a UG student I can't understand many procedures but the staffs there guided me and it was all a wonderful and knowledge gainable time.

And I would thank each and every staffs for spending there valuable time for guiding us

And a special thanks to the HR of the microlab who allowed us to do our internship and for the knowledge he gave us.