

Kualifikasi Kinerja Chest Freezer AB-1200-T-X ID. P05 di PT. Enseval Putera Megatrading, Tbk. DC1 Jakarta = Performance Qualification of Chest Freezer AB-1200-T-X ID.P05 at PT. Enseval Putera Megatrading, Tbk. DC1 Jakarta

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Abstrak

Pendistribusian sediaan farmasi khususnya produk rantai dingin atau Cold Chain Product (CCP) memerlukan perhatian khusus dalam proses pendistribusian. PT Enseval Putera Megatrading memiliki peran penting dalam pendistribusian produk farmasi di Indonesia. Chest Freezer sebagai salah satu peralatan penting yang digunakan dalam membuat dan menyimpan ice pack yang digunakan dalam pengiriman produk CCP perlu dilakukan proses kualifikasi kinerja terlebih dahulu. Kualifikasi kinerja Chest Freezer ini dilakukan untuk memastikan suhu penyimpanan ice pack sesuai standar. Hasil kualifikasi pada Chest Freezer AB-1200-T-X ID. P05 menunjukkan bahwa distribusi suhu berada dalam rentang yang diharapkan (-10-(-15)oC), dengan beberapa penyimpangan pada suhu terendah. Penyimpangan ini disebabkan karena kegiatan operasional seperti buka-tutup freezer atau pengisian kembali ice pack. Namun, persebaran suhu dingin cenderung merata. Chest Freezer AB-1200-T-X ID. P05 memenuhi kriteria keberterimaan dalam kualifikasi kinerja dengan distribusi suhu yang merata. Pengaturan suhu pada -18oC bertujuan untuk mencegah cairnya ice pack selama proses penyimpanan. Selain itu, proses rekualifikasi perlu dilakukan secara berkala untuk menjaga kualitas penyimpanan yang optimal. The distribution of pharmaceutical products, especially Cold Chain Products (CCP), requires special attention in the distribution process. PT Enseval Putera Megatrading plays a crucial role in pharmaceutical product distribution in Indonesia. Chest Freezer, as one of the essential equipment used in making and storing ice packs for CCP product shipments, needs to undergo a performance qualification process first. This performance qualification of the Chest Freezer is conducted to ensure that the storage temperature of the ice packs meets the standards. The results of the qualification on Chest Freezer AB-1200-T-X ID. P05 indicate that the temperature distribution falls within the expected range (-10-(-15)oC), with some deviations at the lowest temperatures. These deviations are caused by operational activities such as opening and closing the freezer or refilling ice packs. However, the distribution of cold temperatures tends to be uniform. Chest Freezer AB-1200-T-X ID. P05 meets the acceptance criteria in performance qualification with a uniform temperature distribution. Setting the temperature at -18oC aims to prevent the ice pack from melting during storage. Additionally, periodic requalification processes are necessary to maintain optimal storage quality.