

Kualifikasi Kinerja Sistem HVAC (Heating, Ventilation and Air Conditioning) Ruang Produksi Kelas A Dan B PT. Global Onkolab Farma = Performance Qualification of the HVAC (Heating, Ventilation, and Air Conditioning) System in Class A and B Production Areas at PT. Global Onkolab Farma

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Abstrak

Sistem HVAC (Heating, Ventilation, and Air Conditioning) memainkan peran penting dalam industri farmasi untuk menjaga kualitas udara di ruang produksi, terutama di ruang kelas A dan B. Laporan ini membahas kualifikasi kinerja sistem HVAC di PT. Global Onkolab Farma, dengan fokus pada parameter kritis seperti integritas HEPA filter, suhu, kelembaban (RH), jumlah partikel, kecepatan aliran udara (air velocity), laju pertukaran udara (air change rate), perbedaan tekanan (differential pressure), dan pemantauan mikroba. Penelitian dilakukan selama periode Mei-Juni 2024 dengan metode non-eksperimental dan analisis kualitatif. Hasil menunjukkan bahwa semua parameter memenuhi syarat yang ditetapkan dalam protokol kualifikasi dan regulasi yang berlaku, seperti Pedoman Cara Pembuatan Obat yang Baik (CPOB) dari BPOM RI. Sistem HVAC di PT. Global Onkolab Farma mampu menjaga kualitas udara sesuai standar, mencegah kontaminasi, dan memastikan keamanan produk farmasi. Kesimpulannya, kualifikasi kinerja sistem HVAC berhasil dilakukan, namun tetap harus dilakukan penelitian lebih lanjut untuk mengikuti perkembangan regulasi dan teknologi terbaru.

.....The HVAC (Heating, Ventilation, and Air Conditioning) system plays a crucial role in the pharmaceutical industry to maintain air quality in production rooms, especially in Class A and B areas. This report discusses the performance qualification of the HVAC system at PT. Global Onkolab Farma, focusing on critical parameters such as HEPA filter integrity, temperature, relative humidity (RH), particle count, air velocity, air change rate, differential pressure, and microbial monitoring. The research was conducted from May to June 2024 using a non-experimental method and qualitative analysis. The results indicate that all parameters met the requirements set in the qualification protocol and applicable regulations, such as the Good Manufacturing Practice (GMP) guidelines from BPOM RI. The HVAC system at PT. Global Onkolab Farma successfully maintained air quality according to standards, preventing contamination and ensuring the safety of pharmaceutical products. In conclusion, the performance qualification of the HVAC system was successfully conducted, but further research is needed to keep up with the latest regulations and technological advancements.