

PRAJONA MARBUN, S.Farm., Apt.

Licensed Pharmacist (Apt.) | Formulation Development | Sterile & Aseptic Pre-formulation, Scale-Up & Technology Transfer
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PROFESSIONAL SUMMARY

Licensed Pharmacist (Apt.) specializing in Industrial Pharmacy, with formulation and manufacturing experience concentrated in sterile and aseptically processed products. Supervised end-to-end sterile production of ready-to-fill injectables (vial and ampoule, WFI) and served as PIC for cleanroom and aseptic-area compliance, supporting media fill process validation and daily cleaning verification of sterile-line equipment. Applied Quality by Design (CMA-CPP-CQA) and continued process verification to aseptically produced isotonic solutions and other commercial products. At bench scale, formulated and characterized sterile nanoparticle delivery systems and carried candidates into *in vivo* efficacy evaluation, spanning vehicle and carrier design, particle size characterization, and stability assessment.

FORMULATION COMPETENCIES

Sterile & Aseptic Operations: Qualified sterile injectable production supervisor (aseptic behavior, compliance, inspection, and packaging); aseptic process validation support (media fill / aseptic process simulation); daily cleaning verification of sterile-line equipment; cleaning validation supervision; sterile machine operation and equipment qualification (DQ-IQ-OQ); cleanroom classification, environmental monitoring, and LAF/interlock-buffer area compliance; WFI-based vial and ampoule filling operations

Dosage Forms Formulated: Ready-to-fill sterile injectables (vial and ampoule, WFI), isotonic solutions produced under aseptic processing, sterile nanoparticle delivery systems (intranasal and systemic), protein-hydrolysate nanoparticles, immediate-release tablets and caplets, coated tablets, hard capsules, dry syrup, oral liquids, and semi-solid preparations

Pre-formulation & Development: Excipient and vehicle selection, carrier system design, particle size and physical characterization, formulation prototype trials, *in vivo* efficacy evaluation of candidate formulations, formulation troubleshooting and optimization

Trial Design & Quality by Design: Risk-based assessment of Critical Material Attributes (CMA), Critical Process Parameters (CPP), and Critical Quality Attributes (CQA); design of experiments (Design-Expert, Minitab); process capability and variability analysis (Cpk, Ppk, 3-sigma/6-sigma); FMEA risk assessment

Scale-Up & Technology Transfer: Pilot-to-commercial batch size scale-up, process validation and post-validation verification, equipment and line qualification (IQ-OQ-DQ), manufacturing documentation (Master Processing Protocol, batch records, work instructions, SOPs)

Formulation Characterization & Stability: Dissolution testing, weight and content uniformity, particle size distribution, bulk and tapped density, viscosity and physical appearance evaluation, long-term stability data compilation and trending; HPLC, GC-MS, UV-Vis spectrophotometry, titrimetry; ELISA and RT-qPCR for biological response characterization

Quality Systems & Project Management: GMP (CPOB), GLP, GDP, deviation handling, CAPA, Quality Risk Management (QRM), root-cause analysis; cross-functional coordination with QA/QC, PPIC, Engineering, Technical Service, and external vendors across 11 development projects

FORMULATION & DEVELOPMENT EXPERIENCE

Junior Scientist — Formulation Development, Synthesis & Analytical Characterization Feb 2023 – Present
Center for Drug Discovery, Development & Translational Medicine, Universitas Gadjah Mada | Yogyakarta, Indonesia

- **Sterile intranasal nanoparticle formulation of human Wharton's jelly-derived vesicles for Alzheimer's disease.** Formulated and characterized a vesicle-loaded nanoparticle system for nose-to-brain delivery, covering carrier and vehicle selection, particle size and physical characterization, and *in vivo* efficacy evaluation of memory impairment in scopolamine-induced mice.
- **Sea cucumber (*Holothuroidea*) hydrolysate nanoparticle formulation for immunomodulation.** Developed a protein-hydrolysate nanoparticle formulation for immunomodulatory delivery, optimizing hydrolysate loading and particle characteristics, and evaluating immune response in tetanus toxoid-induced mice.
- Delivered 11 development projects spanning compound synthesis, purification, formulation, and physicochemical characterization, applying structure-activity relationship analysis and design-of-experiments principles to candidate and formulation optimization.
- Established and applied analytical methods (HPLC, GC-MS, UV-Vis spectrophotometry, titrimetry) for identity, purity, content, and stability characterization of active compounds and formulated preparations under GLP-aligned laboratory practice.
- Authored and co-authored 9 research manuscripts and 14+ peer-reviewed publications and delivered 2 international oral presentations, demonstrating consistent formulation documentation and stakeholder communication.

Project-Based Staff — Existing Product Formulation R&D

Dec 2025

PT Abbott Indonesia | Depok, Indonesia

- Performed continued process verification (CPV) on commercial products including isotonic solution (Pedialyte®), manufactured under aseptic processing, evaluating Critical Material Attributes (CMA), Critical Process Parameters (CPP), and Critical Quality Attributes (CQA) to confirm sustained state of control and define formulation and process optimization targets.

- Conducted formulation Quality by Design (QbD) risk-based evaluation of Critical Material Attributes (CMA), Critical Process Parameters (CPP), and Critical Quality Attributes (CQA) across solid, liquid, and intermediate products, directly supporting formulation and process robustness decisions.
- Performed process capability and variability analysis (Cpk, Ppk, 3-sigma/6-sigma, FMEA) on approximately 1,200 batch manufacturing records across aseptically produced liquid, solid, and intermediate products, identifying formulation and process design weaknesses and defining optimization targets.
- Investigated formulation-related manufacturing deviations through root-cause analysis and authored scientific justification reports for borderline process parameters, providing the technical rationale required by Quality and Regulatory stakeholders.

Jr. Supervisor — Cephalosporin Production (Sterile/Aseptic Injection and Non-Injection) May 2025 – Nov 2025
PT Dankos Farma Laboratories (a Kalbe Company) | Jakarta Timur, Indonesia

- Qualified and certified as sterile injectable production supervisor following internal training in aseptic behavior, aseptic compliance, aseptic filling and inspection, aseptic packaging, and machine operation and qualification. Supervised end-to-end sterile production of ready-to-fill injectables (vial and ampoule, WFI), covering dispensing, compounding, aseptic filling, visual inspection, and packaging, within a dedicated cephalosporin facility operating under segregated CPOB containment requirements.
- Provided formulation scale-up and manufacturing optimization assistance across cephalosporin antibiotic products, delivering a dry syrup batch size increase of up to 60%, capsule manufacturing scale-up of up to 100%, and strip packaging speed improvement of up to 80%, while maintaining product quality and compliance.
- Managed end-to-end production of 32 SKUs across coated tablet, capsule, dry syrup, and ready-to-fill sterile injectable (vial, ampoule WFI) lines, supervising a team of 108 personnel spanning operations, packaging, inspection, and supply.
- Executed technology transfer and process validation activities, including periodic cleaning validation supervision, equipment qualification through IQ-OQ-DQ protocols, and vendor coordination for new, alternate, and maintenance suppliers in collaboration with Engineering and QA.
- Reviewed approximately 170 batch records per month — including ~70 sterile injectable batches — for CPOB compliance and post-validation verification; completed 3 Quality Risk Management assessments covering deviation investigation, FMEA, and CAPA effectiveness monitoring.
- Served as PIC for cleanroom compliance and environmental monitoring across 32 production rooms, 5 LAF units, 2 interlock/buffer areas, and 3 production machines (42 monitoring points).

Student Intern — Technical Service, Existing Product Packaging & Formulation R&D Oct 2024 – Dec 2024
PT Hexpharm Jaya Laboratories (Kalbe Group) | Cikarang, Indonesia

- Performed physical and stability characterization across 50+ product batches (tablet and caplet forms), including dissolution testing, weight uniformity, particle size distribution, and bulk/tapped density, to verify pilot-scale and routine production performance and investigate deviations.
- Compiled and analyzed four years of physical testing data (2021–2024) to identify formulation and process trends, supporting bulk sampling instrument purchasing and evidence-based formulation stability and improvement decisions.
- Prepared technical documentation including Master Processing Protocol (MPP-PPI) evaluations, translating laboratory findings into controlled manufacturing documentation.

Undergraduate Laboratory Assistant — Drug Synthesis, Analysis & Formulation Feb 2022 – May 2024
Faculty of Pharmacy, Universitas Gadjah Mada | Yogyakarta, Indonesia

- Supervised laboratory-scale preparation of sterile and non-sterile dosage forms, including tablets, capsules, suspensions, emulsions, creams, and ointments, guiding ~240 students per semester across 6 formulation, analytical chemistry, and organic synthesis laboratory courses.
- Directed analytical instrument operation training (spectrophotometry, chromatography, titrimetry) and organic synthesis procedures (recrystallization, reflux, distillation), reinforcing procedural adherence and data reliability.

EDUCATION

Pharmacist Professional Program (Apt.) — Industrial Pharmacy Specialization 2024 – 2025
Universitas Gadjah Mada | Yogyakarta, Indonesia

- Final GPA: 3.90 / 4.00 (34 credits); Licensed Pharmacist Summative CBT Score: 176 / 200
- Relevant coursework: Pharmaceutical Industry (GMP/CPOB), Internship in Pharmaceutical Industry, Internship in Pharmaceutical Distribution (GDP).

Bachelor of Pharmaceutical Science (S.Farm.) 2018 – 2023
Universitas Gadjah Mada | Yogyakarta, Indonesia

- Final GPA: 3.50 / 4.00 (155 credits), Pharmaceutical Science and Technology program.
- Relevant coursework: Formulation Technology (solid, liquid, semi-solid, and sterile dosage forms), Analytical Chemistry (Titrimetry/Spectroscopy/Chromatography), Product Stability, Drug Delivery Systems, Pharmaceutical Biotechnology.