# Praktik kerja profesi di PT. Medifarma Laboratories periode bulan Juli-September tahun 2016 = Internship at PT. Medifarma Laboratories period of July-September 2016

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Abstrak

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Industri farmasi merupakan salah satu sarana tempat dilakukan pekerjaan kefarmasian. Praktik kerja profesi yang dilaksanakan di PT Medifarma Laboratories ini, bertujuan agar mahasiswa mendapatkan pengalaman nyata dalam melakukan pekerjaan kefarmasian di industri farmasi. Industri farmasi adalah badan usaha yang memiliki izin untuk melakukan kegiatan pembuatan obat atau bahan obat. Dalam pembuatan obat, industri farmasi harus memenuhi ketentuan Cara Pembuatan Obat yang Baik CPOB agar obat yang dihasilkan aman, berkhasiat dan bermutu. Seluruh aspek CPOB telah diterapkan oleh PT Medifarma Laboratories. Selain itu, PT Medifarma Laboratories juga menerapkan ketentuan GMP dari PIC/s sebagai jaminan tambahan untk keperluan ekspor produk. Seluruh proses produksi dan aspek terkait telah dikendalikan, dan setiap tahapnya telah terdokumentasikan. Salah satu upaya pengendalian dalam proses produksi adalah validasi proses yang menjadi tugas khusus yang diberikan kepada mahasiswa. Validasi proses merupakan usaha untuk membangun bukti terdokumentasi bahwa suatu proses produksi akan senantiasa menghasilkan produk yang memenuhi kriteria yang ditentukan. Validasi ini termasuk dalam validasi konkuren, dilakukan terhadap pada tiga bets tablet suplemen XYZ berturut-turut, dimana tiap bets berukuran 100.000 tablet. Validasi proses telah dilakukan mulai dari tahap wet compounding, dry mixing, compression dan coating. Validasi terhadap proses blistering tablet suplemen XYZ juga telah dilakukan. Dari hasil validasi, disimpulkan bahwa proses produksi tiga bets tablet suplemen XYZ telah tervalidasi.
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ABSTRACT<br>
The pharmaceutical industry is one of the places to do the pharmaceutical works. The internship that held at PT Medifarma Laboratories, intended to make students get the real experience in performing the pharmaceutical works in the pharmaceutical industry. The pharmaceutical industry is an entity that has a license to conduct the manufacture of drugs or drug ingredients. In the manufacture of drugs, the pharmaceutical industry must comply Good Manufacturing Practice GMP so that the resulting drug meet the criteria of safe, efficacy and quality. All aspects of GMP has been applied by PT Medifarma Laboratories. In addition, PT Medifarma Laboratories also applying the GMP provisions of PIC s as an additional guarantee for export products. The whole process of production and its related aspects are controlled, and every stage is documented. One of the actions in order to control the production process is validation process that became task given to the student. The validation process is establishing documented evidence to determine that process consistently produce a product meet its predetermined specifications and quality characteristics. Validation that had been done is classified as concurrent validation, and were carried out on three batches of Tablet Supplements XYZ, where the size of each batch were 100.000 tablets. Validation process were started from wet compounding, dry mixing, compression, and coating. Validation of the blistering process Tablets Supplement XYZ had also been performed. The results showed that the production process of three

batches of Tablet Supplements XYZ had been validated.