

Pengkajian Inspeksi Diri Cold Chain Product (CCP) di Kimia Farma Trading & Distribution Bekasi = Evaluation of Cold Chain Product (CCP) Self Inspection at Kimia Farma Trading & Distribution Bekasi

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Abstrak

Pada distribusi produk rantai dingin, terdapat persyaratan khusus yang harus dipenuhi sebagai standar meliputi aturan yang berkaitan dengan masalah suhu pada saat penerimaan, penyimpanan dan pengiriman. Potensi produk rantai dingin mungkin dapat berkurang atau bahkan hilang bila terkena suhu di luar kisaran yang dipersyaratkan, maka dalam penyimpanannya perlu dijaga suhunya. Terjadinya perubahan suhu hingga diluar rentang yang dipersyaratkan dapat mengubah kualitas produk serta efikasinya. Dalam pengelolaannya, terdapat faktor lain yang memengaruhi seperti seperti bangunan dan peralatan (chiller, freezer, termometer) yang memadai serta personel yang memenuhi kualifikasi sesuai dengan CDOB. Inspeksi diri perlu dilakukan sebagai tindakan pemenuhan terhadap CDOB dan sebagai penjaminan konsistensi mutu terhadap kinerja PBF. Oleh karena itu, dilakukan evaluasi kesesuaian hasil inspeksi diri terhadap CDOB. Metode yang digunakan antara lain studi literatur, wawancara dan observasi. Ketiga metode tersebut dilakukan agar dokumentasi inspeksi diri yang dihasilkan sesuai dengan kondisi pedagang besar farmasi dan dapat memenuhi persyaratan CDOB. Studi literatur dilaksanakan dengan cara mencari referensi melalui pedoman teknis CDOB. Wawancara dilaksanakan untuk memperoleh data-data yang diperlukan untuk mengisi form inspeksi diri. Observasi dilaksanakan dengan cara mengamati secara langsung keberlangsungan penerapan CDOB di Kimia Farma Trading & Distribution cabang Bekasi. Kesimpulan yang bisa dihasilkan adalah Kimia Farma Trading & Distribution cabang Bekasi telah melaksanakan dan mematuhi CDOB melalui standar prosedur operasional yang berlaku berdasarkan hasil inspeksi diri untuk produk rantai dingin/cold chain product (CCP).

.....In the distribution of cold chain products, there are special requirements that must be met as standards, including rules relating to temperature issues at the time of receipt, storage and delivery. The potential of cold chain products may be reduced or even lost if exposed to temperatures outside the required range, so it is necessary to maintain the temperature in storage. Changes in temperature beyond the required range can change product quality and efficacy. In its management, there are other influencing factors such as adequate buildings and equipment (chillers, freezers, thermometers) as well as personnel who meet the qualifications according to the CDOB. Self-inspection needs to be carried out as an act of compliance with CDOB and as a guarantee of quality consistency towards PBF performance. Therefore, an evaluation of the suitability of the results of the self-inspection against the CDOB was carried out. The methods used include literature studies, interviews and observation. These three methods are carried out so that the resulting self-inspection documentation is in accordance with the conditions of pharmaceutical wholesalers and can meet CDOB requirements. The literature study was carried out by looking for references through the CDOB technical guidelines. Interviews were conducted to obtain the necessary data to fill out the self-inspection form. Observations were carried out by directly observing the continuity of CDOB implementation at the Bekasi branch of Kimia Farma Trading & Distribution. The conclusion that can be drawn is that the Bekasi branch of Kimia Farma Trading & Distribution has implemented and complied with the CDOB through the

applicable standard operating procedures based on the results of self-inspection for cold chain products (CCP).