Penyusunan laporan pengkajian Tahunan atas produk “M” kaplet salut selaput Tahun 2019 = Compilation of the annual assessment report of the 2019 "M" Caplet Film-Coated Product

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Abstrak

Tujuan khusus dari penulisan ini Memahami cara pembuatan laporan PTAP di PT Harsen Laboratories sesuai dengan Protap dan persyaratan CPOB dan Mengetahui profil mutu salah satu produk obat yaitu M Kaplet salut selaput yang diproduksi oleh PT Harsen Laboratories selama periode tahun 2019. Pengkajian mutu produk umumnya dilakukan setiap tahun dan dituangkan dalam dokumen Pengkajian Mutu Produk (PMP) atau Product Quality Review (PQR), yang dimana merupakan suatu bagian dari evaluasi .....The specific purpose of this paper is to understand how to make PTAP reports at PT Harsen Laboratories in accordance with the Protap and CPOB requirements and to know the quality profile of one of the medicinal products, namely M membrane coated caplet produced by PT Harsen Laboratories during the period of 2019. Assessment of product quality is generally carried out every time. years and set forth in a Product Quality Review (PQR) document, which is a part of post-production evaluation that analyzes medicinal products within 1 year. The scope of this PTAP report includes procedures for reviewing each product manufactured in one year. The minimum number of batches that a PTAP report can generate is 3 batches. This is based on the number of 3 batches which is the minimum amount of data that can be analyzed statistically validly. QA staff collects batch records consisting of Batch Processing Records (BMR), Batch Packaging Records (BPR), In Process Control (IPC) Reports and Product Analysis Reports that have been released or rejected disposition and ensure the batch is accompanied by the QA Manager initials. The QA staff creates a PTAP attachment template on Microsoft Excel by inputting the data listed in the BMR, BPR, IPC Report and Product Analysis Report according to the predetermined format. The IPC is processed and the results of product analysis are carried out using statistical methods and interpreting the statistics. The results obtained by PTAP made at PT Harsen Laboratories are in accordance with the CPOB requirements, the data displayed is adjusted to the type of product preparation, and the method of making reports has been listed both in the Protap and Production M of film coated caplets in the 2019 period meeting the requirements of the quality specifications that have been determined. It is necessary to record batch record pasca produksi yang menganalisa produk obat dalam jangka waktu 1 tahun. Ruang lingkup dari laporan PTAP ini meliputi prosedur untuk pengkajian setiap produk yang dibuat dalam satu tahun. Jumlah batch minimum yang dapat dibuat laporan PTAP adalah sebanyak 3 batch. Hal ini didasari jumlah 3 batch merupakan jumlah minimum data yang dapat dianalisis statistika secara valid. Staff QA mengumpulkan batch record yang terdiri dari Catatan Pengolahan Batch (BMR), Catatan Pengemasan Batch (BPR), Laporan In Process Control (IPC) dan Laporoan Analisa Produk yang telah dilakukan disposisi rilis atau ditolak serta pastikan batch tersebut sudah disertai dengan paraf Manager QA. Staff QA membuat template Lampiran PTAP pada Microsoft Excell dengan cara menginput data-data yang tercantum dalam BMR, BPR, Laporan IPC dan Laporan Analisa Produk sesuai format yang telah ditetapkan. Dilakukan pengolahan terhadap IPC dan hasil analisa produk dengan menggunakan metode statistik dan melakukan interpretasi terhadap statistika. Hasil yang diperoleh PTAP yang dibuat di PT Harsen Laboratories sudah sesuai dengan

persyaratan CPOB, data yang ditampilkan disesuaikan dengan jenis sediaan produk, serta cara pembuatan laporan sudah tercantum baik dalam Protap dan Produksi M kaplet salut selaput pada peroide tahun 2019 memenuhi persyaratan spesifikasi mutu yang telah ditentukan. Perlu pencatatan peminjaman batch record dengan menginput data di sistem komputer untuk mencegah kehilangan batch record dan perlu dilakukan peningkatan mutu secara bertahap mulai dari kualifikasi dan validasi alat produksi.
.....The specific purpose of this paper is to understand how to make PTAP reports at PT Harsen Laboratories in accordance with the Protap and CPOB requirements and to know the quality profile of one of the medicinal products, namely M membrane coated caplet produced by PT Harsen Laboratories during the period of 2019. Assessment of product quality is generally carried out every time. years and set forth in a Product Quality Review (PQR) document, which is a part of post-production evaluation that analyzes medicinal products within 1 year. The scope of this PTAP report includes procedures for reviewing each product manufactured in one year. The minimum number of batches that a PTAP report can generate is 3 batches. This is based on the number of 3 batches which is the minimum amount of data that can be analyzed statistically validly. QA staff collects batch records consisting of Batch Processing Records (BMR), Batch Packaging Records (BPR), In Process Control (IPC) Reports and Product Analysis Reports that have been released or rejected disposition and ensure the batch is accompanied by the QA Manager initials. The QA staff creates a PTAP attachment template on Microsoft Excel by inputting the data listed in the BMR, BPR, IPC Report and Product Analysis Report according to the predetermined format. The IPC is processed and the results of product analysis are carried out using statistical methods and interpreting the statistics. The results obtained by PTAP made at PT Harsen Laboratories are in accordance with the CPOB requirements, the data displayed is adjusted to the type of product preparation, and the method of making reports has been listed both in the Protap and Production M of film coated caplets in the 2019 period meeting the requirements of the quality specifications that have been determined. It is necessary to record batch record lending by inputting data in a computer system to prevent loss of batch records and it is necessary to gradually increase the quality starting from the qualification and validation of production equipment.