

Penerapan CDOB dan Pelaksanaan Kualifikasi Kinerja Container Chiller di Distribution Center 1 PT. Enseval Putera Megatrading Tbk = Internship at PT Enseval Putera Megatrading Tbk Pharmaceutical Distributor on 17 - 28 October 2022, The Performance Qualification of Chiller Room B at Warehouse A, Distribution Center 1

Fionna Christie Emmanuela, author

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Abstrak

Berdasarkan Peraturan Badan Pengawas Obat dan Makanan Nomor 6 Tahun 2020 tentang Cara Distribusi Obat yang Baik, harus ada seorang apoteker penanggung jawab (APJ) di sebuah Pedagang Besar Farmasi (PBF) yang bertanggung jawab untuk memastikan mutu produk obat di sepanjang jalur distribusi agar sesuai dengan persyaratan dan tujuan penggunaannya. Dalam laporan ini telah dilakukan observasi terhadap peran apoteker di PT. Enseval Putera Megatrading Tbk (EPM) dalam melaksanakan CDOB, khususnya pada pelaksanaan kualifikasi kinerja area penyimpanan suhu terkontrol 2-8°C pada container chiller yang dilakukan dengan melakukan pemetaan suhu, studi buka tutup pintu, dan uji notifikasi alarm. Secara keseluruhan, EPM telah menerapkan CDOB dengan baik, khususnya pada manajemen mutu, bangunan dan peralatan, inspeksi diri, transportasi, dokumentasi, dan ketentuan khusus produk rantai dingin (cold chain product/ CCP). Selain itu, seorang APJ di EPM berperan dalam melakukan pengawasan, pengendalian dan pencatatan terhadap keluar-masuknya produk serta melaksanakan pekerjaan berdasarkan prosedur kerja yang berlaku sesuai standar ISO 9001, CDOB, Quality Manual, GDP, dan peraturan perundang-undangan yang berlaku. Di sisi lain, kualifikasi kinerja yang telah dilakukan pada container chiller menunjukkan bahwa hasil pemetaan suhu memiliki rata-rata suhu terendah 4,26°C dan rata-rata suhu tertinggi 5,39°C. Kemudian, hasil studi buka tutup pintu menunjukkan dan suhu yang terbaca pada sistem sensor suhu berada pada rentang 2,9 – 4,8°C, dan hasil uji notifikasi alarm menunjukkan bahwa sensor yang terhubung ke sistem keamanan dapat membaca penyimpangan suhu saat mesin dimatikan. Alarm buzzer dan alarm pada pos keamanan dapat menyala, serta sistem dapat mengirimkan pemberitahuan penyimpangan suhu melalui whatsapp ke personel terkait dalam waktu 10 menit. Berdasarkan hal-hal tersebut diatas, dapat disimpulkan bahwa proses kegiatan pengadaan, penyimpanan, dan pendistribusian obat serta peran apoteker yang dilaksanakan di Distribution Center PT. Enseval Putera Megatrading Tbk memenuhi aspek-aspek CDOB. Selain itu, kualifikasi kinerja terhadap container chiller diluluskan, dan container chiller tersebut dapat digunakan untuk menyimpan produk rantai dingin (2-8 °C).

..... According to Regulation of The Indonesian Food and Drug Authority (BPOM) Number 6 of The Year 2020 about Good Distribution Practices for Drugs, there must be a responsible pharmacist in a Pharmaceutical Distributor who is accountable for ensuring the quality of drug products along the distribution chain to comply with requirements and intended use. This report presents observations on the role of pharmacists at PT. Enseval Putera Megatrading Tbk (EPM) in implementing Good Distribution Practices, particularly in the performance qualification of the controlled temperature storage area of 2-8°C in the chiller room. This was done through temperature mapping, door open-close studies, and alarm notification tests. Overall, EPM has successfully implemented Good Distribution Practices, especially in quality management, infrastructure and equipment, self-inspection, transportation, documentation, and

specific requirements for cold chain products (CCP). Additionally, a responsible pharmacist at EPM plays a role in supervising, controlling, and documenting the flow of products, while complying with ISO 9001, Good Distribution Practices, Quality Manual, GDP, and relevant regulations. The performance qualification conducted on the chiller room indicated that the temperature mapping results had an average low temperature of 4.26°C and an average high temperature of 5.39°C. The door open-close study showed that the temperature recorded by the sensor system ranged from 2.9°C to 4.8°C, and the alarm notification test indicated that the security system could detect temperature deviations when the machine was turned off. The alarm buzzer and security alarm were triggered, and the system could send the notifications via WhatsApp to relevant personnel within 10 minutes. Based on the informations, it can be concluded that the storage and distribution processes of the products, as well as the role of pharmacists carried out at the Distribution Center 1 of PT. Enseval Putera Megatrading Tbk are comply with the aspects of Good Distribution Practices. Furthermore, the performance qualification of the chiller container has been approved, and the chiller container can be used to store cold chain products (2-8°C).