Studi Proses Produksi Obat Sitostatika Dengan Bentuk Sediaan Injeksi Steril dan Serbuk Injeksi Liofilisasi di PT CKD OTTO Pharmaceuticals = Study of the Production Process of Cytostatics Drugs with Sterile Injection Dosage Forms and Lyophilized Injection Powder at PT CKD OTTO Pharmaceuticals

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Abstrak

Kanker menjadi salah satu penyebab kematian utama pada 10 juta kasus di seluruh dunia pada tahun 2020. Salah satu terapi yang dapat diberikan kepada pasien kanker yaitu menggunakan obat sitostatika. Proses produksi obat sitostatika menurut CPOB memerlukan penanganan khusus seperti produksi di gedung terpisah dari produk non sitostatika, area produksi yang dedikatif, pengaturan sistem tata udara, dan pengaturan kelas kebersihan untuk proses produksi sediaan steril, serta perlindungan terhadap personel dan produk. Penelitian ini bertujuan untuk menelaah proses produksi sediaan sitostatika di PT CKD OTTO Pharmaceuticals, menganalisis kesesuaian proses produksi sediaan sitostatika dengan CPOB dan menganalisis perbedaan proses produksi sediaan sitostatika dibandingkan proses produksi sediaan steril lainnya. Pengambilan data dilakukan dengan observasi, wawancara, dan studi literatur. Hasil penelitian menunjukkan proses produksi sediaan sitostatika di PT CKD OTTO Pharmaceuticals meliputi tahapan penerimaan bahan awal dan bahan kemas, sampling bahan awal dan bahan kemas, penyiapan sebelum produksi, sterilisasi, pencucian vial dan depyrogenation, penimbangan material, mixing, transfer produk, filling, freeze drying, crimping, external washer, inspeksi visual, pelabelan, pengemasan sekunder, hingga proses agregasi. Seluruh proses produksi sediaan sitostatika di PT CKD OTTO Pharmaceuticals telah sesuai dengan CPOB meliputi aspek bangunan-fasilitas, personalia, kelas kebersihan yang digunakan, pengaturan tekanan udara, sistem terkait produksi, hingga monitoring lingkungan. Terakhir, perbedaan proses produksi sediaan sitostatika dibandingkan proses produksi sediaan steril lainnya terletak pada bangunan, tekanan udara yang digunakan, tahapan penerimaan bahan awal, penimbangan material, mixing, filing, dan external washer.

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Cancer is one of the leading causes of death in 10 million cases worldwide in 2020. One of the therapies that can be given to cancer patients is using cytostatic drugs. The production process of cytostatics according to CPOB requires special handling such as production in a separate building from non-cytostatics products, dedicative production areas, air system settings, and hygiene class settings for the production process of sterile preparations, as well as protection of personnel and products. This study aims to examine the production process of cytostatics preparations at PT CKD OTTO Pharmaceuticals, analyze the suitability of the production process of cytostatics preparations with CPOB and analyze the differences in the production process of cytostatics preparations compared to the production process of other sterile preparations. Data collection was carried out by observation, interview, and literature study. The results showed that the production process of cytostatics preparations at PT CKD OTTO Pharmaceuticals included the stages of receiving initial materials and packaging materials, sampling initial materials and packaging materials, pre-production preparation, sterilization, vial washing and depyrogenation, material weighing, mixing, product

transfer, filling, freeze drying, crimping, external washer, visual inspection, labeling, secondary packaging, to the aggregation process. The entire production process of cytostatics preparations at PT CKD OTTO Pharmaceuticals is in accordance with CPOB, including aspects of building-facilities, personnel, hygiene classes used, air pressure settings, production-related systems, and environmental monitoring. Finally, the difference in the production process of cytostatics preparations compared to the production process of other sterile preparations lies in the building, the air pressure used, the stages of receiving initial materials, weighing materials, mixing, filing, and external washers.