SAROJINI NAIDU VANITA PHARMACY MAHA VIDYALAYA

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INDUSTRY AUDIT VISIT REPORT

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Date of Visit: 12th June 2025

Location: Suven Pharma (Cohance), Parsemylaram, Telangana

Purpose: Participation in Audit of API – *Doxofylline*

Visit Details

I, Dr. S. Anuradha, got the opportunity to participate in an industry audit at **Suven Pharma**, currently undergoing rebranding as **Cohance**. I sincerely thank our Chairman, **Dr. B. Prabha Shankar Sir**, for granting me this valuable opportunity.

I had the privilege of accompanying **Mr. Laurens**, Qualified Person (QP) from **Eurodrugs**, Poland, and **Mr. Abhilash** from Euro drugs during the audit. We began our journey at **6:30 AM** and reached the Suven Pharma facility by **9:10 AM**.

A five-member delegation from **Korea**, comprising professionals from **Quality Assurance (QA)** and **Regulatory Affairs (RA)**, also joined the audit team.

The objective was to conduct a comprehensive quality and compliance audit of the **Active Pharmaceutical Ingredient (API) – Doxofylline**.

Reception and Introduction

The **Cohance–Suven Pharma** team extended a warm and formal welcome to all the visiting national and international delegates. The introductory session included:

- Introduction of the **Suven Pharma audit coordination and technical teams**.

- Formal welcome to representatives from **Eurodrugs** and the **Korean QA/RA team**.
- A detailed presentation by **Mr. Sridhar Ayapilla**, Associate Vice President – Quality, highlighting:
    - The history and transition of **Suven Pharma** to **Cohance**.
    - The company's manufacturing capacity, infrastructure, safety regulatory approvals and compliance initiatives.

Mr. Shak Baji, General Manager – Production, was also introduced and acknowledged for his key role in overseeing production operations.

Audit Objectives

The primary objectives of the audit were to:

- The Site tour - and documents review for the manufacturing of *Doxofylline* API.
- Verification documentation-**SMF, GMP Certificates. SOP list. Validation list, Qualification list, Stability list Vendor list**
- Review the company's **Quality Assurance (QA)** and **Regulatory Affairs (RA)** practices.
- Understand the facility's infrastructure, material handling systems, and segregation practices.

Site Infrastructure Overview

The facility is a well-established GMP-compliant unit, comprising the following main areas:

- **Production Blocks 1, 2, 3, and 4**
- **Warehouse and Warehouse Office**
- **Quality Assurance (QA) and Quality Control (QC) Buildings**
- **Solvent Storage Yard and Underground Tanks**
- **Wastewater Treatment Plant (WWTP)**
- **Utilities Block and Boiler House**

- **Formulation Manufacturing Site**

1.Site Visit and Observations

After the introductory session, a guided tour of the facility was conducted. The following key areas were audited:

1.1. Warehouse and Pre-Production Areas

- **Warehouse Office:** Reviewed entry, gowning, and dedusting protocols.
- **Sampling Booth:** Observed sampling under controlled conditions.
- **Solid Raw Material Storage:** Checked segregation, cleaning logs, and access control.
- **Dispensing Area and Booth:** Evaluated equipment maintenance, SOP compliance, and weighing accuracy.
- **Liquid Storage Area:** Inspected storage and safety for flammable/non-flammable solvents.
- **RM, PM, FP, TM Storage:** Verified storage conditions, identification, and documentation practices.

1.2. Production Area

- Observed production operations including:
    - **Agitation, filtration, and drying processes.**
    - **Double cone blender** usage with vacuum drying.
    - **Sifting and transferring** of finished API to containers.
    - **Weighing, labeling, and packing** of final product.
- Reviewed **batch manufacturing records**, **online documentation**, and **data integrity**.
- Inspected **gowning practices**, **environmental classifications**, and **cleanroom behavior protocols**.

1.3. Physical Processing and Utility Blocks

- Visited **Module 10 – Physical Processing Area**.
- **Observed Solvent Yard** with underground tanks and fire safety measures.
- Observed **drying operations** under vacuum.
- Walkthrough of **Utilities Block**, **Boiler House**, and **Effluent Treatment Plant (ETP)** to ensure compliance with environmental and safety norms.

Tour of the production area, the audit team took a short tea break before proceeding to the **Quality Control (QC) Department**.

1.4.Observations at the QC Laboratory:

- **Sample Collection Area:** The sample collection process was carried out in a controlled environment ensuring sample integrity and compliance with GMP standards.
- **Wet Lab – Analytical Testing:** I observed a well-equipped wet laboratory where precise analytical procedures were being performed. The lab was equipped with several **semi-microbalances** capable of measuring samples with high precision up to **0.00000 grams**, ensuring accuracy in trace-level quantification.
- **Instrumentation Facilities:**
  The laboratory housed an impressive array of high-end analytical instruments including:
  - **16 HPLC systems (Few Waters and** from other manufacturers
  - **6 Gas Chromatographs (GCs)**
  - **Karl Fischer (KF) Titrators** for moisture analysis
- **Stability Chambers:** Multiple **stability chambers** were operational, supporting ICH-guided long-term and accelerated stability studies for drug substances.
- **Sample Reserve Room:** A dedicated **sample retention area** was maintained for storing archival samples, complying with regulatory requirements.

During this QC visit, the audit team closely **monitored environmental conditions**, **instrument calibration**, and **maintenance records**, all of which were found to be in compliance with international standards.

Lunch and Post-Lunch Session:

A **lunch break** was arranged following the QC visit, and the hospitality extended by the host company was excellent. The food provided was both hygienic and satisfying.

2.Documentation Verification:

Post-lunch, the audit resumed with an intensive review of critical documentation, including:

- **Site Master File (SMF)**
- **GMP Certificates**
- **Standard Operating Procedures (SOP) List**
- **Validation Master List**
- **Equipment and Facility Qualification Records**
- **Stability Study Data and Stability Protocols**
- **Approved Vendor Qualification List**
- **Batch Production Records (BPRs)**
- **Analytical Reports and Change Control Logs**

This phase of the audit provided deep insights into the **documentation practices**, **regulatory preparedness**, and **systematic recording methods** employed by the organization.

The transition from **Suven Pharma** to **Cohance** signifies the organization's strategic alignment with global standards and its readiness for expanded international operations

This visit also provided a unique opportunity to interact with global QA/RA professionals and gain firsthand exposure to current regulatory expectations. These experiences will significantly benefit our institution's ongoing efforts in strengthening **industry-academia partnerships** and enriching **training modules** for students in **Pharmaceutical Quality Assurance**.

Overall, the audit visit to **Suven Pharma (Cohance)** alsoproved to be a highly valuable and professionally rewarding experience. The facility exhibited robust systems in **quality control,**

regulatory compliance, documentation, and safety. The visit provided a thorough exposure to **current Good Manufacturing Practices (cGMP)** and showcased the company's **state-of-the-art infrastructure**provided an excellent benchmark for industry standards and best practices.

This experience was not only professionally enriching but also enhanced understanding of real-time industry standards in **API manufacturing.**

I extend my sincere gratitude to our **Chairman, Dr. B. Prabha Shankar Sir**, **Director, Mr. N. Srinivas**, **Principal, Dr. Mamatha**, and **Vice Principal, Dr. B. Harika** for their continued encouragement and support in facilitating such valuable learning opportunities.

I also extend my sincere thanks to **Mr. Laurens**, Qualified Person (QP) from **Eurodrugs, Poland**, and **Mr. Abhilash** from **Eurodrugs**, for their valuable company and support during the audit. Their insights, guidance, and collaborative spirit greatly enriched the overall learning experience.

I also wholeheartedly thank the **entire team at Suven Pharma (Cohance)** for their warm hospitality, professional coordination, and the transparent sharing of knowledge and practices throughout the audit. Their cooperation and dedication made this visit both informative and inspiring.

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