

INDUSTRIAL VISIT REPORT

Visit to Akin Laboratories Pvt. Ltd., Balanagar, Hyderabad

1. Introduction

As part of our academic curriculum, a group of four students [V. Shwetha, V. Sai Ashritha, V. Usanthi, V. Nikitha] from the Department of Regulatory Affairs, along with our faculty member Dr. M. Swetha HOD of Regulatory Affairs, visited Akin Laboratories Pvt. Ltd., Balanagar, Hyderabad, for an industrial visit on 25th August 2026. The visit was coordinated by Dr. N. Srinivas Sir, whose continuous coordination and support made the visit possible and well organized.

We were warmly welcomed by Mr. M. Venu Gopal Sir, Executive Director, who interacted with us and encouraged us to gain practical exposure to the pharmaceutical industry. The visit was further coordinated by Mrs. Srilatha from the Production Department and Ms. Bhavani, QC Scientist, who patiently guided us through the different sections of the facility and clearly explained the processes, equipment, documentation, and quality-control practices followed at the manufacturing site.

The visit provided us with valuable practical exposure to pharmaceutical manufacturing, quality control, microbiological testing, pharmaceutical utilities, stability studies, packaging, documentation, and Good Manufacturing Practices (GMP).

2. Objectives of the Industrial Visit

- To understand practical pharmaceutical manufacturing processes.
- To observe the manufacturing of tablets, capsules, and dry syrups.
- To understand the role of Production, QC, Microbiology, and other departments in ensuring product quality.
- To gain practical knowledge of GMP, hygiene, contamination control, and in-process testing.
- To observe pharmaceutical testing equipment and their applications.
- To understand packaging, labelling, and batch identification.
- To gain exposure to SOPs, BMRs, and pharmaceutical documentation.
- To relate Regulatory Affairs concepts with their practical industrial implementation.

3. Visit to the Production Department

Our visit began with the Production Department. Before entering the manufacturing areas, we were taken to the designated changing and gowning area. We were provided with appropriate protective attire, including aprons, head and face masks, and shoe covers. The importance of proper gowning, personal hygiene, and controlled entry procedures was explained to us as

essential measures for maintaining cleanliness and minimizing the possibility of contamination within the manufacturing areas.

We were then taken through different manufacturing sections where the processes involved in the production of tablets, capsules, and dry syrups were explained.

3.1 Manufacturing of Capsules

We observed various equipment involved in the manufacturing process, including:

- Sifters
- Blenders
- Granulators
- Dryers
- Capsule filling equipment

The manufacturing materials are transferred between controlled areas using Dynamic Pass Boxes, which help minimize direct exposure of materials to the external environment and assist in maintaining controlled conditions and preventing contamination.

We observed the S9 semi-automatic capsule filling machine used for capsule filling. The process of filling the powder formulation into capsule shells was explained to us.

After capsule filling, the capsules are subjected to appropriate in-process checks. In the IPQA area, we observed instruments such as:

- Leak test apparatus
- Disintegration apparatus
- Friabilator

The working principles and purpose of these tests were explained to us, particularly how they help ensure that the manufactured dosage forms meet the required quality specifications.

After completion of the required checks, the capsules proceed to the packaging stage.

3.2 Manufacturing of Tablets

We were introduced to the various stages involved in tablet manufacturing. The facility has separate compression machines, including:

- A double rotary tablet compression machine with 27 stations
- A 14-station tablet compression machine

We observed equipment such as:

- Multi Mill

- Mass Mixer
- Tray Dryer
- Tablet Compression Machines
- Coating Machine

A tray dryer was also observed, particularly for products requiring suitable drying conditions, including thermosensitive products.

Following the preparation and processing of the granules, the material proceeds to the compression stage. The compressed tablets undergo appropriate in-process quality checks.

We also observed an inspection area, where inspection and metal detection are carried out to identify and prevent the presence of unwanted metallic contaminants in the finished product.

For film-coated tablets, we observed the tablet coating machine. The process of applying a film coating to tablets and the role of controlled air and heating conditions during the coating process were explained to us.

After coating, the tablets undergo the required quality checks before proceeding to the packaging stage.

3.3 Dry Syrup Manufacturing and Filling

We also had the opportunity to observe the manufacturing, filling, and packaging process of dry syrups.

Before entering the dry syrup filling area, we followed the required **gowning procedure** in the changing area. The importance of maintaining appropriate hygiene and controlled conditions during the filling operation was explained to us.

We were shown the different stages involved in bottle preparation and filling. The process included:

1. **Bottle Washing:** The bottles undergo washing to remove unwanted particles and contaminants.
2. **Drying:** After washing, the bottles are dried appropriately.
3. **Cooling:** The washed and dried bottles are allowed to cool to room temperature before further processing.
4. **Bottle Holding and Inspection:** The bottles are held under controlled conditions and visually inspected before filling.
5. **Bottle Transfer:** A **turntable and conveyor system** are used for controlled movement and positioning of the bottles during the filling operation.
6. **Filling:** The required quantity of dry syrup formulation is filled into the bottles.

7. **Nitrogen Flushing:** Nitrogen gas is passed where required to reduce oxygen exposure and help protect the product quality.
8. **Inner Plug Placement:** An inner plug is fitted appropriately to the bottle.
9. **Measuring Cup:** A measuring cup is provided as part of the product presentation for accurate administration of the reconstituted syrup.
10. **Final Packing:** The filled and closed bottles are then subjected to the required packaging operations.

Observing the dry syrup filling line helped us understand how different operations are integrated to maintain product quality, hygiene, controlled handling, and efficient packaging.

3.4 Packaging of Tablets, Capsules and Dry Syrups

We were also given an opportunity to observe the packaging operations for pharmaceutical products.

For tablets and capsules, we observed the different levels of packaging:

- **Primary packaging:** Strip packing or blister packing
- **Secondary packaging:** Carton packing
- **Tertiary packaging:** Packing into shippers for transportation and distribution

The importance of appropriate packaging at each stage was explained to us. Primary packaging provides direct protection to the dosage form, while secondary and tertiary packaging provide additional protection, identification, handling, storage, and transportation support.

We were also specifically explained the importance of labelling in pharmaceutical packaging. We learned that labels must be prepared and applied according to the organization's approved procedures and applicable regulatory requirements. The information provided on pharmaceutical labels is important for correct identification, traceability, and safe handling of the product.

We were also explained how a batch number is assigned to a particular batch and how batch identification helps in maintaining traceability throughout manufacturing, packaging, storage, distribution, and, when required, during investigations or product recalls.

This was particularly relevant to us as Regulatory Affairs students because it demonstrated the practical importance of labelling, traceability, documentation, and batch-wise identification in pharmaceutical manufacturing.

3.5 Clean Hold Area

We were also shown the Clean Hold Area, where different types of cleaned and appropriately stored equipment such as sifters were maintained. The importance of maintaining proper storage conditions and preventing contamination or mix-ups of equipment was explained to us.

4. Visit to the Quality Control Department

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We then visited the Quality Control (QC) Department, where we were introduced to several analytical and testing instruments used for evaluating pharmaceutical products and materials.

The instruments and equipment observed included:

- pH Meter
- UV Cabinet
- Disintegration Apparatus
- Friabilator
- Sonicator
- Laboratory Centrifuge
- Hot Plate
- Muffle Furnace
- Fume Hood
- Hot Air Oven
- Dissolution Apparatus
- Sartorius Balance
- Shimadzu Balance
- High-Performance Liquid Chromatography (HPLC)

The QC team explained the general purpose and application of these instruments in pharmaceutical analysis. We gained an understanding of how analytical testing is essential for ensuring the identity, purity, strength, quality, and performance of pharmaceutical products.

The exposure to instruments such as HPLC, dissolution apparatus, analytical balances, and other laboratory equipment helped us understand the practical application of analytical concepts that we study theoretically.

5. Microbiology Department

Following the QC department, we visited the Microbiology Department. Similar to the production and other controlled areas, appropriate changing and gowning procedures were followed before entering the department.

We observed:

- Autoclave
- Laminar Air Flow (LAF) room

- BOD Incubators

The importance of microbiological control, sterilization, controlled environmental conditions, and prevention of microbial contamination was explained to us.

The visit helped us understand the role of microbiological testing and environmental control in maintaining the microbiological quality and safety of pharmaceutical products.

6. Water Treatment Section

We were then taken to the Water Treatment Section, where the pharmaceutical water system was explained.

We observed the various components and processes associated with the water treatment system, including:

- Water collection tanks
- Water treatment and distribution arrangements
- UV disinfection system
- Monitoring of anions and cations

The importance of pharmaceutical water as a critical utility in pharmaceutical manufacturing was explained. We understood that appropriate treatment, monitoring, storage, and distribution of water are essential to ensure that the water used in manufacturing and cleaning processes meets the required quality standards.

7. Stability Chamber

We also had the opportunity to visit the Stability Chamber Room, where we observed an advanced stability chamber manufactured by Osworld.

The purpose of stability chambers and their importance in pharmaceutical product development and quality assessment were explained to us. Stability studies are essential for evaluating how the quality of a pharmaceutical product changes over time under specified environmental conditions and are important in establishing appropriate storage conditions and shelf life.

8. Air Handling Units

We were also introduced to the Air Handling Units (AHUs) used within the facility. The importance of controlled air conditions in pharmaceutical manufacturing areas was explained, particularly with respect to maintaining suitable environmental conditions and minimizing the risk of contamination.

This helped us understand the importance of facility and environmental controls as part of GMP requirements.

9. Control Sample Room

We visited the Control Sample Room, where retention samples of pharmaceutical products are maintained.

We learned that retention samples are preserved for future reference and may be useful for investigations, quality evaluation, and other purposes during the product's lifecycle.

10. Documentation and Regulatory Perspective

One of the most valuable parts of the visit for us as M.Pharm Regulatory Affairs students was the opportunity to observe the documentation system maintained within the facility.

We were given an opportunity to have a look at various Standard Operating Procedures (SOPs) maintained by the organization, including general SOPs, pharmaceutical SOPs, QC-related SOPs, industrial SOPs, and other relevant procedures.

We were also introduced to Batch Manufacturing Records (BMRs) and understood their importance in documenting the manufacturing activities carried out for a particular batch.

The visit helped us appreciate the significance of proper documentation, traceability, controlled procedures, labelling, batch identification, and record maintenance in the pharmaceutical industry. From a Regulatory Affairs perspective, we understood that regulatory compliance is not limited to obtaining approvals but also involves maintaining consistent manufacturing practices, quality systems, documentation, and records throughout the product lifecycle.

11. Key Learning Outcomes

The industrial visit provided us with valuable practical knowledge and helped us connect our academic concepts with their application in the pharmaceutical industry. The major learning outcomes were:

- Practical understanding of tablet, capsule, and dry syrup manufacturing.
- Knowledge of GMP, gowning, contamination control, and environmental control.
- Understanding of in-process testing, QC instruments, and microbiological practices.
- Awareness of packaging, labelling, batch numbering, and product traceability.
- Understanding of pharmaceutical utilities, stability studies, and retention samples.
- Practical exposure to SOPs, BMRs, documentation, and quality systems from a Regulatory Affairs perspective.

12. Interaction and Motivation

During the visit, Mr. M. Venu Gopal Sir, Executive Director, interacted with us and motivated us to consider opportunities in the pharmaceutical industry. He encouraged us to gain practical industrial experience, continuously develop our professional skills, and make effective use of our academic knowledge.

He particularly encouraged the girl students to develop confidence and consider entrepreneurship and leadership opportunities in the pharmaceutical industry. His words were

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highly motivating and gave us a positive perspective regarding the professional opportunities available to us in the pharmaceutical sector.

13. Conclusion

The industrial visit to Akin Laboratories Pvt. Ltd., Balanagar, was a highly informative and enriching learning experience. It provided us with an opportunity to observe the practical functioning of different pharmaceutical departments and understand how production, quality control, microbiology, utilities, packaging, documentation, and quality systems work together to ensure the quality and safety of pharmaceutical products.

As M.Pharm Regulatory Affairs students, the visit was particularly valuable because it enabled us to connect our theoretical knowledge of GMP, quality systems, documentation, compliance, labelling, traceability, and regulatory requirements with their practical implementation in an industrial environment.

We sincerely thank Dr. N. Srinivas Sir for his continuous coordination and support in organizing the industrial visit. We are grateful to Mr. M. Venu Gopal Sir, Executive Director, for warmly welcoming us, spending time with us, and motivating us towards professional development and entrepreneurship.

We extend our sincere thanks to Mrs. Srilatha from the Production Department and Ms. Bhavani, QC Scientist, for patiently guiding us through the different departments and explaining the processes, equipment, and documentation in a clear and understandable manner.

We also express our heartfelt thanks to Mr. A. Kartik Rao Sir and all the management members for their constant support and efforts towards upgrading our knowledge and skills.

Finally, we sincerely thank Dr. B. Haarika Mam, Principal, for her valuable support, encouragement, and cooperation in facilitating this industrial visit.

Overall, the visit was a wonderful and memorable learning experience that enhanced our practical understanding of the pharmaceutical industry and will be valuable for our future academic and professional careers.

