ABSTRACT

Erythropoietin is a glycoprotein hormone produced by the kidney. Erythropoietin is a hormone that controls the production of erythrocytic progenitors. Since 1989, erythropoietin (EPO) has been used to treat anemia-related diseases. The formulation of the EPO product was altered in 2004. The occurrence of creutzfeldt-jakob disease (CJD) led to the replacement of the stabilizer, human serum albumin (HSA), with polysorbate 80. The recipe was also altered in order to gain a halal label for distribution in Muslim nations. Changes in the formulation were discovered to cause pure red cell aplasia (PRCA). The PRCA was speculated to occur as a result of an aggregation in the pharmaceutical products. PT. Kalbio Global Medika used liquid chromatography (ultra performance liquid chromatography and high performance liquid chromatography) to detect the aggregate of EPO protein. The ultra high performance liquid chromatography equipment was used in conjunction with a reverse phase column, whereas the high performance liquid chromatography instrument was used in conjunction with a size exclusion column. This study concluded that the size exclusion HPLC gave better results in detecting EPO aggregate than the reverse phase UPLC. The size exclusion HPLC chromatogram result shows the EPO aggregate peak that was separated from the EPO peak. In size exclusion HPLC, the aggregate peak result can be quantified, but in reverse phase UPLC, the aggregate peak was not separated from the EPO peak, making quantification more challenging. The prevalidation method was done after choosing the best liquid chromatography method. Prevalidation was conducted to ensure that the method can be utilized for various EPO and the aggregate separation and detection. The prevalidation using size exclusion HPLC was determined successful since all the trial results were within the acceptance criteria.

Keyword: Erythropoietin (EPO), Pure Red Cell Aplasia, Liquid Chromatography, Prevalidation