

UPDATE – The AAPS Journal publishes FDA paper on metformin testing

Update [7/2/2020] Today, the AAPS Journal, an official journal of the American Association of Pharmaceutical Scientists, published FDA's manuscript entitled, "A Cautionary Tale: Quantitative LC-HRMS Analytical Procedures for the Analysis of N-Nitrosodimethylamine in Metformin [External Link Disclaimer](#)."

This paper assesses the cause for the discrepancy between the NDMA values FDA found in its testing of metformin drug products and the values a private laboratory reported.

The private laboratory reported levels of NDMA above the acceptable intake limit in 16 of the 38 metformin products they tested. FDA immediately acted to analyze the same 38 samples. Overall, FDA observed that in orthogonal tests, the levels of NDMA, when present, were generally lower than reported by the private laboratory.

The paper provides additional details of FDA's investigation and the importance of selection and validation of testing methods.

In summary, the agency found the private laboratory method to be inappropriate for quantifying NDMA in metformin drug products due to presumptive overestimation of NDMA caused by the presence of a substance that interfered with the testing results.