

Kualifikasi Kinerja Sistem HVAC (Heating, Ventilation and Air Conditioning) Ruang Produksi Steril Non-Cephalosporin di PT. Mahakam Beta Farma = Performance Qualification of HVAC (Heating, Ventilation and Air Conditioning) System of Non-Cephalosporin Sterile Production Room at PT. Mahakam Beta Farma

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Abstrak

Kualifikasi kinerja bertujuan untuk memverifikasi bahwa fasilitas, sistem dan peralatan yang telah terpasang dan difungsikan, bekerja secara efektif serta memberikan hasil yang konsisten. Dalam aktivitasnya, industri farmasi wajib menerapkan program kontrol, kualifikasi, dan validasi pada setiap aspek yang dapat berpengaruh terhadap kegiatan produksi dan mutu obat yang dihasilkan termasuk pada sarana penunjang kritis. Adapun salah satu sarana penunjang kritis di industri farmasi yaitu Sistem Tata Udara (HVAC). Laporan ini berisi tentang metode kualifikasi kinerja sistem HVAC terhadap parameter kritis yang dapat mempengaruhi kualitas produk selama proses produksi di Ruang Produksi Steril Non-Cephalosporin PT. Mahakam Beta Farma.

.....Performance qualification aims to verify that facilities, systems and equipment that have been installed and functioned, work effectively and provide consistent results. In its activities, the pharmaceutical industry is required to implement control, qualification and validation programs in every aspect that can affect production activities and the quality of drugs produced, including critical supporting facilities. One of the critical supporting facilities in the pharmaceutical industry is the Air Conditioning System (HVAC). This report contains the method of performance qualification of the HVAC system for critical parameters that can affect product quality during the production process in the Non-Cephalosporin Sterile Production Room of PT Mahakam Beta Farma.