

Praktek Kerja di PT. CKD OTTO PHARMACEUTICALS Periode 03 Juli-31 Agustus 2023, Gap Analysis Kualifikasi Pemasok Bahan Obat Menurut Surat Edaran Kepala BPOM Nomor 5 Tahun 2023 dan Prosedur Tetap di PT. CKD OTTO PHARMACEUTICALS = Internship at PT. CKD OTTO PHARMACEUTICALS for the period 03 July-31 August 2023, Gap Analysis of Medicinal Supplier Qualifications According to The Head Of BPOM Circular Letter Number 5 Of 2023 and Standing Procedures at PT. CKD OTTO PHARMACEUTICALS

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Abstrak

Badan Pengawas Obat dan Makanan (BPOM) telah menerbitkan Surat Edaran Kepala BPOM Nomor 5 Tahun 2023 tentang Pedoman Kualifikasi Pemasok Bahan Obat. Tujuan tugas khusus ini bertujuan untuk menganalisis kesenjangan (GAP) antara kualifikasi pemasok bahan obat menurut Surat Edaran Kepala BPOM Nomor 5 Tahun 2023 dan prosedur tetap di PT. CKD Otto Pharmaceuticals. Metode yang digunakan dalam pembuatan tugas khusus ini adalah metode observasional dengan design Cohort. Data diambil secara konkrit terhadap data sekunder yaitu data Standar Operasional atau Peraturan Tetap PT CKD OTTO Pharmaceuticals. Pada proses pengambilan data dilakukan dengan metode total sampling. Kemudian hasil disajikan secara deskriptif. Hasil yang diperoleh dari hasil gap analysis setelah dibandingkan dengan standar operasional prosedur (SOP) yang berlaku adalah secara keseluruhan PT CKD OTTO Pharmaceuticals sudah memenuhi atau sesuai dengan surat edaran Kepala BPOM nomor 5 tahun 2023 Berdasarkan hasil Praktik Kerja Profesi Apoteker di Industri PT CKD OTTO Pharmaceuticals yang telah dilakukan dapat disimpulkan bahwa seluruh aspek pada Standar Operasional (SOP) PT. CKD OTTO Pharmaceuticals telah sesuai dengan Surat Edaran Kepala BPOM nomor 5 tahun 2023 terkait kualifikasi pemasok bahan baku obat.

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The Food and Drug Supervisory Agency (BPOM) has issued Circular Letter from the Head of BPOM Number 5 of 2023 concerning Qualification Guidelines for Suppliers of Medicinal Ingredients. The purpose of this special assignment aims to analyze the gap (GAP) between the qualifications of medicinal ingredient suppliers according to the Circular Letter of the Head of BPOM Number 5 of 2023 and the permanent procedures at PT. CKD Otto Pharmaceuticals. The method used in making this special assignment was an observational method with a cohort design. Data was taken concretely from secondary data, namely data on Operational Standards or Permanent Regulations of PT CKD OTTO Pharmaceuticals. The data collection process was carried out using the total sampling method. Then the results are presented descriptively. The results obtained from the gap analysis results after being compared with the applicable standard operating procedures (SOP) are that overall PT CKD OTTO Pharmaceuticals has complied with or complies with circular letter from the Head of BPOM number 5 of 2023. Based on the results of Pharmacist Professional Work Practices in PT CKD OTTO Pharmaceuticals Industry What has been done can be concluded that all aspects of PT's Operational Standards (SOP). CKD OTTO Pharmacheuticals is in accordance with the Circular Letter of the Head of BPOM number 5 of 2023 regarding the qualifications of suppliers of

medicinal raw materials</p>