HALO®

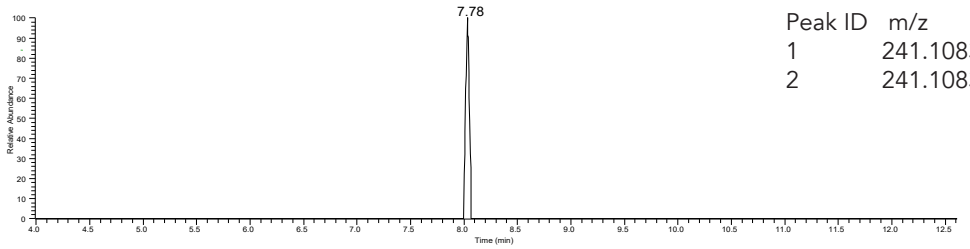
PHARMACEUTICALS

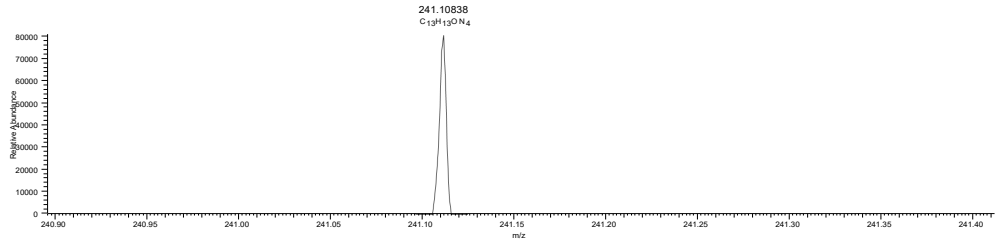
LC-MS Analysis of Chantix® Varenicline NDSRI using HALO® Biphenyl

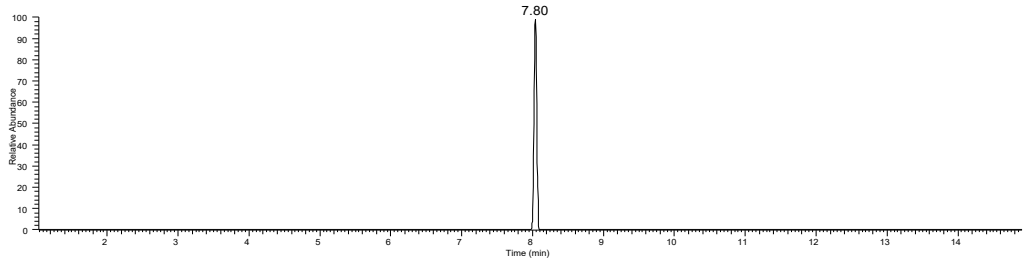
279-P

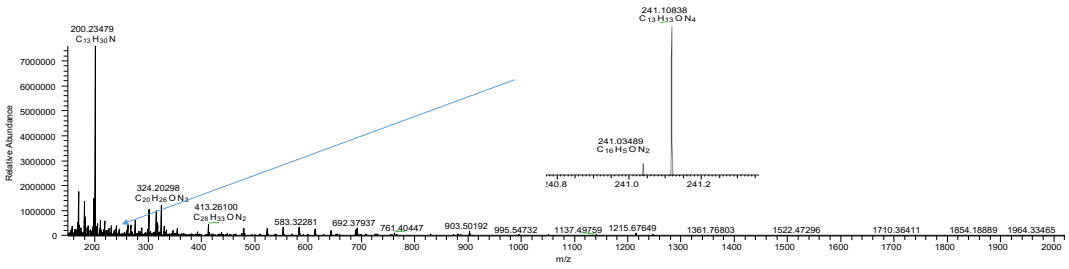
PEAK IDENTITIES:

Peak ID	m/z	Ret. time
1	241.10838	7.78
2	241.10838	7.8









Chantix®, a prescription medication that is used to help people stop smoking, has recently come to attention due to a recall that was initiated by the pharmaceutical company Pfizer. This was due to N-nitroso-varenicline (the Nitroso-Drug Substance Related impurity (NDSRI)) detected above the Pfizer established Acceptable Daily Intake (ADI) level. In-creased ingestion of N-nitroso-varenicline may be associated with an increased cancer risk in humans. The US Food and Drug Administration (FDA) has recently released the method "Liquid Chromatography High Resolution mass spectrometry method for the determination of Varenicline NDSRI in Chantix drug product and drug substance. In this application, the FDA method is used with the HALO® Biphenyl column to detect the impurity in a sample of the drug.

TEST CONDITIONS:

Column: HALO 90 Å Biphenyl, 2.7 µm, 3.0 x 75 mm
Part Number: 92813-511
Mobile Phase A: Water, 0.1 % Formic Acid
Mobile Phase B: MeOH, 0.1% Formic Acid
Flow Rate: 0.5 mL/min
Gradient:

Time	%B
0.0	10
1.0	10
10.0	100
11.1	10
15.0	stop

Pressure: 175 bar
Temperature: 30 °C
Injection Volume: 5.0 µL
Sample Solvent: MeOH
Detection: +ESI
LC System: Shimadzu Nexera X2
ESI LCMS system: QExactive HF

MS Conditions:
Detection: (+) ESI
Spray Voltage: 3.5 kV
Sheath gas: 50 arbitrary units
Aux gas: 15 arbitrary units
Sweep gas: 0
Capillary temp: 250 °C
Heat temp: 400 °C
Scan Type: t-Sim
Resolution: 60,000