

INTISARI

Kualitas produk menjadi elemen penting yang mencakup kesesuaian produk dengan standar untuk memenuhi ekspektasi pelanggan terkait performa, keandalan, dan keamanan. Kualitas ini dipengaruhi oleh komponen seperti bahan baku, proses produksi, dan pengendalian mutu. Deteksi dini masalah kualitas sangat penting untuk menjamin keamanan produk yang beredar di pasaran. Pengawasan yang ketat dilakukan sesuai standar Cara Pembuatan Obat yang Baik (CPOB) dengan bahan baku farmasi harus memenuhi spesifikasi yang ditetapkan. Penelitian ini dilakukan sebagai bentuk konkret mengkaji kualitas bahan baku dalam upaya pemastian kualitas.

Data penelitian dihimpun dari *database* perusahaan yang dilanjutkan dengan analisis statistik. Analisis pengkajian mutu material dilakukan hingga didapatkan rekomendasi *reduce analysis material* terhadap material yang memenuhi persyaratan. Hasil penelitian menunjukkan beberapa parameter dari bahan baku asetosal, dekstrometorfan hidrobromida, dan karboksimetilselulosa natrium dapat direkomendasikan untuk *reduce analysis material*. Parameter *residue on ignition* bahan baku asetosal memiliki Ppk senilai 0,70. Parameter *pH*, *water content*, dan *residue on ignition* bahan baku dekstrometorfan hidrobromida memiliki Ppk senilai 0,81; 1,01; dan 1,23. Parameter *viscosity* dan *loss on drying* bahan baku karboksimetilselulosa natrium memiliki Ppk senilai 0,85 dan 0,86. Pelolosan rekomendasi dilakukan atas justifikasi perusahaan bahwa nilai Ppk minimum sebagai syarat rekomendasi senilai 0,70.

Penelitian yang dilakukan menggambarkan terdapat korelasi antara kualitas mutu material dengan penetapan *reduce analysis material*. Nilai Ppk hasil pemeriksaan berperan signifikan terhadap rekomendasi *reduce analysis material*.

Kata kunci: *Process Performance Index*, *Reduce Analysis Material*, Kualitas, Justifikasi

ABSTRACT

Product quality is a crucial element that includes compliance with standards to meet customer expectations regarding performance, reliability, and safety. This quality is influenced by components such as raw materials, production processes, and quality control. Early detection of quality issues is essential to ensure the safety of products circulating in the market. Strict supervision is carried out following Good Manufacturing Practices (GMP), ensuring that pharmaceutical raw materials meet the specified requirements. This study was conducted as a concrete effort to examine raw material quality as part of quality assurance.

Research data was collected from the company's database and subsequently analyzed statistically. The material quality assessment was performed until recommendations for reduced analysis material of compliant materials were obtained. The results of the study indicate that several parameters of the raw materials acetosal, dextromethorphan hydrobromide, and Carboxymethyl cellulose sodium can be recommended for reduced analysis material. The residue on ignition parameter for acetosal raw material has a Ppk value of 0.70. The pH, water content, and residue on ignition parameters for dextromethorphan hydrobromide raw material have Ppk values of 0.81, 1.01, and 1.23, respectively. The viscosity and loss on drying parameters for carboxymethyl cellulose sodium raw material have Ppk values of 0.85 and 0.86, respectively. The approval of these recommendations is based on the company's justification that the minimum Ppk value required for recommendation is 0.70.

This study demonstrates a correlation between material quality and the determination of reduced material analysis. The Ppk values obtained from inspections play a significant role in the recommendation of reduced material analysis.

Keywords: *Process Capability Index, Process Performance Index, Reduced Analysis Material, Quality, Justification*