SAROJINI NAIDU VANITA PHARMACY MAHAVIDYALAYA

Report on

AUDIT WORK SHOP OF UNIT-2 SRI KRISHNA PHARMACEUTICALS PVT LTD.

AUDIT DATE: 11-04-2024

AUDIT OBJECTIVE: GMP Compliance Assessment Audit of Formulation Manufacturing Site.

PROJECT CODE: 03/HK01/A01/2249/0224-C

AUDIT CLIENT: Eurodrug Laboratories Ltd. Unit 2802, 28th Floor Rykadan Capital Tower 135 Hoi Bun Road, Kwun Tong, Hong Kong.

AUDIT SERVICE PROVIDER:

Pharm Sol Europe Limited

The Victoria Centre, Unit 2,

Lower Ground Floor, Valletta Road,

Mosta, MST 9012, Malta

AUDITORS:

Mr. S. Srinivasa Rao Manager – Quality Affairs CQI & IRCA Certified Auditor.

Mr. Suresh Singaram Executive – Compliance PharmSol Qualified Auditor.

AUDIT CRITERIA:

1. EudraLex Volume 4 - Part I - Medicinal Products for Human and Veterinary Use: Guidelines to Good Manufacturing Practice.
2. US FDA 21 CFR Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals.
3. PIC/S Guide to Good Manufacturing Practice for Medicinal Products, Part I, August 2023.
4. PharmSol' s In-house Audit Agenda & Checklist.

AUDIT CHECKLIST

Company presentation

Copy of Valid Certifications/ Accreditations

Manufacturing License

Site master file

Manufacturing block-wise list of Products manufactured at the site.

Process flow diagram of the reference product

Specification & COA of the Reference product

Product-specific declarations which include Nitrosamine Impurities, Genotoxic Impurities, Elemental Impurities (USP, Q3(D)), TSE and BSE, Allergen-Free, Melamine-Free, Residual solvents (OVI) statements, Kosher/Halal-free, Aflatoxins-Free, Phthalates-Free, Halogenated Organic Chemical Status, Sulfite-free, Gluten-Free, Latex-Free and GMO-Free.

The industrial audit visit to Sri Krishna Pharmaceuticals Pvt Ltd Unit-II, IDA, NACHARAM, Telangana, India was organized by **Dr. B. Prabha Shankar, Chairman, Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (SNVPMV)** and **CEO, Eurodrug Laboratories India** on 11-04-2024. We, **Dr. T.Mamatha, Vice Principal , HOD, Department of Pharmaceutical Quality Assurance, SNVPMV, Dr. M. Swetha, Associate Professor, Department of Regulatory Affairs, Mrs Leemol Varghese Departmnet of Pharmacognosy and Mr.Sandeep Department of Regulatory Affairs, SNVPMV** started to Sri Krishna Pharma Ltd at 09:30 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-II on time. Audit started with Mrs.N.Chandra Kala, AGM-QA Sri Krishna Pharmaceuticals Pvt Ltd.UnitII., and her team in the **conference room** providing an overview about the product and industry policies to maintain the quality.

The auditors **Mr. S. Srinivasa Rao Manager & Mr. Suresh Singaram Executive closely supervised** various **departments** including production, quality control, quality assurance and safety procedures.

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 before entering into 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,
- Production Area
- Quality Control
- Stability and control samples area
- Primary & Secondary packaging area.

After brief introduction we divided into two groups and one team went to production area and other team to Quality Control.

During audit, **t**he inspectors check the weights and measures and the daily adjustment reports an d records, confirm on the 5th floor, then move with the inspectors to the first floor, where it is the company that keeps the warehouse, dot of access. of raw materials, distribution. Implemente d rules to inspect rooms, quality inspection documents, sample records,storage temperature recor ds and daily update tracking of raw materials in goods.

In production the auditor verified weights and measurements, along with daily calibration report & record entry were checked in fifth floor after that along with auditor we went to first floor where the industry is maintaining ware house verified ware house storage ,raw material entry points, dispensing chambers, quality checking documents, sampling records, storage temperature records were verified and instructed some rules to update the tracking of raw materials in stock in day to day basis.

In third floor auditor verified manufacturing facilities (RMG,FBP,FBD. DAI Sifter ,Rotary Tablet punching machine 18,29,47 stations , capsule filling machine , maintenance ,cleaning and sop of equipments IQAC records , Primary packaging facilities i.e blister packaging strip packaging and secondary and tertiary packaging materials were verified.

Team 2 **Dr.T.Mamatha** and **Mrs Leemol Varghese** went along with auditor **Suresh**, Q.C Manager Mr.Aravind shinde and Q.C head explained the process how they are maintain the quality of the product at different stages

Daily temperature conditions in premises, balance, software LABICON software calibration ,documentation &log book . Charts were displayed about the contamination impurities.

After that the auditor verified register for Raw material,inward register for all miscellaneous at different stages &Packing Material.

HPLC ,UV,FTIR methods ,Validation and log books were verified .

Regulatory requirements done -after expiry 1year of storage and to be disposed

Auditor enquire about ICH guidelines for Stability studies (Accelerated for 6 months & Long term done for minimum of 3yrs & maximum for 5yrs and verified the submitted document.

Quality Assurance Documentation.

Post lunch auditors verified all process documentation in each department and verified whether the submitted documents are having compliance with CGMP guidelines.

The following documents were checked during the Audit

Chapter 1

PHARMACEUTICAL QUALITY SYSTEM

Quality Policy Quality Objectives

Change Controls Management System

- SOP for Change control management
- Change controls log for the last 2 years
- Change control record related to the reference product

Deviations/Incidents:

- SOP for Handling Deviations
- Deviation Log for the last 2 years
- One deviation record related to the Reference Product
- SOP for Handling Incidents
- Incidents log for the last two years
- One incident record of the Reference product

CAPA

- SOP for CAPA Monitoring
- CAPA Log for the last 2 years
- One CAPA record related to the Reference Product
- Verification of previous Audit CAPA

Quality Management Review

SOP on Quality Management Review

- Recent Quality Management review records

Product Quality Review

- APQR SOP
- Latest APQR report for the Reference Product

Quality Risk Management

- QRM SOP
- QRM document for the Reference Product
- Cross-contamination risk assessment study report.
- Risk assessment and control of DNA reactive (mutagenic) impurities

- Risk assessment and control of Nitrosamine impurities

Risk assessment and control of Elemental impurities

Organogram:

- Organogram SOP
- Site Organogram including Senior Management

Key Personnel

- Total Employees in the facility, (QA, QC, Production and Others)
- List of Key Personnel
- Job responsibility SOP
- Job responsibility documents of the QA Head, QC Head, Production Head and their deputies.

Training

- Employee Training SOP
- cGMP Training schedule for the current year
- Employee Training records

Personnel Hygiene

- SOP for Health and Hygiene of the Personnel working in the Facility.
- Gowning procedure for Production area, Sampling/Dispensing areas, Microbiology Lab, etc.
- SOP on Medical check-ups and the related records
- Contract agreement with the external medical consultant, if applicable

Quality control

- List of Instruments in QC Laboratory
- Calibration Schedule for QC Instruments
- Calibration record for Analytical balance, HPLC and GC systems.

Sampling Procedures:

- SOP for Sampling of Raw Materials, Excipients and Packaging Materials
- SOP for Sampling of the finished product Volumetric Preparations
- SOP for Volumetric Solution Preparation and standardization - SOP for Reagents Preparation

- Volumetric Glassware Cleaning & Calibration SOP Reference standards & Working Standard

- SOP for Reference standards and working standards management

- COAs of Working standards and Reference standards of the Reference product Analytical method validations

- FP Specification and standard test procedure of audit scope product.

- SOP for Analytical Method Validation/Verification/Transfer

- Analytical method validation/verification/transfer documents (protocol & report) for the test methods of the reference products

- Analytical methods used for assessment of DNA reactive (mutagenic) impurities and Nitrosamine impurities.

Stability

- SOP for Stability

Study - Stability indicating test methods and specification of the audit scope product. - Stability Protocol of the Reference product

- Stability data (Accelerated & Long-term conditions) supporting the shelflife of the reference products

- Recent process validation batches stability study data

- Annual add-on batch stability study data

- Hold-time study data for intermediates of the Reference product

- Calibration/Preventive maintenance of stability chambers

- SOP for Assigning manufacturing date, expiry date and retest date

Control samples/Retention samples

- SOP for Retention samples management

- Retention sample register

- Temperature monitoring record of Retention sample room

- Visual Inspection SOP & records

- Handling of inspection rejects SOP Training record and Qualification program for Visual Inspectors Audit Trails

- Audit Trail SOP - Audit Trail Checklist Microbiology Laboratory

- Entry/exit procedure

- Area cleaning and sanitization procedure
- Media preparation & discarding procedure.
- Media consumption records
- Microbial test procedures and records related to the reference product.

Consultants

- Records of Consultants employed at the site

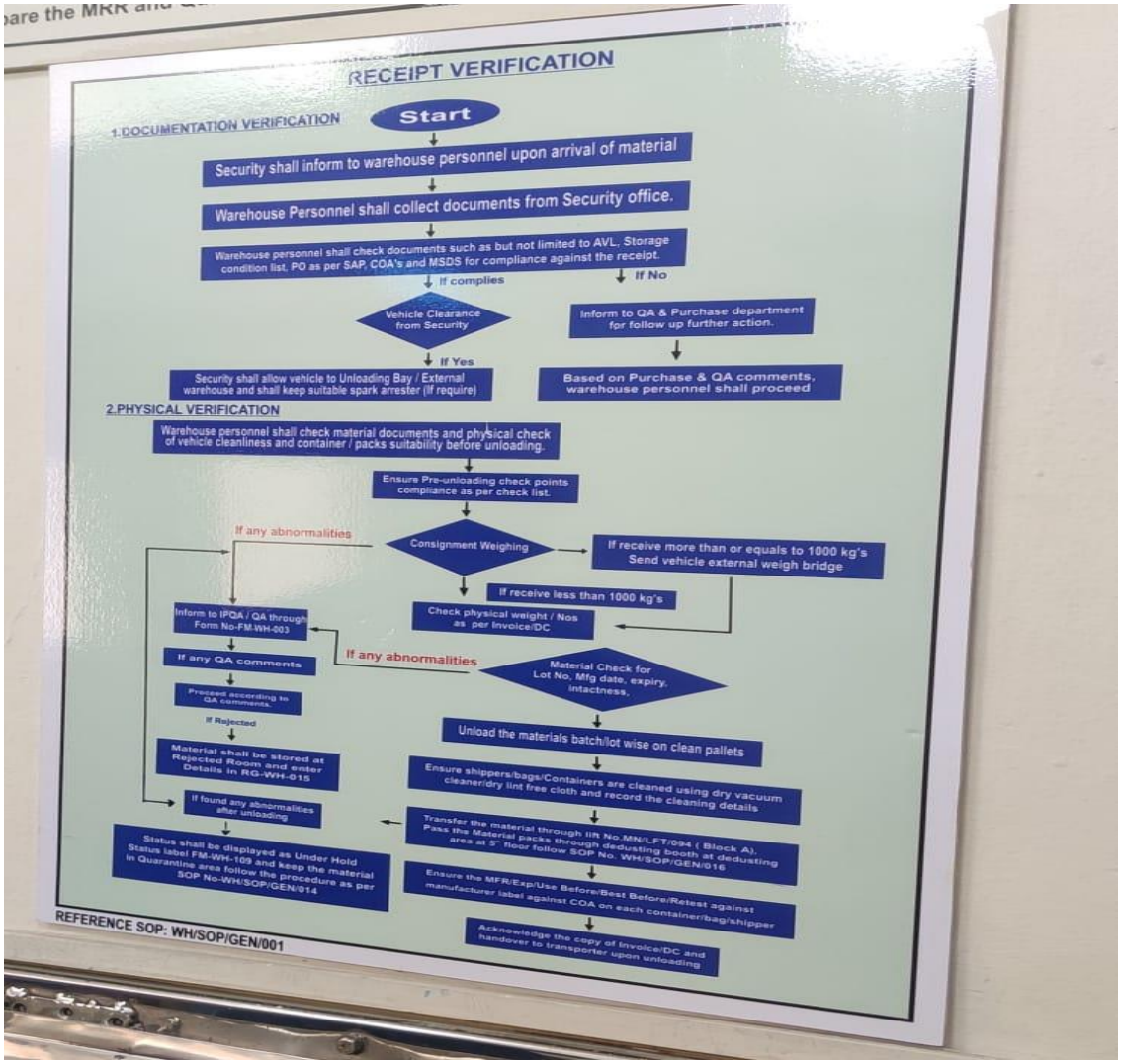
  Agreements with the consultants

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.

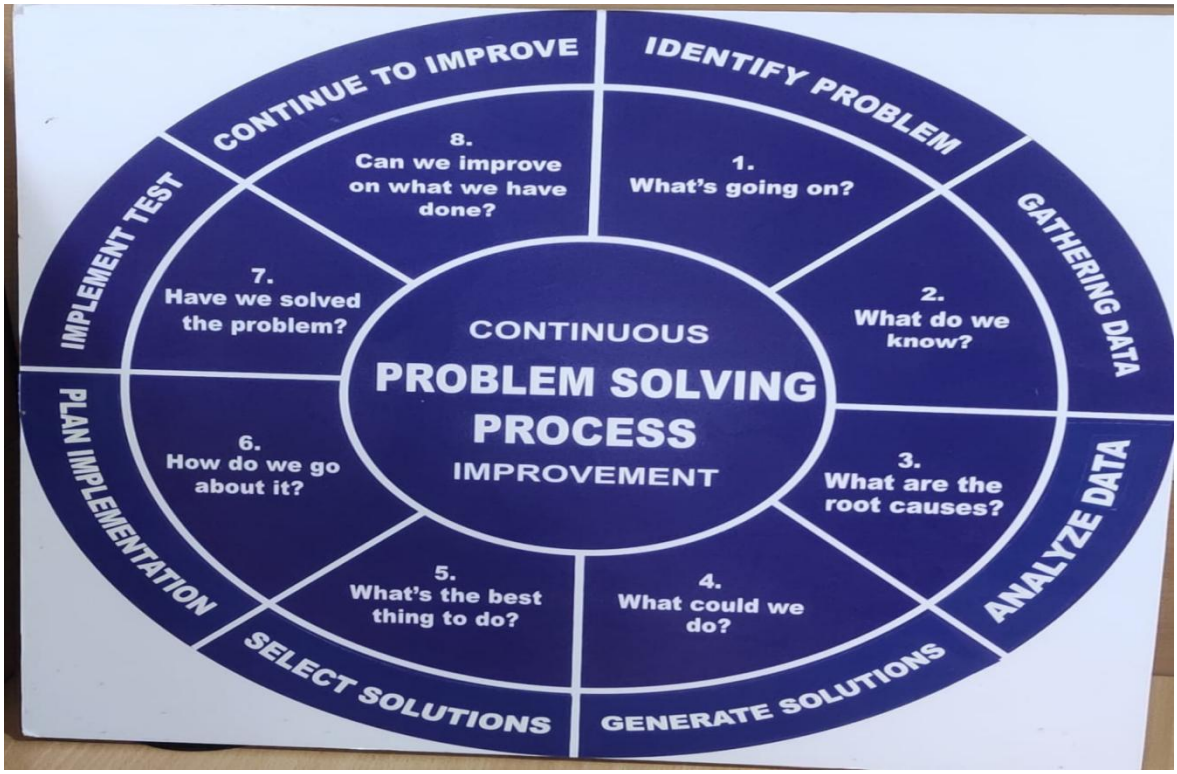
We would like to thank the management and staff of Sri Krishna Pharmaceuticals Pvt Ltd for their support & encouragement on our participation in industry visit. This opportunity is greatly appreciated and will undoubtedly contribute to our personal and profe ssional growth.


SRI KRISHNA PHARMACEUTICALS LIMITED


Sri Krishna
Pharma
TOLERANCE LIMIT FOR RAW MATERIALS
BAGS/CONTAINERS RECEIVED EQUAL TO 1000 KG/MORE _NMT 2%
BAGS/CONTAINERS RECEIVED LESS THAN 1000 KG _NMT 5%


RECEIPT VERIFICATION
1.DOCUMENTATION VERIFICATION
Start
Security shall inform to warehouse personnel upon arrival of material
Warehouse Personnel shall collect documents from Security office.
Warehouse personnel shall check documents such as but not limited to AVL, Storage condition list, PO as per SAP, COA's and MSDS for compliance against the receipt.
If complies
If No
Vehicle Clearance from Security
Inform to QA & Purchase department fpr follow up further action.
If Yes
Security shall allow vehicle to Unloading Bay / External warehouse and shall keep suitable spark arrester (if require)
Based on Purchase & QA comments, warehouse personnel shall proceed
2.PHYSICAL VERIFICATION
Warehouse personnel shall check material documents and physical check of vehicle cleanliness and container / packs suitability before unloading.
Ensure Pre-unloading check points compliance as per check list.
If any abnormalities
Consignment Weighing
If receive more than or equals to 1000 kg's Send vehicle external weigh bridge
If receive less than 1000 kg's
Check physical weight / Nos as per Invoice/DC
Inform to IPQA / QA through Form No-FM-WH-003
If any QA comments
If any abnormalities
Material Check for Lot No, Mfg date, expiry, intactness.
Proceed according to QA comments
If Rejected
Material shall be stored at Rejected Room and enter Details in RG-WH-015
Unload the materials batch/lot wise on clean pallets
Ensure shippers/bags/Containers are cleaned using dry vacuum cleaner/dry lint free cloth and record the cleaning details
If found any abnormalities after unloading
Transfer the material through IIN No.MN/LFT/094 (Block A). Pass the Material packs through dedusting booth at dedusting area at 5" floor follow SOP No. WH/SOP/GEN/016
Status shall be displayed as Under Hold Status label FM-WH-109 and keep the material in Quarantine area follow the procedure as per SOP No-WH/SOP/GEN/014
Ensure the MFR/Exp/Use Before/Best Before/Retest against manufacturer label against COA on each container/bag/shipper
Acknowledge the copy of Invoice/DC and handover to transporter upon unloading
REFERENCE SOP: WH/SOP/GEN/001


STANDARD
WEIGHTS



SRI KRISHNA PHARMACEUTICALS LTD

A-34 & 35, IDA, NACHARAM, HYDERABAD-76

Sri Krishna Pharma UNIT-II

CHECKS FOR INSTRUCTIONS

(HANDLING OF RAW AND PACKING MATERIALS)

Check the followings

Approved vendor list
Storage conditions list
Invoice copy / DC / packing list if any.....
Test certificates and MSDS.....

- Ensure to check purchase order in SAP (T-code ME23N).
- Allow the Materials for Gate inward.
- Ensure to follow safety PPE's during handling of Materials.
- Ensure to placed the Spark Arrestor to the Vehicle by security.
- Ensure to check the physical condition of Vehicle before unloading if any foul smell or any other materials.
- Ensure to use suitable Hand trolley for transfer of materials.
- Ensure Air curtains are in "ON" condition before starting Unloading of Materials.
- Ensure to cleaned the Respective pass boxes / Unload before starting the activity.
- Ensure to Unload the Materials as per Batch wise / Lot wise in separate individual suitable pallets
- Ensure pallets should be cleaned before starting unloading the Materials.
- Ensure to calibrate the suitable weighing balance before activity for cross verification of weight of Bags / Drums / Shippers
- Ensure to fill all the check list online during the activity.
- Ensure Vaccum cleaner cleaned before and after the Activity record the activity timings.
- After unloading activity completion. Ensure shift all the Materials to respective area.
- Ensure Lift are cleaned before placing and transferring the Materials to respective areas.
- Ensure to Dedust the Materials before accepting the materials into respective storage area.
- Ensure to clean the De-dusting Booth before and after de-dusting activity.
- Ensure to update the Respective location boards after placing the Materials into storage racks.
- Ensure to Prepare the MRR and Quarantine Labels Online pasting and inform to QC for sampling.

SRI KRISHNA PHARMACEUTICALS LIMITED

S.No.	AREA	SECONDARY DRESS WITH COLORED STRIP	COLOR CODE
1.	GRANULATION AREA	BLUE COLOR STRIP ON THE SHIRT COLLAR AND BLUE COLOR STRIP ON THE PANT	
2.	COMPRESSION AREA	RED COLOR STRIP ON THE SHIRT COLLAR AND RED COLOR STRIP ON THE PANT	
3.	CAPSULE FILLING AND CHECK WEIGHING AREA	GREEN COLOR STRIP ON THE SHIRT COLLAR AND GREEN COLOR STRIP ON THE PANT	
4.	COATING AREA	PINK COLOR STRIP ON THE SHIRT COLLAR AND PINK COLOR STRIP ON THE PANT	
5.	PRIMARY PACKING AREA	ORANGE COLOR STRIP ON THE SHIRT COLLAR AND ORANGE COLOR STRIP ON THE PANT	