

Protokol Validasi Masa Simpan Media Mikrobiologi di PT Mahakam Beta Farma = Protocol Validation of Microbiology Medium Shelf-life at PT Mahakam Beta Farma

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Abstrak

Industri farmasi diatur ketat secara global karena pentingnya produk farmasi bagi kesehatan masyarakat. Di PT Mahakam Beta Farma, diperlukan protokol validasi masa simpan media mikrobiologi yang sesuai dengan pedoman regulasi. Penelitian ini bertujuan mengembangkan protokol validasi berdasarkan "Cara Pembuatan Obat yang Baik" (CPOB) dan United States Pharmacopeia (USP). Metode Growth Promotion Test (GPT) digunakan untuk mengukur waktu simpan media mikrobiologi dengan memantau kekeruhan sebagai indikator aktivitas mikrobiologi. Hasil penelitian menunjukkan bahwa protokol validasi yang dibuat sesuai USP dan menggunakan bakteri standar internasional, memenuhi regulasi farmasi. Media mikrobiologi memiliki waktu penyimpanan efektif hingga 31 hari berdasarkan hasil Growth Promotion Test.

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The pharmaceutical industry is stringently regulated globally due to the critical importance of pharmaceutical products for public health. At PT Mahakam Beta Farma, a validation protocol for the shelf life of microbiological media is required to comply with regulatory guidelines. This study aims to develop a validation protocol based on Good Manufacturing Practices (GMP) and the United States Pharmacopeia (USP). The Growth Promotion Test (GPT) method was used to measure the shelf life of microbiological media by monitoring turbidity as an indicator of microbiological activity. The results show that the validation protocol, developed in accordance with USP and using internationally standardized bacteria, meets pharmaceutical regulations. The microbiological media demonstrated an effective shelf life of up to 31 days based on the GPT results.