

Detection of nitrosamines in APIs and drugs

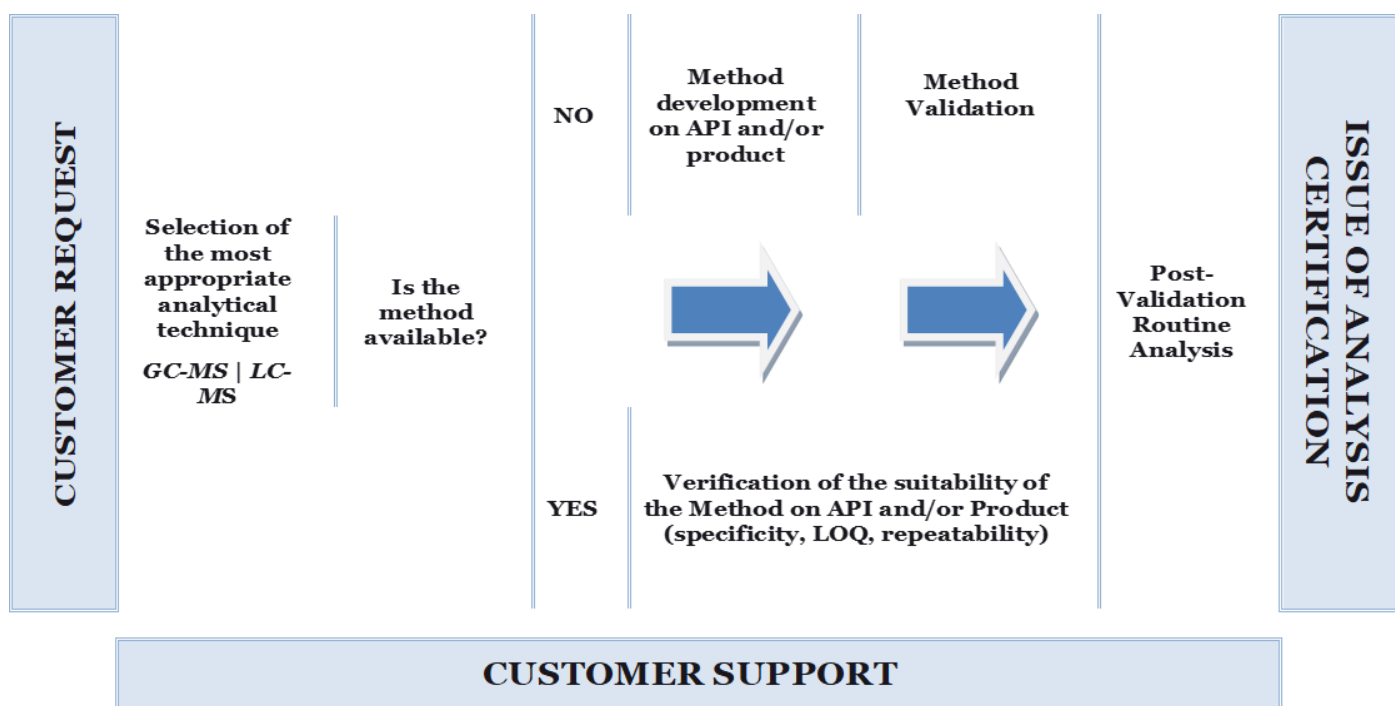
In view of what has recently been indicated by EMA in a note to industry,

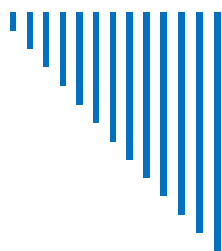
“Marketing authorisation holders (MAH) for human medicines containing chemically synthesised active substances are asked to review their medicines for the possible presence of nitrosamines and test all products at risk.

MAHs should therefore ensure that to have access to relevant information from the API manufacturers concerning potential formation of nitrosamine impurities and the potential for cross-contamination. ”,

Neutron Pharma GMP Lab, on request of several customers, has provided an effective methodological approach for emergency 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 Specificity.





Starting from each new customer's request our specialists select the most appropriate analytical technique to be used [usually GC-MS or LC-MS], then defined the different analytical phases, from sample preparation to extraction and purification, a series of tests shall be immediately initiated in order to:

- ♦ develop a new method, where laboratory methods are not suitable and/or on the basis of a specific customer request;
- ♦ verify the suitability of an existing method already applied in the lab, on the specific product and/or API of the customer.

All this to guarantee satisfactory Limits of Quantification and Specificity.

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.

COMPOUNDS CURRENTLY ANALYSED

NDMA (N-nitroso di-methylamine)

NDEA (N-nitroso di-ethylamine)

NDBA (N-nitroso-di-n-butylamine)

NDIPA (N-nitroso-di-iso-propylamine)

NEIPA (N-Nitroso Ethyl-isopropylamine)

NMBA (N-Nitroso-N-methyl-4-aminobutyric Acid) **(New entry)**

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