

Kualifikasi Kinerja Sistem HVAC Pada Area Tableting Esterogen di PT Sydna Farma = Qualification of HVAC System Performance in Esterogen Tableting Area at PT Sydna Farma

Sartika Harka Putri, author

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Abstrak

Sistem HVAC atau sistem Heating, Ventilation, and Air Conditioning didefinisikan sebagai suatu sistem udara yang harus mencapai empat tujuan secara bersamaan, yaitu kontrol suhu udara, kontrol kelembaban udara, kontrol sirkulasi udara, dan kontrol kualitas udara (Patil et al., 2018). Kualifikasi Kinerja merupakan proses pembuktian terdokumentasi yang menyatakan bahwa suatu mesin/ peralatan ataupun sistem yang telah terpasang/ mengalami modifikasi beserta peralatan/sistem pendukungnya dapat beroperasi efektif dalam jangka waktu tertentu (berulang) berdasarkan proses, metode, maupun spesifikasi yang telah ditetapkan (Departemen QA PTSF, 2019). Kualifikasi Kinerja berkala sistem HVAC di area Tableting, Primary Packaging & Dispensing di Area Estrogenik dengan parameter yang diuji meliputi pengukuran perubahan udara, pemantauan suhu, kelembaban relatif, dan tekanan ruangan, pemeriksaan partikulat udara dan kontaminasi mikroba. Kualifikasi sistem HVAC secara berkala sangat penting untuk dilakukan untuk memastikan bahwa aspek ini dapat mendukung kegiatan produksi. Berdasarkan hasil pelaksanaan kualifikasi kinerja sistem HVAC di area tableting esterogen PT Sydna Farma disimpulkan bahwa kualifikasi kinerja sistem HVAC di area tableting esterogen dalam kondisi yang baik dan dapat beroperasi sesuai dengan spesifikasi yang telah dipersyaratkan.

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HVAC system or Heating, Ventilation, and Air Conditioning system is defined as an air system that must achieve four objectives simultaneously, namely air temperature control, air humidity control, air circulation control, and air quality control (Patil et al., 2018). Performance Qualification is a documented proof process stating that a machine/equipment or system that has been installed/modified along with its supporting equipment/systems can operate effectively within a certain period of time (repeated) based on predetermined processes, methods, and specifications (PTSF QA Department, 2019). Qualification Periodic performance of the HVAC system in the Tableting, Primary Packaging & Dispensing area in the Estrogenic Area with tested parameters including measurement of air changes, monitoring of temperature, relative humidity, and room pressure, inspection of air particulates and microbial contamination. Periodic qualification of the HVAC system is essential to ensure that this aspect can support production activities. Based on the results of the implementation of the HVAC system performance qualification in the esterogen tableting area of PT Sydna Farma, it is concluded that the HVAC system performance qualification in the esterogen tableting area is in good condition and can operate according to the required specifications.