Advisory Note on Mitigation of Risks of Nitrosamine Impurities in Pharmaceutical Products

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Nitrosamine compounds are potent genotoxic agents in several animal species and some are classified as probable or possible human carcinogens by the International Agency for Research on Cancer. They are referred to as *cohort of concern* compounds in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidance for industry *M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk* (July 2023).

The discovery of nitrosamines in some drug products has led health agencies and regulators around the world to take extensive measures to ensure the safety and quality of the medicines supply.

In this context, the Egyptian Drug Authority (EDA), recognizes the necessity of establishing a mitigation strategy to prevent the unexpected finding of nitrosamine impurities in pharmaceutical products. Hence EDA directs all manufacturers of APIs and pharmaceutical products to adopt a risk assessment strategy for the potential presence of nitrosamines in any pharmaceutical product.

Manufacturers are required to consider the potential causes of nitrosamine formation and evaluate the risk for nitrosamine formation in their APIs and drug products**,** perform confirmatory testing if a risk is identified**,** and take appropriate actions to reduce or prevent the presence of these impurities.

Manufacturers and applicants should retain all associated documents, and submit them upon the authority’s request.