ABSTRACT

This report outlines the pharmaceutical formulation internship conducted at PT Kalbe Farma Cikarang, emphasizing hands-on laboratory work, scale-up observation, and regulatory-driven reformulation projects. The internship centered on two key activities: replacing titanium dioxide in an antiplatelet drug coating and eliminating erythrosine from a health supplement coating. Laboratory tasks included granule testing, tablet performance evaluations, and monitoring pilot-scale manufacturing, while documentation work involved preparing Product Development Reports, validation protocols, risk-assessment files, and Master Processing Instructions. In the antiplatelet project, calcium carbonate was examined as an alternative opacifier and produced acceptable physical characteristics but failed to achieve a dissolution profile comparable to the originator, demonstrating its unsuitability for this specific therapeutic application. In contrast, the health supplement project successfully identified Iron Oxide Yellow and Certolake Ponceau 4R as erythrosine-free colorants capable of producing a stable, uniform pink shade that met visual and functional expectations. Through these activities, the internship provided meaningful insight into formulation development, excipient functionality, documentation structure, and the regulatory considerations required to ensure product quality and alignment with updated standards.

Keywords: tablet coating, reformulation, titanium dioxide, calcium carbonate, erythrosine, dyes.