Specialist in chemical analysis

Expert in Nitrosamine analysis

Introduction
Brightlabs is the laboratory for all your analytical questions. Located in the south of The Netherlands, close to the German and Belgium border, it is our mission to support our customers in their pharmaceutical development projects as well as pharmaceutical QC testing.

In finding the correct solution we work in close contact with our customers by Co-Creation, to achieve your end goals in the most efficient manner to maximize your success.

Of course Brightlabs has a GMP permit and opiate permits to work on drug substances and drug products.

Services
Brightlabs offers a complete service ranging from physical, chemical and microbiological quality control testing of pharmaceutical products, from raw materials to finished dosage forms.

We offer a wide range of support at every stage of your drug development. Our capabilities include; method development and validation, elemental impurity, microbiological testing, stability studies, cleaning validations, quality control testing and much much more.

Nitrosamines
In response to nitrosamines present in pharmaceutical products, the European Medical Agency (EMA) and the US Food and Drug Administration (US FDA) have published requirements and limits related to nitrosamine contaminants.

Nitrosamines Screen
Brightlabs has multiple in-house developed and validated methods for the determination of low-level Nitrosamines screen using LC-MS/MS and GC-MS/MS. The most important Nitrosamines as listed by the EMA are present in these methods, and can be measured in very low levels, even as low as < 1 ppb depending on the product and nitrosamine. The generic methods can be easily adapted to different drug substances. Of course, this generic method must be validated for work under GMP for each product, for which Brightlabs has a simple but effective protocol.

Depending on the requested nitrosamines, a combination of UHPLC-MS/MS and GC-MS/MS methods can be used.

All methods can easily be extended with product specific nitrosamines.
Brightlabs team of specialist are well trained and experienced to perform a method development and validation specific on your request.

GC-MS/MS
Our GC method is using a Liquid Liquid Extraction (LLE) sample preparation.
The extraction has several advantages like a high capacity of the extractant and high selectivity of separation. Of course for each API, Drug product or other matrix a Suitability test should be performed to test the efficiency of the extraction and the influence on the analysis method.

LC-MS/MS
For the analyses also UHPLC-(APCI)-MS/MS methods are being used, with the optimized mass settings for all the different Nitrosamines.
Using APCI-MS/MS still very low LOQ's can be reached, with still an acceptable linear range.

Contact
Do you have any questions regarding the nitrosamine or other analysis? Do not hesitate to contact us.
Interested what Brightlabs can do for you? Please contact us by mail or telephone.

BRIGHTLABS
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