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Ellutia presents failsafe total nitrosamine testing in pharmaceuticals at Pittcon 2020

Ellutia Chromatography Solutions Ltd, stand 2326, Pittcon 2020, March 1-5, Chicago

Ellutia is presenting its nitrosamine testing solution for pharmaceuticals using its 800 Series Thermal Energy Analyser (TEA) with Chemical Stripping System, at Pittcon next month.

Nitrosamines are back in the news following the mass recall of a popular US heartburn medication, prompting the US Food and Drug Administration to call in various drugs known as ARBs for testing,ⁱ and suppliers like Novartis and Sanofi to cease distribution.ⁱⁱ In Europe, the European Medicines Agency (EMA) has requested that Marketing Authorisation Holders of all Finished Pharmaceutical Products (FPPs) conduct a risk assessment to determine the potential for nitrosamine content. This is particularly relevant for the nitrosamines NDMA and NDEA that belong to the WHO 'cohort of concern,' classified as 'probable human carcinogens.'ⁱⁱⁱ

The 800 Series TEA interfaced to Ellutia's proprietary chemical stripping system is a unique instrument on the market that offers total nitrosamine analysis of pharmaceutical products. The system allows rapid and accurate quantification of the total nitrosamine content of a sample.

Measuring apparent total nitrosamine content (ATNC) provides a benchmark of the nitrosamine volume in a product. Rather than embark on a lengthy analytical process to deliver detailed and speciated results in the first instance, the ATNC method screens only for the total nitrosamine content (this includes both volatile and non-volatile nitrosamines) and returns an analysis with a single clear peak. This peak either falls within or outside the interim allowable daily intake set by the World Health Organisation (WHO) for specific species of nitrosamines.^{iv} If the peak of the total sample falls within the daily intake allowance, then no single nitrosamine can possibly be above the value and the nitrosamine content is reported as safe.



In contrast, any sample found to contain an ATNC outside the safe level can be red flagged and sent for further analysis by a TEA interfaced to a GC or HPLC to individually identify the species and quantify the presence of nitrosamines such as NDMA.

Ellutia's 800 series TEA and chemical stripping system offers rapid time to results for ATNC, with a typical single-peak analysis taking just between one and ten minutes.

Andrew James, marketing director at Ellutia, said: "The risk assessment requirement from the European medicines agency means that pharmaceutical manufacturers need to take a serious look at potential nitrosamine contamination in their product lines. By adopting the ATNC quantification method in the first instance, any sample that results in a safe analysis can be passed immediately. Any sample found to contain levels outside the safe value can be sent for further analysis with the TEA system."

Ellutia will also hold live demonstrations of its 500 Series GC (gas chromatograph) on stand at Pittcon, the only instrument on the market that offers conventional, fast and ultrafast chromatography in a single system, freeing up valuable space in the lab.

The TEA has become the industry go-to for nitrosamine testing and has set the gold standard in this application in the food industry. Coupled with Ellutia's Chemical Stripping System, the instrument is now seeing success in pharmaceutical testing.

To learn more, watch our [video](#), visit www.ellutia.com or come to booth 2326 at Pittcon to talk to one of our applications specialists.

ENDS

About Ellutia

Ellutia offers a range of gas chromatographs, GC accessories, software, and consumables. Ellutia's instruments are designed and manufactured in the UK at the company headquarters. The instruments are designed to be compact with great energy efficiency, whilst also delivering industry standard analytical performance. Ellutia has regional offices in both the USA and Germany as well as distributors around the world. Ellutia works closely with its customers and regularly produces fully



customised systems tailored to their individual requirements rather than delivering off the shelf products. It is this working relationship with customers and the flexibility to adapt that sets Ellutia apart from other GC manufacturers.

To learn more, watch our video, visit www.ellutia.com or contact andrew.james@ellutia.com

For press enquiries, contact Alice Chamberlain at The Scott Partnership on 01477 539539 or ellutia@scottpr.com

ⁱ [FDA updates and press announcements on Angiotensin II receptor blocker \(ARB\) recalls](#), US Food & Drug Administration, November 13, 2019

ⁱⁱ [More popular heartburn medications recalled due to impurity](#), CNN, January 10, 2020

ⁱⁱⁱ [Information Note: nitrosamine impurities](#), World Health Organisation International Agency for Research on Cancer, 20 November, 2019

^{iv} [Information Note: nitrosamine impurities](#), World Health Organisation International Agency for Research on Cancer, 20 November, 2019