

#### SAROJINI NAIDU VANITA PHARMACY MAHA VIDYALAYA

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NBA Accredited B. Pharmacy Course, Accredited A+ grade by NAAC

# **Department of Pharmaceutical Quality Assurance**

# **Industrial Training Report**

**Date**: 18<sup>th</sup> July 2025

## Industrial Training at Valens Molecules, Jeedimetla, Hyderabad,

From 14<sup>th</sup> July to 17<sup>th</sup> July 2025

Institution: Sarojini Naidu Vanita Pharmacy Mahavidyalaya, Tarnaka, Hyderabad

Faculty Coordinator: Dr. S. Anuradha Bai

Professor & Head, Department of Pharmaceutical Quality Assurance

## M. Pharmacy (Pharmaceutical Quality Assurance) II Semester Students

S. No.	Name of the Student	Roll Number
1.	Diddikadi Likitha	1704-24-868-001
2.	Gambo Nikitha	1704-24-868-004
3.	Gangineti Niharika	1704-24-868-005
4.	Gurrapu Deekshitha	1704-24-868-007
5.	Kadiyam Nikitha Kanthi	1704-24-868-008
6.	Subedar Bhavani Singh	1704-24-868-011
7.	Tahimeem Begum	1704-24-868-012

**About Valens Molecules:** Valens Molecules is a world class manufacturing company partnering with market leaders to offer pharmaceutical products and services. We are a fast emerging API and intermediate manufacturer & supplier set up by specific objective of providing the India advantage to formulators across the world. The company has a global footprint in 5 continents, serving

customers in over 30 countries. The facilities are certified for USFDA, WHO GMP and ISO 9001 2008 and ISO 14001 2004. Their practices are approved by the EDQM, and also Mexican GMP.

An industrial training program was conducted at *Valens Molecules*, Jeedimetla, Hyderabad, for the M. Pharmacy II Semester students from the Department of Pharmaceutical Quality Assurance, Sarojini Naidu Vanita Pharmacy Mahavidyalaya, from **14th to 17th July 2025**. The objective of the visit was to provide students with real-time exposure to pharmaceutical manufacturing processes, quality control, quality assurance, documentation, and microbiological practices.

# Day 1: 14th July 2025

The training commenced at 10:00 AM, and upon arrival at the industry, all mobile phones and personal belongings were deposited at the security desk, following the company's standard operating protocol.

We were received by Mr. Srinivas from the HR Manager, who guided us to the Conference Hall. The session began with an introduction by Mr. R. Yugander Reddy, General Manager, Quality Control. He provided a comprehensive overview of the industry, including its history, growth, branch expansions, and product portfolio.

Following this, **Mr. Shoban, QA Manager**, explained the role of Quality Assurance in Pharmaceutical Manufacturing, QC and Regulatory compliance.

#### Warehouse and Production Department Visit

During our industrial training, we had the opportunity to visit the Warehouse and Production Department, which provided us with a comprehensive understanding of material handling, quality control integration, and manufacturing operations.

**Warehouse**: We received a detailed overview of the warehouse management practices, including:

- Material Entry Procedures: Raw materials entering the facility are initially sent to a quarantine area for Quality Control (QC) sampling.
- QC Analysis: Materials undergo stringent QC testing before being approved for use.
- Approved Material Handling: Only QC-cleared materials are transferred to the designated approved storage area.
- Environmental Controls: Parameters such as temperature and humidity are continuously monitored.
- Material Segregation: Clear color-coded zones are used to distinguish between approved, rejected, and quarantined materials.

• Packaging and Dispensing: Proper procedures for dispensing and handling of packaging materials and finished product labeling were also demonstrated.

### **Production Department:** In the production block, we observed:

- Core Equipment: The use of reactors, centrifugation, and various stages of synthesis.
- Process Documentation: All procedures were backed by meticulously maintained documentation compliant with ALCOA+ (Attributable, Legible, Contemporaneous, Original, Accurate) principles.
- ERP-Based Inventory Tracking: Material movement was systematically recorded using an Enterprise Resource Planning (ERP) system.
- Next session -we checked SOPS. Sop for SOP

# Day 2: 15th July 2025- Visit to the Quality Control (QC) Department

On the second day, our focus was on the Quality Control (QC) Department, a crucial unit ensuring the quality, safety, and efficacy of pharmaceutical products. The day commenced at 10:00 AM in the conference hall, after which we proceeded to the QC section.

#### Introduction & Briefing

Mrs. Geeta, QC In-Charge, provided an overview of the QC operations, from sampling of raw materials to final product testing. She highlighted the importance of adhering to validated Standard Operating Procedures (SOPs) and Good Laboratory Practices (GLP) in maintaining data integrity.

#### Instrumentation and Observations

We observed a range of sophisticated analytical instruments and procedures:

- Analytical Weighing Balance with attached printer for precise measurement and proper documentation.
- Desiccant Substance used to absorb environmental moisture during weighing procedures.
- Samplers for collecting raw material samples from the warehouse.

#### **Chromatography Lab:**

- Gas Chromatography (GC) used for analysis of volatile substances.
- High-Performance Liquid Chromatography (HPLC) for quantifying and identifying active pharmaceutical ingredients (APIs).
- Ultra-Performance Liquid Chromatography (UPLC) an advanced version of HPLC for faster and more sensitive analysis.

Mr. Karunakar, QC Analyst, explained the use of GOST columns in HPLC and UPLC for impurity profiling and removal.

### Spectroscopy Room:

- UV-Visible Spectrophotometer to measure absorbance of solutions at different wavelengths.
- FTIR Spectrometer for identification of functional groups via infrared absorption. The setup ensures controlled ambient light conditions for accurate results.

#### Other Analytical Instruments:

- Karl Fischer (KF) Titrator for moisture content determination.
- Water Analyzer to assess purity levels of water.
- Muffle Furnace used for ignition tests and residue on ignition.
- Hot Air Oven, Sonicator, and Desiccator used in the Wet Lab Area for sample preparation and drying processes.

## Stability Chambers & Retention Sample Room:

- Stability Chambers designed for conducting accelerated and long-term stability studies under ICH-specified conditions (Zone II and Zone IV).
- Retention Sample Room maintained under controlled temperature and humidity to store product samples for regulatory review and batch traceability.

## Visit to the Production Area – Synthesis of Phenazopyridine Hydrochloride

During the industrial training at Valens Molecules, we were taken to the production area where the synthesis process of Phenazopyridine Hydrochloride was demonstrated. The visit began with an overview of the production reactor equipped with a condenser, various sensors, and a storage tank for pyridine, all of which were carefully monitored and explained by the technical team.

The production staff elaborated on each step of the synthesis process. Initially, we observed the setup and functioning of the first reactor, followed by the use of a second reactor for the separation of the organic layer. Subsequently, the diazotization reaction step was demonstrated and its parameters were closely monitored using advanced instrumentation.

We also had the opportunity to examine the batch processing record, which provided a detailed stepwise documentation of the entire synthesis procedure. This exposure gave us valuable insights into Good Manufacturing Practices (GMP) and documentation standards followed in the industry.

The students were thoroughly satisfied and intellectually stimulated by the comprehensive and systematic approach adopted in the production of Phenazopyridine HCl. The visit was marked by great enthusiasm and a sense of excitement as it reinforced theoretical knowledge with practical industrial experience.

#### Day 3: 16th July2025: The visit to the Quality Assurance (QA) department

The visit to the Quality Assurance (QA) department offered valuable insights into the critical role QA plays in maintaining regulatory compliance and ensuring product quality in pharmaceutical manufacturing.

## a. Standard Operating Procedures (SOPs):

- SOP for Documentation Control: Ensures only current, approved versions are used, with restricted access and traceability via electronic and physical systems.
- SOP for SOP Preparation: Standardized structure for creating SOPs, defining responsibilities of authors, reviewers, and QA approvers.
- SOP for Validation System: Detailed validation lifecycle (DQ, IQ, OQ, PQ) covering equipment, process, and cleaning validations. Supported by VMPs and detailed protocols.

### b. Document Control and Monitoring:

• Documents were version-controlled and securely archived. Change control and audit logs were meticulously maintained.

#### c. Audit Trails and Compliance:

• Routine internal and external audits. Documented handling of deviations, CAPAs, and change requests. Strong adherence to GxP principles.

## d. Real-Time Monitoring & QA Oversight:

• Regular review of BMRs, BPRs, and logbooks to ensure procedural compliance and detect discrepancies.

#### 2. QA Department Responsibilities Observed:

- Lifecycle management of SOPs.
- Planning, monitoring, and execution of validation activities.
- Documentation review and quality control.
- Oversight of deviations and regulatory compliance. Coordination of training and audit preparedness.

# Day 4:17th July 2025: Microbiology Laboratory

On the fourth day of our industrial training at Valens Molecules, we had the opportunity to explore the Microbiology Laboratory, an essential unit in ensuring the microbial safety and quality of pharmaceutical products. Access to the lab was highly regulated, requiring adherence to strict aseptic and hygiene protocols. This visit provided firsthand exposure to the advanced infrastructure and operations involved in microbiological quality control.

### 2. Rooms and Equipment Observed

## a. Preparation Room

- Weighing Balance: Used for precise measurement of culture media and reagents.
- pH Meter: Checked the pH of culture media before sterilization to ensure accuracy.
- Horizontal Autoclave: Sterilized media, instruments, and glassware at high pressure and temperature.
- Pass Box: Connected to adjacent sterile rooms to facilitate safe material transfer while minimizing contamination risks.

#### b. Incubation Room

- Bacterial & Fungal Incubators: Enabled growth of microorganisms, including *E. coli*, under controlled conditions.
- Environmental Control Systems: HEPA filters with an air inlet at the top and outlet on the side-maintained air purity and sterility.

#### c. Decontamination Room

- Pass Box Connectivity: Allowed transfer of used or contaminated items for safe disposal.
- Cleaning Station: Designated area for decontaminating glassware and reusable materials.

#### d. Cool Zone and Laminar Air Flow Units

- Observation Window: Provided a clear view of sterile zones without disturbing the environment.
- Laminar Air Flow Units (1 & 2): Utilized for aseptic microbiological testing.
- Cleanroom Compliance: Maintained to ensure minimal particulate and microbial contamination.

#### **Faculty Involvement and Observations**

The industrial training program at Valens Molecules, Jeedimetla, was conducted over four days from **14th to 17th July 2025**. **Dr. S. Anuradha Bai, Professor** and HOD accompanied the M. Pharmacy II Semester students

We extend our sincere gratitude to Mr. Cherukuri Surya Ratna Prasad, Managing Director of Valens Molecules, and to **Mr. R. Yugander Reddy**, General Manager, Quality Control, for granting us permission and facilitating our industrial visit.

We are especially thankful to Mr. Srinivas, HR Manager, for his warm welcome, meticulous coordination, and unwavering support throughout the training program.

Our heartfelt appreciation goes to Mr. Shoban, Quality Assurance In-charge, for his detailed and patient explanation of QA documentation and practices, and to Mrs. Geetha, Quality Control In-

charge, for sharing valuable insights into the QC processes. We also extend our thanks to Mr. Karunakar for his informative guidance and assistance during the training sessions.

We sincerely acknowledge the support and cooperation of the entire staff and security team at Valens Molecules, whose efforts contributed to making this industrial training a successful and enriching experience for our students.

We would like to express our heartfelt gratitude to the esteemed leadership of our institution for their unwavering encouragement and continuous support. Our sincere thanks go to Dr. B. Prabha Shankar Garu, Chairman, for his visionary leadership; Sri B. Hanumanth Rao Garu, Hon. Secretary, and the Governing Body Members for their constant guidance and encouragement in all our academic and professional pursuits. We are also deeply thankful to Dr. N. Srinivas, Director, for his support Dr. T. Mamatha, Principal, for her dynamic and inspiring guidance and Dr. B. Harika, Vice Principal, for her ever-supportive role in coordinating and facilitating such valuable opportunities. Their unwavering support was key to the successful completion of industrial training.

Overall, the students expressed enthusiasm and appreciation for the learning experience, noting that the training helped bridge the gap between theoretical concepts and industrial practices.

## **Outcome of the Industry Visit:**

The industrial visit to Valens Molecules Pvt. Ltd., Jeedimetla, Hyderabad, provided M. Pharmacy II Semester students from the Department of Pharmaceutical Quality Assurance with a comprehensive understanding of pharmaceutical manufacturing processes, quality systems, and regulatory compliance practices.

### **Key Outcomes:**

- Enhanced Practical Knowledge:
   Students gained firsthand exposure to the functioning of various departments including
   Production, Quality Assurance (QA), Quality Control (QC), Warehouse, and Microbiology.
- Understanding of Documentation Practices:
   The visit helped students understand the importance of regulatory documentation, including cleaning validation, process validation, equipment qualification, batch processing records, and SOPs.
- 3. Analytical Instrumentation Skills:
  Students observed and understood the working principles of critical instruments such as
  HPLC, UPLC, GC, UV-Vis Spectrophotometer, IR Spectrometer, and Karl Fischer Titrator.
- 4. Real-Time Observation of Drug Synthesis:

  The synthesis process of Phenazopyridine Hydrochloride was demonstrated, allowing students to connect organic chemistry principles with industrial-scale manufacturing.

- 5. Awareness of GMP and Compliance: Students gained insights into Good Manufacturing Practices (GMP), the role of SOPs, data integrity, and compliance with regulatory requirements in the pharmaceutical industry.
- 6. Exposure to Microbiological Testing: Students learned about microbiological assays, testing for *E. coli* and antifungal agents, and the importance of sterility and environmental monitoring in production environments.
- 7. Soft Skills and Professional Conduct:
  The visit helped students appreciate industrial discipline, safety protocols, team coordination, and the importance of effective communication and observation.

#### **Students feed Back:**

- 1. Watching the synthesis of Phenazopyridine HCl, Diazotization reaction was exciting. It brought our classroom learning to life."— Ms. Gambo Nikitha and Ms. Bhavani Singh
- 2. "Understanding QA documentation and validation protocols directly from industry professionals was extremely valuable." -- Ms. Tahmeem and Ms. Likitha
- 3. "The Microbiology Department's testing procedures were impressive. I now have a clear idea of the importance of sterile practices."— Ms. Niharika and Ms. Deekshitha
- 4. "The Quality Control (QC) lab was well-equipped, and the staff provided clear insights. The overall experience was truly enriching." Ms. Kanti Nikitha

#### **Overall Feedback:**

- All students expressed a high level of satisfaction with the training program.
- The hands-on exposure to production, QA, QC, and microbiology departments provided clarity and depth to their academic learning.
- The professional environment, well-structured sessions, and patient explanations by industry experts enhanced their understanding of documentation practices, validation procedures, and analytical instrumentation.
- The visit significantly boosted their confidence and career preparedness, especially for roles in quality assurance, quality control, and regulatory affairs.

The training served as a motivational and enlightening experience, helping students better align their academic knowledge with industry expectations.













