Dear Sir, Madam,

On September 13, the US Food and Drug Administration had issued a safety alert citing the low-level presence of NDMA in ranitidine. The N-nitrosodimethylamine (NDMA) has been classified by the International Agency for Research on Cancer (IARC) as probably carcinogenic to humans," . In this sense FDA has published – LCMS method on Thermo Fisher's Q Exactive LCMS to quantitate the nitrosamine impurities in drug substance or drug product

In this contest we , at IIT Mumbai have Q Exactive Plus HRMS instrument at our SAIF laboratory Site , Q Exactive Plus has resolution 2,80,000 which can resolve low mass 70.0553 with less than 1 PPM accurately till four decimal of NDMA . Principle hers is - The six nitrosamine isobaric impurities (NDMA, NDEA, NEIPA, NDIPA, NDBA, and NMBA) are separated with four decimal accuracy from each other and from losartan by reverse phase chromatography and are detected by a **Q Exactive high-resolution and high-mass accuracy** (HRAM) mass spectrometer

As per US FDA guideline ,We have confidently developed the LCMS method to quantify the NDMA to LOQ of 1 Ng/ml (0.033 PPM) . As per as a precautionary measure, some manufacturers of have already sent their ranitidine samples to IIT Mumbai ,SAIF laboratories for testing of NDMA .

For your sample to be investigated , Please feel free to contact under sign for additional information. Ensure our best support all the times.

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