EXTRACTABLES & LEACHABLES SUMMIT 2020

Originally set to take place April 2 - April 3, the ***Extractables, Leachables, & Elemental Impurities - East Coast*** conference has been rescheduled for July 30 - 31. Boston Analytical is looking forward to meeting all conference attendees in person at this later date.

In a better effort to get to know the team that will be on site July 30-31, we invite you to attend our virtual conference series. Whether you were planning to attend the conference or are simply looking for a testing facility, our goal is to provide you with the ability to make an educated and informed decision as to why Boston Analytical is the best testing facility for your project.

At Boston Analytical we continuously pride ourselves in our ability to help you find the right service for your business. The following pages provide a snapshot of the services we offer, including links to our website that contains further information for your individual or business needs. This also includes ways to get in touch with our team of business development representatives - please reach out to Alyssa, Christine or Rebecca to start your partnership with us today.

We'll see you in July!

meet our team!

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Boston ANALYTICAL

VIRTUAL
CONFERENCE SERIES

A SPECIAL **PRESENTATION BY**

ERIC HILL
Director of Extractables &
Leachables Laboratories

EXTRACTABLES & LEACHABLES CASE STUDY FOR TRANSDERMAL PATCH PRODUCT (SUMMARY)

Transdermal patches are used to incorporate the active ingredient of the drug into the circulatory system through the skin. Transdermal products are gaining popularity in the industry due to their ease of use, however they present unique leachables concerns compared to traditional drug products. Transdermal products incorporate a backing layer, release liner and storage pouch that all can serve as sources of leachables to the patient during the administration of the transdermal patch. The U.S. Food and Drug Administration (FDA) Guidance for industry has categorized transdermal patches as a packaging type with a high concern associated with the route of administration.

The FDA has specifically requested leachables studies be performed for transdermal patch products, which include methodologies that mimic skin-contact during typical usage including exercise conditions. Design of suitable leachables studies that mimic “in-use” conditions is very challenging. Herein, we propose a skin-contact simulation study based on the single-side extraction to mimic the skin-contact under conditions of exercise in the worst-case clinical usage. In this study, a special customized extraction vessel is applied to perform the single-side extraction without extracting the backing layer. A sweat simulation solvent is used to mimic the extracting power of sweat under conditions of exercise.

The resulting extracts were analyzed as appropriate for volatiles, semi-volatiles, non-volatiles, and metals with gas chromatography/mass spectrometry (GC-MS), liquid chromatography/mass spectrometry (LC-MS) and inductively coupled plasma mass spectrometry (ICP-MS) to provide comprehensive leachables profiles. These data were used to develop target compounds for a subsequent leachables study. Example data and the study outline will be presented.

PRESENTATION TO TAKE PLACE
Friday July 31 2:50pm-3:30pm

SNAPSHOT OF OUR E&L SERVICES

CLICK ANY SERVICE FOR FURTHER INFORMATION

E&L SERVICES

We offer full Extractables & Leachables testing for the Pharmaceutical, Bio-Pharmaceutical, Medical Device, and Consumer Products industries. Extractables & Leachables in drug products have become an area of concern to patient safety and to the FDA. We have staff with vast experience working directly with the FDA to address concerns and demonstrate drug product safety. Our processes adhere to ISO 10993, USP <661.1>, <661.2>, <1663>, <1664>, <1664.1>, as well as industry best practices from the Product Quality Research Institute (PQRI) and BioPhorum Operations Group (BPOG). ***Learn More.***

SNAPSHOT OF OUR E&L SERVICES

CLICK ANY SERVICE FOR FURTHER INFORMATION

EXTRACTABLE STUDIES

Boston Analytical has extensive experience with extractables testing of all forms of drug product packaging, processing components, and medical devices. Our knowledgeable staff can guide you through the regulatory process and industry best practices to put the best plan in place for producing safe products. ***Learn More.***

LEACHABLES STUDIES

Boston Analytical regularly performs leachables studies with all drug forms; including parenterals, inhalation products, topicals, opthalmics, combination products, biopharmaceuticals, and medical devices. Our team of experts can help you identify and address potential risks to ensure effective closure systems, process equipment and packaging. ***Learn More.***

BPOG PROTOCOL TESTING

Boston Analytical is well versed in the BPOG protocol, “Standardized Extractables Testing Protocol for Single-Use Systems in Biomanufacturing.” We can help you navigate the protocol and develop strategies to meet compliance requirements. ***Learn More.***

OTHER SERVICES WE PROVIDE

CLICK ANY SERVICE FOR FURTHER INFORMATION

ANALYTICAL DEVELOPMENT & VALIDATION

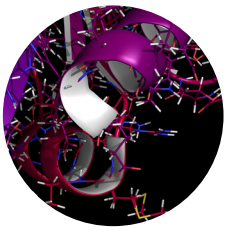
FEASIBILITY / OPTIMIZATION / DEVELOPMENT
VALIDATION / TROUBLESHOOTING

ANALYTICAL TESTING

ELEMENTAL IMPURITIES / DISSOLUTION TESTING
IN-PROCESS & LOT RELEASE TESTING / RAW MATERIAL TESTING
PRODUCT CHARACTERIZATION

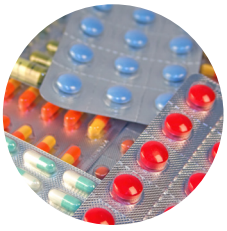
MICROBIOLOGY TESTING

MICROBIOME / MICROBIAL IDENTIFICATION
PHARMACEUTICAL TESTING / MEDICAL DEVICES TESTING
CLEANROOM / UTILITIES TESTING / CONTAMINATION RESPONSE INVESTIGATION



BIOLOGICS

PROTEIN ANALYSIS / PROTEIN CHEMISTRY CHARACTERIZATION



STABILITY & STORAGE

STABILITY STORAGE / THERMAL CYCLING STABILITY TESTING PHOTOSTABILITY TESTING & PHOTODEGRADATION STUDIES
CLINICAL REGISTRATION & ANNUAL STABILITY STUDIES
BLIND COMPARATOR STABILITY STUDIES

OUR **FAQ'S**

HERE ARE SOME OF THE MOST FREQUENTLY ASKED QUESTIONS FROM LAST YEAR'S E&L CONFERENCE

Q: Full E&L studies tend to be expensive, what is BA's recommendation to start? (ie Risk Assessments)
A: We recommend starting with a Materails Risk Assessment. This will evalute and document the leachables risk for the study, and recommend an appropriate study to mitigate this risk to ensure patient safety & compliance. This approach also assures unnecessary tests are not performed.

Q: What is BA's experience and lab capacity regarding E&L testing?
A: The E&L team at BA has an average of 8+ years of experience. The director of the group has 21 years of experience in polymer material characterization and E&L testing. We recognize the growing need for E&L testing, and are maintaining resource levels (both personnel and instrumentation) to allow us to start studies withing 1-2 weeks of the approval of a quotation.

Q: How does BA approach an E&L Study?
A: BA takes a materials based approach to all E&L studies. We follow PQRI and USP guidance for container closure systems and manufacturing componets. For medical devices, we follow ISO 10993.

Q: Are E&L studies similar for different product types, medical device, sterile syringe etc?
A: No, the risks and requirements for these different types of products are quite different. We tailor all E&L studies to the product type, the risk, and regulatory expectations.

Q: Do you have experience with all of these product types?
A: Yes, we have experience conducting E&L studies on drug products, combination products, transdermal patch products, medical devices, implantables, and manufacturing equipment.

Q: Does BA do Container Closure testing?
A: Yes, we offer full Extractables & Leachables testing on all forms of container closure systems. This includes USP <661.1>, <661.2>, <1663>, and <1664> methods.

Q: I don't want to commit to a full BPOG, what are the different options that BA offers?
A: We can test per USP <665>, as well as design a custom program that meets the needs of you manufacturing process and drug product/substance.

Q: Most labs I talk to have a long start time, what is BA's? Do you have the capacity to take on new projects?
A: We have the capacity to take on new projects, and typically can start within 1-2 weeks of receiving a PO. We are adding capacity all the time to maintain the ability to start new projects immediately.

Q: Can BA help support biocompatibility?
A: Yes, we do help support this.

REACH OUT

ASSISTING YOU & YOUR TESTING NEEDS!

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