

Praktek Kerja di PT. Guardian Pharmatama Periode September-Oktober 2022 "Penyusunan Prosedur Tetap Umum Cara Penanganan Peralatan atau Mesin yang Terkena Najis di PT. Guardian Pharmatama" = Internship at PT. Guardian Pharmatama on period September-October 2022 "Preparation of General Standard Procedures for Handling Equipment or Machines Affected by Pollution at PT. Guardian Pharmatama"

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Abstrak

Halal dan haram menjadi titik kritis dalam pola konsumsi masyarakat, khususnya di Indonesia yang mayoritas masyarakatnya memeluk agama Islam. Penyelenggaraan jaminan produk halal dalam proses pembuatan obat telah diatur oleh Peraturan Pemerintah Republik Indonesia Nomor 39 Tahun 2021 tentang penyelenggaraan bidang jaminan produk halal pasal 141 yang menyatakan bahwa industri farmasi berkewajiban melaksanakan penahapan sertifikat halal pada produknya. Kelancaran setiap proses pembuatan obat di industri farmasi dipengaruhi oleh beberapa faktor, salah satunya adalah prosedur kerja. Dalam mencapai kinerja yang profesional, efektif, dan efisien, maka diperlukan suatu prosedur standar yang menjadi pedoman pada setiap pelaksanaan kegiatan dalam sebuah industri farmasi. Prosedur dalam sistem kerja dikenal sebagai standar operasional prosedur (SOP) atau prosedur tetap (Protap). Salah satu protap yang diterapkan industri farmasi dalam upaya pemastian dan pengawasan mutu produk obat yaitu mengenai cara penanganan kebersihan peralatan maupun mesin, khususnya ketika terkena najis. Protap dibuat untuk merinci tiap tahap pembersihan dan sanitasi peralatan maupun mesin yang digunakan selama proses produksi guna meminimalisir terjadinya kontaminasi pada masing-masing peralatan yang nantinya akan disimpan dalam keadaan bersih dan kering. Melalui tugas khusus ini, telah disusun protap umum cara penanganan peralatan atau mesin sesuai dengan kriteria SJH, cara pembersihan dan sanitasi peralatan sesuai persyaratan yang terdapat pada CPOB, serta Prosedur Tetap Umum Cara Pembuatan dan PenomoranHalal and haram are a critical point in people's consumption patterns, especially in Indonesia where the majority of people embrace Islam. Implementation of halal product guarantees in the drug manufacturing process has been regulated by Government Regulation of the Republic of Indonesia Number 39 of 2021 concerning the implementation of halal product guarantees article 141 which states that the pharmaceutical industry is obliged to carry out halal certificate stages for its products. The smooth running of every drug manufacturing process in the pharmaceutical industry is influenced by several factors, one of which is work procedures. In achieving professional, effective and efficient performance, a standard procedure is needed to guide every activity in the pharmaceutical industry. Procedures in the work system are known as standard operating procedures (SOP) or regular procedures (Protap). One of the procedures applied by the pharmaceutical industry in an effort to ensure and control the quality of medicinal products is regarding how to handle the cleanliness of equipment and machines, especially when exposed to feces. Protaps are made to detail each stage of cleaning and sanitizing equipment and machines used during the production process in order to minimize the occurrence of contamination on each equipment which will later be stored in a clean and dry condition. Through this special assignment, a general procedure for handling equipment or

machines has been prepared in accordance with the SJH criteria, a method for cleaning and sanitizing equipment according to the requirements contained in GMP, as well as the General Procedures for Making and Numbering the Standard Procedures applicable at PT. Guardian Pharmatama.