N-Nitrosamines

Introduction

In 2018, nitrosamine impurities became a focus for authorities, when a recall of angiotensin II receptor blocker (ARB) medicines, known as "sartans", was announced. In bioactive compounds, a toxic impurity, *N*-nitrosodimethylamine (NDMA), was found. Since then, more cases of drug product batches contaminated with nitrosamines came to be known (Ranitidine, Nizatidine and Metformin). In 2020, FDA announced the availability of a guidance for industry, entitled "Control of *N*-Nitrosamine Impurities in Human Drugs." In this context, Enamine offers a library of various nitrosamines for investigation.

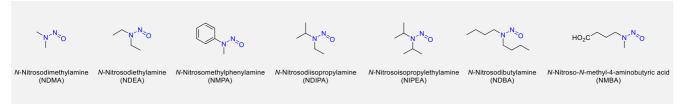
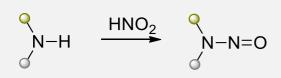


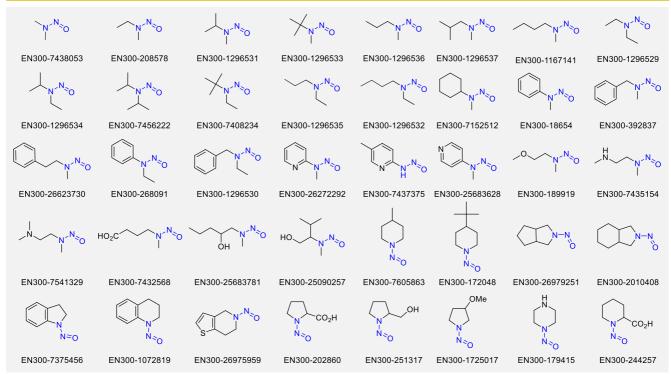
Figure 1. Chemical structures of 7 potential nitrosamine impurities in APIs and drug products identified by FDA in 2020.

Case studies



- Figure 2. Representative reaction to form nitrosamines.
- Nitrosamine compounds can form by a nitrosating reaction between amines and nitrous acid.
- Nitrosamine compounds are potent genotoxic agents in several animal species and some are classified as probable or possible human carcinogens.¹⁻⁴

We offer: more than 50 of nitrosamines from stock on a 5-10 g scale.



References

- 1. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/control-nitrosamine-impurities-human-drugs.
- 2. https://ntp.niehs.nih.gov/ntp/roc/content/profiles//nitrosamines.pdf

- 3. N.T. Crosby et al. Adv. Food Res. 1976, 22, 1.
- 4. I. W. Ashworth et al. Org. Process Res. Dev. 2020, 24, 1629.





ご興味があるものがあれば、こちらまでお問い合わせ下さい!!

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