Praktik Kerja di Industri PT Harsen Laboratories Periode 31 Oktober - 23 Desember 2022, Validasi Metode Analisa Penetapan Kadar Deksametason dengan Kromatografi Cair Kinerja Tinggi = Internship at Industry PT Harsen Laboratories Period October 31th - December 23 th 2022, Validation of Determination Analytical Method Dexamethasone Assay with High Performance Liquid Chromatography

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Abstrak

Mutu obat dalam CPOB bergantung pada berbagai faktor, salah satunya yaitu bahan awal (Bahan aktif obat). Bahan aktif obat (BAO) sebelum digunakan sebagai produk obat harus dapat dipastikan telah memenuhi persyaratan mutu bahan zat aktif melalui suatu prosedur analisis. Salah satu atribut mutu bahan obat yang perlu diuji adalah kadar komponen utama yang terkandung dalam BAO harus memenuhi persyaratan kadar yang tercantum dalam Farmakope Indonesia (standar mutu) atau standar baku lainnya. Dalam hal ini, prosedur analisis penetapan kadar harus divalidasi sebelum digunakan untuk tujuan pengendalian mutu. Validasi metode analisa penetapan kadar deksametason merupakan salah satu pengujian validasi metode analisa bahan baku (bahan aktif obat) yang dilakukan di laboratorium Departemen Penelitian dan Pengembangan (R&D) PT Harsen Laboratories. Metode pengujian yang digunakan merujuk pada Farmakope Indonesia Edisi VI tahun 2020 dengan menggunakan Kromatografi Cair Kinerja Tinggi (KCKT). Berdasarkan hasil dari pengujian validasi metode analisa penetapan kadar deksametason secara keseluruhan memenuhi persyaratan untuk parameter uji kesesuaian sistem, spesifisitas, linearitas, akurasi, presisi, dan rentang, serta robustness.

..... The quality of drugs in GMP depends on various factors, one of which is the starting material (active drug ingredient). The active drug substance before being used as a drug product must be ensured that it meets the quality requirements for the active ingredient through an analytical procedure. One of the attributes of the quality of medicinal ingredients that needs to be tested is that the levels of the main components contained in APIs must meet the content requirements listed in the Indonesian Pharmacopoeia (quality standards) or other standard standards. In this case, the analytical assay procedure must be validated before it is used for quality control purposes. Validation of the analytical method for determining dexamethasone levels is one of the validation tests for the raw material analysis method (active drug substance) carried out in the laboratory of the Research and Development Department (R&D) of PT Harsen Laboratories. The test method used refers to the Indonesian Pharmacopoeia VI Edition 2020 using High Performance Liquid Chromatography (HPLC). Based on the results of the validation test for the analytical method for determining dexamethasone levels as a whole meets the requirements for system suitability test parameters, specificity, linearity, accuracy, precision, and range, as well as robustness