Report on

Industrial Visit to Sri Krishna Pharmaceuticals Pvt Ltd. (SKPL)., Unit III Shamshabad

Place : Hyderabad , Telangana
Date of Visit: 28 / 03/ 2024
Time : 8:30 to 5:00

Sarojini Naidu Vanita Pharmacy Maha Vidyalaya faculty attended GMP Audit Certified Training at USFDA approved plant of Sri Krishna Pharmaceuticals Pvt Ltd., Unit III., Shamshabad, Hyderabad.

- To gain insights into the latest GMP regulations and best practices.
- To Learn strategies for ensuring compliance and quality in pharmaceutical manufacturing.
- To network with industry peers and experts.
- To receive practical guidance on preparing for GMP audits.
- To enhance capabilities to maintain high standards of quality and safety.

Introduction:

On March 28th, 2024, a faculty delegation from Sarojini Naidu Vanita Pharmacy Maha Vidyalaya, comprising Dr. P.Vivek Sagar, Mrs. R.Swetha Sri, and Mrs. P. Kavitha, visited Sri Krishna Pharmaceuticals Pvt Ltd. located at Gollapalle Kalan, Shamshabad, Telangana. The visit aimed to provide the faculty with firsthand exposure to Sri Krishna Pharmaceuticals Pvt Ltd. operations, facilities, and various departments. Renowned for their contributions to the pharmaceutical industry and commitment to quality and innovation, Sri Krishna Pharma offered valuable insights for the visiting faculty.

Overview of Sri Krishna Pharmaceuticals Pvt Ltd. (SKPL):

Sri Krishna Pharma Ltd. is a leading pharmaceutical company specializing in research, development, and manufacturing of active pharmaceutical ingredients (APIs) and intermediates. Sri Krishna Pharmaceuticals Pvt Ltd. was established in 1974 by Dr. V V Subba Reddy at Uppal, Hyderabad (Unit I), Second facility at Nacharam (Unit II) established as a direct compression facility and third facility set up as Sri Krishna Pharmaceuticals Pvt Ltd. at Shamshabad (Unit III) . The company has grown significantly over the years and has earned a reputation for its high-quality products and adherence to stringent regulatory standards.

Achievements of SKPL:

- USFDA, TGA and WHO GMP inspections at Unit I are in process for Acetaminophen (Paracetamol) and Domperidone / Domperidone Maleate.
- Unit II is approved with GMP compliance certificates from German, Brazilian (ANVISA) and Mexican (COFEPRIS) regulatory authorities.
- Unit II gains Italian (AIFA) approval for all solid dosage formats.

- Unit III receives surveillance inspection and certification by USFDA for Folic Acid manufacturing.

AUDIT SERVICE PROVIDER:

Pharm Sol Europe Limited
The Victoria Centre, Unit 2,
Lower Ground Floor, Valletta Road,
Mosta, MST 9012, Malta

AUDITORS:

Mr. K. Pavana Narasimhulu

Senior Manager – Compliance
APIC certified auditor
ECA Certified QA Manager and Auditor for APIs

Mrs. Mogga Saraswathi

Manager – Compliance
ASQ Certified Quality Auditor CQI & IRCA Certified Auditor

The industrial audit visit to Sri Krishna Pharmaceuticals Pvt Ltd.Unit-III, Shamshabad, Telangana, India was organized by **Dr. B. Prabha Shankar,** Chairman, Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (SNVPMV) and CEO, Euro drug Laboratories India on 28-03-2024. We, **Dr. P. Vivek Sagar, Professor, Head, Department of Pharmaceutical Analysis, SNVPMV, Mrs. R. Swetha sri, Assistant Professor, Department of Pharmaceutical Quality Assurance, SNVPMV and Mrs. P. Kavitha, Assistant Professor, Department of Pharmaceutical Chemistry, SNVPMV** started to Srikrishna Pharma Limited.Unit-III at 08:30 AM along with our Chairman **Dr. B. Prabha Shankar Sir** and reached the destination at 10.00 AM. The auditing team also reached Sri Krishna Pharmaceuticals Pvt Ltd.Unit-III on time.

The audit commenced with a briefing session by **Mr. S. Venkata Rami Reddy,** Manager, Quality Assurance Sri Krishna Pharmaceuticals Pvt Ltd.Unit-III., and his team in the board room, providing an overview of the company's operations, quality management systems, and regulatory compliance.

The auditors **Mr. K. Pavana Narasimhulu** and **Mrs. Mogga Saraswathi** conducted thorough inspections of various departments, including production, quality control, quality assurance, and safety protocols.

Detailed discussions were held with department heads and personnel to understand processes, procedures, and challenges.

Initially we were provided with Aprons and head caps following the instructions given in posters kept in that room. Soon after we started for Plant Tour at 10.30 am and visited the following areas:

- Warehouse - Raw materials, Intermediates, packing materials and Finished goods stores,
- Manufacturing Area
- Production Area
- Utilities
- Water treatment plant
- Quality Control
- Stability and control samples area

Facilities Visited:

1. **Manufacturing Unit:**
    - The manufacturing unit is where the synthesis and production of APIs and intermediates take place.
    - We observed the manufacturing processes firsthand and gained insights into the meticulous procedures followed to ensure product quality and purity.
    - Emphasis was placed on adherence to Good Manufacturing Practices (GMP) and other regulatory requirements.
2. **Quality Control (QC) Department:**
    - The QC department plays a critical role in ensuring that all products meet the highest quality standards.
    - We were shown the testing procedures carried out to assess the purity, potency, and stability of finished products and raw materials.
    - The use of advanced analytical techniques and instruments was highlighted during our visit.
3. **Packaging and Warehousing:**
    - Sri Krishna Pharmaceuticals Pvt Ltd., maintains modern packaging facilities to ensure the safe and efficient packaging of pharmaceutical products.
    - We were briefed on the packaging materials used, labeling requirements, and storage conditions.
    - The warehousing facilities were organized and well-maintained, adhering to industry best practices for inventory management and logistics.

We moved to Manufacturing Department along with our Chairman Dr. B. Prabha Shankar and Dr. M. Ananth Suryanarayana Sr. G.M. Quality observed various, Manufacturing Area, Production Area, water plant Area and Storage warehouse rooms.

Dr. M. Ananth Suryanarayana began the tour by giving us an overview of Sri Krishna Pharmaceuticals Pvt Ltd. manufacturing operations. He explained that the company specializes in producing pharmaceutical intermediates and active pharmaceutical ingredients (API), serving both domestic and international markets. We discussed the company's commitment to quality, safety,

and environmental sustainability. Before entering the facility, we were provided with disposable safety head cap and protective footwear.

The Professionals near each and every department explained us with the manufacturing processes conducted in the area and explained the types of products (**Fenoverine , Metadoxine , Folic Acid** and **Meclazine**) being manufactured, the machinery and equipment used, and the overall layout of the facility.

As we walked through the manufacturing area, we had the opportunity to interact with several staff members. We met with operators overseeing the reactors and centrifuges, as well as technicians responsible for quality control and assurance. They graciously shared insights into their roles, the specific processes they managed, and the importance of adherence to Good Manufacturing Practices (GMP).

Throughout the tour, we observed the production lines in operation, noting the precision and efficiency with which raw materials were transformed into pharmaceutical products. We asked questions about the technologies employed, the measures in place to ensure product purity and potency, and the company's efforts to minimize waste and energy consumption.

Water Treatment Plant :

Dr. M. Ananth Suryanarayana also provided an overview of Sri Krishna Pharmaceuticals Pvt Ltd. water treatment plant. He explained that the plant plays a critical role in the company's manufacturing processes by supplying high-quality water for various purposes, including production, cleaning, and cooling. Inside the water treatment plant, we observed the various stages of the water treatment process. We were explained about each step, including filtration, chemical treatment, and disinfection, emphasizing the importance of maintaining water quality standards in compliance with regulatory requirements. As we observed the operations of the water treatment plant, we asked questions about the sources of water, the specific treatment methods employed, and the measures in place to conserve water and minimize environmental impact. we also inquired about the plant's capacity and its ability to adapt to fluctuations in water demand.

Post Lunch at 2:00 pm it was scheduled to visit Quality control department at Sri Krishna Pharmaceuticals Pvt Ltd.

We moved to QC Department along with our Chairman Dr. B. Prabha Shankar and Dr. P . M. Krishna Prasad VP- Corporate Quality and Compliance . Dr. P . M. Krishna Prasad gave us an overview of Sri Krishna Pharmaceuticals Pvt Ltd. QC department. Sir explained that the department is responsible for ensuring the quality and consistency of raw materials, in-process materials, and finished products through rigorous testing and analysis.

Throughout the visit, we had the opportunity to interact with QC analysts responsible for performing tests and interpreting results. They shared their expertise on methods such as high-

performance liquid chromatography (HPLC), gas chromatography (GC), and Fourier-transform infrared spectroscopy (FTIR), explaining how these techniques are used to assess the quality and purity of pharmaceutical products. QC analysts at work, patiently answered our questions about the validation of testing methods, the documentation of test results, and the measures in place to ensure compliance with regulatory standards such as Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP). We also inquired about the department's role in investigating and addressing quality issues that may arise during production.

Interaction with Professionals: Throughout the visit, we had the opportunity to interact with professionals ranging from scientists and researchers to production managers and quality assurance personnel. Their willingness to share their knowledge and experiences enriched our understanding of the pharmaceutical industry and provided valuable insights into career opportunities in this field.

The following is the sample Questionnaire (Checklist) verified by Auditors :

I. Documentation and Records

Master Batch Records (MBRs) and Batch Production Records (BPRs):

- ✓ Are they present, complete, and accurate for all batches manufactured?
- ✓ Do they follow established procedures and specifications?
- ✓ Are changes documented and approved?

Standard Operating Procedures (SOPs):

- ✓ Are current and approved SOPs available for all critical manufacturing and quality control activities?
- ✓ Are SOPs followed by personnel?

Cleaning and Sanitation Records:

- ✓ Are cleaning procedures documented and followed?
- ✓ Are cleaning and sanitation records maintained?

Calibration Records:

- ✓ Are all equipment and instruments used in manufacturing and quality control calibrated according to a defined schedule?
- ✓ Are calibration records maintained?

Change Control Records:

- ✓ Are there documented procedures for managing changes to processes, materials, equipment, and specifications?

- ✓ Are change control records maintained?

Deviations and Investigations:

- ✓ Are procedures for handling deviations from SOPs or specifications documented and followed?
- ✓ Are investigations of deviations thorough and documented?

II. Facilities and Equipment

General Housekeeping:

- ✓ Is the facility clean and well-maintained?
- ✓ Is there proper segregation between clean and non-clean areas?

Equipment:

- ✓ Is equipment in good working order and properly calibrated?
- ✓ Are preventive maintenance procedures in place and followed?

Environmental Monitoring:

- ✓ Are appropriate environmental conditions (temperature, humidity, pressure) monitored and controlled according to product specifications?
- ✓ Are environmental monitoring records maintained?

Warehouse and Storage:

- ✓ Are materials and finished products stored appropriately under controlled conditions?
- ✓ Are first-in, first-out (FIFO) principles followed for materials usage?

III. Production

Material Control:

- ✓ Are materials properly identified, labeled, and stored?
- ✓ Are procedures in place to prevent mix-ups and contamination?

Weighing and Dispensing:

- ✓ Are procedures for accurate weighing and dispensing of materials documented and followed?
- ✓ Are appropriate weighing equipment and balances used?

Manufacturing Processes:

- ✓ Are manufacturing processes conducted according to established SOPs and BPRs?
- ✓ Are there procedures for in-process controls to ensure product quality?

Packaging and Labeling:

- ✓ Are packaging and labeling procedures documented and followed?
- ✓ Do labels contain all required information and meet regulatory requirements?

IV. Quality Control (QC)

Sampling Procedures:

- ✓ Are procedures for sampling raw materials, in-process materials, and finished products documented and followed?
- ✓ Are sampling plans adequate to ensure product quality?

Testing Procedures:

- ✓ Are QC tests conducted according to established SOPs and validated methods?
- ✓ Are qualified personnel performing the tests?

QC Records:

- ✓ Are QC test results documented and reviewed?
- ✓ Are procedures for handling out-of-specification (OOS) results in place and followed?

V. Additional Considerations

Personnel Training:

- ✓ Are personnel adequately trained on relevant procedures and regulations?
- ✓ Are training records maintained?

Self-Inspection Program:

- ✓ Does the company have a documented self-inspection program?
- ✓ Are self-inspection reports reviewed and addressed?

Complaints and Recalls:

- ✓ Are procedures for handling complaints and product recalls documented and followed?
- ✓ Are complaint and recall records maintained?

Conclusion: The industrial visit to Sri Krishna Pharmaceuticals Pvt Ltd. was both educational and inspiring. We gained a comprehensive understanding of the various processes involved in

pharmaceutical research, development, and manufacturing. At QC department we gained a deeper understanding of the meticulous testing processes involved in ensuring the safety and efficacy of pharmaceutical products before they are released to the market. We greatly appreciate the dedication and expertise of the team at QC-department in upholding Sri Krishna Pharmaceuticals Pvt Ltd. commitment to quality and customer satisfaction. The commitment to quality, innovation, and regulatory compliance demonstrated by the company serves as a testament to its leadership in the industry. We extend our gratitude to the management and staff of Sri Krishna Pharmaceuticals Pvt Ltd. for their hospitality and for providing us with a memorable learning experience.

During the visit, we gained invaluable insights into the operations and practices of Sri Krishna Pharma Ltd., which have significantly broadened our understanding of the pharmaceutical industry. Witnessing firsthand dedication to quality, innovation, and excellence has been truly inspiring and motivating.

Moreover, the opportunity to network and learn from professionals at Sri Krishna Pharmaceuticals Pvt Ltd. has been invaluable. The interactions and discussions have provided us with a deeper appreciation for the complexities and dynamics of the industry, as well as valuable insights that we are eager to apply in our academics and professional pursuits.

We are committed to utilizing the knowledge and experiences gained from this visit to contribute effectively to our organization's objectives and goals.

We thank our Management, Director, Principal and Vice-Principal for their unwavering support and encouragement in facilitating our participation in the industrial audit visit to Sri Krishna Pharmaceuticals Pvt Ltd. This opportunity is deeply appreciated and will undoubtedly contribute to our personal and professional growth.

We would like to express our sincere thanks to our Chairman Dr. B. Prabha Shankar, who facilitated our visit and provided valuable insights into the operations of Sri Krishna Pharmaceuticals Pvt Ltd. Special thanks to all the staff members at Sri Krishna Pharmaceuticals Pvt Ltd., who took the time to interact with us and answered all our questionnaire.It has been an enriching and enlightening experience that we are deeply grateful for.

Once again, we thank our Chairman Dr. B. Prabha Shankar , for the generosity and support . We look forward for future such opportunities for learning and development under Sir’s guidance.


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Long 78.419398°
28/03/24 09:56 AM GMT +05:30


Sri Krishna Pharmaceuticals Limited, Unit – III
Welcomes
Auditors:
From:
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Long 78.419398°
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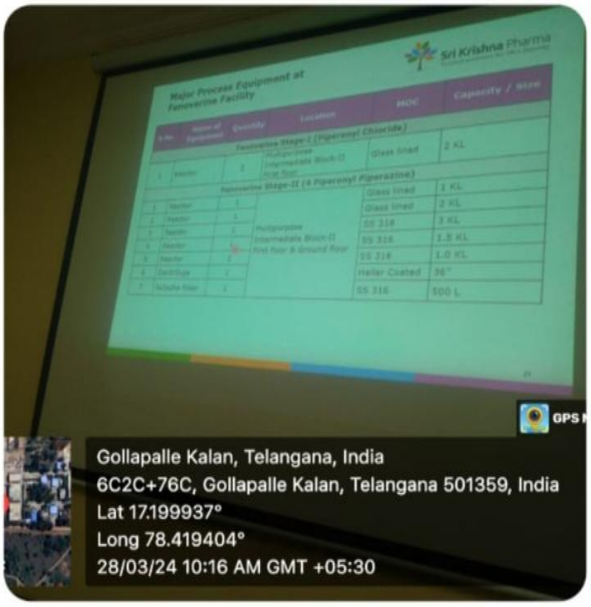
Major Process Equipment at Fenoverine Facility
Gollapalle Kalan, Telangana, India
6C2C+76C, Gollapalle Kalan, Telangana 501359, India
Lat 17.199937°
Long 78.419404°
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GPS Map Camera
Gollapalle Kalan, Telangana, India
Service Rd, Gollapalle Kalan, Telangana 501218, India


GPS Map Camera
Gollapalle Kalan, Telangana, India


Gollapalle Kalan, Telangana, India
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GPS Map Camera
Gollapalle Kalan, Telangana, India

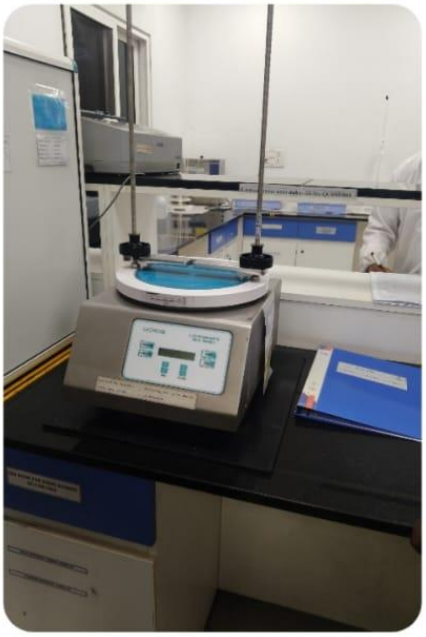

HPLC NEW
GLASS WARE


RE-817
RE-833


RE-905


V 910
V-909

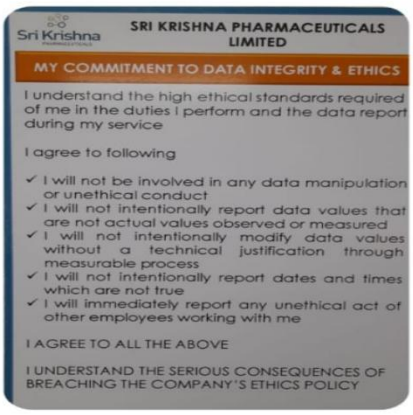

Polarimeter
sample
preparation area




INSTRUMENT NAME : SINGLE PAN BALANCE
INSTRUMENT I.D. No.: QC/INS/027
METTLER TOLEDO


LIMITED
QUALITY POLICY
Krishna Pharmaceuticals Limited strives for Market Leadership by supplying Quality oducts consistently to the Full satisfaction of Customers in National and Global markets with a commitment of compliance of its products with regulatory and customer's requirements.
Sri Krishna Pharmaceuticals Limited is committed to implement and improve the Quality Management System on a continual basis with its established quality objectives nderstood by all within the organization and their periodical review for a continuing suitability.
SD/-


Sri Krishna
SRI KRISHNA PHARMACEUTICALS LIMITED
DATA INTEGRITY @ LAB


Sri Krishna
SRI KRISHNA PHARMACEUTICALS LIMITED
MY COMMITMENT TO DATA INTEGRITY & ETHICS
I understand the high ethical standards required of me in the duties I perform and the data report during my service
I agree to following
✓ I will not be involved in any data manipulation or unethical conduct
✓ I will not intentionally report data values that are not actual values observed or measured
✓ I will not intentionally modify data values without a technical justification through measurable process
✓ I will not intentionally report dates and times which are not true
✓ I will immediately report any unethical act of other employees working with me
I AGREE TO ALL THE ABOVE
I UNDERSTAND THE SERIOUS CONSEQUENCES OF BREACHING THE COMPANY'S ETHICS POLICY


Laboratory safety Guidelines
Basic Laboratory Practices
Chemical spills
Personal injury
Major chemicals spill -call your supervisor
Report ALL incidents to Safety Department


3 CAUSES OF ACCIDENTS
"I Didn't SEE"
"I Didn't THINK"
"I Didn't KNOW"


16
SOME ONE NEEDS
FIRST AID?


DOCUMENTS & RECORDS