



DEVANI RAHMALIA

Analytical Development Scientist

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SUMMARY

"Analytical Development Scientist experienced in developing and validating analytical methods within the pharmaceutical industry. Skilled in conventional and instrumentation with a strong understanding of GMP, GLP, GDoCP, ICH guidelines, compendial monograph, CFR 21 and data integrity principles. Proven ability to troubleshoot analytical issues, support method transfer, and collaborate effectively to ensure high-quality and compliant product development.

WORK EXPERIENCE

Analytical Development Staff

Apr 2025 – Apr 2026

PT Sukses Abadi Farmindo

Development of Analytical Method

- Design and analysis of methods for developing raw materials and finished products based on compendial standards (FI, USP, BP, EP, CP, FCC) and supporting scientific literature
- Determine physical, chemical, and microbiological testing specifications according to pharmaceutical product needs to support according with applicable regulatory guidelines

Verification or Validation of Analytical Method

- Preparing document validation or verification of analytical methods according to regulations
- Conduct validation tests, data interpretation, and compile validation results reports
- Monitoring implementation of verification or validation analytical method

Laboratory Management

- Led and effectively delegated tasks to the team to ensure analytical development and testing targets were achieved on schedule
- Organize work plans, task allocations, and daily testing priorities
- Ensure smooth laboratory operations and instrument maintenance

Technical Documentation

- Develop SOPs (Standard Operating Procedures) for the development and testing of analytical methods
- Prepared, reviewed and supported quality data for registration product and submission

Compliance and Standards

- Ensure all analytical activities comply with pharmaceutical industry regulations (e.g. GMP/GLP, ICH guidelines)
- Maintain data quality standards, result integrity, and laboratory safety procedures

Cross-departmental Coordination

- Coordinate with Quality Control, Regulatory Affairs, Quality Assurance, and Formulation R&D teams for transfer of analytical methods and data support
- Involved in technical discussions and decision making regarding analytical aspects of new products
- Conducting OOS/OOT result investigations, CAPA and root cause analysis

Troubleshooting & Continuous Improvement

- Acted as a strong problem solver, open to team input, and capable of making data-driven and solution-oriented decision
- Performed troubleshooting of analytical instruments to ensure reliability and continuity of laboratory operation
- Propose and implement process or method improvements to increase efficiency and accuracy of results

WORK EXPERIENCE

Analytical Development Analyst

May 2023 – Apr 2025

PT LAPI Laboratories

- Research, development, and validation of analytical methods for raw materials or finished goods includes testing for assay, identification, impurities, or dissolution
- Raw material or finished goods testing for stability data and formulation development using conventional (physical, gravimetric, volumetric, or potentiometric) and instrumentation (UPLC/UHPLC/HPLC, GC, AAS, Spectrophotometric UV-Vis, or FTIR)
- Research and development of analytical method for nasal & inhalation testing especially Delivered Dose Uniformity (DDU) and Particle Size Distribution (PSD)
- Particle size testing for raw materials or finished goods
- Comparative dissolution test product
- Verification, monitoring and maintenance or troubleshooting of analytical instruments
- Perform laboratory management for used on working/references standard, reagen, and column

Oversight QA Inspector

Oct 2020 – Apr 2023

PT Kalbe Farma

- Create protocol document, monitoring, and reporting of process validation, cleaning validation, qualification, holding time, batch campaign, and verification process
- Perform physical testing check during validation and qualification
- Carry-out product sampling, In-Process Control and deviation handling
- Implementation of Process Analytical Technology (PAT) with Real-Time Released Testing and Continuous Process Verification

Quality Control Analyst (Intern)

Jan 2020 – Apr 2020

PT Abbott Indonesia

- Physical/chemical/microbiology testing for raw material, packaging material, semi-finished goods, finished goods, stability and validation product
- Transfer method analysis
- Sampling raw material or finished product
- Calibration or verification of analytical instrument
- Perform laboratory management for used on working/references standard, reagen, and column

EDUCATION

Bachelor of Chemical Engineering

Sep 2022 – Feb 2024

Jayabaya University (Extention program)

- GPA : 3.66
- *"Pre-design of Ethylene-Oxide Plant from Ethylene and Air with Capacity of 550,000 ton/year"*

Diploma of Chemical Analysis

Jul 2017 – Jul 2020

AKA Bogor Polytechnic

- GPA : 3.61
- *"Analysis of Sodium Benzoat in Raw Materials at PT Abbott Indonesia"*

OTHER SKILLS

- Ms. Office
- Google Spreadsheet
- Statistic app (Minitab)
- Photo/videographic
- Software Eng (Aspen Hysis, AutoCAD)
- Laboratory Information Management System (LIMS)
- Chromatography Data System (CDS) & Software Instrumentation

CERTIFICATION & TRAINING

Communication Effective NALA Training	2025
Analytical Development – Pharmaceutical Industry TemanLab	2025
Halal Product Assurance System PT Sukses Abadi Farmino	2025
Halal Pharmacy LPPOM RI	2025
Health Supplement – Stability Test BPOM RI	2025
Inhaler testing: Aerodynamic Particle Size Distribution & Delivered Dosage Uniformity PT Andaru Persada Mandiri	2024
WATERS Software: Custom Field & Impurities PT Kromtekindo Utama Services	2024
Gas–Chromatography PT Berca Niaga Medika	2023
Computerized System Validation (CSV) PT Kalbe Farma	2022
Quality Control Circle (QCC) PT Kalbe Farma	2022
ISO 9001:2015 ISO 22000:2018 ISO 14001:2015 ISO 17025:2017 AKA Bogor Polytechnic	2019

ACHIEVEMENT

Nominee of Employee of The Years (1–3) PT Kalbe Farma	2023
Finalist – QCC Group PT Kalbe Farma	2022
Bronze Winner – QCC Group PT Kalbe Farma	2021
CONIM Stars PT Kalbe Farma	2021
Cum Laude Scholarship AKA Bogor Polytechnic	2020