Praktik Kerja di Industri PT Guardian Pharmatama Periode 3 Juli - 30 Agustus 2023, Rekualifikasi Instalasi, Operasional, dan Kinerja Instrumen High Performance Liquid Chromatography (HPLC) Shimadzu LC-2010C HT di PT Guardian Pharmatama = Internship at PT Guardian Pharmatama for the Period July 3rd - August 30th 2023, Requalification for Installation, Operational, and Performance of Shimadzu LC-2010C HT High Performance Liquid Chromatography (HPLC) Instrument at PT Guardian Pharmatama

Feby Dita Aprilia, author

Abstrak

Kualifikasi merupakan salah satu persyaratan dari Good Manufacturing Practice (GMP). Kualifikasi merupakan tindakan pembuktian dan pendokumentasian berdasarkan data yang menunjukan kelayakan peralatan, fasilitas, sarana penunjang atau sistem bekerja dengan benar sesuai dengan spesifikasi yang telah ditetapkan. Kualifikasi terhadap peralatan sangat penting dilakukan guna menjamin bahwa peralatan yang digunakan dapat bekerja sebagaimana mestinya sehingga dapat mengurangi adanya biaya terkait kemungkinan kurang bermutunya obat yang dihasilkan. Pengerjaan rekualifikasi dilakukan pada instrumen High Performance Liquid Chromatography (HPLC) Shimadzu LC-2010C HT yang terdapat pada laboratorium instrumen QC BA dan IPC PT Guardian Pharmatama guna memastikan kesesuaian kondisi peralatan dengan protokol kualifikasi yang telah ditetapkan PT Guardian Pharmatama. Pengerjaan rekualifikasi mencakup peninjauan pustaka, penyusunan protokol, dan melakukan rekualifikasi terkait Kualifikasi Instalasi (KI), Kualifikasi Operasional (KO), dan Kualifikasi Kinerja (KK) pada instrumen High Performance Liquid Chromatography (HPLC). Berdasarkan hasil rekualifikasi pada instrumen High Performance Liquid Chromatography (HPLC) Shimadzu LC-2010C HT yang terdapat pada laboratorium instrumen QC BA dan IPC PT Guardian Pharmatama dapat disimpulkan instrumen masih memenuhi syarat yang ditetapkan PT Guardian Pharmatama.

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Qualification is one of the requirements of Good Manufacturing Practice (GMP). Qualification is a process of proof and appropriate documentation based on data that shows the suitability of equipments, facilities, supporting facilities or systems to work correctly according to predetermined specifications. Qualification of equipment is very important to ensure that the equipment used can work as it should so as to reduce costs related to the possibility of poor quality medicines being produced. Requalification work was carried out on the Shimadzu LC-2010C HT High Performance Liquid Chromatography (HPLC) instrument at PT Guardian Pharmatama's QC BA and IPC instrument laboratory to ensure the suitability of the equipment condition with the qualification protocol established by PT Guardian Pharmatama. Requalification work includes reviewing literature, preparing protocols, and carrying out requalification for Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) on the High Performance Liquid Chromatography (HPLC) instruments. Based on the requalification results of the Shimadzu LC-2010C HT High Performance Liquid Chromatography (HPLC) instrument at PT Guardian Pharmatama's QC BA and IPC instrument laboratory, it can be concluded that the instrument still meets the requirements set by PT

Guardian Pharmatama.