Product Quality Review Produk Injeksi X Tahun 2021 = Period, Product Quality Review of Injection X in 2021

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Abstrak

Seluruh industri farmasi di Indonesia wajib menerapkan aspek-aspek Cara Pembuatan Obat yang Baik (CPOB) sebagai pedoman untuk menjamin agar proses produksi dan pengendalian mutu menghasilkan obat dengan mutu yang tinggi dan konsisten. Kualitas dari sistem dan produksi secara keseluruhan dari suatu produk dapat dikaji melalui rangkuman berupa Product Quality Review (PQR). Melalui laporan PQR, analisis dilakukan untuk melihat konsistensi dari proses yang ada dan kesesuaian spesifikasi dari produk. Pada tugas akhir ini dilakukan penyusunan laporan PQR Produk Injeksi X Tahun 2021 di PT. CKD OTTO Pharmaceuticals. Penyusunan laporan PQR dilakukan dengan cara pengumpulan data terkait produksi seperti batch record, uji stabilitas, daftar status kualifikasi pemasok bahan baku, bahan kemas, data validasi protokol produksi, laporan Out of Specifications (OOS), deviasi dan Corrective and Preventive Action (CAPA), Change Request Form (CRF), status kualifikasi dan kalibrasi peralatan dan utilitas, penarikan produk, serta status registrasi obat dan dan kontrak dari produk injeksi X, serta laporan in-process control dan finished goods. Seluruh data dilakukan analisa dengan pembuatan tren analisis data stabilitas, menganalisa process capability menggunakan perangkat lunak Minitabs. Hasil pengkajian terhadap proses dan produk Injeksi X menunjukkan tidak terdapat permasalahan signifikan terkait bahan awal dan proses produksi injeksi X, dan proses dalam kondisi terkendali. Rekomendasi yang diajukan adalah untuk melanjutkan studi stabilitas sesuai jadwal untuk setiap bets, melakukan pembaharuan terkait tanggal kualifikasi alat serta melakukan asesmen dan monitoring terhadap proses pada periode pengkajian berikutnya.

..... Pharmaceutical industries n Indonesia are required to apply aspects of Good Manufacturing Practices (GMP) as guidelines to ensure that the production and quality control processes produce drugs with consistent quality. The quality of the system and the overall production of a product can be assessed through Product Quality Review (PQR) where analysis is carried out to see the consistency of the existing process and the suitability of the specifications of the product. In this report, the PQR report of Injection X produced in 2021 at PT. CKD OTTO Pharmaceuticals was prepared. Data related to production such as batch records, stability tests, lists of qualification status of raw material suppliers, packaging materials, production protocol validation data, Out of Specifications (OOS) reports, deviations and Corrective and Preventive Action (CAPA), Change Request Form (CRF), status of qualification and calibration of equipment and utilities, product recalls, as well as drug and contract registration status , as well as reports on in-process control and finished goods were collected. All data was analyzed for trends and process capability using Minitabs software. The results of the review of the X Injection process and products indicated that there were no significant problems related to the starting materials and the X injection production process, and the process was under controlled conditions. Stability study should be carried out continuously according to schedule for each batch, update the qualification date of the equipment and conduct an assessment and monitoring of the process in the next review period.