Praktik Kerja di Industri PT Mahakam Beta Farma Periode 31 Oktober 2022 - 29 Desember 2022, Gap Assessment Prosedur Tetap Disposisi Bahan Awal dan Bahan Kemas terhadap WHO Annex 4 TRS 929 di PT. Mahakam Beta Farma = Work Practice at the PT Mahakam Beta Farma Industry for the Period 31th October 2022 - December 29th 2022, Gap Assessment of Disposition of Starting Materials and Packaging Materials against WHO Annex 4 TRS 929 at PT. Mahakam Beta Farma

Kandida Syifaa Diandra Putri, author

Abstrak

Obat merupakan produk dengan sifat dinamis sehingga kualitas dari obat tersebut haruslah terus dijaga, salah satunya dengan cara kontrol mutu. Kontrol mutu dapat dilakukan dimulai dari pengujian bahan awal dan bahan kemas untuk memastikan spesifikasi dan identitas sesuai. Prosesur tetap terkait dengan pengambilan sampel serta disposisi bahan awal dan bahan kemas penting untuk dibuat dan diterapkan agar seluruh proses tersebut berlangsung secara teratur, terdokumentasi dengan baik, dan sesuai dengan ilmu serta regulasi terbaru. Maka dari itu, perlu dilakukan secara berkala penilaian kesenjangan prosedur tetap. Metode yang digunakan yaitu studi literatur mengenai regulasi terbaru yaitu WHO Annex 4, kemudian dilakukan pengamatan serta analisis kesenjangan antara prosedur tetap dan WHO Annex dengan memberikan nilai kesesuaian. Selanjutnya dibentuk solusi untuk permasalahan yang terjadi. Berdasarkan penilaian kesenjangan yang telah dilakukan, prosedur tetap telah memenuhi setidaknya 8 poin, hanya memenuhi sebagian dari 6 poin, dan tidak memenuhi sebanyak 2 poin dari total 16 poin yang tertera pada WHO Annex 4. Persentase pemenuhan prosedur tetap disposisi bahan awal dan bahan kemas yaitu sebesar 68,75%. Beberapa daftar poin yang belum terpenuhi atau hanya sebagian terpenuhi meliputi belum lengkapnya detail pernyataan fasilitas pengambilan sampel, tanggung jawab untuk pengmabilan sampel, hingga metode serta pola pengambilan sampel di prosedur operasional. Namun, pada kondisi aktual, poin yang belum terpenuhi tetap dilakukan sesuai dengan regulasi yang berlaku.
..... Drugs are products with dynamic properties so that the quality of these drugs must be maintained, one of which is by means of quality control. Quality control can be carried out starting from testing of starting materials and packaging materials to ensure proper specifications and identity. It is important to have established and implemented standard operation procedure related to the sampling and disposition of starting materials and packaging materials to ensure that these processes are appropriate, well-documented and in accordance with the latest science and regulations. Therefore, it is necessary to periodically assess the fixed procedure gap. The method used is a literature study regarding the latest regulations, namely WHO Annex 4, then do an observation and analysis regarding the gaps between the standard procedures and the WHO Annex by giving values for each statement. Then a solution is formed for the problems that occur. Based on the gap assessment that has been carried out, the standard operation procedures have fulfilled at least 8 points, only fulfilled a portion of the 6 points, and did not fulfil as many as 2 points out of the total 16 points listed in WHO Annex 4. The percentage of compliance with WHO Annex 4 is 68.75%. Some of the list of points that have not been fulfilled or only partially fulfilled include incomplete detailed statements of sampling facilities, responsibilities for sampling, to methods and patterns of sampling in operational

procedures. However, in actual conditions, points that have not been fulfilled are still carried out in accordance with applicable regulations.