Genotoxic Impurities pada Industri Farmasi = Genotoxic Impurities in the Pharmaceutical Industry

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Abstrak

Genotoxic impurities adalah senyawa kimia yang membahayakan organisme dengan merusak materi genetik (DNA) yang dapat ditemukan dalam senyawa obat. Sebagai instansi pembuatan obat, industri farmasi memiliki izin dari menteri kesehatan untuk melakukan kegiatan pembuatan obat atau bahan obat, sehingga perlu mengetahui lebih dalam terkait Genotoxic impurities. Penelitian ini bertujuan untuk mengetahui definisi, jenis senyawa yang rentan, metode analisa dan perhitungan batas deteksi, serta upaya yang perlu dilakukan oleh PT. Novell Pharmaceutical Laboratories sebagai salah satu industri farmasi dalam menangani temuan genotoxic imutirities. Studi ini merupakan penelitian kualitatif dengan metode literature review untuk pelaksanaan penelitiannya. Pencarian database berupa Google Scholar, ResearchGate, Pubmed, acs.org. Hasil dari penilaian kualitas studi selanjutnya akan mengumpulkan dan menggali informasi berdasarkan analisa PICO (Problem, Purpose, Population, Intervention, Comparison, Outcome). Hasil penelitian menunjukkan jika genotoxic impurities bersifat karsinogenik dan dapat ditemukan dalam senyawa obatmelalui bahan awal dalam sintesis obat, zat antara dan produk sampingan yang terbentuk dalam proses sintesis, pelarut, katalis dan reagen yang digunakan dalam proses sintesis, serta produk degradasi yang dihasilkan pada penyimpanan dan pengiriman atau karena paparan cahaya, udara, oksidasi atau hidrolisis. Metode analisis yang dapat digunakan untuk mengidentifikasi keberadaan genotoxic impurities adalah dengan metode HPLC (High Performance Liquid Chromatography), GC (Gas Chromatography), TLC/HPTLC (Thin Layer Chromatography), dan elektroforesis kapiler dengan perhitungan batas deteksi menggunakan nilai TTC (threshold of toxicological concern) dan staged TTC.
..... Genotoxic impurities are chemical compounds that harm organisms by damaging genetic material (DNA) which can be found in drug compounds. As a drug manufacturing agency, the pharmaceutical industry has permission from the Minister of Health to carry out drug or medicinal ingredient manufacturing activities, so it is necessary to know more about Genotoxic impurities. This research aims to determine the definition, types of susceptible compounds, analysis methods and detection limit calculations, as well as the efforts that need to be made by PT. Novell Pharmaceutical Laboratories as one of the pharmaceutical industries in handling findings of genotoxic cuteirities. This study is qualitative research with a literature review method for conducting the research. Database searches include Google Scholar, ResearchGate, Pubmed, acs.org. The results of the study quality assessment will then collect and explore information based on PICO analysis (Problem, Purpose, Population, Intervention, Comparison, Outcome). The research results show that genotoxic impurities are carcinogenic and can be found in drug compounds through starting materials in drug synthesis, intermediates and by-products formed in the synthesis process, solvents, catalysts and reagents used in the synthesis process, as well as degradation products produced during storage. and shipping or due to exposure to light, air, oxidation or hydrolysis. Analytical methods that can be used to identify the presence of genotoxic impurities are HPLC (High Performance Liquid Chromatography), GC (Gas Chromatography), TLC/HPTLC (Thin Layer Chromatography), and capillary

electrophoresis with detection limit calculations using the TTC (threshold of toxicological) value. concern) and staged TTC. Several efforts that can be made by active substance manufacturers to deal with genotoxic impurities are changes in synthesis, adjustment of reaction conditions to reduce the formation of genotoxic impurities, and purification of active substances.