Pembuatan Protokol Verifikasi Metode Analisa Spektrofotometri FTIR Di PT. Pfizer Indonesia Berdasarkan Farmakope Indonesia Edisi 6 Dan Standar PT. Pfizer Indonesia = Creation of Verification Protocol for FTIR Spectrophotometric Analysis Method at PT. Pfizer Indonesia Based on Indonesian Pharmacopoeia Edition 6 and PT Standards. Pfizer Indonesia

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Abstrak

Obat merupakan bahan atau campuran bahan yang digunakan untuk diagnosis, pencegahan, penyembuhan, pemulihan, peningkatan kesehatan, dan kontrasepsi manusia. Industri farmasi yang memiliki izin edar harus memastikan obat memenuhi standar keamanan, khasiat, mutu, dan informasi produk sesuai peraturan perundang-undangan. Sistem mutu industri farmasi mengharuskan dokumentasi seluruh kegiatan pembuatan obat untuk membangun, mengendalikan, dan memantau kualitas obat, dengan contoh protokol yang mencakup kualifikasi, validasi, verifikasi, dan uji stabilitas. Verifikasi metode analisis, menggunakan instrumen seperti spektrofotometri inframerah, UV-Visible, dan KCKT, menegaskan validitas data laboratorium. Peraturan Badan Pengawas Obat dan Makan mengatur bahwa obat harus mematuhi standar Farmakope Indonesia, yang diikuti oleh PT. Pfizer Indonesia dengan mengonversi metode analisis sesuai Farmakope Indonesia Edisi 6. PT. Pfizer Indonesia menetapkan standar internal untuk protokol verifikasi metode analisis di laboratorium kimianya, termasuk pembuatan protokol verifikasi metode analisis spektrofotometri inframerah berdasarkan Farmakope Indonesia Edisi 6.

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Medicines are substances or mixtures of substances used for diagnosis, prevention, healing, recovery, health improvement and human contraception. The pharmaceutical industry that ensures distribution permits for drugs must meet safety, efficacy, quality and product information standards in accordance with statutory regulations. The pharmaceutical industry quality system requires documentation of all drug manufacturing activities to establish, control, and integrate drug quality, with example protocols that include qualification, validation, verification, and stability testing. Verification of analytical methods, using instruments such as infrared spectrophotometry, UV-Visible, and HPLC, confirms the validity of laboratory data. The regulations of the Food and Drug Supervisory Agency stipulate that medicines must comply with the standards of the Indonesian Pharmacopoeia, which PT. Pfizer Indonesia with the analysis conversion method according to the Indonesian Pharmacopoeia Edition 6. PT. Pfizer Indonesia sets internal standards for analytical method verification protocols in its chemical laboratories, including creating infrared spectrophotometric analytical method verification protocols based on the Indonesian Pharmacopoeia Edition 6.