IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 2, July 2024

Review on Nitrosamine Impurities Present in Drugs and Medicines

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Abstract: *The detection of more than one nitrosamine impurity in pharmaceuticals, exceeding a total quantity of 26.5 ng/day based on the maximum daily dose (MDD), prompts the FDA to request manufacturers to contact the agency for evaluation. This review focuses on the presence of nitrosamine impurities in drugs and the importance of controlling potentially mutagenic impurities to assess carcinogenic risk in humans. The recent identification of nitrosamine impurities in various marketed pharmaceuticals has heightened interest in their mutagenic and carcinogenic potential. Nitrosamines belong to a 'cohort of concern,' meaning standard control protocols, such as the threshold of toxicological concern (TTC), are not applicable. Drugs such as sartans, ranitidine, and nizatidine have been found to contain these impurities, which often arise from the use of solvents, catalysts, and raw materials during the manufacturing process. Regulatory agencies have issued interim notices and press releases regarding the control of these impurities. Preventing nitrosamine impurities can be achieved by modifying the manufacturing process or implementing precautions during the production of drug substances and products. Validated analytical methods, including gas chromatography, mass spectrometry, and liquid chromatography, are used to identify and quantify these impurities. Nitrosamines typically form due to reactions between secondary and tertiary amines or ammonium salts and nitrosating agents. The European Medicines Agency (EMA) was the first to finalize guidelines on the presence of nitrosamine impurities in sartan medications.*

Keywords: Chromatography, medicine, nitrosating agent, European Medical Agency, Food and Drug Administration

DOI: 10.48175/568