

# Validasi Sistem Komputerisasi Analytical Worksheet pada Aplikasi QC Cikarang Apps Departemen Quality Control PT Bintang Toedjoe = Validation of Analytical Worksheet Computerized System in QC Cikarang Apps Application of Quality Control Department PT Bintang Toedjoe

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## Abstrak

Revolusi industri 4.0 membawa transformasi signifikan melalui digitalisasi, otomatisasi, dan konektivitas, yang berdampak pada berbagai industri, termasuk industri farmasi. PT Bintang Toedjoe, dalam rangka mendukung program Making Indonesia 4.0, mengadopsi teknologi digital dengan mengembangkan aplikasi QC Cikarang Apps. Aplikasi ini memudahkan pemantauan pemantauan real-time inventaris, sampel dan pengawasan data di Departemen Quality Control (QC). Tugas khusus ini bertujuan untuk memvalidasi sistem komputer QC Cikarang Apps guna memastikan fungsi pengendalian yang cukup, mencegah akses tidak sah dan menjamin integritas data sesuai prinsip ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate). Metode yang digunakan meliputi observasi, wawancara dengan administrator dan user, dan penyusunan berbagai dokumen kualifikasi dan validasi. Hasil validasi sistem komputer menunjukkan bahwa Analytical Worksheet pada Aplikasi QC Cikarang Apps memenuhi spesifikasi dan standar kualitas yang ditetapkan sesuai dengan pedoman CPOB 2018 dan CPOTB 2021 tentang sistem komputerisasi dan dokumentasi. Pengoperasian aplikasi ini juga memenuhi prinsip data integrity ALCOA, memastikan semua aspek pada laporan Analytical Worksheet yang digunakan oleh Departemen QC PT Bintang Toedjoe sesuai dengan standar ALCOA.

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The Industry 4.0 revolution has brought significant transformation through digitalization, automation, and connectivity, impacting various industries, including the pharmaceutical industry. PT Bintang Toedjoe, in support of the Making Indonesia 4.0 program, has adopted digital technology by developing the QC Cikarang Apps application. This application facilitates real-time monitoring of inventory, samples, and data supervision in the Quality Control (QC) Department. This special project aims to validate the Analytical Worksheet in QC Cikarang Apps computer system to ensure adequate control functions, prevent unauthorized access, and guarantee data integrity in accordance with the ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate) principles. The methods used include observation, interviews with administrators and users, and preparation of various qualification and validation documents. The computer system validation results show that the Analytical Worksheet in the QC Cikarang Apps Application meets the specifications and quality standards set in compliance with the 2018 Good Manufacturing Practices (CPOB) and 2021 CPOTB guidelines on computerized systems and documentation. The operation of this application also adheres to the ALCOA data integrity principle, ensuring that all aspects of the Analytical Worksheet reports used by the QC Department of PT Bintang Toedjoe comply with ALCOA standards.