Pembuatan dummy batch record sediaan solid dan draft product quality review (Pqr) sediaan injeksi steril = Making dummy batch records for solid preparations and drafting product quality reviews for sterile injection preparations

Edrina Elfia Rosa, author

Abstrak

Salah satu penerapan aspek sistem mutu industri farmasi yang di atur dalam CPOB adalah pengkajian mutu produk. Pengkajian Mutu Produk (PMP) / Product Quality Review (PQR) yang dilakukan berkala pada tiap tahun untuk menganalisa tren dan perbaikan dengan mempertimbangkan hasil kajian terhadap produk yang diproduksi setahun sebelumnya dan didokumentasikan. Aspek lain yang diatur dalam CPOB adalah personalia, personil harus terkualifikasi, salah satu nya yaitu kualifikasi personil dengan menggunakan dummy batch record. Tujuan dari penulisan ini adalah mengetahui prosedur pemeriksaan catatan bets, memahami tahapan proses kualifikasi personil untuk pemeriksaan catatan bets menggunakan Dummy Batch Record, memahami cara pembuatan laporan Product Quality Review, membuat Dummy Batch Record sediaan solid dan laporan Product Quality Review sediaan injeksi steril produksi PT. Mahakam Beta Farma. Pelaksanaan dilakukan di PT Mahakam Beta Farma pada periode Agustus – September 2020. Pembuatan dummy Batch Record dan draft Product Quality Review (PQR) dilakukan dengan tahap pengumpulan data, tahap pembuatan dummy Batch Record dan tahap pembuatan draft Product Quality Review (PQR). Hasil yang didapat yaitu kualifikasi personil dengan dummy batch record dinyatakan lulus apabila nilai yang diperoleh selama kualifikasi minimal 70 dan tidak satupun penyimpangan kritikal yang terdeteksi dan Penyusunan Product Quality Review di PT. Mahakam Beta Farma telah memenuhi kriteria regulasi (persyaratan CPOB) yang ada.

.....One of the aspects of the pharmaceutical industry quality system that is regulated in CPOB is the assessment of product quality. Product Quality Review (PQR) which is carried out periodically every year to analyze trends and improvements by considering the results of the study on products produced a year earlier and documented. Another aspect that is regulated in the CPOB is personnel, personnel must be qualified, one of which is the qualification of personnel using a dummy batch record. The purpose of this paper is to know the procedure for checking batch records, understand the stages of the personnel qualification process for checking batch records using the Dummy Batch Record, understand how to make a Product Quality Review report, make a Dummy Batch Record for solid preparations and a Product Quality Review report for sterile injection preparations produced by PT. Mahakam Beta Farma. The implementation was carried out at PT Mahakam Beta Farma in the period August - September 2020. The production of a dummy Batch Record and a draft Product Quality Review (PQR) was carried out with the data collection stage, the dummy Batch Record preparation stage and the Product Quality Review (PQR) drafting stage. The results obtained are personnel qualifications with a dummy batch record passed if the scores obtained during the qualification are at least 70 and no critical deviation is detected and the Preparation of Product Quality Review at PT. Mahakam Beta Farma has met the existing regulatory criteria (CPOB requirements).