

Quantitation on the SCIEX QTRAP® 4500 LC-MS/MS System with the ExionLC™ AD System



LC-MS/MS method for identification and quantification of Nitrosamine impurities in API of Losartan

A highly selective, sensitive and reproducible analytical method was developed for the quantitation of six nitrosamine impurities (NDMA, NDEA, NEIPA, NDIPA, NDPA and NMBA) in Losartan API samples using the QTRAP® 4500 system coupled with the ExionLC™ AD System. The advantages of this method include simple sample preparation, brief analysis time, and high sensitivity allowing accurate and quantitative analysis of nitrosamine impurities in Losartan API samples. The LC-MS/MS method was developed with accurate and precise simultaneous determination of all six nitrosamine impurities in Losartan drug products and its API substances at much lower levels than 1.2 ng/mL (0.03 ppm, specification level w.r.t 40 mg/mL API). The calibration curve was made from 0.2ng/mL to 153.6ng/mL, (0.005ppm to 3.84ppm) with good repeatability and reproducibility.

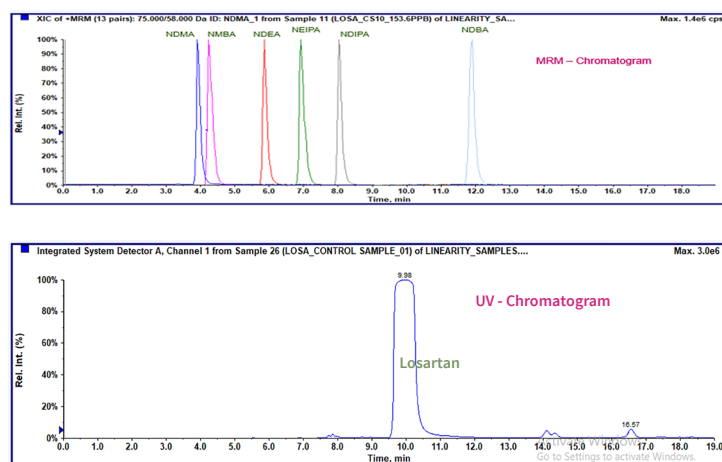


Figure 1. LC-APCI -MS/MS representative chromatogram for Nitrosamine impurity analysis

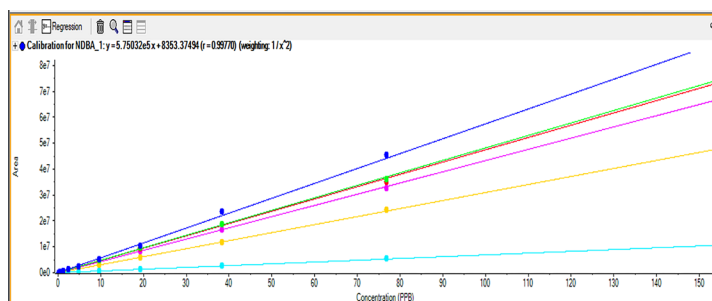


Figure 2. Linearity graphs for all 6 Nitrosamines in range (0.2 – 153.6 ng/ml) (r > 0.99)

Analytes	Retention Time (Min)	Spiked LOQ (0.01 ppm w.r.t 40mg/mL API Sample) (n=6)		Spiked Spec Level (0.03 ppm w.r.t 40mg/mL API Sample) (n=6)		Recovery (%) (n=6)
		Precision	Accuracy	Precision	Accuracy	
NDMA	3.94	9.21	89.36	4.15	81.81	(70-120)
NMBA	4.27	8.36	79.77	4.47	78.01	(70-120)
NDEA	5.85	2.83	98.72	4.10	90.85	(70-120)
NEIPA	6.95	3.00	94.46	4.31	82.93	(70-120)
NDIPA	8.06	2.19	88.64	4.54	77.22	(70-120)
NDPA	11.90	4.83	111.01	2.54	98.38	(70-120)

Table 1. Accuracy, precision and recoveries at LOQ (0.010 ppm) and limit level (0.030 ppm)

To learn more about this method, send us an email at: Marketing.India@sciex.com

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