Gap Analisis Spesifikasi dan Metode Pengujian Raw Material dan Finished Product PT Fonko International Pharmaceuticals terhadap Farmakope Indonesia = Gap Analysis of Specifications and Testing Methods for Raw Material and Finished Products of PT Fonko International Pharmaceuticals Compared to the Indonesian Pharmacopoeia

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Abstrak

Di Indonesia, sampai 5 Desember 2022 kasus Gangguan Ginjal Akut Progresif Atipikal pada anak (GGAPA) diduga akibat intoksikasi EG/DEG terdapat 324 kasus. Akar permasalahan dari kasus EG/DEG tersebut diimplikasikan dengan beberapa kelalaian, yaitu industri farmasi tidak melakukan uji identifikasi secara lengkap khususnya verifikasi kemurnian terhadap raw material gliserin sebagai pelarut. Menindaklanjuti kasus tersebut, WHO menegaskan kembali kepada pemegang otoritas seperti industri farmasi dan BPOM. Industri farmasi wajib menggunakan bahan baku pharmaceutical grade dari suplier dengan lisensi resmi, serta pengujian bahan baku harus dilakukan secara hati-hati. Project Gap Analisis dipilihkan oleh QC Supervisor berkoordinasi dengan bagian TS. Penulis sudah meminta izin untuk mencantumkan beberapa data Fonko ke dalam laporan ini. Gap analisis spesifikasi diketahui terdapat 1 jenis API yang sudah OK, yaitu Oxaliplatin dan 17 jenis API yang NOK. Gap analisis spesifikasi diketahui terdapat 3 jenis excipient yang sudah OK dan 10 jenis excipient yang NOK. Gap analisis spesifikasi diketahui terdapat 3 jenis finished product yang sudah OK dan 26 jenis finished product yang NOK. Gap analisis metode pengujian diketahui 7 jenis API, 4 jenis excipient, dan 11 jenis finished product yang belum memiliki monografi di FI VI.

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In Indonesia, as of December 5th 2022, there were 324 cases of Acute Kidney Disease caused by EG/DEG intoxication. The EG/DEG intoxication cases were implicated as the pharmaceutical industry did not carry out complete identification tests, especially verification of the purity of the raw material glycerin as a solvent. Following up on this case, WHO reiterated this to the pharmaceutical industry and BPOM. The pharmaceutical industry is obliged to use pharmaceutical grade raw materials from suppliers with official licenses, and raw material testing must be carried out carefully. The Gap Analysis Project wass selected by the QC Supervisor in coordination with the TS department. The author has requested permission to include some Fonko’s data in this report. Gap analysis of specifications revealed that there was 1 type of API that was OK, namely Oxaliplatin and 17 types of API that were NOK. Gap analysis of specifications shows that there are 3 types of excipient that are OK and 10 types of excipient that are NOK. Gap analysis of specifications shows that there are 3 types of finished products that are OK and 26 types of finished products that are NOK. The gap analysis of testing methods identified 7 types of API, 4 types of excipient, and 11 types of finished products that do not yet have monographs in FI VI.