Protokol studi masa simpan purified water dalam carboy tahun 2022 = Protocol shelf life study of purified water in carboy 2022

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Abstrak

Produksi sediaan di Industri Farmasi tidak terlepas dari peran apoteker pada pengawasan mutu terhadap bahan baku yang digunakan, salah satunya adalah purified water berdasarkan spesifikasi fisik, kimia, dan mikrobiologi. Purified water yang digunakan oleh PT Darya Varia Laboratoria Plant Gunung Putri tersimpan pada Carboy sebelum digunakan oleh Departemen Produksi sehingga waktu simpan perlu diketahui dengan protokol studi yang jelas untuk mengetahui ketahanan mutu purified water dan menentukan waktu pencucian dan pergantian purified water. Protokol studi dibuat melalui studi literatur, wawancara dengan salah satu laboran dan salah satu analis Quality Control (QC) Laboraorium Kimia, penentuan parameter dan periode pemeriksaan purified water. Berdasarkan proses tersebut, dihasilkan protokol studi yang telah disetujui oleh supervisor Laboratorium Kimia dan Mikrobiologi, manager QC, dan manager QA dengan isi berupa tujuan, cakupan, tanggung jawab, peralatan dan bahan, prosedur, dan kriteria penerimaan seperti pemerian, pH, konduktivitas, Total Organic Carbon (TOC), Total Count Bacteria, Escherichia coli, dan Pseudomonas aeruginosa disertai form pemeriksaan pada hari ke-0, 1, 2, 3, 4, 7, 10, dan 14.

.....The production of preparations in the Pharmaceutical Industry cannot be separated from the role of pharmacists in quality control of the raw materials used, one of which is purified water based on physical, chemical, and microbiological specifications. Purified water used by PT Darya Varia Laboratoria Plant Gunung Putri is stored in Carboy before being used by the Production Department so that the shelf time needs to be known with a clear study protocol to determine the quality resistance of purified water and determine the time for washing and changing purified water. The study protocol was made through literature studies, interviews with one of the laboratory assistants and one of the Quality Control (QC) analysts of the Chemistry Laboratory, determining the parameters and period of purified water inspection. Based on this process, a study protocol was produced that was approved by the Chemistry and Microbiology Laboratory supervisor, QC manager, and QA manager with contents in the form of objectives, scope, responsibilities, equipment and materials, procedures, and acceptance criteria such as description, pH, conductivity, Total Organic Carbon (TOC), Total Count Bacteria, Escherichia coli, and Pseudomonas aeruginosa accompanied by inspection forms on days 0, 1, 2, 3, 4, 7, 10, and 14.