

REVIEW ARTICLE

EXPLORING NITROSAMINES: NITROSATION PATHWAY, ROOT CAUSES AND MITIGATION STRATEGIES

Sharma S.S.M. Sonti^a and Buchi N. Nalluri^{a*}

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ABSTRACT

Nitrosamine impurities, classified as human carcinogens, have been detected in pharmaceutical drugs over the past several years. They are distinguished by the presence of the nitroso functional group and may develop under numerous conditions, including manufacturing and shelf life. Metabolic activation of nitrosamines is primarily mediated by membrane protein cytochrome P450 2E1. This review provides a comprehensive overview of nitrosamines, including compromised risk factors, nitrosation pathway, root causes, and acceptable intake limits. In addition, this review presents mitigation strategies aimed at addressing and controlling the nitrosamine impurity formation.