# Abstract

In such a competitive market for generic drugs, pharmaceutical manufacturers need to make their quality control (QC) labs more efficient. High-performance liquid chromatography (HPLC) as a standard method sometimes takes longer to run and uses more solvent. This study is investigating whether upgrading to ultra-performance liquid chromatography (UPLC) from the HPLC method is feasible from both a regulatory acceptance and an economic perspective, including ESG impact. This study concentrates on four APIs commonly produced by Indonesian generic drug companies: piroxicam (anti-inflammatory), amlodipine (antihypertensive), ranitidine (antihistamine), and cefixime (antibiotic). Based on expert interviews, high initial investment, regulatory challenges, and skilled workers are the main obstacles to upgrading current methods to HPLC in pharma QC labs. In this study, UPLC showed a significant improvement in analytical performance, with a reduction in run time analysis of 83.7%, solvent use of 87.5%, and savings in energy consumption of 60%. The experimental results from UPLC showed that the system sustainability test (SST) value changed by less than 1%, tailing factors were under 2.0 (except for cefixime), and most active pharmaceutical ingredients (APIs) had more than 2,000 theoretical plates, meeting the standards of USP 612 and ICH Q2(R1). By utilizing a single UPLC instrument for multiple APIs and processing approximately 58,080 samples per year, UPLC offers cost savings by reducing cost per test from IDR 32,020 to IDR 28,684. Additionally, it requires a lower initial investment because it only needs one instrument, while HPLC requires at least three units, which impacts the overall annual cost. Implementation of UPLC could generate annual cost savings of around IDR 359 million, making a payback period of approximately 3.34 years, which looks feasible for this industry. In terms of environmental, social, and governance (ESG perspective), UPLC implementation could reduce carbon emissions by around 1.48 metric tons per year, chemical waste by 88.2%, and water use by 90%, which supports SDG 6 (Clean Water), SDG 12 (Responsible Consumption), and SDG 13 (Climate Action). In summary, the study finds that UPLC could become a solution for pharma QC labs and generic drug companies to speed up product release times, better cost per test, less initial investment for more than 58,080 tests per year, and better environmental friendliness.



**Keywords:** *Cost Analysis; Environmental, Social, and Governance (ESG); Generic Drugs; High-Performance Liquid Chromatography (HPLC); Pharmaceutical Industry; Quality Control (QC) Laboratory; Ultra-Performance Liquid Chromatography (UPLC)*