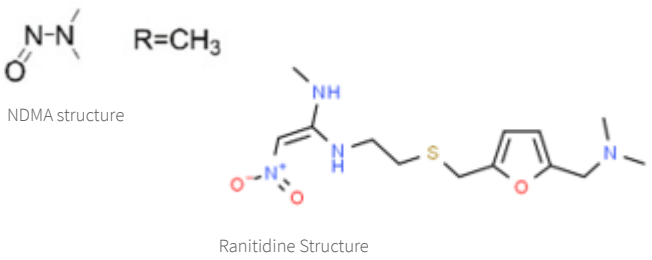
Nitrosamines impurity analysis using SCIEX QTRAP® 4500 LC-MS/MS System

Sensitive and reproducible LC-MS/MS based quantification method for NDMA in ranitidine API and drug products

Nitrosamines are potent carcinogens in animals and humans, so they must be strictly controlled in pharmaceutical development. A potential quantitative method for the analysis of **N-Nitrosodimethylamine** (NDMA) in ranitidine active pharmaceutical ingredient (API) and drug products using the QTRAP 4500 system has been developed. This method is capable of meeting the regulatory requirements in terms of limits, LOQ and LOD levels.



Ranitidine Structure

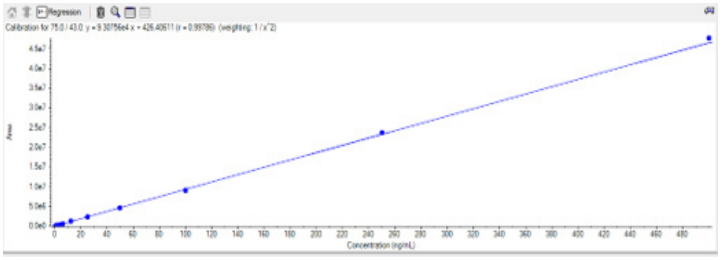


Figure 2. Calibration curve for NDMA with linearity range 0.5 – 500 ng/ml & r = 0.998

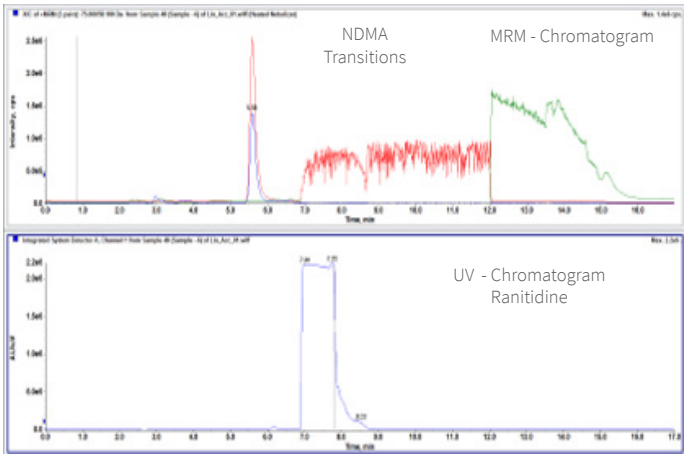


Figure 1. MRM & UV chromatogram of NDMA and ranitidine showing well separated retention time

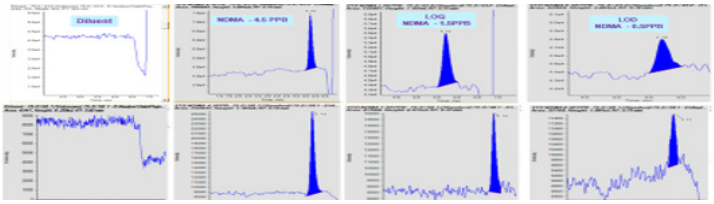


Figure 3. MRM chromatogram of NDMA for showing diluent, Specification level, LOQ & LOD

	Concentrations
Limit	4.5 ng/ml (0.09 ppm)
LOQ	1.5 ng/ml (0.03 ppm)
LOD	0.5 ng/ml (0.01 ppm)
CC	0.5-500 ng/ml (0.01-10 ppm)

Table 1. Details of concentrations analyzed using QTRAP 4500 system.

To learn more about this method please email: Marketing.India@sciex.com

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