

Laporan praktek kerja profesi di PT Novell Pharmaceutical Laboratories Jalan Pos Pengumben Raya No.8 Jakarta Barat periode Juli-September tahun 2016 = Internship at PT. Novell Pharmaceutical Laboratories Jalan Raya Pos Pengumben 8 West Jakarta from July to September 2016

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Abstrak

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Praktek Kerja Profesi Apoteker di PT Novell Pharmaceutical Laboratories dilaksanakan pada bulan Juli sampai September tahun 2016. Pelaksanaan praktek kerja profesi ini bertujuan untuk memahami peran serta tanggung jawab Apoteker di industri farmasi dan dalam proses pengembangan produk, khususnya di Departemen Business Development PT. Novell Pharmaceutical Laboratories. Proses pengembangan produk obat dan regulasi obat di industri farmasi harus sesuai dengan aturan pemerintah Indonesia. Tugas khusus diberikan berjudul penyusunan dokumen registrasi nonklinik dan klinik larutan injeksi magnesium sulfat sesuai kriteria dan tatalaksana registrasi obat oleh Badan Pengawas Obat dan Makanan BPOM . Tujuan penyusunan tugas khusus adalah untuk mengetahui tujuan dilakukan penyusunan dokumen klinik dan nonklinik serta memahami prosedur penyusunan dokumen klinik dan nonklinik injeksi magnesium sulfat sesuai dengan Kriteria dan Tatalaksana Registrasi Obat oleh BPOM.

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ABSTRACT

Pharmacists profession internship at PT Novell Pharmaceutical Laboratories was held on July to September 2016. Implementation of this internship aimed to understand the role and responsibilities of pharmacists in the pharmaceutical industry and the development of medicinal products, especially in Department of Business Development, PT. Novell Pharmaceutical Laboratories. The process of development of medicinal products in the pharmaceutical industry must be in accordance with the rules of the Indonesian government. Special task given to support the internship activities was entitled Preparation of Non Clinical and Clinical Registration Documents of Magnesium Sulfate Injection according to the drug registration criteria and procedure by drug and food supervisory agency BPOM . The purpose of the special task are to understand the purpose of composing clinic and nonclinical documents, as well as understand the procedure of clinical and nonclinical documents arrangement of magnesium sulfate injection in accordance with BPOM drug registration criteria and procedure.