

# Waters Xevo TQ Absolute-A highly sensitive LCMSMS for quantification of low concentration of seven Nitrosamine impurities



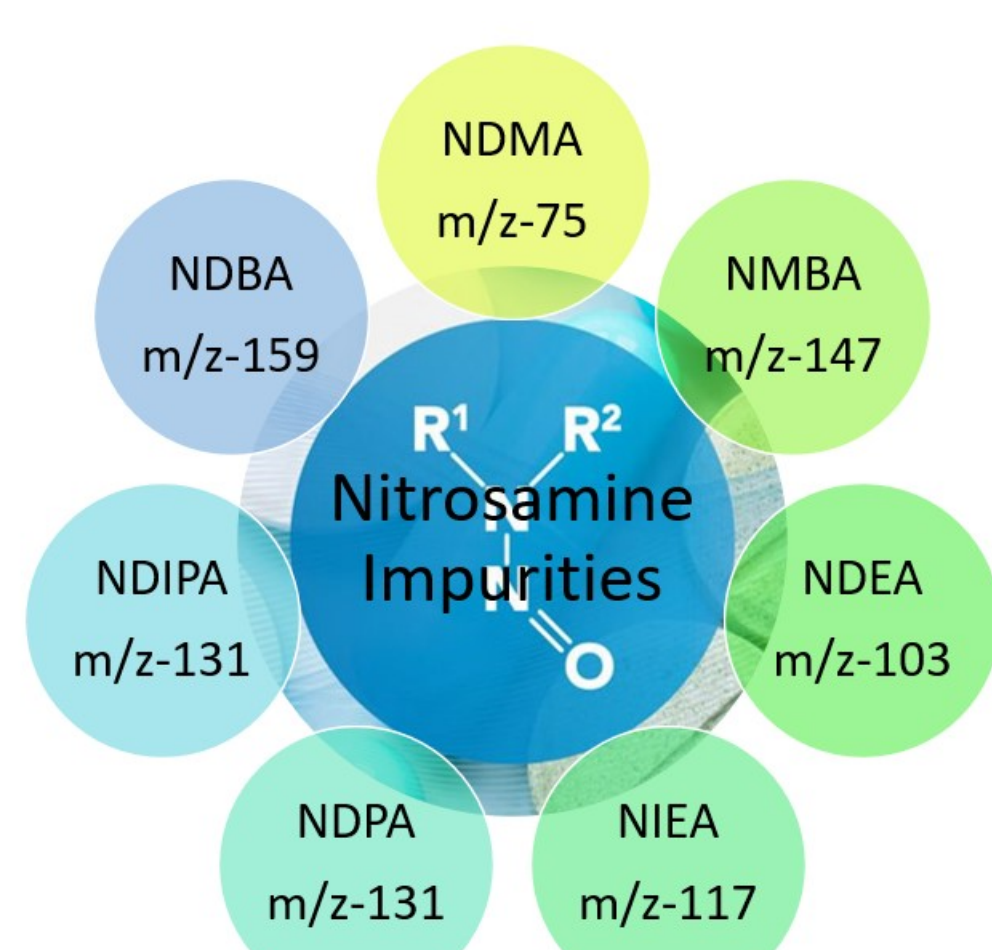
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## INTRODUCTION

Since Mid-2018, Nitrosamine impurities have become a concern in pharmaceutical industry because of their contamination in multiple drug products. In Analytical lab the nitrosamines pose unique challenges such as low-level detection and the matrix effect and to overcome these challenges often highly sensitive mass spectrometer prove to be helpful. Recently Waters Introduced Xevo TQ Absolute instrument which provides unparalleled sensitivity for these nitrosamine impurities. In this presented work, we optimized the performance of TQ Absolute with UPLC H class plus UPLC and Acquity premier column for the most common seven nitrosamine impurities in the range of 0.010 ng/mL to 100 ng/mL. We obtained excellent sensitivity, repeatability, and linear performance for all the seven nitrosamine impurities with the LOQ values for all the seven nitrosamine impurities at or below 0.010 ng/mL

## MS Conditions:

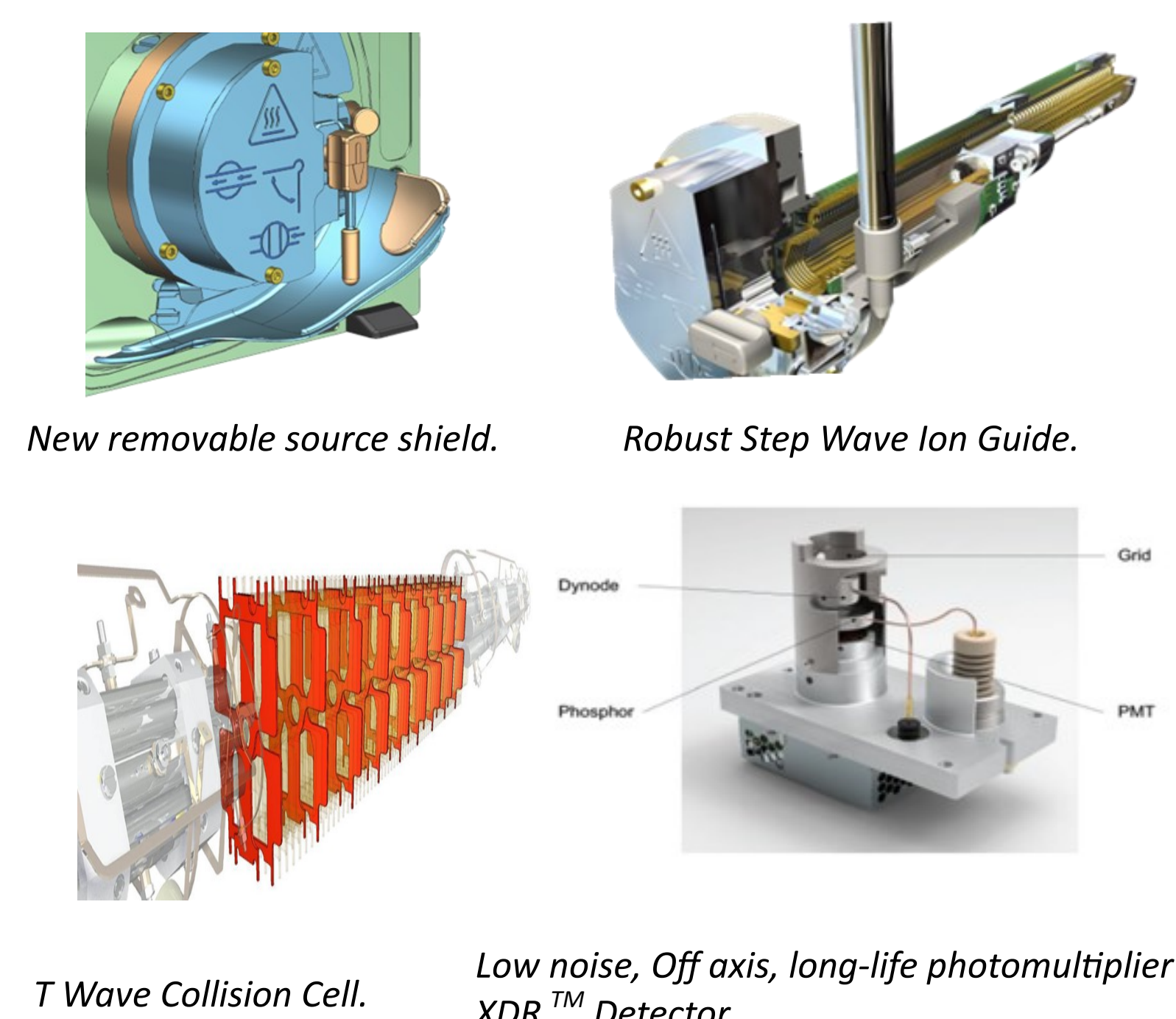
MS System : Xevo TQ Absolute  
Corona Voltage : 4.0Kv  
Mode : APCI +Ve  
Cone gas : 150 L/Hr  
Probe Temp : 250 °C  
Source Temp : 120 °C  
Desolvation gas flow : 800 L/hr



Seven nitrosamine impurities

## LC Conditions:

LC System : Acquity UPLC H- Class Plus  
Column : Acquity Premier UPLC HSS T3  
1.8µm, 2.1 X 100 mm  
Mobile Phase A : 5mM Ammonium Formate+0.1% Formic acid in Water  
B : 5mM Ammonium Formate+0.1% Formic acid in Methanol  
Run Time : 15mins



## ACQUITY UPLC H-CLASS PLUS AND XEVO TQ ABSOLUTE

SL.No	Impurity	Parent m/z	Daughter m/z	Cone (V)	Collision Energy (V)
1	NDMA	74.95	57.96	10	10
2	NDEA	103.02	74.93	5	15
3	NIEA/NEIPA	117.03	74.91	5	15
4	NDPA	131.05	88.94	15	10
5	NDIPA	131.05	88.94	15	10
6	NMBA	147.01	116.95	5	5
7	NDBA	159.12	56.92	15	15

## MRM CONDITIONS

## RESULTS AND DISCUSSION

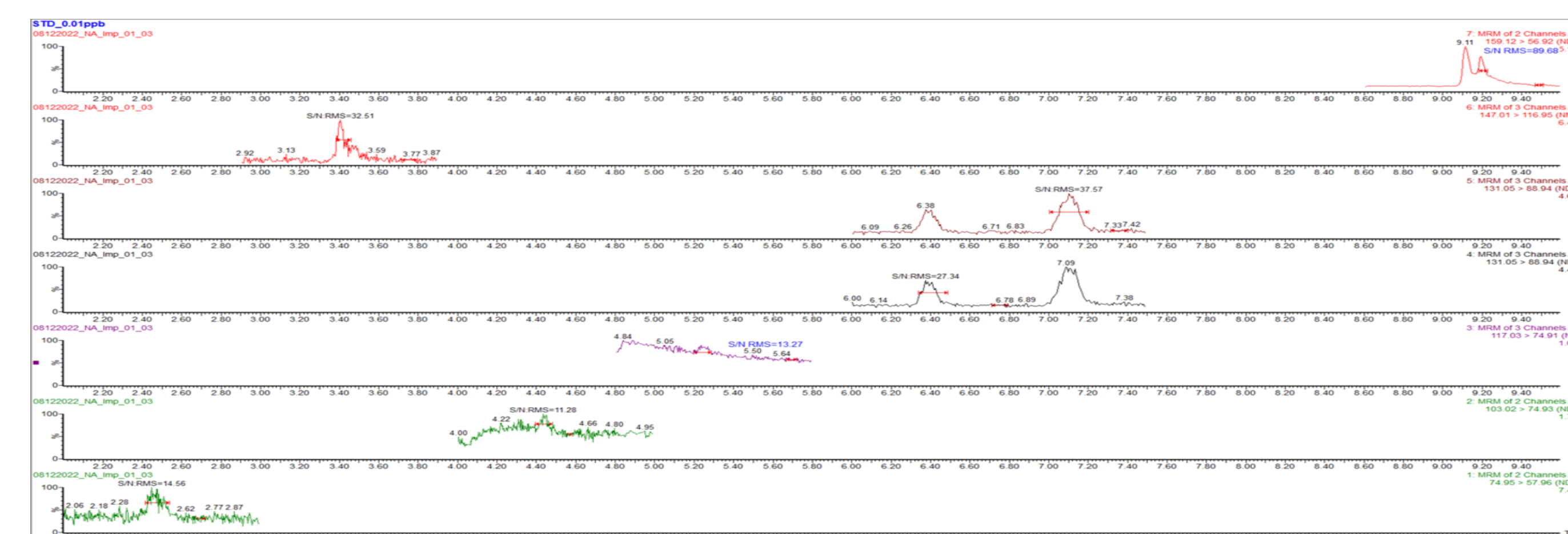


Table 1: Sensitivity of seven nitrosamine impurities at 0.01ng/mL

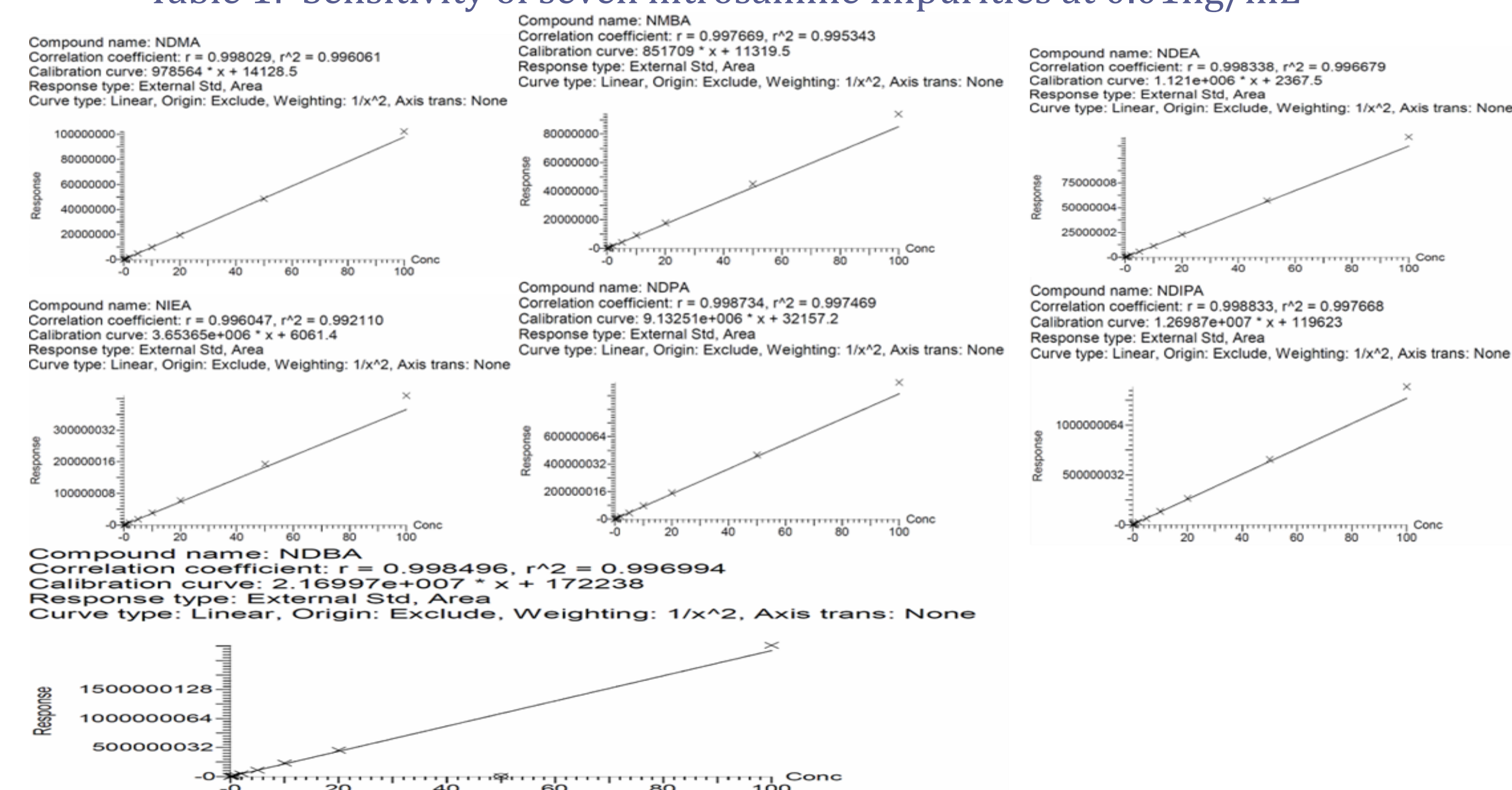


Fig 2: Calibration curves for seven nitrosamine from 0.01ng/mL to 100ng/mL

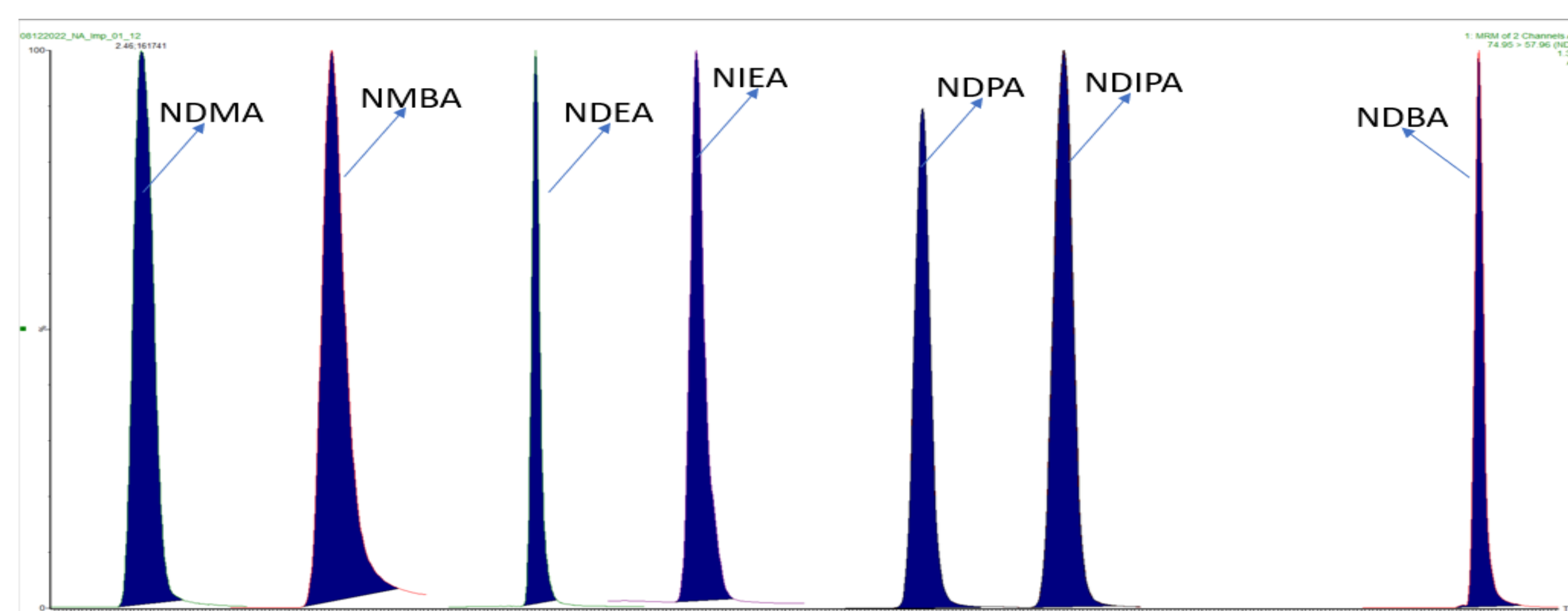


Fig 1: Separation of seven nitrosamine impurities

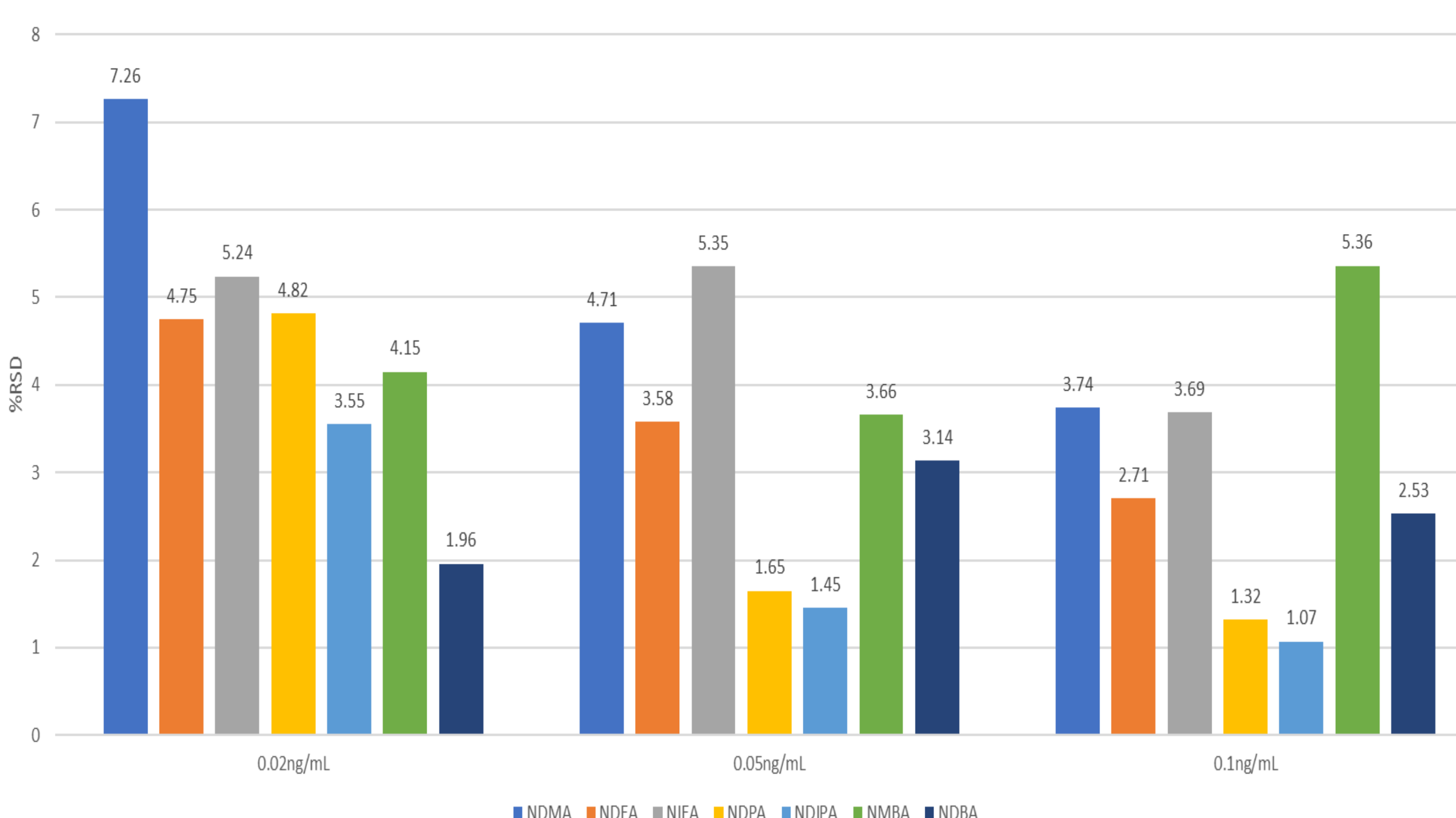


Fig 2: Reproducibility of seven nitrosamine impurities with six replicates

## BENIFITS

- 1) Achieve lower limits of Quantification for seven nitrosamines up to 0.01ng/mL to meet evolving regulatory requirements.
- 2) Ensures consistency in the area and linear response for seven nitrosamines.
- 3) Achieve improved environmental sustainability and lower your laboratory operation cost by 50% less electricity, gas and heat than most other high performance TQ instruments in the market.

## REFERENCE

- 1) Margaret Maziarz Paul D. Rainville Amy Bartlett High Sensitivity Quantification of Nitrosamines in Metformin Using Xevo™ TQ Absolute Tandem Quadrupole Mass Spectrometer With an ACQUITY™ Premier System Application Note:720007725