Analisis Gap Inspeksi Hasil Produk Steril di PT Ferron Par Pharmaceuticals terhadap Pedoman yang Berlaku = Gap Analysis of Sterile Product Inspection Processes at PT Ferron Par Pharmaceuticals Against Applicable Guidelines

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Abstrak

Penelitian ini bertujuan untuk menganalisis kesesuaian proses inspeksi hasil produk steril di PT. Ferron Par Pharmaceuticals dengan pedoman yang berlaku, seperti Cara Pembuatan Obat yang Baik (CPOB) 2018, Anneks 1, dan The United States Pharmacopeia (USP) edisi 43 tahun 2020. Metodologi yang digunakan adalah deskriptif observasional dengan data diperoleh melalui observasi langsung, wawancara, dan studi dokumen. Hasil analisis menunjukkan bahwa proses inspeksi di PT. Ferron Par Pharmaceuticals dilakukan melalui metode manual, semi-otomatis, dan otomatis. Proses ini mencakup inspeksi visual terhadap kontaminasi partikulat, integritas penutup wadah, serta cacat kosmetik dan non-kosmetik. Perbandingan dengan pedoman menunjukkan tingkat kesesuaian sebesar 100%, mengindikasikan bahwa seluruh aspek inspeksi telah sesuai dengan standar yang ditetapkan. Kesimpulan ini memberikan kontribusi penting dalam mendukung persiapan audit Eropa mendatang dan meningkatkan kualitas inspeksi produk steril.
.....This study aims to analyze the compliance of sterile product inspection processes at PT. Ferron Par Pharmaceuticals with applicable guidelines, including Good Manufacturing Practices (GMP) 2018, Annex 1, and The United States Pharmacopeia (USP) 43rd Edition 2020. The methodology employed was descriptive observational, with data obtained through direct observation, interviews, and document review. The analysis revealed that the inspection processes at PT. Ferron Par Pharmaceuticals were carried out using manual, semi-automated, and automated methods. These processes include visual inspections for particulate contamination, container closure integrity, as well as cosmetic and non-cosmetic defects. A comparison with the guidelines showed a 100% compliance rate, indicating that all inspection aspects adhered to the established standards. These findings contribute significantly to supporting the preparation for the upcoming European audit and enhancing the quality of sterile product inspections.