ABSTRACT

PT. Etana Biotechnologies Indonesia (or “Etana”) plans to produce mRNA vaccines on a large-scale basis. To ensure product and batch qualities, it is imperative to implement the cleaning validation program. Cleaning validation is a procedure which ensures that there are no residues of Active Pharmaceutical Ingredients (APIs) left after the cleaning process. It is generally performed as part of the current good manufacturing practice (cGMP) to maintain product quality. The cleaning validation procedure for different types of residues should be established and developed beforehand. The determination of residual matter in cleaning validation depends on two factors: the sampling methods and the assay procedure. The two commonly used sampling methods in the determination of residual matters are the swab sampling method and the rinse sampling method. Additionally, the Quant-iT Ribogreen Fluorescence Assay is found to be the procedure that is generally applied for the detection of RNA in solutions. Before these methods and procedure can be applied on site, a study should be performed to ensure that the methods and procedures are suitable for its intended use. The acceptance criteria for the recovery of the tested residue was set based on the Technical Report No. 49 Points to Consider for Biotechnology Cleaning Validation where percentage (%) recovery of the sample shall be >50%. The results of this study indicate that both sampling methods are suitable for use (>50% sample recovered for both sampling methods). Further study involving the replications and optimization of the methods are to be performed to ensure method validity.

Keywords: mRNA residue; cleaning validation; swab sampling method; rinse sampling method