

Praktik Kerja di PT CKD OTTO Pharmaceuticals (Revisi Standar Operasional Prosedur Manajemen Kontainmen di PT CKD OTTO Pharmaceuticals) = Internship at PT CKD OTTO Pharmaceuticals (Revision of Standard Operating Procedures for Containment Management at PT CKD OTTO Pharmaceuticals)

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Abstrak

Manajemen kontainmen dimulai dari penentuan marker produk, kriteria penerimaan, penentuan lokasi sampling dan penentuan metode sampling. Manajemen kontainmen perlu dilakukan setelah kegiatan produksi dilakukan. Manajemen kontainmen berlaku untuk fasilitas penanganan produk farmasi (termasuk zat aktif) yang mengandung zat berbahaya. PT. CKD OTTO Pharmaceutical telah menerapkan Manajemen kontainmen sejak 2018, dan SOP Manajemen Kontainmen yang telah diperbaharui pada kegiatan PKPA diantaranya melakukan pembaruan struktur organisasi, lokasi pengambilan sampel, kriteria penerimaan, dan frekuensi kegiatan manajemen kontainmen. Hasil dari pelaksanaan manajemen kontainmen PT. CKD OTTO Pharmaceutical yang dilakukan di pada area-area lokasi pengambilan sampel yaitu tidak ditemukan marker produk pada area-area tersebut dan dapat dikatakan memenuhi kriteria penerimaan.

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Containment management starts from determining product markers, acceptance criteria, determining sampling locations and determining sampling methods. Containment management needs to be carried out after production activities are carried out. Containment management applies to facilities handling pharmaceutical products (including active substances) containing hazardous substances. PT. CKD OTTO Pharmaceutical has implemented containment management since 2018, and the updated Containment Management SOPs for PKPA activities include updating the organizational structure, sampling locations, acceptance criteria, and frequency of containment management activities. The results of the implementation of PT. OTTO Pharmaceutical CKD was carried out in the areas where the samples were taken, meaning no product markers were found in these areas and can be said to have met the acceptance criteria.