Implementasi Continued Process Verification (CPV) terhadap Produk X dan Y Di PT CKD OTTO = Implementation of Continued Process Verification (CPV) for Product X and Y at PT CKD OTTO Pharmaceuticals

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Abstrak

Continued Process Verification (CPV) adalah pengumpulan dan analisis data terkait produk dan proses yang berhubungan dengan kualitas produk yang bertujuan untuk menunjukkan pemeliharaan kontrol selama siklus hidup yang memenuhi syarat. PT CKD OTTO Pharmaceuticals selaku Industri Farmasi yang berspesialisasi pada pengobatan onkologi juga menerapkan Continued Process Verification (CPV) yang dilakukan terhadap dua produk obat yakni produk X dan Y. Aktualisasi alur pelaksanaan Continued Process Verification (CPV) yang dilakukan terhadap produk X dan Y yang diproduksi oleh PT CKD OTTO Pharmaceuticals dimulai dari Quality Risk Assessment (QRA) Continued Process Verification (CPV), pembuatan protokol Continued Process Verification (CPV), pengumpulan dan analisis data, serta evaluasi dan pembuatan laporan Continued Process Verification (CPV). Analisis data dilakukan menggunakan metode Statistical Process Control (SPC), meliputi bagan kontrol dan analisis kapabilitas proses. Analisis kemampuan proses yang dihitung dalam pelaksanaan Continued Process Verification (CPV) antara lain Process Performance (Pp) dan Process Performing Index (Ppk). Hasil dari analisis data yang dilakukan menunjukkan bahwa nilai Pp yang diperoleh lebih dari 1,00 yang berarti memenuhi syarat. Namun, pada beberapa parameter, seperti suhu sterilisasi, pH mixing, particulate matter 25m, serta related substance 10-deacetylpaclitaxel, 7-epipaclitaxel, total impurities, dan bioburden diperoleh nilai Ppk kurang dari 1,00 atau tidak memenuhi syarat dikarenakan analisis yang dilakukan masih menggunakan Capability Process Sixpack dengan mengasumsikan bahwa data terdistribusi normal (belum dilakukan analisis data menggunakan pola distribusi yang sesuai untuk masing-masing parameter). ..... Continued Process Verification (CPV) is the collection and analysis of product and process data related to product quality that aims to demonstrate the maintenance of controls throughout the qualified life cycle. PT CKD OTTO Pharmaceuticals as a Pharmaceutical Industry which specializes in oncology treatment also implements Continued Process Verification (CPV) which is carried out on two medicinal products namely products X and Y. Actualization of the flow of implementation of Continued Process Verification (CPV) which is carried out on products by PT CKD OTTO Pharmaceuticals starting from Quality Risk Assessment (QRA) Continued Process Verification (CPV), creating a Continued Process Verification (CPV) protocol, collecting and analyzing data, as well as evaluating and creating a Continued Process Verification (CPV) report. Data analysis was carried out using the Statistical Process Control (SPC) method, including control charts and process capability analysis. Analysis of process capabilities calculated in the implementation of Continued Process Verification (CPV) includes Process Performance (Pp) and Process Performing Index (Ppk). The results of the data analysis carried out show that the Pp value obtained is more than 1.00, which means it meets the requirements. However, for several parameters, such as sterilization temperature, pH mixing, particulate matter 25m, as well as related substances 10-deacetylpaclitaxel, 7-epipaclitaxel, total impurities, and bioburden, the Ppk value was less than 1.00 or did not meet the requirements due to the analysis carried out.

still using Capability Process Sixpack assuming that the data is normally distributed (data analysis has not been carried out using appropriate distribution patterns for each parameter).