Prosedur Pembuatan Risk Assessment Elemental Impurities pada Produk Jadi di Industri Farmasi = Procedures for Making Risk Assessments for Elemental Impurities in Finished Products in the Pharmaceutical Industry

Zahidah Raihanah, author

Abstrak

Industri farmasi memerlukan izin dari Kementerian Kesehatan untuk memproduksi obat dan mendapatkan Nomor Izin Edar untuk menjual produknya di pasar lokal atau internasional. Proses registrasi produk melibatkan pengajuan dossier, seperti Common Technical Document (CTD), yang berisi data administratif, ringkasan umum, klinis dan non-klinis, serta mutu obat. Dossier ini disesuaikan dengan persyaratan negara yang berbeda dan menggunakan format CTD yang diakui secara internasional. Untuk modul mutu, dokumen Risk Assessment Elemental Impurities diperlukan untuk mengendalikan kontaminan logam dalam produk jadi. Proses Risk Assessment ini penting untuk mengidentifikasi dan mengurangi risiko dari Elemental Impurities. Apoteker memainkan peran kunci dalam menyusun dokumen ini untuk memastikan keamanan produk farmasi. Usulan prosedur pembuatan Risk Assessment Elemental Impurities dalam Industri Farmasi disusun berdasarkan penelusuran literatur tatalaksana internasional yang berlaku. Proses pembuatan Risk Assessment dilakukan dengan tahapan: identifikasi Elemental Impurities, evaluasi tingkat Elemental Impurities dan membuat kesimpulan penilaian keamanan Elemental Impurities tersebut.

.....

The pharmaceutical industry requires permission from the Ministry of Health to produce medicines and obtain a Marketing Permit Number to sell its products on local or international markets. The product registration process involves submitting documents, such as the Common Technical Document (CTD), which contains administrative data, general, clinical and non-clinical summaries, and drug quality. This dossier is adapted to the requirements of different countries and uses the internationally recognized CTD format. For the quality module, a Risk Assessment Elemental Impurities document is required to control metal contaminants in finished products. This Risk Assessment process is important to identify and reduce the risk of Elemental Impurities. Pharmacists play a key role in preparing these documents to ensure the safety of pharmaceutical products. The proposed procedure for creating a Risk Assessment for Elemental Impurities in the Pharmaceutical Industry was prepared based on a search of applicable international management literature. The process of making a Risk Assessment is carried out in stages: identifying Elemental Impurities, evaluating the level of Elemental Impurities and making conclusions regarding the security assessment of the Elemental Impurities.