Genotoxic nitrosamines in pharmaceutical products.

The FDA is making ongoing assessment, oversight, compliance and pharmaceutical grade efforts in every area of product, and they will continue to work with drug manufacturers to ensure safe, effective, and high-quality drugs for the public. When the FDA identifies new and previously unrecognized risks to safety and quality, they act quickly to resolve the issue, as they have done by responding to the recent findings of nitrosamines in certain drugs.

Manufacturers are responsible for understanding their processes, which includes preventing the presence of unacceptable impurities. Manufacturers are also responsible for developing and using suitable methods to detect and limit unacceptable impurities, including any new impurities that may arise when they make changes to their manufacturing processes.

Today we have better testing methods than ever before and know what to look for in the chemical structures and manufacturing processes of products that can increase the risk of low nitrosamine formation. Improved technology allows us to detect even trace amounts of impurities in medicines and this may be the reason why more products contain low **nitrosamines.**

To ensure the safety, the FDA guidance recommends that manufacturers should conclude the risk assessment of approved or marketed products, the first of three steps manufacturers should follow to mitigate nitrosamine impurities in their products, within 6 months of publication of the guidance.

Sample Q has developed several methods using GC/MSMS headspace & fibertrapping or direct injection to detect the presence of N-nitrosodimethylamine, N-Nitrosodiethylamine, N-diisopropylnitrosoamine, N-ethyl-N isopropylnitrosoamine and N-Nitrosodibutylamine.

Do you want to know more about our approach or are you interested in this lab, let us know and we will contact you to discuss the details?