Validasi Pembersihan Alat-Alat Sampling Dan Perhitungan Permitted Daily Exposure (PDE): Ceftriaxone & Pantoprazole di PT. Mahakam Beta Farma = Cleaning Validation of Perpitted Daily Exposure (PSD) Sampling and Calculation Equipments: Ceftriaxone & Pantoprazole at PT. Mahakam Beta Farma

Uray Sandy Kurniawan, author

Abstrak

Salah satu hal yang dapat mempengaruhi mutu produk adalah terjadinya kontaminasi silang pada produk obat, maka dari itu perlu dilakukan proses validasi pembersihan (cleaning validation). Hasil perhitungan PDE dapat digunakan untuk mengetahui nilai Maximum Allowable Carryover (MACO), yaitu batas yang dapat diterima untuk residu obat dipastikan tidak adanya kontaminasi silang untuk bets berikutnya yang akan diproduksi. Pada tugas khusus ini dilakukan validasi terhadap pembersihan alat-alat sampling yang diterapkan di PT. Mahakam Beta Farma. Validasi yang dilakukan diharapkan dapat menjadi bukti yang menjamin bahwa pembersihan alat-alat sampling akan senantiasa memberikan hasil yang efektif.Validasi pembersihan alat-alat sampling di PT Mahakam Beta Farma dilakukan mengikuti protokol yang tersedia dengan nama Sampling Tools Cleaning Validation. Pengukuran yang telah dilakukan terhadap air bilasan alat-alat sampling Liquid Sampler dan Volumetric Pipette ini menunjukkan hasil yang memenuhi spesifikasi. Hasil pengukuran pH berada pada rentang 5-7 untuk semua alat, hasil pengukuran konduktivitas berada dibawah 1,3 ?S/cm dan hasil pengukuran TOC berada dibawah 500 ppb. Sedangkan untuk parameter jumlah kontaminasi mikroba, hasilnya belum diketahui ketika laporan ini ditulis karena masih berada dalam masa inkubasiMembuat prosedur pembersihan terhadap alat-alat sampling Liquid Sampler dan Volumetric Pipette terhadap senyawa Penanda Y di PT. Mahakam Beta Farma, sehingga memberikan hasil pembersihan yang memenuhi syarat dan konsisten. Menguji hasil pengukuran pH, konduktivitas, Total Organic Carbon (TOC), dan jumlah mikroba dari hasil validasi pembersihan yang berada dalam batas penerimaannya.
.....One of the things that can affect product quality is the occurrence of cross-contamination in drug products, therefore it is necessary to carry out a cleaning validation process. The results of the PDE calculation can be used to determine the Maximum Allowable Carryover (MACO) value, which is the acceptable limit for drug residues to ensure there is no cross-contamination for the next batch to be produced. In this special assignment, validation was carried out on cleaning the sampling tools applied at PT. Mahakam Beta Farma. It is hoped that the validation carried out will provide evidence that guarantees that the cleaning of the sampling tools will always provide effective results. The cleaning validation of the sampling tools at PT Mahakam Beta Farma is carried out following the protocol available under the name Sampling Tools Cleaning Validation. Measurements that have been made on the rinse water of the Liquid Sampler and Volumetric Pipette sampling tools show results that meet specifications. The pH measurement results were in the range of 5-7 for all tools, the conductivity measurement results were below 1.3 ?S/cm and the TOC measurement results were below 500 ppb. As for the parameter of the amount of microbial contamination, the results were not yet known when this report was written because it was still in the incubation period. Create a cleaning procedure for the Liquid Sampler and Volumetric Pipette sampling tools for the Y Marker compound at PT. Mahakam Beta Farma, thus providing cleaning results that meet the

requirements and are consistent. Testing the results of measurements of pH, conductivity, Total Organic Carbon (TOC), and the number of microbes from the cleaning validation results that are within their acceptance limits.