

Praktik Kerja di PT Mahakam Beta Farma Periode November-Desember 2022 “Review Protokol Stabilita Pasca Pemasaran Produk PT Mahakam Beta Farma” = Internship at PT Mahakam Beta Farma Industry from October 31th to December 29th 2022, âReview Stability Post Market Protocol Product at PT. Mahakam Beta Farmaâ

Qinthara Alifya Pramatiara, author

Deskripsi Lengkap: <https://lib.ui.ac.id/detail?id=9999920533040&lokasi=lokal>

Abstrak

Menurut CPOB pada tahun 2018, program stabilitas pascapemasaran hendaklah diuraikan dalam suatu protokol yang disusun menurut aturan umum. Oleh karena itu, proses uji stabilitas setiap produk obat perlu diatur sesuai dengan spesifikasi dan metode analisa produk jadi dalam protokol stabilitas yang berguna untuk memastikan kesetaraan perlakuan uji stabilitas pada setiap bets. Tugas khusus ini bertujuan untuk memastikan protokol stabilitas setiap produk sudah terbaharui dari segi spesifikasi dan metode Analisa, serta mengidentifikasi protokol stabilitas yang sudah tidak sesuai, serta memperbaharui protokol stabilitas sesuai dengan spesifikasi dan metode Analisa terbaru. Penyusunan tugas khusus ini dilakukan dengan melihat kesesuaian antara protokol stabilitas yang berlaku dibandingkan dengan acuan, yaitu Prosedur Tetap Pengujian Stabilita Post Market, Spesifikasi Produk Jadi, dan Metode Analisa. Protokol yang telah direview adalah sebanyak 95 dari 136 protokol stabilitas produk milik PT. Mahakam Beta Farma yang tersedia. Berdasarkan hal tersebut, terdapat 48 produk dengan protokol stabilitas yang sudah terbaharui dari segi spesifikasi dan metode Analisa dan terdapat 22 protokol stabilitas produk yang telah diperbaharui menjadi protokol baru sesuai dengan spesifikasi dan metode analisa terbaru.

..... According to CPOB in 2018, post-marketing stability programs should be described in a protocol prepared according to general rules. Therefore, the stability test process for each medicinal product needs to be regulated in accordance with the specifications and analysis methods for the finished product in a stability protocol which is useful for ensuring the equality of stability test treatment in each batch. This special task aims to ensure that the stability protocol for each product is updated in terms of specifications and analysis methods, as well as identifying stability protocols that are no longer appropriate, as well as updating the stability protocol in accordance with the latest specifications and analysis methods. The preparation of this special task is carried out by looking at the suitability of the applicable stability protocol compared to the reference, namely the Fixed Procedure for Post Market Stability Testing, Finished Product Specifications, and Analysis Methods. The protocols that have been reviewed are 95 of PT's 136 product stability protocols. Mahakam Beta Farma is available. Based on this, there are 48 products with stability protocols that have been updated in terms of specifications and analysis methods and there are 22 product stability protocols that have been updated into new protocols in accordance with the latest specifications and analysis methods.