Penerapan CDOB dan CDAKB dalam Validasi Tempat Penyimpanan dan Kalibrasi Alat Monitoring Suhu di PT MJG = Application of CDOB and CDAKB in Validation of Storage and Calibration of Temperature Monitoring Equipment at PT MJG

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Abstrak

Pedagang Besar Farmasi (PBF) bertugas mendistribusikan obat dan atau alat kesehatan dengan memastikan mutu tetap terjamin saat sampai di tangan konsumen. Dalam rangka mencapai hal tersebut, diperlukan pedoman yang terstandarisasi dalam rangkaian kegiatan distribusi dan pengendalian mutu untuk menjamin produk yang didistribusikan memenuhi persyaratan yang ditetapkan sesuai tujuan penggunaannya. Tugas khusus ini ditulis dengan tujuan agar penulis dapat memahami lebih dalam terkait penerapan CDOB dan CDAKB dalam proses validasi tempat penyimpanan dan kalibrasi alat monitoring suhu di PT MJG. Pelaksanaan tugas ini dilakukan dengan metode studi literatur dan perolehan informasi melalui sesi penyampaian materi, serta pengamatan langsung terhadap kegiatan operasional di PT MJG. Berdasarkan studi literatur, serta pengamatan, dan wawancara yang telah penulis lakukan, dapat disimpulkan bahwa PT MJG telah menerapkan aspek validasi penyimpanan, dan kalibrasi alat monitoring suhu dengan baik sesuai dengan kaidah-kaidah yang diatur dalam pedoman Cara Distribusi Obat yang Baik (CDOB) dan Cara Distribusi Alat Kesehatan yang Baik (CDAKB).

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Pharmaceutical Wholesalers (PBF) are tasked with distributing drugs and/or medical devices by ensuring that quality remains as guaranteed when they reach consumers. In order to achieve this, standardized guidelines are needed in a series of distribution and quality assurance activities to ensure that distributed products meet the requirements set according to their intended use. This special assignment was written with the aim that the author can understand more deeply the application of CDOB and CDAKB in the validation process of storage and calibration of temperature monitoring devices at PT MJG. The implementation of this assignment was carried out using the literature study method and obtaining information through material delivery sessions, as well as direct observation of operational activities at PT MJG. Based on the literature study, as well as observations, and interviews that the author has conducted, it can be concluded that PT MJG has implemented aspects of storage validation, and calibration of temperature monitoring devices properly in accordance with the rules regulated in the guidelines for Good Drug Distribution Practices (CDOB) and Good Medical Device Distribution Practices (CDAKB).