Abstract

Quality Control (QC) is part of the quality assurance system and holds a critical activity of ensuring drug products' safety, efficacy, and quality fulfill the requirement. Current Good Manufacturing Practice (cGMP) is a standard regulation enforced by the Food and Drug Administration (FDA) to guarantee product quality and must be followed by all pharmaceutical companies. One of the crucial components of cGMP is the execution of Good Documentation Practices (GDocP) that allow traceability of all activities in the manufacturing process. The cGMP of Indonesia, namely *Cara Pembuatan Obat yang Baik* (CPOB) guideline describes various forms of documents (e.g. logbook and report) and may exist in paper-based and electronic. Test Item Control (TICO) and Project division utilized Logbook and Google Spreadsheet to ensure the traceability of information related to the sample tested, while the final report known as Quality Control Analysis Report (QAR) was prepared to summarize the result of the test conducted to be shared to the requestor department. An approximately 150 to 170 QARs were successfully generated per week, in which the completion was also indicated by the approval from the QC manager and can be handed over to the related department.

Keywords: Test item control and project, quality control, current good manufacturing practice, quality control analysis report, good documentation practices