

Praktik kerja di PT Enseval Putera Megatrading Tbk periode bulan November tahun 2022, penyusunan protokol kualifikasi operasional dan kualifikasi kinerja stand freezer di PT Enseval Putera Megatrading Tbk Cabang Jakarta-1 = Work practice at PT Enseval Putera Megatrading Tbk for the period November 2022, compilation of operational qualification and performance qualification protocol of stand freezer at PT Enseval Putera Megatrading TBK Jakarta-1 branch

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Abstrak

PT Enseval Putera Megatrading Tbk merupakan pedagang besar farmasi (PBF) di bawah naungan Kalbe Farma yang berdiri sejak Oktober 1973. PT Enseval Putera Megatrading bergerak dalam bidang distribusi, pemasaran, dan penjualan produk kesehatan, salah satunya adalah cold chain product (CCP) seperti vaksin dan produk biologis. Penyimpanan CCP memerlukan freezer yang telah terqualifikasi. Proses kualifikasi peralatan meliputi empat tahap yang terdiri dari kualifikasi desain, instalasi, operasional, dan kinerja. Penyusunan protokol kualifikasi operasional dan kualifikasi kinerja stand freezer dilakukan untuk memastikan cold chain product (CCP) pada rentang suhu yang sesuai. Dalam tugas khusus ini, dilakukan penyusunan protokol kualifikasi operasional dan kinerja stand freezer di PT Enseval Putera Megatrading Tbk Cabang Jakarta 1. Hasil menunjukkan bahwa komponen protokol kualifikasi operasional dan kinerja mencakup tujuan, ruang lingkup, penanggung jawab, deskripsi mesin, dan prosedur pengujian dari stand freezer. Pengujian kualifikasi operasional mencakup menyalakan/mematikan daya, pengaturan suhu, distribusi dingin dalam keadaan kosong, dan operasi defrost. Pengujian kualifikasi kinerja melibatkan pengujian distribusi dingin dengan muatan pada freezer.

..... PT Enseval Putera Megatrading Tbk is a Pharmaceutical Wholesalers under Kalbe Farma that established since October 1973. PT Enseval Putera Megatrading Tbk is engaged in the distribution, marketing and sales of health products, one of which is cold chain products (CCP) such as vaccine and biological product. CCP storage requires a qualified freezer. Qualification process consist of four stages, design, installation, operational, and performance qualification. The development of operational qualification and performance qualification protocols for stand freezer is to ensure cold chain products (CCP) is stored at the required temperature range. In this report, the compilation of operational and performance qualification protocols for the stand freezer at PT Enseval Putera Megatrading Tbk Jakarta-1 Branch was conducted. The results indicate that the components of the operational and performance qualification protocols include objectives, scope, responsibilities, machine descriptions, and testing procedures for the stand freezer. Operational qualification testing includes powering on/off, temperature adjustment, cold distribution in empty condition, and defrost operation. Furthermore, performance qualification testing involves cold distribution testing with load on the freezer.