

# **INDUSTRIAL TRAINING AT PHARMA INDUSTRY**



A practice school report under the pharmaceuticals submitted to

PSG College of pharmacy, Coimbatore -04

in partial fulfilment of **VII SEMESTER** for

**BACHELOR OF PHARMACY**

by

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**IV B. PHARM-VII SEMESTER**

**UNDER THE GUIDANCE OF**

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**NOVEMBER – 2024**

**PSG COLLEGE OF PHARMACY**

**COIMBATORE – 641 004**

**CERTIFICATE**

This is to certify that the practice school work entitled **Industrial training at pharma industry** has been carried out by **Mohamed mufees E M** under the guidance **Mr. M.Nithyananth, M. Pharm., Assistant Professor**, Department of Pharmaceutics, PSG College of Pharmacy, Coimbatore-04 towards the partial fulfilment of **VII Semester** for **Bachelor of Pharmacy** under the Tamil Nadu Dr. M.G.R Medical University, Chennai.

Place: Coimbatore

Guide's signature:

Date:

Head of Department signature:

Principal signature:

## **DECLARATION BY THE CANDIDATE**

I, do hereby declare that the practice school work entitled **Industrial training at pharma industry** is based on my observation at my internship carried out during the course of Practice school under the supervision of **Mr. M. Nithyananth, M. Pharm., Assistant Professor**, Department of Pharmaceutics, PSG College of Pharmacy , Coimbatore, during the academic year 2023-2024, submitted to the PSG College of Pharmacy, Coimbatore-04 towards the partial fulfilment of **VII Semester** for **Bachelor of Pharmacy** under the Tamil Nadu Dr. M.G.R Medical University, Chennai.

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## EVALUATION CERTIFICATE

This is to certify that the practice school work entitled **Industrial training at pharma industry** has been carried out by **Mohamed mufees E M** under the guidance **Mr. M. Nithyananth, M. Pharm., Assistant Professor**, Department of Pharmaceutics, PSG College of Pharmacy, Coimbatore-04 towards the partial fulfilment of **VII Semester** for Bachelor of Pharmacy , a bonafide work carried out by the candidate at the Department of PSG College of Pharmacy, Coimbatore and was evaluated by us during the academic year 2023-2024.

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Coimbatore-641004,  
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**Evaluator's signature:**

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## **1.INTRODUCTION:**

This practice school report encapsulates my enriching internship experience at SAI MIRRA INNOPHARM Pvt Ltd, a well-renowned formulation company with an established reputation in the pharmaceutical industry. This opportunity is not only crucial for enhancing my academic knowledge but also for gaining practical insights into the intricacies of research, development, manufacturing, and marketing within a fully integrated pharmaceutical organization.

This internship tenure quality, innovation, and research, aligns seamlessly with my career aspirations and passion for improving patient outcomes through pharmaceuticals. I look forward to contributing meaningfully while learning from experienced professionals in a collaborative and dynamic environment. This internship represents a pivotal step toward achieving my goal of becoming a proficient pharmacist dedicated to advancing healthcare solutions.

## **2. COMPANY OVERVIEW:**

### **SAI MIRRA INNOPHARM**

This is one of the leading pharmaceutical companies in the service of Health Care, producing and exporting products to more than 55 countries across the globe.

Their Vision mainly focuses on to be the Most valued Company in their customers mind and their Mission to deliver the benefit of innovative and Quality formulations to all, which made their research and development, clinical research and marketing of the formulations successfully based on the demand of customers.

They produce a diverse portfolio of speciality and generic drug products with regulatory compliance, for a wide range of therapeutic usage. They cover a range of dosage forms which include tablets, capsules (both soft and hard), liquid dosage form and oral sachets.

They produce products of various therapeutic segment comprises of Anti-retroviral, Cardiovascular, Diabetic, Gastroenterology, Antiulcer preparation, Probiotics, Anti-infective, Anti-Malarial, Gynaecology, Anti-allergic, Cough syrup, Anti emetics, Anti Inflammatory, Neurology, Urology, Multivitamins with Minerals, Nutraceuticals, Ayurvedic & Herbal products and others.



### **3. INTERNSHIP OBJECTIVE:**

During my internship at Sai Mirra Innopharm Pvt Ltd, I focused on several key objectives to enhance my understanding and develop my skills in pharmaceutical manufacturing.

#### **Industry-Specific Skills:**

1. Deepen my knowledge of pharmaceutical processes, including manufacturing, formulation, and quality assurance techniques.

#### **2. Practical Experience:**

1. Apply my academic background in a real-world pharmaceutical environment, learning about drug development, quality control, and regulatory compliance.

#### **Manufacturing:**

1. Acquire knowledge of batch production processes.
2. Understand cleaning and sanitization protocols.
3. Get involved in packaging and labelling activities.

#### **Quality Control:**

1. Perform testing on raw materials and finished products.
2. Analyse data and interpret results.
3. Develop proficiency in documentation and reporting.

#### **Research and Development:**

1. Assist in the development of formulations.
2. Conduct stability studies.
3. Engage in literature reviews to support research initiatives.

#### **Quality Assurance:**

1. Participate in audits and inspections to aid in quality risk management.
2. Learn about standard operating procedures (SOPs) and annual product quality review (APQR).



#### **4. INTERNSHIP EXPERIENCE:**

➤ **PLAN OF WORK:**

DATE	DEPARTMENT
JULY 15	GENERAL VISIT
JULY 16 & JULY 17	WAREHOUSE & PRODUCTION- VISIT
JULY 18	QUALITY CONTROL-VISIT
JULY 19	QUALITY ASSURANCE-VISIT
JULY 22 – AUGYST 2	QUALITY ASSURANCE
AUGUST 5- AUGUST 9	PACKING

### ❖ **GENERAL VISIT:**

As part of my internship at Sair Mirra innopharm pvt ltd, I had the opportunity to visit and observe various departments within the pharmaceutical industry.

Departments visited:

- Warehouse
- Production
- Quality control
- Quality assurance
- Research and development
- Regulatory affairs

On my first day I had the opportunity to visit and familiarize myself with all the departments within the pharmaceutical company. This initial orientation allowed me to gain a basic understanding of the roles and functions of key departments, such as Research and Development (R&D), Manufacturing, Quality Assurance (QA), Quality Control (QC), and Regulatory Affairs. Each department played a crucial role in ensuring the production of safe and effective pharmaceutical products. I learned about the importance of coordination between these departments to maintain product quality and compliance with regulatory standards. This foundational knowledge helped me grasp the broader workings of the pharmaceutical industry and prepared me for the hands-on experience that followed.

## ❖ **WAREHOUSE:**

The warehouse in a pharmaceutical company plays a critical role in the supply chain, managing the storage, handling, and distribution of raw materials, components, and finished products. Its operations are essential to ensure that products are available for manufacturing and that finished goods are delivered to customers efficiently and in compliance with regulatory standards.

### **Key Functions of the Warehouse:**

1. Storage of Raw Materials
  - The warehouse is responsible for storing raw materials used in drug manufacturing. These materials must be kept in controlled environments to maintain their integrity and efficacy.
2. Inventory Management
  - Effective inventory management systems track stock levels, expiration dates, and reorder points. This helps prevent shortages and reduces waste.
3. Quality Control
  - Upon receipt, raw materials undergo quality inspections to ensure they meet specified standards. Only materials that pass inspection are released for production.
4. Packaging and Labelling
  - Some warehouses are equipped to package and label products before they are shipped, ensuring compliance with regulatory requirements and proper product identification.
5. Returns Management
  - The warehouse handles returns and recalls efficiently, ensuring that products are assessed and properly disposed of or restocked as necessary.



## ❖ **PRODUCTION:**

The production department is a critical component of a pharmaceutical company, responsible for the actual manufacturing of pharmaceutical products. This department ensures that medications are produced efficiently, safely, and in compliance with regulatory standards. Here's an overview of its key functions and roles:

### **Key Functions of the Production Department**

1. Manufacturing Processes,
2. Equipment Operation,
3. Production Planning,
4. Batch Production,
5. Documentation and Record-Keeping,
6. Continuous Improvement.

### **MANUFACTURED PRODUCTS:**

#### **Solid dosage forms:**

- a. Anti-Retroviral – Lamivudine, Ritonavir
- b. Vitamins and Minerals – Calcitriol
- c. Cold and Cough - (Acetaminophen + Phenylephrine Hydrochloride + Chlorphenamine Maleate) etc.
- d. Antibiotics – Azithromycin, Ofloxacin & Ornidazole (OFTOL)
- e. Anti-diabetic- Glimepride

#### **Liquid dosage forms:**

- a. Amino prep Forte Liquid syrup
- b. Ulgicid - (Antacid)
- c. Aristo V-Total Drops and Syrups.
- d. Nugel-O suspension

## INTRUMENTS USED:



Rapid mixer granulator



Fluidized bed dryer



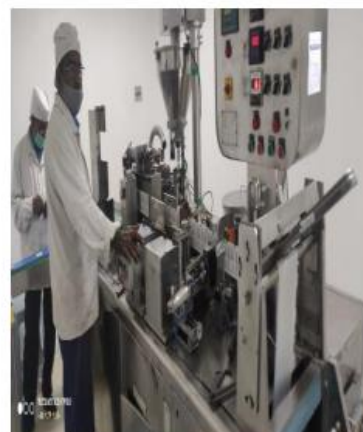
Shifter



Manual capsule filling Machine



Automatic tablet punching machine



Sachet filling machine



Multi station rotary press



Neo Cota



Double cone blender

❖ **QUALITY CONTROL:**

The Quality Control (QC) department plays a vital role in ensuring the quality, safety, and efficacy of pharmaceutical products. As a critical component of a pharma company, the QC department verifies the identity, strength, purity, and performance of raw materials, intermediates, and finished products.

**Major tests done in QC:**

- **Physical Tests:**  
Weight Variation  
Hardness Testing  
Friability Testing  
Disintegration Testing  
Dissolution Testing
- **Chemical Tests:**  
Assay (Potency)  
Impurity Testing (HPLC, GC)  
Moisture Content  
pH Testing
- **Microbiological Tests:**  
Sterility Testing  
Microbial Limits Testing  
Antimicrobial Effectiveness Testing.
- **Performance Tests:**  
Release Rate Testing (Dissolution)  
Stability Testing (Short-term, Long-term)  
Bioequivalence Testing.
- **Instrumental Tests:**  
High-Performance Liquid Chromatography (HPLC)  
Gas Chromatography (GC)  
Atomic Absorption Spectroscopy (AAS)
- **Raw Material Testing:**  
Identification Testing  
Purity Testing  
Moisture Content

○ **Finished Product Testing:**

Visual Inspection

Labelling Verification

Packaging Integrity Testing

Stability Testing

**Instruments and Equipment used in QC:**

- Refractometer
- UV spectrophotometer
- Sonicator
- Disintegration apparatus
- Dissolution apparatus
- Gas Chromatography
- FTIR
- HPLC



Sonicator



Disintegration apparatus





Gas Chromatography



FTIR



HPLC



Dissolution apparatus



## ❖ **QUALITY ASSURANCE:**

The Quality Assurance (QA) Department is one of the most critical departments in a pharmaceutical company. It ensures that every step in the manufacturing process is done according to predefined quality standards and regulatory guidelines. Its role is not just to inspect but to prevent errors by implementing stringent quality management systems.

### **Roles and Functions of the QA Department:**

- **Quality Management System (QMS) Development**
  - Establishes and maintains the QMS to ensure consistent product quality and compliance with regulatory requirements.
- **Regulatory Compliance**
  - Ensures adherence to regulations from agencies such as the FDA, EMA, and other relevant authorities.
  - Prepares for inspections and audits by regulatory bodies.
- **Documentation Control**
  - Oversees the creation, approval, and revision of all quality-related documents, including Standard Operating Procedures (SOPs), batch records, and training materials.
- **Training and Education**
  - Provides training programs for employees on quality standards, regulations, and procedures to promote a quality-focused culture.
- **Change Control**
  - Manages changes to processes, equipment, or materials to assess potential impacts on product quality and ensures proper documentation and validation.
- **Risk Management**
  - Conducts risk assessments related to quality processes and product safety to identify and mitigate potential issues.
- **Deviation and CAPA Management**
  - Investigates deviations from established protocols and implements Corrective and Preventive Actions (CAPA) to prevent recurrence.
- **Supplier and Vendor Quality Management**
  - Evaluates and monitors the quality of suppliers and contract manufacturers to ensure they meet company standards.

### ❖ **ANNUAL PRODUCT QUALITY REVIEW(APQR):**

The Annual Product Quality Review (APQR) is a comprehensive evaluation conducted in pharmaceutical companies to assess the quality performance of products over a specified period, usually one year. It serves to ensure ongoing compliance with regulatory requirements and to identify areas for improvement.

During my internship at Sai Mirra Innopharm, I had the valuable opportunity to learn how to build an Annual Product Quality Review (APQR) for a product called Amino-prep. The team guided me through the entire process, emphasizing the importance of data collection from Batch Manufacturing Records (BMR), Batch Production Records (BPR), and Quality Control (QC) reports. I gained hands-on experience in analysing trends, documenting findings, and making recommendations for quality improvements. This practical exposure not only deepened my understanding of quality assurance in the pharmaceutical industry but also equipped me with essential skills for my future career.

### **Purpose of APQR:**

: The APQR serves as an in-depth evaluation of a product's performance by reviewing its quality attributes over a year. It ensures that the product is manufactured consistently and controlled in accordance with Good Manufacturing Practices (GMP).

### **Need for APQR:**

1. **Regulatory Compliance:** Regulatory agencies often mandate APQRs to ensure that companies are continuously monitoring product quality and safety.
2. **Quality Assurance:** It helps in identifying trends and deviations, ensuring that corrective actions are taken to maintain product quality.
3. **Continuous Improvement:** APQRs provide insights that can drive process improvements and enhance product consistency and reliability.
4. **Risk Management:** By reviewing data from the past year, potential risks can be identified and mitigated proactively.

## **Elements of APQR:**

- **Product Description**

Includes basic details of the product, such as its composition, manufacturing process, and critical quality attributes.

- **Specifications and Analytical Methods**

A review of the quality control specifications, analytical methods, and validation results to ensure the consistency of the product.

- **Validation Review**

Assessment of process validation data, including cleaning and equipment validation, to confirm that the product consistently meets its intended quality attributes.

- **Stability Data**

A detailed evaluation of the product's stability data over time. This includes tests such as shelf-life determination, storage conditions, and packaging integrity.

- **Deviations and Investigations**

Reviews all deviations or non-conformances that occurred during the manufacturing process and how they were managed and resolved.

- **Complaints and Recalls**

This section covers customer complaints, adverse drug reactions, and any instances where product recalls were necessary.

- **Training and Qualification**

Review of the personnel qualifications and the training programs related to the product's manufacturing process.

## **Building an APQR**

At Sai Mirra Innopharm, the staff were instrumental in teaching me the fundamentals of building an Annual Product Quality Review (APQR) from the ground up.

They provided clear guidance on the data collection process, helping me understand the significance of each component, including Batch Manufacturing Records (BMR), Batch Production Records (BPR), and Quality Control (QC) reports.

Whenever I made mistakes during data entry, they were quick to provide constructive feedback, ensuring I understood the correct procedures and the importance of accuracy in quality assurance.

### **Steps in building an APQR:**

#### **1. Define the Scope**

- Identify the products to be reviewed and the time frame (typically one year).

#### **2. Data Collection**

Data collection includes collecting data about following things,

- Batch Manufacturing Records (BMR)
- Batch Packing Records (BPR)
- Quality Control (QC) Reports:
- Stability Data
- Deviation Reports

#### **i. BATCH MANUFACTURING RECORD(BMR):**

The BMR is a comprehensive record that documents the manufacturing process of a specific batch of a product. It serves as a complete history of the production process, ensuring that all steps are executed according to established procedures and specifications.

### **Importance in APQR**

**Quality Assurance:** The BMR helps verify that the manufacturing process complies with Good Manufacturing Practices (GMP) and company standards, ensuring the quality and safety of the product.

**Deviation Analysis:** During the APQR, BMRs are reviewed to identify any deviations or inconsistencies in the manufacturing process. This

analysis helps in assessing the impact of these deviations on product quality.

**Data for Continuous Improvement:** Insights gathered from reviewing BMRs during the APQR can inform process improvements and help enhance overall operational efficiency.

### **Components of BMR**

- **Raw Material Information:** Details of the raw materials used, including batch numbers, suppliers, and quantities.
- **Manufacturing Process Steps:** A detailed account of each step in the manufacturing process, including specific parameters and conditions (e.g., temperature, time).
- **Equipment Used:** Identification of the equipment utilized during production and any calibration details.
- **Personnel Involved:** Names and signatures of personnel involved in the manufacturing process, ensuring accountability.
- **Testing and Results:** Information on in-process testing, results, and any adjustments made during production.

### **ii. BATCH PACKING RECORD(BPR):**

The BPR is a comprehensive record that outlines all relevant information related to the packaging of a particular batch, ensuring that the product is packed according to specified standards and regulatory requirements.

### **Importance in APQR:**

1. **Quality Assurance:** The BPR ensures that the packaging process adheres to Good Manufacturing Practices (GMP) and company standards, which is vital for maintaining the product's integrity and safety.
2. **Identification of Issues:** During the APQR, BPRs are reviewed to identify any packaging-related deviations or issues that occurred during the process. This helps in assessing their impact on product quality and taking corrective actions.
3. **Regulatory Compliance:** BPRs demonstrate compliance with packaging regulations, serving as documented evidence during inspections by regulatory agencies.

4. **Data for Continuous Improvement:** Insights from BPR analysis during the APQR can highlight areas for improvement in packaging processes, contributing to overall operational efficiency.

**Components of BPR:**

- **Packaging Process Steps:** A detailed account of each step in the packaging process, including equipment used, settings, and specific procedures followed.
- **Materials Used:** Documentation of all packaging materials, such as containers, labels, and inserts, along with their respective batch numbers and suppliers.
- **Personnel Involvement:** Names and signatures of the personnel involved in the packaging process to ensure accountability.
- **In-Process Checks:** Records of any in-process quality checks conducted during packaging, including labeling accuracy and packaging integrity.
- **Final Product Verification:** Confirmation that the final product meets all specifications, including proper labeling and sealing.
- 

iii. **QUALITY CONTROL REPORTS:**

Quality Control (QC) reports play a vital role in the Annual Product Quality Review (APQR) process within the pharmaceutical industry. These reports provide essential data and insights that help ensure the quality, safety, and efficacy of pharmaceutical products.

**Importance in APQR:**

**1. Data Collection and Analysis**

- **Test Results:** QC reports document the results of various quality tests performed on raw materials, in-process samples, and final products. This data is critical for evaluating whether the product meets specified quality standards.
- **Trend Analysis:** Reviewing QC reports allows for the identification of trends over time, such as recurring issues or improvements in product quality. This trend analysis is essential for proactive quality management.
- 

**2. Compliance Verification**

- **Regulatory Standards:** QC reports provide evidence of compliance with regulatory requirements and internal quality standards, which is crucial for maintaining the integrity of the manufacturing process.

- **Specification Adherence:** They confirm that products have been tested against established specifications, ensuring that only compliant products are released to the market.

### **3. Identification of Deviations**

- **Non-Conformance:** QC reports highlight any deviations from quality specifications, including out-of-specification (OOS) results. This information is vital for investigating root causes and implementing corrective and preventive actions (CAPA).

## **iv. STABILITY DATA:**

Stability reports are a crucial component of the Annual Product Quality Review (APQR) process in the pharmaceutical industry. These reports provide vital information about the shelf life and storage conditions of pharmaceutical products, ensuring their quality and efficacy over time.

### **Importance in APQR:**

#### **1. Assessment of Product Quality Over Time**

- **Shelf life Determination:** Stability reports help establish the expiration date of a product by assessing how its quality attributes change under specified conditions over time.
- **Effectiveness Evaluation:** They provide insights into whether the product maintains its intended efficacy throughout its shelf life.

#### **2. Compliance with Regulatory Requirements**

- **Regulatory Standards:** Stability data is often a requirement for regulatory submissions. Stability reports demonstrate that the product has been tested and meets required specifications throughout its shelf life.
- **Support for Labelling:** These reports provide the necessary data to support labelling claims regarding storage conditions and expiration dates, ensuring consumer safety and compliance.

#### **3. Identification of Degradation Trends**

- **Trend Analysis:** Stability reports allow for the identification of degradation patterns and trends in product quality. Analysing these

trends helps in understanding potential issues and planning for necessary interventions.

- **Risk Management:** By identifying potential stability issues early, companies can implement risk management strategies, such as reformulations or changes in storage conditions.

## v. **DEVIATION REPORTS:**

Deviation reports are an essential component of the Annual Product Quality Review (APQR) in the pharmaceutical industry. They document any instances where processes, procedures, or specifications are not followed as intended, providing critical insights for quality assurance.

### **Importance in APQR:**

#### **1. Identification of Quality Issues**

- **Root Cause Analysis:** Deviation reports detail instances of non-compliance, enabling thorough investigation into the root causes of quality issues. This helps identify systemic problems that need addressing.
- **Impact Assessment:** They assess the impact of deviations on product quality and safety, allowing for informed decision-making regarding batch release or rework.

#### **2. Regulatory Compliance**

- **Documentation of Non-Conformance:** Deviation reports serve as official records of non-conformance, demonstrating to regulatory bodies that the organization is monitoring and addressing quality issues.
- **Audit Preparedness:** They provide a clear trail of actions taken in response to deviations, which is essential for regulatory audits and inspections.

#### **3. Corrective and Preventive Actions (CAPA)**

- **Implementation of CAPA:** Deviation reports often lead to the development and implementation of CAPA plans aimed at correcting identified issues and preventing their recurrence.
- **Monitoring Effectiveness:** They help in tracking the effectiveness of corrective actions over time, ensuring continuous improvement in quality processes.



### **3. Data Analysis**

- Analyse the collected data to identify trends, recurrent issues, and areas for improvement.
- Compare actual performance against established quality standards and specifications.

### **4. Document Findings**

- Prepare a comprehensive report summarizing findings, including:
  - Overview of product quality and compliance status.
  - Summary of deviations and CAPA effectiveness.
  - Recommendations for improvements.

### **5. Review and Approval**

- Present the APQR to relevant stakeholders for review and approval, ensuring it meets organizational and regulatory standards.

### **6. Action Plan**

- Develop an action plan based on the findings, outlining steps to address identified issues and implement improvements.

## **Challenges Faced During APQR Development**

### **1. Data Availability and Quality**

- Incomplete or inaccurate data can hinder thorough analysis. Ensuring proper documentation and data integrity is crucial.

### **2. Cross-Departmental Collaboration**

- Gathering information from various departments (Production, QC, Regulatory, etc.) can be challenging, requiring effective communication and coordination.

### **3. Time Constraints**

- Preparing a comprehensive APQR can be time-consuming, especially if data collection and analysis are not managed efficiently.

### **4. Regulatory Changes**

- Keeping up with changing regulatory requirements can complicate the APQR process, necessitating constant updates to procedures and documentation.

### **5. Resource Allocation**

- Limited personnel or financial resources can impact the thoroughness of the APQR.

### ❖ **PACKING:**

Packing is a critical step in the pharmaceutical industry, ensuring that products are safely and effectively delivered to consumers. It involves selecting the right materials and methods to protect the product, maintain its integrity, and comply with regulatory standards.

#### **Types of packing :**

1. **Primary Packaging:** Directly contacts the product (e.g., bottles for liquids, blisters for tablets).
2. **Secondary Packaging:** Groups primary packages together (e.g., cartons, shrink wraps).
3. **Tertiary Packaging:** Used for bulk handling and transportation (e.g., pallets, containers).

During my time in the packing department at Saimirra, I gained hands-on experience with various dosage forms, including tablets, syrups, and soft gels. Each type presented unique challenges and required specific packing techniques:

- **Tablets:** Ensuring accurate blister sealing and preventing damage during transport was crucial. I learned to monitor machine settings and quality control procedures to maintain high standards.
- **Syrups:** Working with liquid formulations required careful handling to prevent spillage and contamination. I developed skills in maintaining cleanliness and ensuring that each bottle was filled accurately.
- **Soft Gels:** Packing soft gels involved managing delicate materials and ensuring proper labeling. I learned to work efficiently under tight deadlines while adhering to safety protocols.

#### **Challenges Faced:**

Throughout my experience, I encountered several challenges, including:

- Quality issues with packaging materials.
- Meeting changing regulatory requirements.
- Preventing contamination or damage.
- Accurate label application and verification

## **Skills Gained**

My time in the packing department enhanced several skills, such as:

- Enhanced hand-eye coordination.
- Ability to inspect products for defects or damage.
- Accuracy in counting and packaging correct quantities
- Attention to labeling and packaging details.
- Collaborating with colleagues to streamline processes improved my communication and teamwork skills.

## **5. LEARNING OUTCOMES:**

### **Understanding Production Processes:**

- Gain insights into the entire pharmaceutical production workflow, including formulation, manufacturing, and equipment operation.
- Learn about Good Manufacturing Practices (GMP) and how they ensure product quality and safety.

### **Quality Control Proficiency:**

- Develop skills in conducting various tests and assays to evaluate raw materials, in-process samples, and finished products.
- Understand the importance of compliance with regulatory standards and documentation in maintaining product quality.

### **Quality Assurance Awareness:**

- Learn the principles and practices of quality assurance, including how to develop and implement quality systems and procedures.
- Gain experience in internal audits and inspections, understanding their role in maintaining compliance and continuous improvement.

### **APQR Building Skills:**

- Understand the process of compiling and analyzing data for the Annual Product Quality Review (APQR).
- Develop skills in data interpretation and reporting, focusing on product performance, trends, and areas for improvement.

### **Packing and Packaging Knowledge:**

- Learn about different types of packaging materials and methods, and their impact on product stability and shelf life.
- Understand the significance of labeling, documentation, and regulatory requirements in the packaging process.

### **Collaboration and Teamwork:**

- Experience working in cross-functional teams, understanding the importance of collaboration in achieving common goals.
- Develop interpersonal skills through interaction with professionals from various departments.

## **6. CONCLUSION:**

My internship at Sai Mirra Inno Pharm Private Limited has been a valuable experience, significantly enhancing my understanding of management, quality, research, and production challenges. As a research intern, I gained firsthand insight into the research process, including the levels of critical thinking involved and how existing technologies are integrated.

The production team demonstrated how they create various dosage forms for different routes of administration, providing as much information as possible within our limited time. I observed the processes of production, quality checking, packing, labeling, and aliquoting, which taught me that hard work is as essential as research.

In the Quality Control and Quality Assurance teams, I learned how they conduct purity and limit tests for both solid and liquid dosage forms, as well as the meticulous attention to detail required at each step to ensure proper production. The Formulation Research and Development (FR&D) team shared their techniques and experiments, helping me understand the protocols and regulations that govern R&D.

Overall, this internship has been a crucial step in my career journey, and I am thankful for the knowledge, skills, and experiences I have gained.