



**INSURING THE
SAFETY OF
OUR PRODUCTS**



SAFETY BULLETIN

NDELA Nitrosamine Analysis in Pharmaceutical Products

N-Nitrosodiethanolamine (NDELA), classified as category 1B carcinogens, was detected in widely used consumer products such as cosmetics, hand and body lotions, hair shampoos, raw materials and pharmaceuticals such as angiotensin II receptor blockers (ARBs) (valsartan), ranitidine, nizatidine, and metformin. Nitrosamines and *N*-nitroso compounds such as NDELA are strong carcinogens that produce cancer of the liver and kidneys. In experiments conducted to date, 75–80% of nitrosamines tested have been found to be carcinogenic to mammals. An increased number of pharmaceutical companies follow the latest FDA guidance to industry recommending evaluation of APIs and drug products.

ADPEN Laboratories has LC-MS/MS methodology for the determination of NDELA at a limit of quantitation of 25 ppb and also can determine 12 N-nitrosamines at a limit of quantitation of 50 ppb.

Value Proposition

ADPEN is a leading provider of analytical testing services, offering solutions to facilitate global trade and improve the safety of the supply chain.

ADPEN will provide analytical testing services to:

- ◇ Help our clients mitigate risks and make business operations more sustainable.
- ◇ Verify raw materials, pharmaceuticals, and other consumer products are in full compliance with current industry regulations.
- ◇ Ensure the highest level of quality and safety you demand in your products and the supply chain.

LC-MS/MS methodology is used for the analysis of N-nitrosamines with a limit of quantification of 50 ppb.

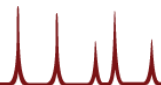
ANALYTES	LOQ
NDELA	0.025 µg/g
NDELA, NDMA, NMOR, NDiPLA, NMBA, NMEA, NPYR, NDEA, NPIP, NEIPA, NDiPA and NDPA	0.05 µg/g



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ADPEN
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QUALITY AND EXCELLENCE