

Detection of extractables and leachables in drug products using the SCIEX Triple Quad™ 3500 LC-MS/MS System



Targeted analysis of extractables/leachables in drug products, containers and closure systems

The formulation and storage of drug products means that the product will come in contact with a variety of containers and packaging systems. Impurities from these packaging and transfer materials have the possibility of contaminating the drug product. Therefore it is very important to be able to measure whether any additional unwanted compounds have entered the drug product due to this contact. A sensitive analytical method using the SCIEX Triple Quad 3500 System with an ExionLC™ AD LC System for the simultaneous detection of 15 leachables and extractables commonly found in drug, products and packaging has been developed.

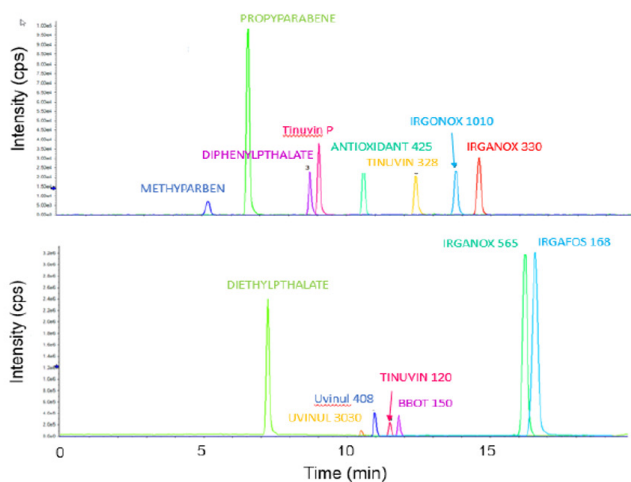


Figure 1. Chromatogram of mixture of 15 known extractable and leachable compounds.

Separation was achieved using the Kinetix column for these 15 analytes. Figure drawn in two parts to highlight the chromatographic peak shape and separation achieved on all analytes.

Sample	Diethylphthalate (ppb)	Tinuvin (ppb)	BBOT 150 (ppb)	Tinuvin p (ppb)	Irganox 1010 (ppb)	Irgafos 168 (ppb)
Nasal Spray Container	62.94	14	13.23	15.7	151.44	958.74
Ophthalmic Drug Container	1277.09	10.84	13.55	30.5	N/A	248.16
Ophthalmic Drug	N/A	N/A	5.82	N/A	N/A	12.25

Table 1. Results of analytes in detection range from different pharmaceutical products, Containers and closures.

To learn more about this method please email: Marketing.India@sciex.com

The SCIEX clinical diagnostic portfolio is For In Vitro Diagnostic Use. Rx Only. Product(s) not available in all countries. For information on availability, please contact your local sales representative or refer to <https://sciex.com/diagnostics>. All other products are For Research Use Only. Not for use in Diagnostic Procedures.

Trademarks and/or registered trademarks mentioned herein are the property of AB Sciex Pte. Ltd. or their respective owners in the United States and/or certain other countries. © 2020 DH Tech. Dev. Pte. Ltd.

Related to RUO-MKT-02-10630-A

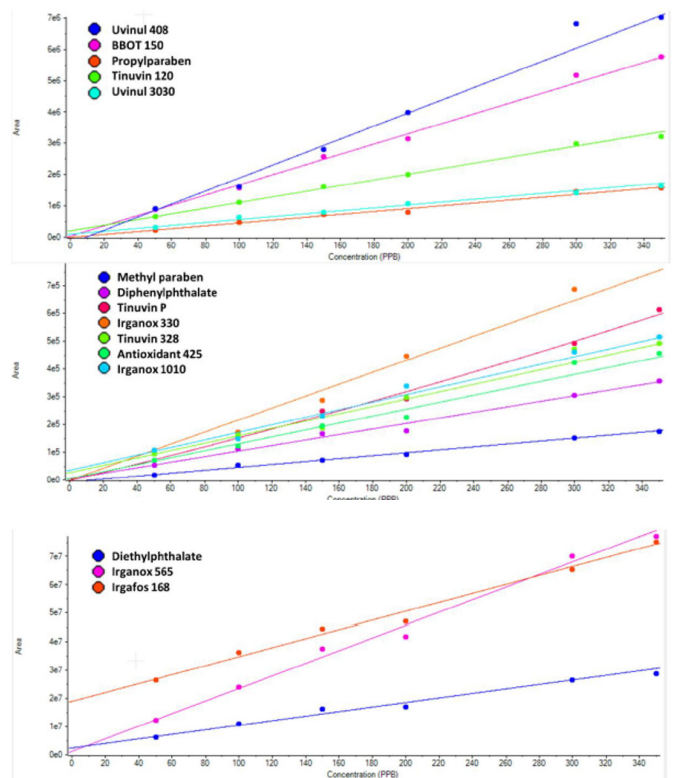


Figure 2. Calibration curves for the 15 different E&L compounds. Calibration curves were generated from 50 to 400 ppb.