

NAJWA SHIFA SAHARA

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Registered Pharmacist with 1+ year experience in drug development and pharmaceutical operations. Specialized in instrumental analysis (HPLC, UV-Vis, GC, AAS, and FT-IR) and quality systems, including OOS investigations and CAPA implementation. International conference presenter with proven problem-solving expertise, dedicated to contributing to drug development and manufacturing excellence.

EXPERIENCE

PT SATORIA ANEKA INDUSTRI – Pasuruan, East Java

Analytical Development (R&D) Intern

Feb 2025 - Apr 2025

- Executed physicochemical testing and analytical characterization for 7 injection and infusion products using HPLC, UV-Vis, GC, AAS, and FT-IR to support R&D operations prior to method transfer.
- Monitored IPC parameters during Pilot Batch cycles and assisted in cross-functional coordination between R&D and Production to ensure compliance with specifications for 2 new antibiotic releases.
- Identified and documented 2 analytical deviations and Out of Specification (OOS) results, collaborating with supervisors to perform thorough investigations and ensure proper documentation.
- Performed analytical feasibility studies for 2 New Product Development (NPD) projects to establish testing methodologies and determine required reagents for stability and assay testing.

Key Achievements:

- Conducted Assay, Impurity, and Stability testing for 7 developmental products to establish analytical profiles ensuring regulatory compliance prior to method transfer.
- Validated and optimized analytical methods for 2 NPD projects in accordance with comprehensive ICH Quality standards, ensuring data integrity for regulatory submission.
- Led the method transfer of a new Dextrose product from R&D to QC, achieving zero discrepancies in method reproducibility and accuracy.
- Resolved analytical deviations and OOS results through systematic CAPA implementation, ensuring complete documentation and data integrity compliance.

PT TEKNOLOGI MEDIKA PRATAMA (SwipeRx) – Surabaya, East Java

Pharmacist Intern

Aug 2024 - Sept 2024

- Ensured strict regulatory compliance and product integrity by validating NIE (BPOM), batch numbers, and expiry dates for all incoming stock to maintain pharmaceutical supply chain quality, safety, and integrity.
- Maintained high-level data integrity in processing 200–300 daily shipping documents, ensuring zero discrepancies in the pharmaceutical supply chain and managing inventory control (FIFO/FEFO, etc).
- Managed pharmacy product returns (20–30 daily), overseeing GDocP-compliant records and coordination with the APJ to ensure proper disposition and assisting in drafting CAPA reports.

Key Achievements:

- Achieved high-level data integrity in processing 200–300 daily shipping documents, ensuring zero discrepancies between physical stock and digital records while managing inventory control.
- Maintained strict regulatory compliance by validating NIE (BPOM) and expiry dates for all incoming batches, preventing illegal stock entry, and participating in counterfeit drug identification.
- Oversaw the end-to-end disposition for 20–30 daily pharmacy returns, ensuring accurate documentation, coordinating with the APJ, and assisting in drafting CAPA reports for quality deviations.

EDUCATION

UNIVERSITAS AIRLANGGA - Surabaya

Profession Pharmacy

Aug 2024 – Oct 2025

- GPA 3.64/4.00; Cumlaude

Activities:

- International Presenter at IMU University, Malaysia (2024) for the International Pharmacy and Pharmaceutical Science Conference.
- New Product Development Project: Designed conceptual development plans for Gadobutrol Injection and Gliclazide Mucoadhesive Tablets.
Integrated aseptic processing and sterilization cycle validation into parenteral formulation design. Evaluated dosage forms, analytical methods, stability protocols, and BA/BE requirements. Produced a Product Development Dossier encompassing stability protocols and packaging designs aligned with regulatory standards.
- Pharmacy Intern at PT Kimia Farma Apotek and RS Pendidikan UNAIR.

UNIVERSITAS AIRLANGGA - Surabaya

Bachelor of Pharmacy

Aug 2020 – Aug 2024

- GPA 3.52/4.00; Cumlaude

Activities:

- Final Research Project: Profile of Antibiotic Use and Resistance in Pediatric Patients (Study at UNAIR Hospital, Surabaya), [2024].
- Community Pharmacy Research Project: Sahara, et al. (2023). "Profil Pengetahuan dan Perilaku Masyarakat terkait DAGUSIBU Obat yang Digunakan di Rumah Tangga." Jurnal Farmasi Komunitas, Vol. 10, No. 2, 183-188.
- Head of Business and Sponsorship Department Student Executive Board FF UNAIR (2023 - 2024).
- Sponsorship Coordinator PHARMASHARE Community Service (2022).
- Sponsorship Coordinator KOFEIN UNAIR (2022).
- Staff of HRD Division Garuda Sakti UNAIR (2021 - 2022).

SKILL

- **Manufacturing & Quality** (In-Process Control (IPC), Sterile Manufacturing (Aseptic & Terminal Sterilization), CPOB/GMP, Quality by Design (QbD) principles, Lean Lab/Manufacturing (6S), GLP Compliance, Scale-up Support).
- **Laboratory & Analysis** (Instrumental Analysis (HPLC, UV-Vis, GC, AAS, FT-IR), Analytical Characterization (Assay & Impurity Profiling), Method Validation & Optimization (ICH Q2), Method Transfer, Stability Testing (ICH Q1), Impurities Testing (ICH Q3), Product Specifications (ICH Q6), Pharmaceutical Development (ICH Q8), Physicochemical Testing, Compendial Analysis (USP, BP, FI), Data Integrity).
- **Quality Management System (QMS)** (Deviation Handling, CAPA (Corrective and Preventive Action), OOS Investigations, Root Cause Analysis (RCA), Good Documentation Practice).
- **Supply Chain & Distribution** (Good Distribution Practice (CDOB/GDP), Inventory Management (FEFO/FIFO, SO, Monitoring Storage Conditions), Customer Qualification, Regulatory Compliance, Returns & Disposition Handling).
- **Tools** (MS Office Suite, SPSS, Minitab, Empower 3).
- **Language** (Bahasa Indonesia and English).

CERTIFICATION AND TRAINING

Surat Tanda Registrasi Apoteker (2025), Halal Regulatory Compliance Study (2025).