

Praktik Kerja Di PT Finusolprima Farma Internasional Periode Bulan Mei Juni 2023 (Pembuatan Risk Assessment Viscometer Viscoqc 300 Sebagai Penerapan Quality Risk Management di PT Finusolprima Farma Internasional) = Work Practice at PT Finusolprima Farma Internasional for the Period of May - June 2023 (Making Risk Assessment Viscometer Viscoqc 300 as the Application of Quality Risk Management at PT Finusolprima Farma International)

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Abstrak

Manajemen Risiko Mutu merupakan proses sistematis untuk menilai, mengendalikan, mengkomunikasikan dan mengkaji risiko terhadap mutu obat di sepanjang siklus hidup mutu tersebut. Pada laporan ini akan dilakukan pembuatan risk assessment instrument viscometer ViskoQC 300 sebagai bentuk aplikasi manajemen risiko mutu tahap penilaian risiko. Tugas khusus ini dilaksanakan dengan dilakukan gap analysis dengan membandingkan protokol tetap instrument yang dibuat departemen QC PT Finusolprima Farma Internasional dengan User Guide Instrument Viskometer ViscoQC 300 dari industri manufaktur alat. Tindakan tindak lanjut yang perlu dilakukan antara lain: menambahkan spesifikasi sampel/cairan yang tidak bisa diukur di ViscoQC 300, menambahkan pedoman cara menyesuaikan measuring head dan head retention pada viscometer ViscoQC 300, dan ditambah panduan keamanan instalasi kelistrikan untuk menghubungkan dan menghidupkan ViscoQC 300.

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Quality Risk Management is a systematic process to assess, control, communicate and assess risks to drug quality throughout the quality life cycle. In this report, the ViscoQC 300 risk assessment instrument viscometer will be made as a form of quality risk management application at the risk assessment stage. This special task was carried out by conducting a gap analysis by comparing the fixed protocol of the instrument made by the QC department of PT Finusolprima Farma Internasional with the User Guide Instrument Viscometer Viscometer 300 from the tool manufacturing industry. Follow-up actions that need to be taken include: adding specifications for samples/liquids that cannot be measured on the ViscoQC 300, adding guidelines on how to adjust the measuring head and head retention on the ViscoQC 300 viscometer, and adding an electrical installation safety guide for connecting and turning on the ViscoQC 300.