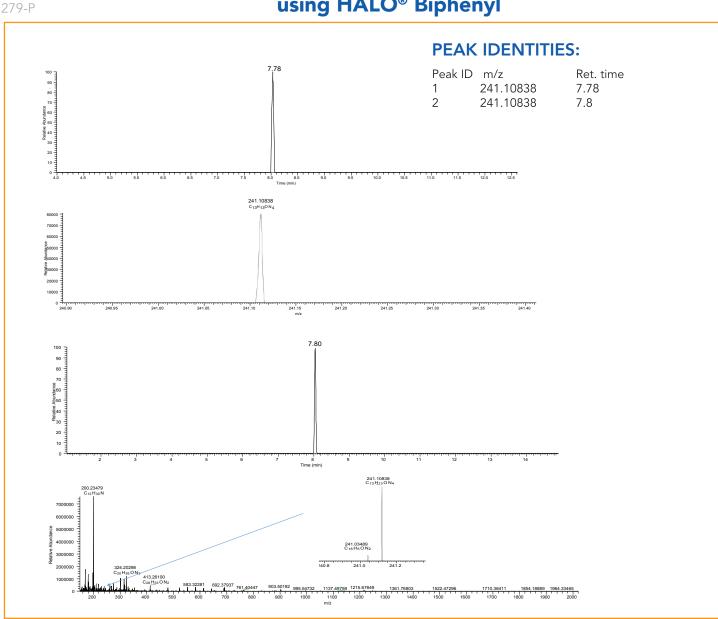


## **PHARMACEUTICALS**



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



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.







## **PHARMACEUTICALS**



## **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:  $5.0~\mu L$  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

