

Abstract

PT Phapros TBK is a pharmaceutical company founded in 1954, which is now owned and operated under PT Kimia Farma TBK. Research and development falls under the production department, which is one of the 3 main departments in PT Phapros. The Research and development team centers on drug development and analysis, among which Analytical development plays an integral part in the process. During this internship, there were 3 main tasks involved. The first task involved an analytical method verification of organic impurities and assay content in Adenosine Disodium Triphosphate raw material using UPLC. It follows the Chinese Pharmacopoeia 2015 guidelines, with few adjustments made to the procedure. Verification of Assay was performed using Karl Fischer Titration, UPLC and UV Spectrophotometer, and the results revealed an assay content of 96.77%, demonstrating a significant portion of ATP present in the sample. Similarly, impurity verification was only performed using UPLC, with results showing a low organic impurity content of 1.1308% present in the sample. The second project focused on conducting gap analysis of raw materials and dosage forms by comparing products in Phapros database with those listed in other pharmacopoeia. This was needed to comply towards BPOM and to avoid risks of non-compliance that aligns with the GMP guidelines. The last project were miscellaneous tasks of different projects, including AMV for assay content in pyrazinamide, physical evaluation of Trampara, and a research paper on clopidogrel bisulfate to gain a comprehensive knowledge about different critical processes present within a pharmaceutical industry.

Keywords: Analytical Method Verification of organic impurities and assay content in Adenosine Disodium Triphosphate, gap analysis, Miscellaneous projects and PT Phapros