# Validasi Metode Analisa Stasis Test pada Uji Sterilitas Produk Sediaan Steril di PT. Mahakam Beta Farma = Validation of the Stasis Test Analysis Method in Sterility Testing of Sterile Preparation Products at PT. Mahakam Beta Farma

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Abstrak

Industri farmasi merupakan industri yang memproduksi suatu obat. Setiap industri farmasi harus mampu memenuhi kriteria Cara Pembuatan Obat yang Baik (CPOB) agar dapat menjamin dan menghasilkan produk yang bermutu. Industri farmasi yang memproduksi produk sediaan steril harus memenuhi persyaratan fisika, kimia dan bebas dari mikroorganisme baik bakteri maupun jamur, maka dari itu harus dilakukan validasi untuk memberikan jaminan telah efektifnya proses sterilisasi pada sediaan steril yang telah diproduksi. Tujuan penelitian ini yaitu untuk melakukan validasi metode analisa stasis test pada uji sterilitas produk sediaan steril di PT. Mahakam Beta Farma. Penelitian dilakukan pada tanggal 03 Juli - 31 Agustus 2023 di Departemen Quality Control (QC) PT. Mahakam Beta Farma. Hasil dari validasi metode analisa stasis test yang telah dilakukan bahwa hasil dari validasi sudah valid karena hasil pengujian sudah sesuai dengan kriteria keberterimaan yang sudah ditetapkan pada protokol validasi uji sterilitas produk sediaan steril di PT. Mahakam Beta Farma.

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The pharmaceutical industry is an industry that produces drugs. Every pharmaceutical industry must be able to meet the criteria for Good Medicine Manufacturing Practices (CPOB) in order to guarantee and produce quality products. The pharmaceutical industry that produces sterile preparation products must meet physical, chemical requirements and be free from microorganisms, both bacteria and fungi, therefore validation must be carried out to provide assurance that the sterilization process has been effective for the sterile preparations that have been produced. The aim of this research is to validate the stasis test analysis method for sterility testing of sterile preparation products at PT. Mahakam Beta Farma. The research was conducted on 03 July - 31 August 2023 at the Quality Control (QC) Department of PT. Mahakam Beta Farma. The results of the validation of the stasis test analysis method that have been carried out show that the results of the validation are valid because the test results are in accordance with the acceptance criteria that have been determined in the sterility test validation protocol for sterile preparation products at PT. Mahakam Beta Farma.