

Detection of nitrosamines in APIs and Drugs

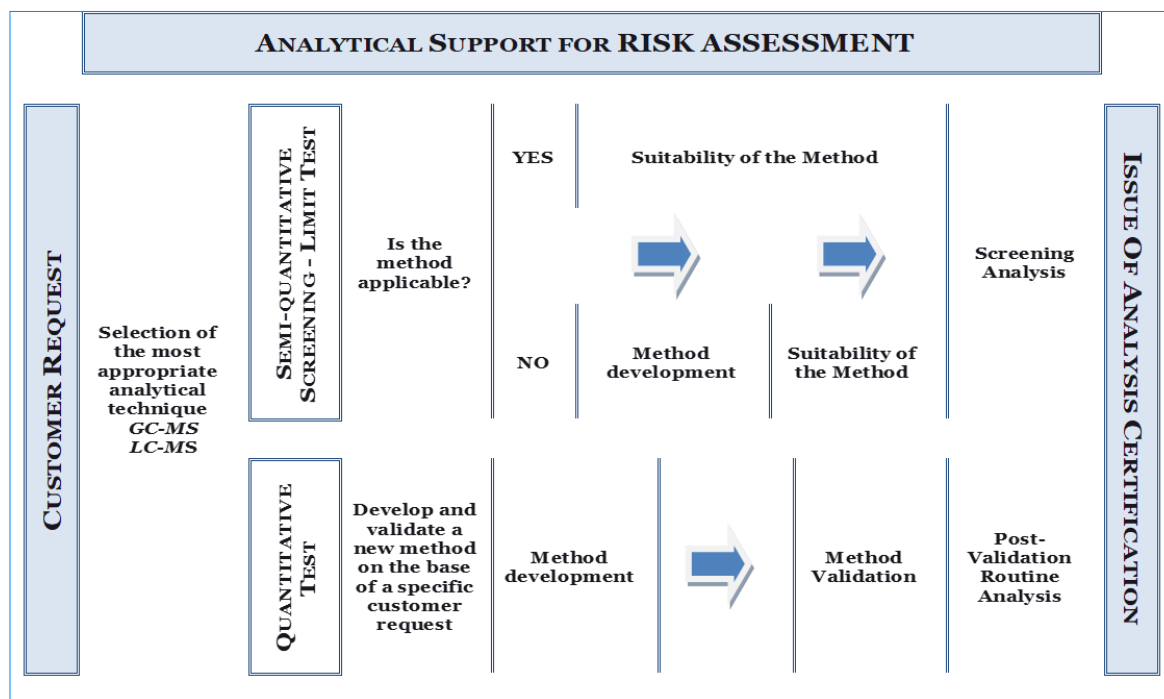
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In view of what has recently been indicated by EMA in a note to industry, “All marketing authorisation holders are asked to review their manufacturing processes and take precautionary measures to mitigate the risk of nitrosamine formation or presence during the manufacture of all medicinal products containing chemically synthesized APIs”

Neutron Pharma GMP Lab, on request of several customers, has provided an effective methodological approach for alerts management to support the pharmaceutical industry.

The approach applied guarantees to manage successfully every issue identified by our customer and to determine satisfactory Limits of Quantification and Specificities.

- A. Starting a semi-quantitative screening on APIs or Drugs**
B. Develop and validate a new method for APIs or Drugs on the base of a specific customer request



Starting from each new customer’s request our specialists select the most appropriate analytical technique to be used [GC-MS_MS or LC-MS_MS], then defined the different analytical phases, from sample preparation to extraction and purification.

A series of tests shall be immediately carried out in order to guarantee satisfactory Limits of Quantification and Specificities.

Therefore, a series of repeated tests and consequent statistical analyses allow our analysts to determine the performance of the method and start the validation phase or even more simply the verification of the applicability of the method on the API and/or pharmaceutical product.

The analysis of post-validation routine of the different APIs and/or pharmaceutical products finally allows us to provide the expected responses and give full support to our client.

NDMA (N-nitroso di-methylamine)
 NDEA (N-nitroso di-ethylamine)
 NEIPA (N-Nitroso ethyl-isopropylamine)
 NDIPA (N-nitroso-di-iso-propylamine)
 NDBA (N-nitroso-di-n-butylamine)
 NMBA (N-Nitroso-N-methyl-4-aminobutyric Acid)
 NMOR (N-Nitrosomorpholine)
 NPYR (N-Nitrosopyrrolidine)
 NPIP (N-Nitrosopiperidine)
 NDPA (N-nitrosodi-n-propylamine)
 NPRO (N-Nitrosoproline)
 MNPIP (1-Methyl-4-nitrosopiperazine)