

Laporan Praktek Kerja Profesi Apoteker di PT. Clinisindo Laboratories Jl. Ulujami Raya No. 12 Jakarta Selatan Periode 1 Maret ? 30 April 2013

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Abstrak

Praktek Kerja Profesi Apoteker dilaksanakan di PT. Clinisindo Laboratories Jalan Ulujami Raya No.12, Jakarta Selatan. Kegiatan PKPA ini bertujuan agar mahasiswa profesi apoteker dapat melihat langsung aktivitas yang berlangsung dalam suatu laboratorium biokivalensi, memperoleh pengetahuan dan wawasan tentang segala aspek yang terkait dalam uji bioekivalensi obat terutama dalam hal penerapan GLP dan GCP di PT. Clinisindo Laboratories dan dapat memiliki pemahaman yang mendalam mengenai peran dan tugas apoteker di laboratorium ekivalensi. Tugas khusus yang diberikan berjudul Analisa Perbedaan Guideline Validasi Metode Bioanalisa FDA 2001 dengan EMA 2011. Tugas khusus ini bertujuan memberikan data perbedaan antara antara Guidance for Industry: Bioanalytical Method Validation yang diterbitkan oleh Food and Drug Administration (FDA) dengan Guideline on Bioanalytical Method Validation yang diterbitkan oleh European Medicines Agency (EMA).

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Pharmacists Professional Practice implemented in PT. Clinisindo Laboratories Jalan Ulujami Raya No.12, South Jakarta. PKPA activity is intended that students can see the direct profession pharmacists activity that takes place in the bioequivalence laboratory, gaining knowledge and insight into everything related aspects in the bioequivalence test, especially in terms of the implementation of GLP and GCP in PT. Clinisindo Laboratories and may have a deep understanding of the role and duties of the pharmacist in the bioequivalence laboratory. Special task given Requalification entitled Analysis of the Differences between Guidelines of Bioanalytical Method Validation published by FDA 2001 with EMA 2011. This particular assignment aims to provide the data of differences between Guidance for Industry: Bioanalytical Method Validation published by Food and Drug Administration (FDA) with Guideline on Bioanalytical Method Validation published by European Medicines Agency (EMA).