

## “NDELA” Nitrosamine in Pharma products

**N-Nitrosodiethanolamine (NDELA)**, classified as category 1B carcinogens, was detected in widely used consumer products such as cosmetics, hand and body lotions and hair shampoos. The source of the NDELA was presumably the nitrosation of the di- and/or triethanolamine additives.

More and more pharmaceutical companies, involved in the production of finished pharmaceutical products, such as **topical creams** or **foams**, following the **risk assessment** envisaged by **EMA guidelines**, must investigate the presence of any traces of NDELA in their finished products.

[Neutron Pharma](#) has developed a method for the determination of NDELA in LC-MSMS on **pharmaceutical matrices**, such as topical medicinal creams and foams, with the following target limits:

Limit of Detection (LOD)	Limit of Quantification (LOQ)
10 ppb*	20 ppb*
<i>* the above values are indicative and must always be verified according to the MDD of the product, composition and type of matrix.</i>	

To request an analysis, or to learn more about this specific topic, please do not hesitate to contact the Neutron team <https://www.neutron.it/en/contacts>.