Renewal Certified For Material Active Pharmaceutical Ingredients (API), Excipient, and Bulk Product Import in PT Kalventis Sinergi Farma = Renewal Certified For Material Active Pharmaceutical Ingredients (API), Excipient, and Bulk Product Import in PT Kalventis Sinergi Farma

Holie Fransiska, author

Abstrak

Berdasarkan CPOB, pemasok bahan awal harus dievaluasi dan disetujui untuk memenuhi spesifikasi mutu yang telah ditentukan oleh perusahaan. Dalam rangka membuktikan konsistensi proses, kesesuaian dari spesifikasi bahan, pengurangan program pengambilan sampel dan pengujian harus dinilai ulang setiap tahun berdasarkan tinjauan analisis batch dan hasil audit. Tujuan dari pemeriksaan ulang (renewal) adalah untuk menilai konsistensispesifikasi material bersertifikasi. Pelaksanaan dilakukan dengan membuat matriks perbandingan referensi dan spesifikasi hasil pengujian berdasarkan CoA manufacturer, PT Kalventis, dossier, dan Farmakope Indonesia VI; menganalisis OOS (Out of Specification) dan deviasi bahan kemudian menentukan status pemasok. Berdasarkan matriks perbandingan spesifikasi hasil pengujian Glibenklamid, Hidroksipropil metilselulosa, tablet Glimepirid 2 mg/Metformin HCl 500 mg semua parameter hasil pengujian berstatus “acceptable”. Material Hidroksipropil metilselulosa dan tablet Glimepirid 2 mg/Metformin HCl 500 mg menunjukkan tidak adanya kejadian OOS maupun deviasi. Material Glibenklamid terdapat kejadian OOS akibat kesalahan laboratorium sehingga hasil yang dilaporkan adalah berdasarkan hasil analisis ulang yang hasilnya memenuhi spesifikasi. Zat aktif Glibenklamid, eksipien Hidroksipropil metilselulosa, dan produk ruahan Tablet Glimepiride 2 mg / Metformin HCl 500 mg sesuai dengan spesifikasi bahan PT Kalventis sehingga status “certified” dari ketiga bahan tersebut dapat berlaku.

..... Based on GMP, suppliers of raw materials must be evaluated and approved to meet the quality specifications set by the company. To prove process consistency, compliance with material specifications, reduced sampling and testing programs should be reassessed annually based on batch analysis reviews and audit results. The renewal aims to assess the consistency of the specifications for the certified material. Implementation is done by making a reference comparison matrix and specification of the test results based on the CoA manufacturer, PT Kalventis, dossier, and the Indonesian Pharmacopoeia VI; analyzing OOS (Out of Specification) and material deviation, then determining supplier status. Based on the specification comparison matrix of the test results for Glibenclamide, Hydroxypropyl methylcellulose, and Glimepiride 2 mg/Metformin HCl 500 mg tablets, all parameters tested were "acceptable". Hydroxypropyl methylcellulose material and Glimepiride 2 mg/Metformin HCl 500 mg tablets showed no OOS or deviation. The Glibenclamide material has OOS events due to laboratory errors, so the results reported are based on the results of re-analysis and the results meet specifications. The active substance Glibenclamide, the excipient Hydroxypropyl methylcellulose, and the bulk product Glimepiride 2 mg / Metformin HCl 500 mg tablets conform to the material specifications of PT Kalventis, so that the "certified" status of the three ingredients can apply.