

Extractables and Leachables

The need for universal HPLC detection in analytical laboratories is widespread. While several detection technologies (e.g., low wavelength UV, refractive index, evaporative light scattering, chemiluminescent nitrogen detectors) are currently being used, there is significant room for improvement in performance characteristics such as sensitivity, dynamic range, consistency of response factors and gradient or solvent compatibility.

To help address the many challenges of universal detection, ESA has developed the Corona CAD™ detector. This novel technology offers many benefits to analytical scientists including:

- High Sensitivity - Low ng limits of detection.
- More Consistent Response Factors - Response magnitude does not significantly depend on analyte properties (e.g. molar absorptivity, proton affinity).
- Broad and Useful Dynamic Range - 4 orders of magnitude (ng - µg quantities).
- Excellent Reproducibility - Typically less than 2% RSD.
- Broad Applicability - Can be used with a wide variety of HPLC conditions to measure virtually any nonvolatile analyte including proteins, lipids, carbohydrates and small molecules.
- Ease of Use - Easy setup. Uses minimal bench space and requires only gas input pressure and signal output range to be set.

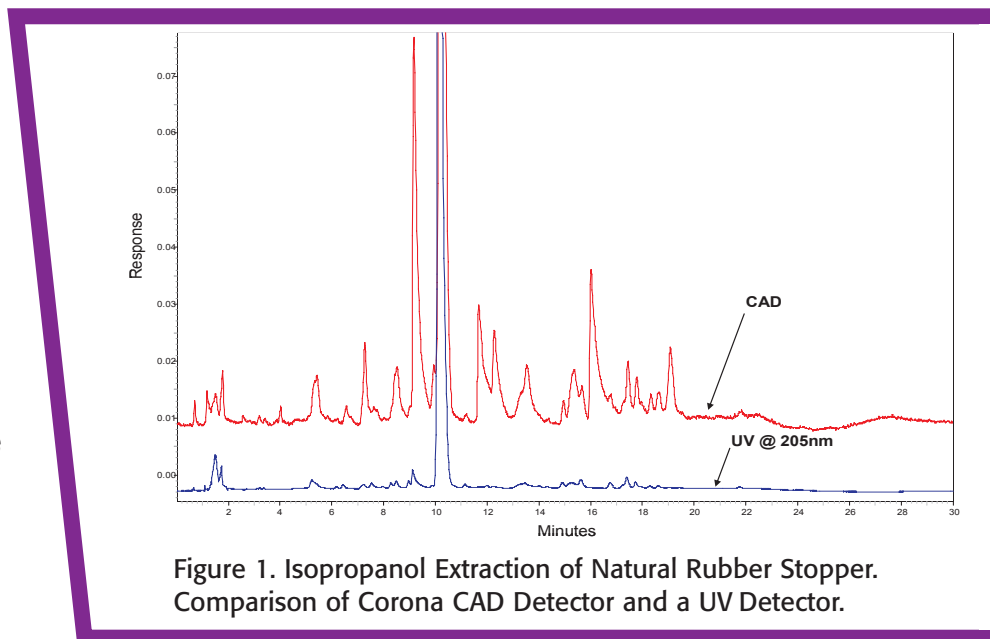


Figure 1. Isopropanol Extraction of Natural Rubber Stopper. Comparison of Corona CAD Detector and a UV Detector.

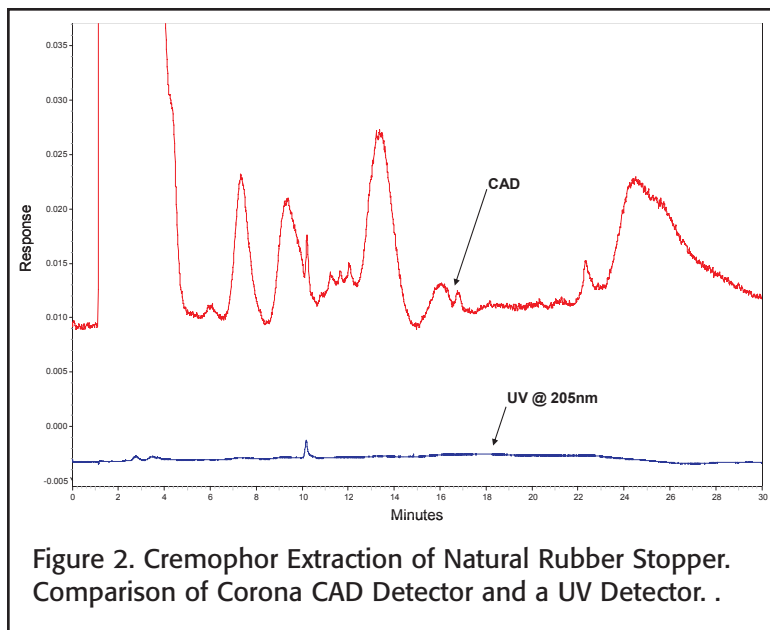
This application note describes the use of the Corona CAD for the measurement extractables and leachables using either isopropanol (Figure 1) or Cremophor (Figure 2) solvents. The Corona CAD detector was able to measure many more extractables and leachables than the upstream UV detector. As many potential extractables do not contain chromophores, the Corona CAD detector shows a much more complete picture of species extracted from these types of materials than UV detection alone.

Corona parameters

Gas: 35psi via nitrogen generator
Filter: none
Range: 100pA

HPLC Parameters:
Mobile Phase A: Acetonitrile
Mobile Phase B: Water
Gradient: 30% to 10% B over 15mins. Hold - 5mins; 10% to 30% B over 5mins
Flow Rate: 0.6mL/min
Column: MD150, 3.2 x 150mm; 3µm
Column Temperature: 40°C
Injection Volume: 10µL

The Corona™ Charged Aerosol Detector



Sample preparation

Five Wheaton 13mm snap-on natural rubber stoppers (Fisher - 06-447C) were placed in a vial and extracted via ultrasonication for 2 hours using 6.0mL of either IPA or a 50:50 Cremophor:EtOH mix. The extracts were injected on column without further dilution.

Conclusions

The Corona CAD provides universal detection of nonvolatile analytes with response independent of chemical properties, a wide dynamic response range, high sensitivity and good precision. These characteristics, along with reliability and simple operation, make this a superior detector for a wide range of HPLC analyses.

For more information about this application, the Corona CAD, or charged aerosol detection visit www.coronacad.com. We are interested in your opinions and are available to answer any questions you may have: please contact a technical representative at 978.250.7082, or if e-mail is more convenient, send your questions to coronacad@esainc.com.

Ordering information

Description

Corona Plus
Thermal Organizer Module
Nitrogen generator
Pump, model 584
Autosampler, model 542
Elite software including PC
Column, MD150

Part Number

70-7041
70-5499TA
70-6003
70-7058
70-4152
70-5073
70-0636



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The Corona CAD is covered by multiple patents