TOWA PHARMACEUTICAL

Press Release

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TOWA PHARMACEUTICAL CO., LTD.

N-Nitroso Duloxetine Analytical Method Published in *ACS Omega*

Towa Pharmaceutical Co., Ltd. (Head office: Kadoma, Osaka; President and Representative Director: Itsuro Yoshida) has developed a new analytical method for *N*-nitroso duloxetine (NDXT: nitrosamine impurity), which has been suggested to be present in the antidepressant duloxetine. It is pleased to announce that the results of the study have been published in the American Chemical Society's journal *ACS Omega*.

[Academic journal] *ACS Omega* (2024)
https://pubs.acs.org/doi/full/10.1021/acsomega.4c00136

[Title] Simple and Practical Method for the Quantitative High-Sensitivity Analysis of *N*-Nitroso Duloxetine in Duloxetine Drug Products Utilizing LC-MS/MS

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In recent years, there have been many reports of contamination with nitrosamines (NDSRIs), which are formed by the reaction of active pharmaceutical ingredients (APIs) with nitrous acids. However, the analytical methods for assessing the amount of NDSRIs contained in pharmaceutical products have not been established in some cases, making it difficult to detect the inclusion of minute amounts of NDSRIs.

By focusing on NDXT, one of the NDSRIs published in the EMA's guidance, we have developed a new analytical method for NDXT in duloxetine drug products.

The results of this study, which enable high-sensitivity analysis of the level of NDXT in duloxetine drug products without requiring special reagents or techniques, are expected to contribute significantly to the assessment of the risk of NDXT contamination in duloxetine drug products and to the improvement of the quality thereof.

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