

Praktik kerja profesi di PT. Combiphar Padalarang Jalan Raya Simpang No. 383 Padalarang periode bulan Maret - April tahun 2018 =
Internship at PT. Combiphar Padalarang Plant March-April 2018 period

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Abstrak

ABSTRAK

Apoteker dalam industri farmasi memegang peranan penting dan tanggung jawab dalam penerapan aspek ndash; aspek yang tercantum dalam CPOB. Personil kunci di industri farmasi, yang terdiri dari penanggung jawab produksi, penanggung jawab pengawasan mutu, dan penanggung jawab pemastian mutu harus dijabat oleh seorang Apoteker. Pengetahuan mengenai aspek CPOB, proses registrasi produk, pelaksanaan pengawasan mutu, proses produksi, dan penelitian atau pengembangan produk adalah beberapa hal dasar yang perlu dimiliki oleh seorang apoteker di industri farmasi. Untuk dapat mengetahui dan memahami tugas serta peran Apoteker di industri, maka mahasiswa apoteker melaksanakan kegiatan Praktek Kerja Profesi Apoteker PKPA di PT Combiphar. Kegiatan PKPA ini bertujuan agar mahasiswa dapat mengetahui dan memahami tugas pokok dan fungsi instansi-intansi pemerintahan di bidang farmasi; memiliki wawasan, pengetahuan, ketrampilan dan pengalaman praktis; serta memiliki gambaran nyata tentang permasalahan kefarmasian di industri farmasi. Tugas khusus yang diberikan berjudul Penetapan Produk Marker Worst Case Product dan Batas Penerimaan Residu Kimia Berdasarkan Hasil Analisa Risiko Sebagai Bahan Validasi Pembersihan. Tujuan dari tugas khusus ini agar mahasiswa memahami prinsip, tujuan, dan tahapan yang dilakukan dalam proses risk assesment / bracketing untuk menentukan produk marker worst-case product dan batas penerimaan residu kimia sebagai bahan validasi pembersihan.

ABSTARCT

Pharmacists in the pharmaceutical industry play an important role and responsibility in the application of aspects listed in the CPOB. Key personnel in the pharmaceutical industry, which consists of the person in charge of production, the person in charge of quality control, and the person in charge of quality assurance must be served by a Pharmacist. Knowledge of CPOB aspects, product registration process, implementation of quality control, production processes, and product research or development are some of the basic things that a pharmacist needs to have in the pharmaceutical industry. To be able to know and understand the duties and roles of Pharmacists in the industry, pharmacist students carry out Pharmacist Professional Work Practice PKPA activities at PT Combiphar. PKPA 39;s activities aim to enable students to know and understand the main tasks and functions of government agencies in the pharmaceutical sector; have insight, knowledge, skills and practical experience; and has a real picture of pharmaceutical problems in the pharmaceutical industry. Specific assignments were given entitled Determination of Product Markers Worst Case Products and Limits for Receiving Chemical Residues Based on Risk Analysis Results as a Validation Cleaning Material. The purpose of this special task is for students to understand the principles, objectives and stages carried out in the risk assessment / bracketing process to determine the worst-case product and the acceptance limit of chemical residues as cleaning validation material.