

NATIONAL



AUTHORITY

24th June 2020

Attention: Pharmaceutical Manufacturers and
Local Technical Representatives

CIRCULAR NO. 006/DIE/2020

RE: ANALYSIS FOR NITROSAMINE IMPURITIES IN DRUGS

National Drug Authority has noted that some drugs including Ranitidine and Angiotensin II Receptor Blockers may contain Nitrosamine impurities including N-nitrosodimethylamine (NDMA) as a result of the production processes. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) following exposure over time based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables. Other Nitrosamine impurities include N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) and N-nitrosodiethylamine (NDEA). These have led to voluntary recalls by different manufacturers globally.

All manufacturers of drugs with potential for Nitrosamine impurities will be required to establish specifications and validated test methods for these impurities and carry out laboratory testing for confirmation of these impurities in the finished drug product to acceptable levels.

Further note, for the safety of the patients taking these drugs, National Drug Authority will evaluate analysis reports per batch, during import verification, and therefore the tests for Nitrosamine impurities would be required for the affected drugs manufactured effective 1st August 2020.

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SECRETARY TO THE AUTHORITY

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OUR MISSION

Promoting and protecting public health
through the effective regulation of human
and animal medicines and healthcare
products

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