Praktik Kerja di Industri PT Sydna Farma Periode 2 Mei - 30 Juni 2023, Penyusunan Protokol Verifikasi Metode Analisa Penetapan Kadar Bahan Baku LXX Berdasarkan Farmakope Indonesia Edisi VI dan SOP PT Sydna Farma = Internship at PT Sydna Farma Industry Period May 2nd- June 30th 2023, Preparation of Verification Protocol for Analytical Methods of LXX Raw Material Content Determination Based on Indonesian Pharmacopoeia 6th Edition and PT Sydna Farma SOP

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Abstrak

Pengawasan mutu merupakan salah satu aspek dalam Cara Pembuatan Obat yang Baik yang berperan dalam sampling, pengujian, dokumentasi, dan perilisan baik pada bahan awal, bahan kemas, produk antara, produk ruahan, dan produk jadi. Proses pengujian pada sampel harus menggunakan metode yang sesuai dan telah tervalidasi, sehingga dapat memastikan suatu karakteristik kinerja suatu prosedur analisa telah sesuai dengan tujuan penggunaanya. Pada metode analisa yang sudah tertera dalam Farmakope Indonesia, tidak diperlukan validasi, namun hanya verifikasi kesesuaian metode dengan kondisi nyata di lapangan. Laporan ini bertujuan untuk menyusun protokol verifikasi metode analisa penetapan kadar bahan baku LXX berdasarkan Farmakope Indonesia edisi VI dan standar operasional prosedur PT Sydna Farma. Protokol verifikasi metode analisa penetapan bahan baku LXX meliputi bagian pendahuluan, tujuan, penanggungjawab, alat dan bahan, prosedur preparasi reagen, prosedur analisa sampel, prosedur verifikasi metode analisa, dan referensi.

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Quality control is one of the aspects of Good Manufacturing Practice that plays a role in the sampling, testing, documentation, and release of starting materials, packaging materials, intermediate products, processed products, and finished products. The testing process on samples must use an appropriate and validated method, to ensure that the performance characteristics of an analytical procedure are by the intended use. For analytical methods that have been listed in the Indonesian Pharmacopoeia, validation is not required, only verification of the suitability of the method with real conditions in the field. This report aims to compile a verification protocol for the analytical method for determining the content of LXX raw materials based on the VI edition of the Indonesian Pharmacopoeia and the standard operating procedure of PT Sydna Farma. The verification protocol for the analytical method for determining the content of LXX raw materials includes an introduction, objectives, responsible persons, tools and materials, reagent preparation procedures, sample analysis procedures, analytical method verification procedures, and references.