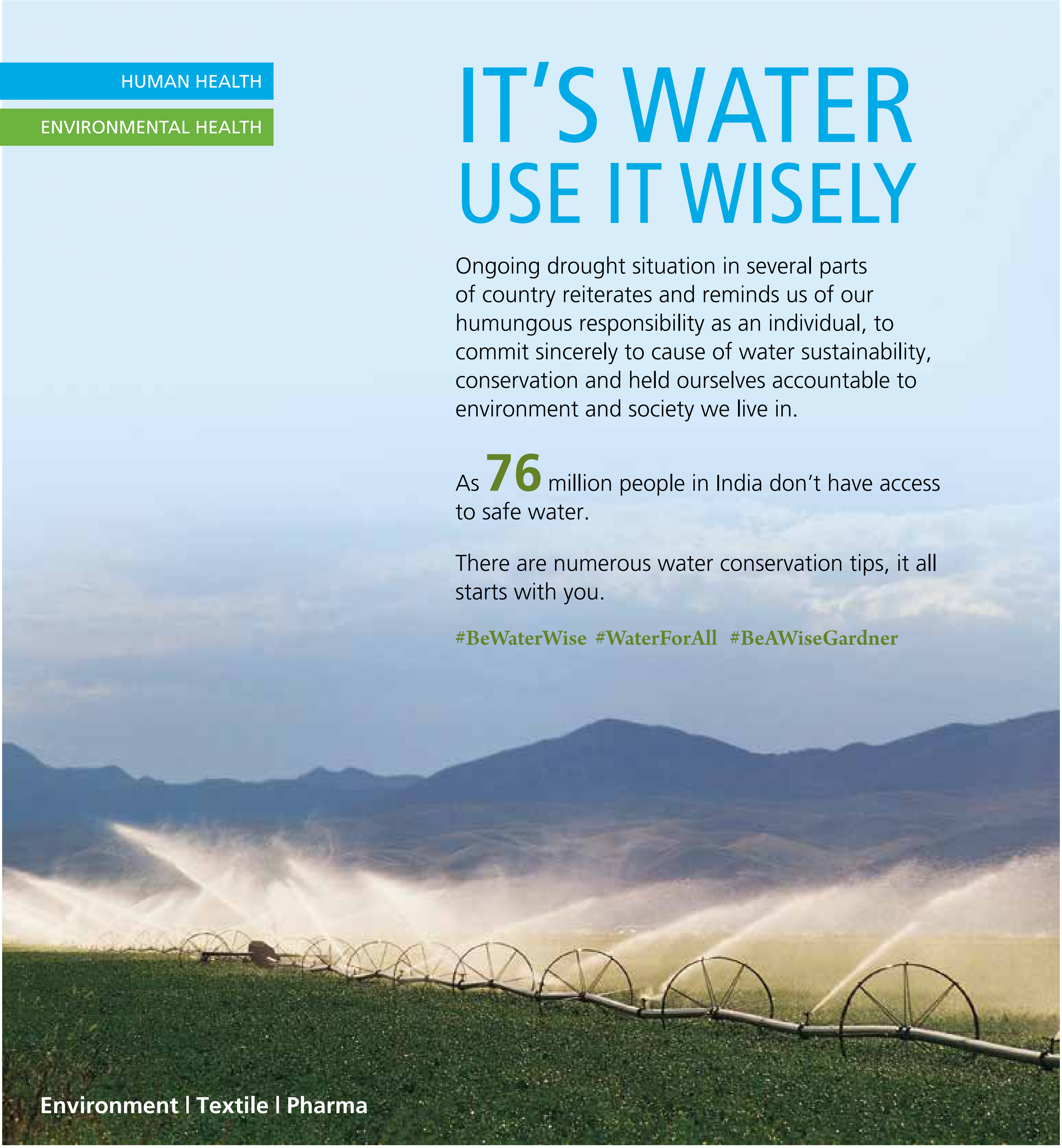
HUMAN HEALTH

ENVIRONMENTAL HEALTH



IT'S WATER USE IT WISELY

Ongoing drought situation in several parts of country reiterates and reminds us of our humungous responsibility as an individual, to commit sincerely to cause of water sustainability, conservation and held ourselves accountable to environment and society we live in.

As **76** million people in India don't have access to safe water.

There are numerous water conservation tips, it all starts with you.

#BeWaterWise #WaterForAll #BeAWiseGardner

Environment | Textile | Pharma

Fresh

VOLUME 49 | Summer Edition, 2016 | Environmental Health

PerkinElmer

For the Better

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Dear customers,

Thanks for downloading Fresh 49, Summer Edition!

Occurence of events-world conference-COP 21, ongoing drought situation, our own capital's tryst with odd even rule, NGT seeking ban on use of microplastics, PM Narendra Modi laying emphasis on clean drinking water, has once again placed environment to priority focus area, which indeed should be, keeping with that we have dedicated beginning sections of this edition to environment with textile and pharma in subsequent sections.

We would like to thanks Arbro team for sharing their experience with our application and service team as they continue to use our ICPMS for food contaminants.

Through this edition of Fresh we are very pleased to introduce Perten Instruments in our food testing portfolio, thereby expanding capabilities to assist our customers in addressing rigorous regulations for food quality control.

As you must be aware of that we are engaged in customer satisfaction survey through our partners "Market Insight Consultants", sincere thanks for your feedback, being a responsible organization we are trying to implement your suggestions to serve you better and request to kindly oblige with more enthusiastic response.
We would really appreciate your feedback on this edition of Fresh also, as we continuously thrive to introduce new sections and more informative content.

With anticipation that you will enjoy reading Fresh, we wish you all safe and healthy living in summer!

Sincerely
PerkinElmer India

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Customer Success Story

ARBRO, market leader in food testing, is cracking down on food contaminants using PerkinElmer's ICPMS

Introduction

The Food Safety and Standards Authority of India (FSSAI) has been established under the Food Safety and Standards Act, 2006 which consolidates various acts & orders that have, up till now, handled food related issues in various Ministries and Departments. FSSAI was created for developing and upholding science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure safe and wholesome food is available for human consumption. The Act also aims to establish a single reference point for all matters relating to food safety and standards, by moving from multi- level, multi- departmental control to a single line of command. To this effect, the Act establishes an independent statutory Authority – the Food Safety and Standards Authority of India, headquartered in Delhi. Food Safety and Standards Authority of India (FSSAI) and the State Food Safety Authorities shall enforce various provisions of the Act.

ARBRO Pharmaceuticals Ltd., Analytical Division

ARBRO is a multi-disciplinary contract research organization and food testing lab in India. ARBRO Analytical Division was established in 1990 in New Delhi. Subsequently, two additional state of the art laboratories were added one in Baddi and another in Bangalore. They specialize in pharmaceutical testing, food testing, herbal testing, water testing and more. ARBRO offers analytical method development, method validation, stability testing, product testing, product development, chemical testing and microbiology testing lab services along with pre-shipment inspection. They are one of the largest food testing labs in India, accredited by NABL as per ISO/IEC 17025 and authorized by FSSAI for chemical and biological testing of food, beverages and agricultural products. Having more than 20 years of experience as a food testing lab, ARBRO offers a single point solution to all the food testing needs of the industry for both domestic and export markets. They have a team of over 300 professionals backed by an ultramodern food testing lab infrastructure and state of the art equipment. They analyze foods & agricultural products as per FSSAI, BIS, EIC/EIA, APEDA & European (EU) standards and FSSA (Food Safety and Standards Act). The testing carried out complies to national and international standards using globally acceptable methods laid out by AOAC, ASTA, AOCS, CODEX, PFA, BIS, EU and USFDA.

Investment in ICP-MS

A critical component of ARBRO's mission is to determine heavy metal content in different food samples such as grains, fruits, vegetables, water, cereals, milk, dairy products, herbal products, edible oils, honey, beverages and spices. They were looking for a fast throughput analytical tool or instrument to meet their demand of over 50 samples per day to determine heavy metal content to meet various regulations including FSSAI and AOAC. Seven years ago, they decided to invest in the PerkinElmer ELAN ICP-MS model DRC- e. The criteria for selecting this unit was its unique reaction and collision cell technology, rugged unit, less user maintenance, local support, long term stability and precision. The ELAN ICP-MS has become an integral part of ARBRO's testing for various food samples. Before they invested in this technique, they adopted other methods like AAS with graphite furnace and ICP-OES. Using the ICP-MS, they are able to analyze 10-20 times as many samples per day as they did before. ARBRO says, 'the PerkinElmer instruments are the most important pieces of equipment we own, particularly to help us conform to various regulations like FSSAI and AOAC for the determination of metal impurities like lead, cadmium, arsenic, mercury, selenium, tin, copper, zinc, nickel and chromium.'

A typical ICP- MS analysis for a few samples was carried as per ARBRO's standard internal protocols and validated methods as laid out by the AOAC. Samples of honey and rice were analysed for heavy metals like arsenic, lead and cadmium using the PerkinElmer ELAN DRC-e ICP-MS.

Honey

Approximately 1gm of honey was taken in a volumetric flask and 5ml of Supra pure grade nitric acid was added. Digestion was carried out on a hot plate until brown fumes were no longer seen. After cooling to room temperature, the volume was increased up to 50ml with deionized water and aspirated into the spectrometer.

Rice

Same procedure as honey, but approximately double the amount of sample was digested each time.

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Results

Honey

Sample	As (ppb)	Pb (ppb)	Cd (ppb)
Honey-1	56.379	24.777	1.385
Honey-2	60.831	15.875	1.484
Honey-3	58.717	27.190	1.462
Honey-4	58.381	16.015	1.068
FSSAI Limit	1100	2500	1500
EIC Limit		250	1000

Rice

Sample	As (ppb)	Pb (ppb)	Cd (ppb)
Rice-1	65.343	7.515	7.737
Rice-2	34.169	3.226	4.888
Rice-3	21.963	1.657	3.413
FSSAI Limit	1100	2500	1500
EIC Limit		200	200

Conclusion

In all samples, the levels of heavy metals were far below the limits specified by FSSAI and EIC.

Analytical Solutions:

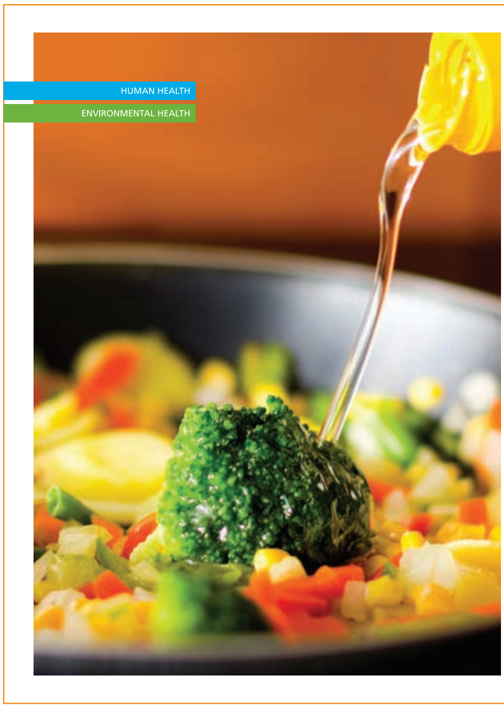
For the last seven years, ARBRO has analyzed various food samples like honey, milk, cheese, namkeen, cooked foods, beverages, juice and water using a PerkinElmer ICP-MS. Being a NABL accredited lab, ARBRO are receiving samples from different parts of the country to comply with FSSAI regulations. They are following various global standard methods as mentioned above to analyze these food matrices. They have a team of chemists and scientists to develop and validate robust methods, check accuracy, precision and recovery. These data produced can also be used in the court of law. Today, ARBRO has analyzed more than 50,000 samples catering to different clients throughout the globe.

ARBRO is a very customer focused organization due to their quality service and loyalty to their clients and have grown multi fold over the last 10 years. Today, ARBRO has become one of the largest food testing labs in India. By having high quality analytical equipment like the PerkinElmer ICP-MS, they are a market leader in food testing.

PerkinElmer feels proud to be associated with ARBRO as they have shown the trust in this partnership to achieve their goals. ARBRO has, 'always found the technical and service support of PerkinElmer and its partners to be nothing less than extraordinary. Whether it is a new installation or preventative maintenance, PerkinElmer service engineers always conduct themselves in a very professional manner. We've also found PerkinElmer's technical and application support specialists to be equally impressive.'

Thank you, Dr. Saurabh Arora for acknowledging PerkinElmer's support to help ARBRO become one of the highest quality leading global testing labs. PerkinElmer looks forward to continue supporting you in the future as you continue to grow.

References:
- ARBRO website https://testing-lab.com/2012/05/arbro-authorized-by-fssai-for-testing-of-food-samples/
- FSSAI website www.fssai.gov.in/



Featured Article

Detection and Identification of Microplastic Particles in Cosmetic Formulations using IR Microscopy

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Introduction

Microplastics or Microbeads are plastic pieces or fibres which are very small in size, typically sub millimeter, measuring less than 5mm, infact microbeads found in personal care products are almost always smaller than 1mm. These are mainly made of polyethylene (PE), but can also be made of polypropylene (PP), polyethylene tetrapthalate (PET), polymethyl methacrylate (PMMA) and nylon.

Many cosmetic products, such as facial scrubs, toothpastes, and shower gels, currently contain microplastic beads as abrasive materials. These microplastics, which are typically submillimetre in size, get washed down the sink and are too small to be filtered by sewage treatment plants consequently ending up in the river systems and ultimately in the oceans, where they contribute to huge chunk of plastic soup in environment. These microplastics can be ingested by marine organisms and fish and end up in the human food chain.

With ongoing international campaign for ban on usage of plastic microbeads and momentum gaining in India also for regulating the use of microbeads in cosmetics, it is now time for Indian manufacturers to equip themselves in advance for addressing this upcoming regulatory change and above all deliver to cause of environmental sustainability.

March 2016: NGT seeks centre's response on plea for ban on use of microplastics

National Green Tribunal issued notices to the Union Health, Ministry of Environment & Forest and Ministry of Water Resources seeking their comments on what has been done to identify and curb this growing threat of use of microbeads in cosmetic and personal care products in India alleging their use is extremely dangerous for aquatic life and environment.

December 2015:
Obama signs bill against microbeads: the Microbead-Free Waters Act

October 2015:
Gothenberg (Sweden) bans plastic microbeads

September 2015:
California (USA) signs a complete ban on use of microbeads without loopholes

July 2015:
Canada signs a complete nationwide ban on use of microbeads in personal care products

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In 2014 a number of U.S. states banned the use of microplastics in cosmetic formulations and most cosmetic companies are voluntarily phasing out their use.

Infrared (IR) spectroscopy is the established technique for identifying polymer materials and has been used extensively for identifying large (over 100 micrometer) polymer materials. The Spectrum Two™ is a portable FT-IR spectrometer that can operate from a battery pack and has been used on boats for immediate identification of these polymers.1 For microplastics, down to a few micrometers in size, an IR microscope can be used for the detection and identification of these materials.

Two commercially available products were tested using the Spotlight™ 200i IR microscope system in order to determine whether microplastics were present as the exfoliant and to identify the types of plastics used.

Product 1 is a commercially available facial scrub. Product 2 is a commercially available body scrub. Each of these products was mixed with hot water in order to dissolve the soluble ingredients in the formulation. The resulting solution was filtered through a 50 micrometer mesh, capturing any insoluble components greater than 50 micrometers in size. The filter was then allowed to dry in air prior to IR microscopy measurements. The samples were measured both directly on the mesh and also after transferring the residual particles onto an IR transmitting window on a microscope holder. Visible images of the collected microplastics are shown as Figures 1a and 1b.

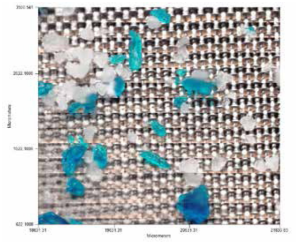

Figure 1a: Microplastics in Product 1 (facial scrub) collected on mesh.

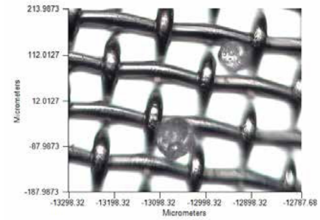

Figure 1b: Magnified view of microplastics collected from Product 2 (body scrub).

It is clear from these images that Product 1 has irregular-shaped microplastics with particles of two different colors. The particles from Product 2 are regular spheres with those visible in Figure 1b being approximately 50 and 80 micrometers in diameter. Infrared spectra of these materials can be measured in either transmission or reflectance on the IR microscope. Spectra measured on one of the particles in Figure 1a, in-situ on the mesh, are shown as Figure 2.

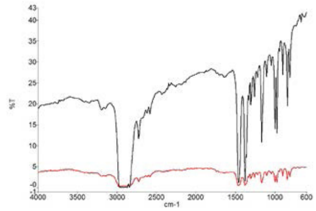

Figure 2: Spectra from a microplastic particle in Product 1. Transmission spectrum (black) and reflectance spectrum (red).

The transmission spectrum has a much higher signal than the reflectance spectrum and gives better sensitivity for this measurement. In addition, the bands in the reflectance spectrum are more intense due to the fact that the IR beam is effectively passing twice through the sample, known as transflectance. For smaller particles this does not cause any problems; but for larger particles the path length may be too large leading to totally absorbing bands, thus making identification more difficult. However, in this case, it would be possible to identify the material from either the transmission or reflectance spectrum. The mesh may interfere with the transmission measurement, slightly decreasing the amount of energy reaching the detector. This explains the baseline slope observed in the spectrum, but it does not significantly impact the overall measurement.

To obtain the best quality spectrum of the material, the sample can be transferred onto an IR-transmitting window material, such as potassium bromide (KBr). A KBr window was placed onto the mesh containing the sample and the mesh inverted thereby transferring the microplastic particles directly onto the KBr window.

A "Visible Image Survey" was collected over the area containing the majority of the particles in Product 1. Selecting the "Analyze Image" function in the Spectrum 10 software invokes the intelligent automated routine for detecting particles within this Visible Image Survey, which is displayed as "analyze image result" shown in Figure 3.

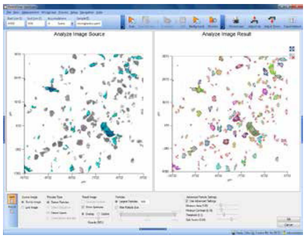

Figure 3: The Analyze Image software routine detects the particles in Product 1.

This routine will automatically detect any particles present in the visible image and mark them as regions of interest. It will then calculate the maximum rectangular aperture size that can fit wholly inside each of the particles, thus maximizing signal-to-noise when the data is scanned. In the past, manual selection of the regions of interest and setting of apertures took a considerable amount of time. Clicking "Scan Markers" initiates the collection of transmission spectra (using equivalent apertures for the background) for each particle, displaying ratioed sample spectra in real time as they are collected. Automatic processing of the spectra, using software routines such as Search, Compare, or Verify, can be performed during data collection. In

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this case, the analysis of the microplastics, a spectral search was performed against a library of polymer spectra to give the identity of each of the particles as shown in the results screen in Figure 4.

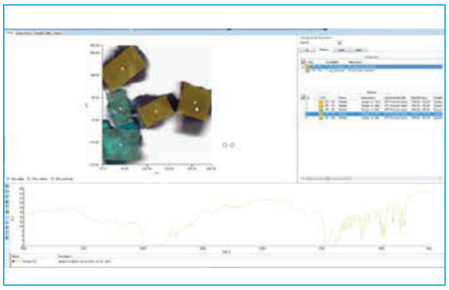

Figure 4. Results screen for the detection and identification of particles.

The results show that Product 1 has two different types of polymers present, polypropylene and polyethylene. Product 2 contains only particles of polyethylene. Representative spectra are shown in Figure 5. Small differences are observable in the spectra of the polyethylene between the two different products, most likely due to additives present.

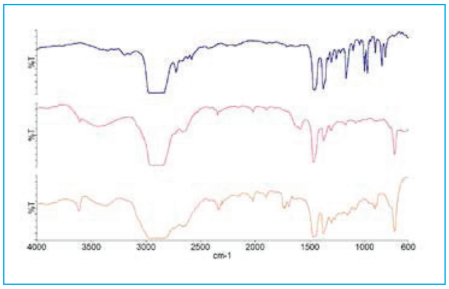

Figure 5: Top – spectrum of polypropylene in Product 1. Middle – spectrum of polyethylene in Product 1. Bottom – spectrum of polyethylene in Product 2.

Summary

Microplastics are a major concern regarding their impact on the environment and as such their use in consumer products is increasingly being prohibited. An automated IR microscopy system has been shown to be an invaluable method for the detection and identification of a source of microplastics in cosmetic formulations. The work presented here will be extended to analyze samples of microplastics collected from European river systems to illustrate how widespread this pollution problem is within marine environments.

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- http://www.beatthemicrobead.org/en/results
- http://www.thehindu.com/news/cities/Delhi/national-green-tribunal-seeks-centres-response-on-ban-of-microplastics/article8379260.ece
- http://timesofindia.indiatimes.com/home/environment/pollution/NGT-seeks-Centres-response-on-plea-for-ban-on-micro-plastics/articleshow/51383268.cms

Fresh

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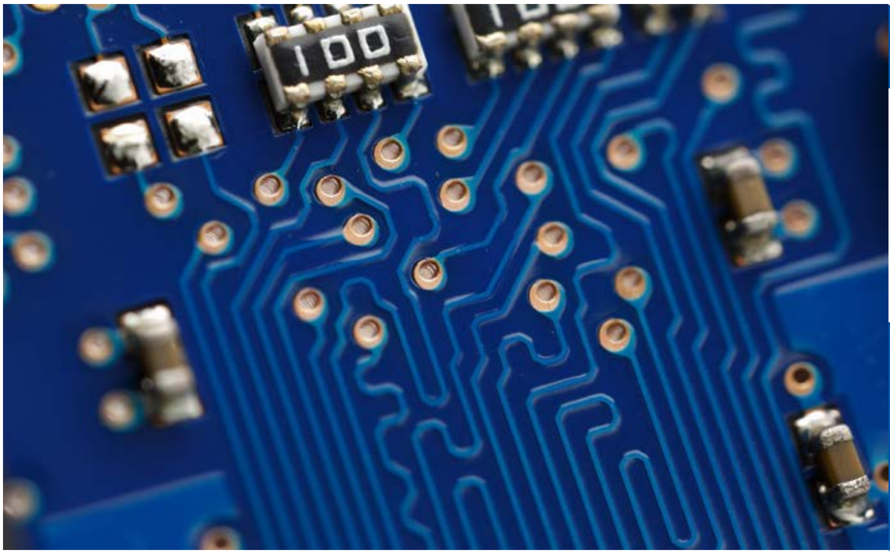

Application focus

TGA and IR hyphenation applied to routine analysis of components used in electronic circuits

Authors:
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Introduction

Failure of electronic circuits is often caused by the adverse effects of excessive heat buildup. Thermal analysis techniques have long been applied to quantify the effect of elevated temperature on component expansion, reactivity, and mass loss. A new tool in this family of techniques is the TGA 8000™ interfaced to other analyzers for evolved gas analysis (Figure 1).

The TGA 8000, with the Spectrum Two™ FT-IR and TL 8000 interface controller, has several new features that make it especially applicable for routine analysis of components used in the electronics industry. These features include improved baseline and purge control characteristics, and a patent-pending autosampler. Furthermore, the interface to the infrared spectrometer features a heated valve and other features that allow it to be easily switched in and out of the line in order to make it convenient to analyze the evolving degradation products. Primarily, the key to performance is a balance-and-furnace system designed for measuring small changes in weight over time and temperature.

Figure 1. TGA 8000, TL 8000 interface and Spectrum Two FT-IR.

TGA 8000: Keys to Performance

High Sensitivity

One of the primary requirements of electronic circuit and housing components is that they are stable over time even when subjected to somewhat elevated temperatures. When detecting the loss of mass over time it is necessary to have the highest sensitivity in order to quantify small changes in weight, since these volatiles may find their way into sensitive components. Detecting low levels of volatiles accurately requires a stable, flat, reproducible baseline, against which the mass loss is measured. Figure 2 shows several components extracted from a failed smart phone that was dissembled and analyzed. The temperature program is the same as that used for the delamination test for PCB materials.[1] The Y-scale shows the weight loss of the first 2.5% of weight under these rateaccelerated conditions using samples of a few up to 20 mg of sample for analysis. Also shown on a weight Y-scale is a no-sample baseline, stable within a few micrograms - although no baseline was subtracted from the data displayed. As part of product verification testing in manufacturing, the baseline must pass rigid tests of reproducibility and drift of within 10 µg when heated between 50 °C and 1000 °C.

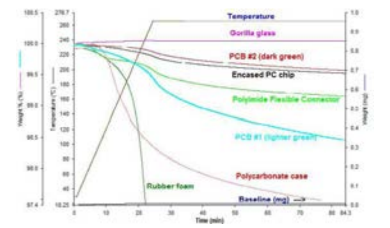

Figure 2. Volatile losses of smart phone components (PCB, pc chip, gorilla glass, polycarbonate case material, and flexible connectors).

Temperature Control and Accuracy

The TGA 8000 can be calibrated such that the temperature of the sample is accurate within 1°C over a range of eating and cooling rates and when held isothermally. This capability is especially important for the reliability of isothermal stability testing. The use of a closely coupled, low mass furnace facilitates rapid equilibrium and cool-down rates. For even faster cool-down times a water cooled furnace accessory is available.

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Automated Testing

The TGA 8000 now incorporates a newly designed and patented autosampler with a 48-sample carousel. This system features improved reliability and ease of use of sample handling that will be appreciated even if the sample throughput is not expected to be great. An autosampler facilitates fully automated testing, including automated run-time weighing, optional run-time capsule opening, and routines for optimizing, calculating, and testing the data using the powerful Pyris™ Player software.

Sample Atmosphere Control

Purge streams are controlled with precision mass-flow controllers which are pre-calibrated to common gas types, so that only the desired gas type and flow rate need selecting. The applied run-time gas flow rates are stored with the data versus time and temperature to later confirm the gas flow changes have been executed as specified by the test protocol. For example, a rapid nitrogen purge at the start of the analysis can ensure that oxygen from incursion during sample loading has been expelled before a pyrolysis. The GMD 8000 gas mixing accessory is also available for multi-gas mixing and more advanced programming requirements. The small furnace enclosure volume means that purge gas switchover between oxidative and inert atmospheres is rapid, thus reducing the time required to purge out oxygen introduced when the sample is loaded. The TGA 8000 is a sealed system, which means that oxygen is excluded once it has been purged out from loading.

Evolved Gas Analysis using Infrared Spectroscopy

The TL 8000 interface to a spectrometer features a new purge system to minimize the detection of water moisture and CO_2 from the lab atmosphere. This enables the detection of lower levels of water and CO_2 coming off the sample, which together with identification of epoxy, phenolic, adhesive, and solder paste products, can give useful information on the mechanisms of thermal degradation. This evolved gas analysis is compatible with the thermogravimetric analyzer (TGA) autosampler and can be incorporated at a later date, if the need arises. Additionally, to enable detection of trace level impurities the TGA can interface with gas chromatography or mass spectrometry with the aid of the TL 8000.

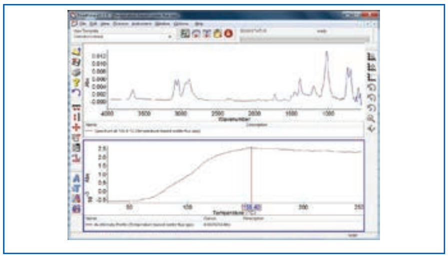

Figure 3. PerkinElmer's TimeBase software screen as displayed after TG-FT-IR analysis. Bottom pane: Absorption versus temperature as solder paste sample is heated in nitrogen. The vertical line can be placed anywhere along the curve to display the IR spectrum at that time or temperature. Top pane: The absorption spectrum at 155.4°C. A gas phase spectral library identified the component evolving at that temperature as Phenylmethanol.

Conclusion

Whether the need is to quantify carbon content, inert fillers, low levels of volatiles or combustible organics, the improved performance and usability of the TGA 8000 will result in an enhanced laboratory experience. The state-of-the art TGA 8000 autosampler makes sample handling easier and streamlines laboratory procedures, leading to improved laboratory throughput. With the help of TL 8000 a single TGA analysis can coincide with IR spectroscopy, chromatography, and mass spectroscopy leading to detailed materials characterization. This additional information can provide the grist for problem solving and insights leading to product improvement.

References:

- IPC-TM-650 TEST METHODS MANUAL, The Institute for Interconnecting and Packaging Electronic Circuits, 2215 Sanders Road, Northbrook, IL 60062-6135.

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Global Solutions for Changing World

When regulations keep changing and new environmental threats emerge every day, one company offers the tools and expertise you need to respond quickly and effectively: PerkinElmer

Cleaner Water

With most reliable technologies to detect very low concentration of contaminants in drinking water, we bring you the systems with stability to handle complex matrices while achieving required detection limits.

Key Applications:
- Toxic and trace metals
- Mercury content
- Mineral content
- Volatile organic compounds (VOC's)
- Semi-volatiles
- Grease and oil
- Carbamates
- Speciation

Fresher Air

Rising air pollution level is posing serious health risks and is now the area of top concern all over the world with both developed & developing economies working towards reducing carbon emission and implementing environmental friendly solutions.

We have helped people everywhere breathe little easier with our sophisticated air monitoring methods & systems.

Key Applications:
- Air toxics
- Air particulate monitoring
- Ozone precursors
- Soil vapor intrusion
- Industrial hygiene
- Incident monitoring

Safer Soil

For improving soil health and to promote judicial use of fertilizers & pesticides, we have solutions for quantifying micro-nutrients and to detect even the smallest concentration of toxic metals in soil, solids and hazardous wastes.

Key Applications:
- Toxic and trace metals
- Hexavalent chromium
- Mercury content
- Pesticides and PCB's
- DRO's and GRO's
- Semi volatile compounds
- Radiation detection

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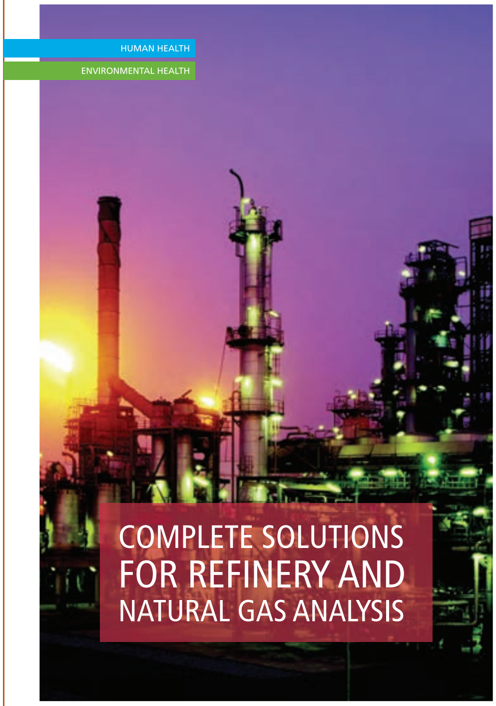
Choose the right solution for your application	**APPLICATIONS**				
	Metals	**Pesticides and Residues**	**Volatiles and Semi-volatiles**	**Hydrocarbons**	**Radiation**
Sample Preparation	■	■	■	■	
Automated Liquid Handling	■	■	■	■	■
Atomic Absorption (AA)	■				
Gas Chromatography (GC)		■	■	■	
Gas Chromatography/Mass Spectrometry (GC/MS)		■	■	■	
Inductively Coupled Plasma-Mass Spectrometry (ICP-MS)	■				■
Inductively Coupled Plasma-Optical Emission Spectroscopy (ICP-OES)	■				
Infrared (IR)			■	■	
Liquid Chromatography (LC)			■ PAH		
Liquid Chromatography/Inductively Coupled Plasma-Mass Spectrometry (LC/ICP-MS)	Speciation	■			
Liquid Chromatography/Mass Spectrometry (LC/MS)		■			
Liquid Scintillation					■
Thermal Analysis		■	■	■	
Ultraviolet (UV/Vis)	■		■		
Informatics	■	■	■	■	■

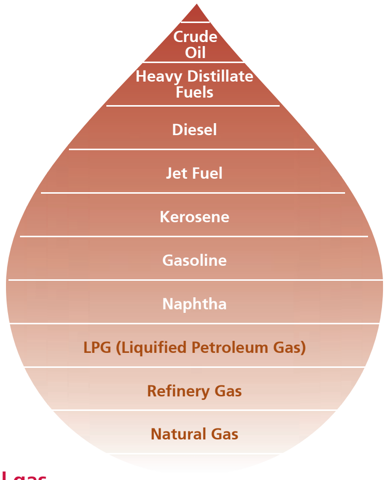
Have a highly specific application? Kindly mail us at marketing.india@perkinelmer.com



Whether you're analyzing crude oil, natural gas, or any other associated products in the industry, PerkinElmer offers a full range of instrumentation and proven applications to streamline and simplify every stage of your process.

Designed specifically for today's most common industry methods, our systems can help you analyze following crucial components in oil and natural gas samples:

- Hydrocarbon analysis
- DHA
- Sulfur
- Aromatics
- Light gases
- Elemental
- FAME's
- Simulated distillation
- Oxygenates
- Methanol
- Metals
- Mercury
- Napthalenes
- Glycerin



Download refinery and natural gas analysis brochure.

Environment

Measurement and Analysis of Silver Nanoparticles in Wastewaters with Single Particle ICP-MS

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Chady Stephan
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Introduction

The drastic increase in production and consumption of engineered nanoparticles (ENPs) has raised the concern and questions about their release into the environment and potential harm to aquatic and terrestrial species. The characteristic properties of nanoparticles, such as small size and high specific surface area and reactivity, make them desirable for their use in various products.

Silver (Ag) nanoparticles are among the most commonly used nanoparticles in consumer products due to their antimicrobial properties. Therefore, it is expected that Ag ENPs will find their way into the environment, necessitating a way to accurately and rapidly detect and characterize them in a variety of environmental matrices. Work has already been performed demonstrating the ability to successfully characterize Ag ENPs in a variety of water samples[1-3] and biological media which may be exposed to Ag ENPs in the environment[4].

A major source of environmental release is wastewaters, a complex matrix which must be evaluated for the fate of Ag ENPs. The complexity and variety of the wastewater matrices can make the analysis of ENPs challenging.

This work evaluates the ability of SP-ICP-MS to characterize Ag NPs in a dissolved organic solution containing alginate (a common wastewater component) and two wastewater matrices: mixed liquor and effluent.

Experimental

Samples and Sample Preparation The water samples were collected from a wastewater treatment plant near Montreal, Quebec, Canada. The effluent wastewater was collected after the secondary settling tank, while the mixed liquor was collected from the secondary aeration tank. Both water types were collected in acid-washed, dark glass bottles and sealed. Effluent wastewater is the ultimate treated wastewater which is discharged to the river from this treatment plant, while the mixed liquor is the wastewater which leaves the aeration tank after biological treatment to the secondary settling tank for the suspended solids to sediment. As a result, the mixed liquor has much higher levels of suspended solids and relatively higher dissolved carbon content compared to the effluent wastewater.

Alginate is a polysaccharide which is detected in wastewaters at ppm levels and comprises the dissolved organic carbon fraction of wastewaters. The alginate solution was used as a known control/ surrogate for comparison with the wastewater samples. The alginate solutions were prepared from alginic acid sodium salt from brown algae (Sigma-Aldrich, St. Louis, Missouri, USA) at 6 ppm in deionized water by shaking end-over-end for an hour.

Ag ENPs capped with polyvinylpyrrolidone (PVP) with a mean diameter of 67.8±7.6 nm (as determined with transmission electron microscopy [TEM], nanoComposix™ Inc., San Diego, California, USA) were spiked into 10 mL of all samples at a concentration of 10 ppb (5 million particles/mL). The samples were then diluted 10-1000x with deionized water and sonicated for five minutes prior to analysis. All samples were prepared in triplicate.

Instrumental Conditions

All analyses were carried out on a PerkinElmer NexION® 300D/350D ICP-MS operating in SP-ICP-MS mode using the Syngistix™ Nano Application Software Module. Instrumental parameters are shown in Table 1. With these parameters, a transport efficiency of 8.3% was determined.

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Table 1. NexION 300D/350D ICP-MS Instrumental Parameters

Parameter	Value
Sample Uptake Rate	0.3 mL/min
Nebulizer	Glass Concentric
Spray Chamber	Glass Cyclonic
RF Power	1600 W
Analyte	Ag107
Analysis Time	100 sec
Dwell Time	100 µsec

Results and Discussion

To determine the accuracy of SP-ICP-MS, the Ag ENPs were added to deionized (DI) water at a concentration of 0.1 ppb (50,000 particles/mL). SP-ICP-MS measurement determined the mean size of the Ag ENPs to be 63.2±0.2 nm (which agrees with the TEM measurements), and the concentration to be 53,758±1363 particles/mL, thus validating the accuracy of the measurements. The values and standard deviations are from the mean of three replicate analyses.

Next, the Ag ENPs were measured in a 6 ppm alginate solution. Figure 1 shows the Ag particle size distribution for 0.1 ppb (50,000 particles/mL), which corresponds to a mean particle size of 66.1±0.1 nm, with a concentration of 52,302±2102 particles/mL. The agreement between the measured and TEMdetermined particle sizes indicates that the alginate matrix does not affect the measurement accuracy.

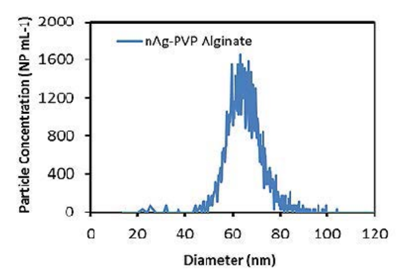

Figure 1. Measured Ag particle size distribution in 6 ppm alginate solution.

With the accuracy of the technique established in the alginate solution, the effluent wastewater and mixed liquor samples were measured next. First, the total Ag concentration was measured in both wastewater samples and was found to range from 25-40 ppt, a level which should not inhibit the determination of Ag ENPs. Figures 2 and 3 show the measured particle size distributions for the effluent and mixed liquor, respectively. The samples were diluted 100x prior to analysis, with Table 2 showing both the measured particle sizes and particle concentrations. Again, the mean particle size agrees with the certificate value, and the particle concentration is close to the calculated value, indicating that neither of the wastewater matrices affects the measurement. These results indicate that Ag ENPs can be successfully measured in wastewater samples.

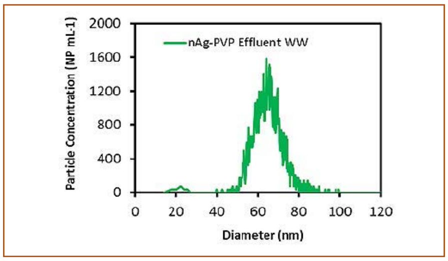

Figure 2. Measured Ag particle size distribution in effluent wastewater diluted 1000 times.

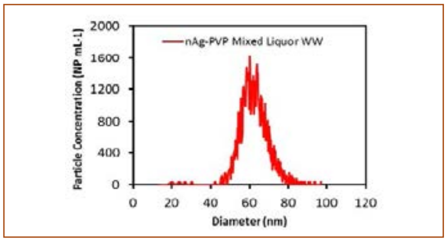

Figure 3. Measured Ag particle size distribution in mixed liquor wastewater diluted 1000 times.

Table 2. Results from Analysis of Wastewater Samples Spiked with Ag NPs.

Sample	Mean Particle Size (nm)	Spiked Particle Conc. (particles/mL)	Measured Particle Conc. (particles/mL)
Effluent Wastewater	66.3±0.2	50,000	54,691±1185
Mixed Liquor Wastewater	63.7±0.4	50,000	53,123±1216

The detection limits for both the Ag particle size and concentrations in the wastewaters were determined. For the determination of particle size detection limits, the diluted samples were analyzed without any Ag ENPs being added. The detection limit was determined by running the unspiked wastewater matrices and observing the particle size which corresponded to the smallest peak recorded in the Syngistix Nano Application Module. For the effluent, the detection limit is about 18 nm, while for the mixed liquor, it is about 12 nm.

This work has demonstrated the ability of SP-ICP-MS to accurately detect and measure silver nanoparticles in three different types of wastewater samples. Although wastewater matrices are complex, they do not inhibit the ability of SP-ICP-MS to accurately measure the size and nanoparticle concentration.

Consumables Used

Component	Part Number
Green/Orange (0.38 mm id) PVC Sample Uptake Tubing	N0777110
Gray/Gray (1.30 mm id) Santoprene Drain Tubing	N0777444
Sample Tubes	B0193233 (15 mL) B0193234 (50 mL)

References:

- Mitrano, D., Ranville, J.F., Stephan, C., "Quantitative Evaluation of Nanoparticle Dissolution Kinetics using Single Particle ICP-MS: A Case Study with Silver Nanoparticle", PerkinElmer Application Note, 2014.
- Hadioui, M., Wilkinson, K. "Assessing the Fate of Silver Nanoparticles in Surface Waters using Single Particle ICP-MS", PerkinElmer Application Note, 2014.
- Dan, Y., Zhang, W., Xingmao, M., Shi, H., Stephan, C. "Gold Nanoparticle Uptake by Tomato Plants Characterized by Single Particle ICP-MS", PerkinElmer Application Note, 2015.
- Gray, E., Higgins, C. P., Ranville, J.F. "Analysis of Nanoparticles in Biological Tissues using SP-ICP-MS", PerkinElmer Application Note, 2014.

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Environment

Analysis of Minerals in Drinking Water using PinAAcle 500 Flame AA

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Training and Consulting
Kenneth Neubauer
PerkinElmer, Inc.

Introduction

With water quality varying widely with geography and geology, as well as pollution considerations, it is important to know the metal content of waters, both for consumption and industrial use. Although a variety of techniques can measure minerals in water, one of the simplest, least expensive, and fastest is flame atomic absorption (AA) spectrometry. As a result, the technique continues to enjoy widespread use, despite the increasing popularity of ICP-OES and ICP-MS.

This work focuses on the determination of seven non-toxic elements usually found in drinking waters with the PerkinElmer PinAAcle™ 500 flame atomic absorption spectrometer. Although other lower-level elements can also be measured by flame AA, these are most commonly analyzed by either graphite furnace AA, ICP-OES, or ICP-MS.

Experimental

Samples consisted of municipal and well waters collected locally, spring waters purchased from a local grocery store, and a certified drinking water standard (Trace Metals in Drinking Water – High-Purity Standards™, Charleston, South Carolina, USA). Sample preparation consisted only of acidifying each water with 1% HNO3 (v/v) and adding 0.1% lanthanum chloride as a releasing reagent for calcium (Ca) and magnesium (Mg) and as an ionization suppressant for sodium (Na) and potassium (K).

All analyses were carried out with the PinAAcle 500 flame AA spectrometer using the conditions in Tables 1 and 2. Due to the high mineral content, the burner was rotated 30 degrees to decrease the signal intensity for the analysis of the minerals. In addition, K and Na were analyzed in emission mode, which allowed the PinAAcle 500 to be auto-configured in such a way to extend the analytical range so that even higher concentrations could be measured. This allowed minimal dilution for K and elimination of dilution for Na.

Samples were introduced via self-aspiration with a highsensitivity nebulizer, which is standard on the PinAAcle 500 spectrometer. The nebulizer was used without the spacer (providing maximum sensitivity) for the determinations of copper (Cu), iron (Fe), and zinc (Zn). The spacer was inserted for the determinations of Na, K, Mg and Ca.

Table 1. PinAAcle 500 instrument and analytical conditions common to all elements.

Parameter	Value
Air Flow (L/min)	2.5
Acetylene Flow (L/min)	10
Read Time (sec)	3
Replicates	3

> ***"Clean drinking water means better health, helps to boost economic growth and contributes to GDP, says PM Narendra Modi during 19th session of Mann Ki Baat programme on All India Radio".***

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Table 2. PinAAcle 500 instrument and analytical conditions specific to each element.

Element	Wavelength (nm)	Slit (nm)	Mode	Burner Angle (degrees)	Calibration Standards (mg/L)	Calibration Curve
Ca	422.67	0.7	Absorption	30	0.5, 1.0, 2.0, 5.0, 10, 20, 40	Non-Linear through Zero
Cu	324.75	0.7	Absorption	0	0.05, 0.10, 0.25, 0.50	Linear Through Zero
Fe	248.33	0.2	Absorption	0	0.05, 0.10, 0.25, 0.50, 1.0	Linear Through Zero
Mg	285.21	0.7	Absorption	30	0.5, 1.0, 2.0, 5.0, 10	Non-Linear Through Zero
K	766.49	0.7	Emission	30	2, 5, 10, 20, 30, 40, 50	Non-Linear Through Zero
Na	589.00	0.2	Emission	30	2, 5, 10, 20, 30, 40, 50	Non-Linear Through Zero
Zn	213.86	0.7	Absorption	0	0.05, 0.10, 0.25, 0.50	Linear Through Zero

Results and Discussion

All calibrations yielded correlation coefficients of 0.999 or greater. The accuracy of the calibrations was assessed with an independent calibration verification (ICV) solution, which was diluted 100 times to fall within the range of the calibration curve. The results of the ICV appear in Table 3 and demonstrate the accuracy of the calibration curves.

To validate the methodology, a reference material was first analyzed, with the results shown in Table 4. All recoveries are within 10% of the certified value, demonstrating the accuracy of the methodology.

Table 3. Results for independent calibration verification (ICV).

Element	Concentration (mg/L)	Experimental (mg/L)	% Recovery
Ca	5.00	4.86	97
Cu	0.25	0.26	104
Fe	1.00	1.00	100
Mg	5.00	4.88	98
K	5.00	4.78	96
Na	5.00	5.12	102
Zn	0.20	0.21	105

Table 4. Results for reference material (all units in mg/L).

Element	Concentration (mg/L)	Experimental (mg/L)	% Recovery
Ca	33.4	35.0	95
Cu	0.022	0.020	110
Fe	0.095	0.100	95
Mg	8.69	9.00	97
K	2.28	2.50	91
Na	5.90	6.0	98
Zn	0.070	0.070	100

Table 5. Results for samples (all units in mg/L).

Element	Municipal Water (mg/L)	Well Water-1 (mg/L)	Well Water-2 (mg/L)	Well Water-3 (mg/L)	Spring Water-1 (mg/L)	Spring Water-2 (mg)
Ca	17.7	0.148	35.3	32.4	3.43	19.2
Cu	0.048	< DL	0.052	0.017	< DL	< DL
Fe	< DL	< DL	0.019	< DL	< DL	< DL
Mg	6.43	0.026	4.90	5.12	0.799	6.09
K	< 0	233*	4.89	4.10	0.73	0.69
Na	38.4	3.63	10.9	42.9	6.60	7.25
Zn	0.008	0.043	0.010	0.023	< DL	< DL

* Sample required a 10x dilution

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With the accuracy of the method established, several drinking water samples from various sources were analyzed. The municipal and well water samples were collected directly from a faucet, while the spring water samples were poured from the bottles in which they were purchased. The results appear in Table 5. The presence of Cu and Zn in the four samples collected from the faucet is most likely due to leaching from copper pipes, fittings, and solder. Well Water-1 is interesting as it contains the lowest levels of all samples, except for an extraordinarily high level of K. Further investigation determined that this residence has a water softener installed which utilizes K as the counter-ion to remove high levels of Ca and Mg from the well water.

As expected, Cu and Zn are not detected in the spring waters; only the minerals are present. The variation in mineral concentration is indicative of the different geologies of the areas where these waters originate.

Finally, detection limits were determined for Cu, Fe, and Zn as three times the standard deviation of ten blank measurements (i.e. 1% HNO3), as shown in Table 6. Because of their elevated levels, detection limits were not determined for the mineral elements (i.e. Ca, K, Mg, Na). In addition, since these elements are usually present at high concentrations, the instrument was detuned for their analysis. Therefore, detection limits would be meaningless.

Table 6. Detection limits.

Element	Detection Limit (mg/L)
Cu	0.002
Fe	0.006
Zn	0.004

Conclusion

This work has demonstrated the ability of the PinAAcle 500 to successfully measure mineral elements in drinking water samples, including municipal, well, and spring waters. By taking advantage of the ability to rotate the burner and measure in emission mode, both trace and mineral elements could be measured. With Syngistix Touch™ software, the PinAAcle 500 AA spectrometer can be operated exclusively from a touchscreen interface. For greater flexibility, the ability to run Syngistix™ for AA software from an on-board computer is also available. This flexibility makes the PinAAcle 500 flame AA spectrometer an excellent choice for the analysis of drinking waters.

Consumables Used

Component	Part Number
High Sensitivity Nebulizer	N3160144
Autosampler Tubes	B0193233 (15 mL) B0193234 (50 mL)
Ca Hollow Cathode Lamp	N3050114
Cu Hollow Cathode Lamp	N3050121
Fe Hollow Cathode Lamp	N3050126
Mg Hollow Cathode Lamp	N3050144
Zn Hollow Cathode Lamp	N3050191
Quality Control Standard, 21 Elements	N9300281
Initial Calibration Verification Standard	N9300224
Pure-Grade Ca Standard (1000 mg/L)	N9303763 (125 mL) N9300108 (500 mL)
Pure-Grade K Standard (1000 mg/L)	N9303779 (125 mL) N9300141 (500 mL)
Pure-Grade Mg Standard (1000 mg/L)	N9300179 (125 mL) N9300131 (500 mL)
Pure-Grade Na Standard (1000 mg/L)	N9303785 (125 mL) N9300152 (500 mL)

PinAAcle™ 500 Flame AA

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Textile

Rapid and Reliable PVC Screening in Packaging Material used in Textile Industry

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Introduction

A qualitative rapid and reliable method for detection of Polyvinyl Chloride (PVC) in different packaging materials can be achieved by a simple ielstein Test followed by FT-IR measurement. The method involves spotting characteristic absorption bands of PVC in the sample by comparing it with standard PVC spectra.

Poly Vinyl Chloride (PVC) is one of the most important and widely used thermoplastics due to good processability, chemical resistance, and low flammability. The physical property of PVC can be controlled by varying the plasticizer content. PVCs are usually used as packaging materials, wires, films and sheet, floor tiles, and a variety of soft children's products. Due to the persistent, bio-accumulative nature of many of the chemicals released by PVC production, their effects are irreversible and pose a huge environmental risk. Textile industry compliance requires that materials, chemicals, parts, and other goods, used or supplied in the manufacture of textile products, comply with the applicable chemical content and chemical exposure laws of every governmental jurisdiction in which those products are manufactured or distributed to protect the health and safety of consumers and others handling finished products. The RSL (Restricted Substance List) of finished products, including apparel, non-apparel, footwear, accessories, and other products requires that parts, other goods, and finished products provided by suppliers and sources comply with the "Limit Value Final roduct" (LVFP) levels. The use of PVC in the packaging material in the textile Industry comes under RSL and there is a complete ban on the usage of PVC. The mandatory requirement for screening this material has to be tested using the Beilstein test and FT-IR for confirmation.

Experimental

In this application note we show that Beilstein and FT-IR testing can be used to confirm the presence of PVC in packaging materials. Here we have used various packaging plastics as test samples. The presence of halogens using the Beilstein test in any material containing bound or ionic halogens (chlorine, bromine, iodine) such as salt or polyvinyl chloride (PVC) will react with a copper wire when heated in a flame and produce a brilliant, long-lasting green flame indicating the presence of halogens. The presence of a greenish flame indicates the presence of halides. The flame will burn green for a long period of time if PVCs are present. For PVC confirmatory presence, FT-IR measurement was carried out on a Spectrum Two™ FT-IR using a Diamond ATR. Experimental parameters used for measurement were scanning range of 4000 – 400 cm^{-1}, resolution of 4 cm^{-1} and 16 scans.

Table 1. Characteristic IR spectra absorption bands for PVC.

Spectral Range (cm^{-1})	Functional Assignment
2900 to 3000	Aliphatic C-H Stretching
1725 to 1740	Ester Peak for Phthalates platsticizers
Peak around 1426	Bending of aliphatic C-H Bonds
Peak around 1240 to 1260	Bending of C-H bonds near Cl
Peak around 1000	Stretch of C-C bonds
Doublet at 610 and 630 and peak at 695	C-Cl gauche bond

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Figure 1. Spectrum Two with Diamond ATR .

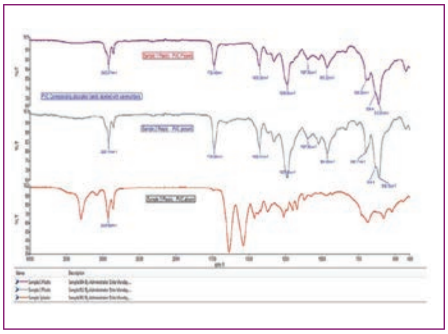

Figure 2. The IR absorption spectra show the confirmation of PVC in Sample 1 and Sample 2, while the absence of PVC in Sample 3.

Data Analysis

The following samples were tested by PerkinElmer Spectrum Two instrument with Diamond ATR for PVC qualification. Samples spectra listed in Figure 2 were monitored for PVC characteristic absorption bands. Given in Figure 2 are the spectra of each sample with observations.

Conclusion

In order to characterize and identify the presence of PVC in plastics, a Beilstien test followed by FT-IR analysis was carried out. For PVC which is banned in packaging material in the textile industry, FT-IR with ATR technique can be used as a verification test which is a very fast, reliable, cost effective method for PVC qualification with a good detection limit. The methodology provides the ability to screen PVC qualification of different samples with little or no sample preparation. The portability of the PerkinElmer FT-IR system enables these measurements to be made in the field and help to ensure that plastic parts and objects do not enter the commercial marketplace.

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ChemDraw Tip #7

By selecting a molecule and holding "Ctrl" while dragging it creates a copy of the original molecule. (video)

ChemDraw Tip #8

If you select a molecule and hold "shift" you can move it in a straight line horizontally or vertically. (video)

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Textile

Analysis of Azo-Dyes, Chlorinated Phenols, Organotin and PAH's in textiles

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Shelton, CT

Azo dyes are compounds characterized by their excellent coloring properties. They are important and widely used as coloring agents in the textile and leather industries. The risk in the use of azo dyes arises mainly from the breakdown products that can be created in vivo by reductive cleavage of the azo group into aromatic amines. Due to the toxicity, carcinogenicity and potential mutagenicity of thus formed aromatic amines, the use of certain azo dyes as textile and leather colorants, and the exposure of consumers using the textile and leather colored with azo compounds causes a serious health concern.

The two main routes of consumer exposure are the skin absorption of the azo compounds from the dyed clothes worn, and potential oral ingestion, mainly referring to the sucking of textiles by babies and young children. The EU Commission classified 22 amines as proven or suspected human carcinogens & limits their concentrations up to 30 ppm.

Azo-dyes analysis by GCMS (DIN EN 14362-1: 2012-04)

The EN ISO 17234-1 standard method for the analysis of textiles made of cellulose and protein fibers, for example cotton, viscose, wool, or silk is the chemical reduction of azo dyes followed by solid phase extraction (SPE).

For all the said Azo dyes the DIN EN 14362-1 : 2012-04 method is used which recommends analysis using GCMS system. PerkinElmer Clarus SQ8 GCMS is most suitable and flexible system to provide very reliable analysis as per the global norms.

Chlorinated phenols in textiles (DIN EN ISO 17070:2007)

To prevent mold spots caused by fungi, chlorinated phenols like PCP are applied directly on textiles, leather and wood. PCP is very toxic and regarded as a cancer-inducing agent. So it is important to determine the exact quantity of PCP in textile to avoid its carcinogenic effect on human health. These compounds are determined by Clarus x80 Gas chromatograph with Electron Captured Detector (ECD) or Clarus SQ GCMS also can be used for better identification. In most of the cases compounds are monitored as per the DIN EN ISO 17070:2007 method.

Analysis of Organotin compounds in textiles by GCMS (BS ISO 17353:2004 (German Version: DIN EN ISO 17353:2005)

Synthetic fibres in particular were frequently treated with TBT, monobutyl- and dibutyltin. The organotin compounds prevent the development of an unpleasant smell in textiles during heavy sweating. All organotin compounds are considered to be toxic. The most notorious compound is tributyltin (TBT), a very persistent and highly toxic cell poison that is difficult to degrade. TBT is one of the most poisonous compounds released into the environment, and in humans it causes damage to the hormonal, immune and central nervous systems as well as to the liver and kidneys. The permissible concentration of TBT value of 0.025 mg/kg textile, and for other organotin compounds a value of 0.25 mg/kg.

Polycyclic-aromatic Hydrocarbons Content (PAH) in textiles by GCMS (ZEK-01.4-08)

PAH's are widely used in various textile products. These are mostly carcinogenic in nature. Some are genotoxic too. e.g- benzo pyrene. Hence recently, the German Board for Technical Work Equipment and Consumer Products (AtAV) has further extended the list of mandatory PAHs (16 by EPA) to 18 PAHs for the GS-certification process. All these can be analyzed easily with best detection levels with PerkinElmer Clarus SQ8 GCMS system.

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Textile

Determination of Extractable Metals in Textiles as per ISO 105 E-04 Methodology

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Textile is categorized according to its utilization into products for babies, products with direct contact to skin, products without direct contact to skin, and decorative materials. For risk estimations the determination of the extractable amounts of heavy metals is of importance, due to possible impact on human health. According to the recently introduced regulation, common heavy metals extractable with synthetic gastric juice from textile used in baby clothes and toys should also be monitored. This method simulates contact with gastric juice when a material has been swallowed.

Toxic effects of textile dyes

Toxic effects of heavy metals on human health are very well known: damages of organs, disorders in the respiratory tract and lung diseases, dysfunction of the heart, blood and blood producing organs, skin diseases and some others. Due to the toxicity of some heavy metals, guidelines for testing of these metals in textile products have been provided vide ISO 105 E04 methodology.

The major chemical pollutants on textiles are dyes containing carcinogenic amines and toxic heavy metals. Heavy metals can exist in natural structures of textiles or they can penetrate into textiles during their production, dying process or via the protection agents used for the storage or from the environment.

PerkinElmer analyzer for ISO 105 E04 method

The extractable metals found in the garments and fabric may vary in their concentrations from product to product. Hence it is necessary to have a system like NexION 350; where the ultra-trace metals in a wide range of sample types can be measured.

The common heavy metals can be easily digested using Titan MPS microwave digestion system. However for the determination of extractable cadmium, chromium, copper, lead and nickel in textiles as per the published method the extraction procedure recommends Textile Testing ISO 105 E04 Methodology synthetic gastric juice as an extractant. This process is required to be optimized for consistent results.

A complete analyzer with support

- PerkinElmer ISO 105 E04 analyzer system is supplied with the NexION 350 ICPMS or Optima 8x00 ICP with required software for control and data acquisition.
- It is recommended to have Titan MPS for the digestion process.
- Pre-installation and site readiness guidance
- Extensive operators training and application support
- Ready to use methods as hand holding approach.

Permissible limits of the extractable metals in textile (non- metallic parts) ISO 105 –E04 (2013)

Extractable heavy metals	Limits mg/Kg	
Arsenic (As)	0.2	Usage banned as biocide
Antimony (Sb)	5	Usage as flame retardant
Lead (Pb)	Traces 0.2	Usage banned
Cadmium (Cd)	Traces 0.1	Usage banned
Mercury (Hg)	Traces: 0.02	Usage banned
Copper (Cu)	25-50	Complex dyed textiles
Chromium (Cr)	0.5 to 1.0	For metal dyed complex
Chromium VI (Cr VI)	< 0.5	Usage banned
Cobalt (Co)	1.0-4.0	For metal dyed complex
Nickel (Ni)	1.0-4.0	Complex dyed textiles

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Pharmaceuticals

Implementation of USP Chapters <232><233> using NexION 350 ICPMS and ICH Q3D Toolkit

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Introduction

With revision to **General Notices 5.60.30 Elemental Impurities in USP Drug Products and Dietary Supplements, January 1, 2018 is the date on which General Chapters <232> and <2232> will become broadly applicable to drug products (<232>) and finished dietary supplement dosage forms (<2232>) in the USP-NF.** The removal of references to <231> from USP-NF monographs also will be official as of January 1, 2018.

These new mandates will soon require a more demanding elemental impurities method to be in place – and in operation – within your organization.

USP's Chapter 232 (Elemental Impurities-Limits) specifies the list of elements of concern, potentially found as contaminants in pharmaceutical products and their maximum daily dose by element and delivery mechanism (oral, parenteral, large-volume parenteral, or inhalation). Chapter 233 (Elemental Impurities-Procedures) details the sample preparation, analytical procedures, and quality control validation protocols that are required for measuring the elements specified in Chapter 232.

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceutical Products for Human Use (ICH) is working to harmonize the major global pharmacopeias' approach to heavy metal testing, to provide a global policy for limiting metal impurities qualitatively and quantitatively in drug products and ingredients (ICH Q3D – Guideline for Elemental Impurities), specifying 24 elemental impurities including 15 outlined in USP <232>.

PerkinElmer offers a complete, integrated solution to USP 232/233 compliance, including:

- Fast, safe and cost-effective sample preparation equipment
- Intelligent sample handling that includes automated auto-dilution systems for USP 233 methods
- Choice of best-in-class ICP-MS/ICP-OES and software solutions
- Complete validation services,
- Enhanced Security™ software to help comply with Regulation 21 CFR Part 11

USP Chapter <232> key points summarized

- Chapter <232> - specifies the list of elements and their toxicity limits (maximum daily doses of different drug categories) as:
  - Maximum permissible daily exposure (PDE) values (refer Table 1)
  - Mode of administration: Oral, Parenteral (intravenous injection), Inhalation and LVP
- Following on from ICH Q3D Step 4 in Dec 2014, the limits in Chapter <232> have been updated to align with ICH Q3D.
- December 1, 2015: Updated chapter has already appeared in second supplement to USP 38-NF 33 with modified limits as proposed in ICH Q3D.

The toxicity of an elemental impurity is related to its extent of exposure (bioavailability).

Exposure factor is used to modify the permissible daily exposures (PDE's) on the route of administration, assuming 100% bioavailability for parenteral and inhalation routes. (refer: Target Value calculator on page no. 23)

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Table 1. Modified maximum permissible daily exposure (PDE) values (in µg/day) for the administration of drug products, based on an "average" 50 Kg person

Including elements specified in ICH Q3D guidelines:

Elements	USP <232>	Class	Oral Daily Dose PDE*	Parental Daily Dose PDE (ug/day)	Inhalational Daily Dose PDE (ug/day)
Cd	Yes	1	5	2	2
Pb	Yes	1	5	5	5
As[b]	Yes	1	15	15	2
Hg[b]	Yes	1	30	3	1
Co	No	2A	50	5	3
V	Yes	2A	100	10	1
Ni	Yes	2A	200	20	5
Ti	No	2B	8	8	8
Au	No	2B	100	100	1
Pd	Yes	2B	100	10	1
Ir	Yes	2B	100	10	1
Os	Yes	2B	100	10	1
Rh	Yes	2B	100	10	1
Ru	Yes	2B	100	10	1
Se	No	2B	150	80	130
Ag	NO	2B	150	10	7
Pt	Yes	2B	100	10	1
Li	No	3	550	250	25
Sb	Yes	3	1200	90	20
Ba	No	3	1400	700	300
Mo	Yes	3	3000	1500	10
Cu	Yes	3	3000	300	30
Sn	No	3	6000	600	60
Cr	Yes	3	11000	1100	3

[a] *PDE = Permissible daily exposure based on a 50 kg person*

[b] *See Speciation Section of USP <232>*

Chapter <233> describes two analytical procedures with associated sample preparation steps for determination of elemental impurities in the drug products, Procedure 1: ICP-AES/OES and Procedure 2: ICP-MS

USP <233> specifies 4 different sample preparation techniques:

- Use neat, undiluted sample, if in suitable liquid form
- Dilute in aqueous solution, if soluble in water
- If not soluble in water, dilute in appropriate organic solvent

Preparing insoluble samples as per USP <233> guideline using Titan MPS™ Microwave Digestion System

For insoluble samples that require closed-vessel acid digestion, our Titan MPS™ system is the ideal solution. This top-loading microwave employs a triple-interlocked lid that allows easy loading

Implementing analytical procedures 1 and 2 as described in Chapter <233>

With the lowest detection limits of any ICP-OES and a full suite of enhanced data security features, PerkinElmer's Optima® 8x00 series ICP-OES makes it easy to comply with stringent regulatory requirements. Dual viewing of the plasma allows the Optima 8x00 ICP-OES to provide a wide calibration range for enhanced productivity. Added features, such as superior interference correction and patented Flat Plate™ plasma technology make the Optima 8x00 ICP-OES easy to use and easy to maintain.

The bottom line is that depending on the element and the mode of adminis-

There is no question that ICP-MS is the most suitable multi-element technique for determining elemental impurities at levels specified in Chapter <232> for pharmaceutical products. The desired limits, even for the large volume parenterals (LVP) at a maximum 2 L dosage level, which are the lowest specifications of all the different drug delivery methods, can be reached with relative ease.

PerkinElmer's NexION 350 ICPMS with patented Universal Cell Technology™ (UCT) offers the simplicity of both collision cell and exceptional detection limits of true reaction cell.

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and removal of vessels, while the polymer-coated, stainless steel construction provides maximum corrosion resistance. tering the drug, careful evaluation of the ICP-AES/OES technique is needed before selecting it for this analytical procedure. With its patented ion optics design (Triple Cone Interface and Quadrupole Ion Deflector), no matrix particulate enters the mass spectrometer, thereby dramatically reducing routine maintenance.

Calculate target limits (acceptance value of the elemental impurity being evaluated) using unique J value calculator:

J Value (Target Limit) is calculated by:

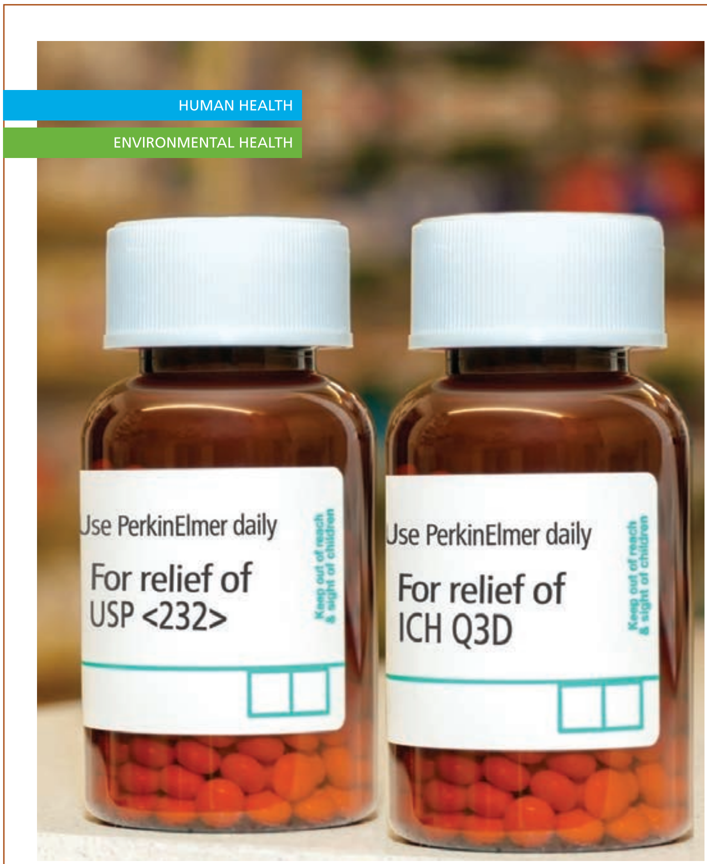
$$J = \frac{\text{PDE}}{(\text{Maximum Daily Dose} \times \text{Dilution Factor})}$$

For example: Hg has an Oral Daily Dose PDE of 15 µg/day. If we digest 0.1g of a material that has a daily dosage of 1 g and dilute the resulting solution to 50 mL, the J value with therefore be:

$$J = \frac{15\ \mu\text{g/day}}{\frac{1\text{g}}{\text{day}} \ \text{X} \ \frac{0.1\text{g}}{50\text{mL}}} = 30\ \mu\text{g/L}$$

Download the white paper detailing the elemental & dosage form specific PDE values and analytical procedures as specified in USP Chapter <232> <233> and ICH Q3D guidelines Click here

References:
- http://www.usp.org/sites/default/files/usp_pdf/EN/faq/ei-implementation-faq-2015-03-27.pdf
- http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html



USP <232>/<233> and ICH Q3D Toolkit

The USP <232>/<233> and ICH Q3D guidelines offer great benefits to consumers, but also provide some challenges for pharmaceutical manufacturers. With the new USP/ICH Toolkit, you can rest assured that complying with these limits and procedures will be easier than ever. The Toolkit provides:

- Information to help get you started
- Tools to assist with standard preparation and method development
- Method validation reporting tool
- Standard Operating Procedures (SOP)
- Sample preparation methods
- NexION® software information

The USP/ICH Toolkit includes a J Value Calculator for accurate calculations of Target Limits (J values) of elemental impurities, making standard preparation and method development easier. The Toolkit also helps improve efficiencies with the Method Validation Report Tool, which calculates and summarizes method validation data instantly.

With this one tool you'll be complying with the elemental impurities testing requirements in no time.

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Pharmaceuticals

Implement USP <857> Compliance with Lambda 365 UV-Vis Spectrophotometer

Until this year the relevant chapters in US Pharmacopoeia for UV-Vis spectrophotometry were General Chapter <851> Spectrophotometry & Light Scattering and General Chapter <1058> Analytical Instruments Qualifications. As part of the USP–NF modernisation process, the General Chapters (Chemical Analysis) Expert Committee has reviewed chapters holistically to align concepts and contents to ensure consistency, resulting in suite of technique specific General Chapters-Ultraviolet Visible Spectroscopy Chapter USP <857>. This chapter details qualifications regarding the parameters of wavelength accuracy, photometric accuracy/linearity, stray light, and resolution that must be met on a UV-Visible spectrophotometer.

With this instrument vendor IQ/OQ, PQ, IPV documents and software, previous qualification or calibration SOPs and worksheets are now out-of-date.

US Pharmacopoeia General Chapter USP <857> is now official in NF 38; however it is staged to become mandatory in USP NF 39 from 1st May 2016. Hence, all FDA auditors visiting pharmaceutical laboratories will be now required to identify instruments & labs globally that need to comply for:

- Testing drug or intermediate or excipient that is sold in USA
- Method development labs for drug or intermediate or excipient testing sold in USA
- Labs where full latest international compliance is required by internal policy or customer expectations

Knowing the upgrade route to remain compliant

PerkinElmer has thoroughly interpreted the requirements of USP <857> as New Chapters in United States Pharmacopeia will affect compliance status now. This leaves existing double beam UV-Vis spectrometers and Diode Array spectrometer of most of the international brands certified with vendor IQ/OQ/PQ, IPV documents and instrument software out of date. The established SOPs for calibration of the instruments will not hold good.

The USP <857> effectively extends the test to UV and Visible range. The EP limits the test to UV region. PerkinElmer Lambda 25, 35 and 45 (not older than 5 years) are guaranteed to pass all USP and EP requirements. PerkinElmer offers UOQ as service and record of compliance including the new stray light procedure.

New Lambda 365 UV-Vis spectrometer with UOQ

For all laboratories under regulatory environment; it is worth having the consideration for latest Lambda 365 UV-Vis spectrometer with state-of-the-art UV/Vis performance that meets the needs of pharmaceuticals, analytic chemists, geneticists, and manufacturing QA/QC analysts. It has following salient features which suit the USP <857> criteria:

- Wavelength range 190 to 1100 nm with accuracy of +/- 0.1 nm
- True double beam sealed optics with low stray light
- Variable slit width 0.5, 1, 2 ,5, 20 nm
- Dual Silicon photo diodes and wider dynamic range up to 4 Abs
- Wavelength scan, scanning kinetics, bio-applications, quantification etc. standard functions
- Wide range of accessories for solid and liquid samples and remote measurement capability
- Fully controlled by PC with Windows' 7 or 8 environments

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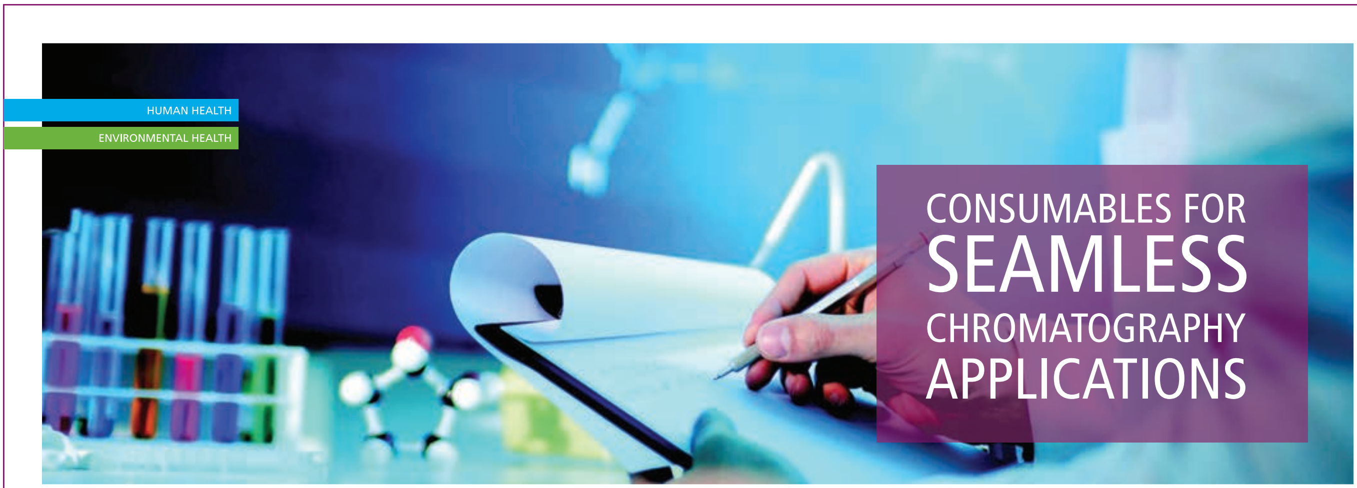
PerkinElmer UOQ offering

- The UOQ for UV Protocol and Qualification Report irrespective of manufacturer
- All of the test procedures and formula descriptions are embedded in the Protocol
- An automated, fully-configurable, fast and secure method to qualify instruments utilizing your existing data acquisition
- Easy review and automated calculations as well as pass/fail determination
- UOQ for UV can be delivered on any standard UV-Vis Spectrophotometer made by PerkinElmer or other manufacturers
- Ultra secure smart PDF report format with unique ID and digital certificate
- UOQ for UV meets USP <857>, EP and JP regulations

For further information and upgrade of your existing Lambda UV-Vis spectrophotometer for USP <857>, request contact

References

http://www.usp.org/usp-nf/development-process/publication-comment-schedule



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- FlowMark electronic flow meters provide continuous real-time measurements of gas streams flow ranging from 0.50 mL/min to 500 mL/min.
- Compact handheld electronic gas leak detector is the ideal solution for detecting gas leaks in your gas chromatography systems.

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Pharmaceuticals

Determination of Cholesterol Level in Human Serum - Enzymatic Colorimetric Method

Introduction

Clinical chemistry uses chemical processes to measure levels of chemical components in the blood. It is very useful for the early diagnostic of disease and for monitoring organ function. The most common specimens used in clinical chemistry are blood and urine. Table 1 shows the common blood tests and measurable items using UV/Vis spectrophotometers. In this application note, the cholesterol level in human serum was determined by the enzymatic method using the LAMBDA™ 465 UV/Vis Spectrophotometer and UV Lab™ software.

Principle

The cholesterol esters of the sample are hydrolyzed by cholesterol esterase. 4-Cholesten-3-one and H_2O_2 are then formed from the released free cholesterol by cholesterol oxidase. A measurable red quinoneimine derivative, that has an absorbance at 500 nm, is formed from hydrogen peroxide (H_2O_2) and 4-aminoantipyrine in the presence of phenol and peroxidase.

Cholesterol levels in serum are calculated using Equation 1. (Normal range : 130 - 250 mg/dL)

Equation 1

$$\text{Cholesterol Level (mg/dl)} = \frac{\text{Absorbance of Sample}}{\text{Absorbance of Standard}} \times 300 \cdots (1)$$

A schematic representation of the reaction is shown in Equation 2.

Equation 2

$$\text{Cholesterol ester} \xrightarrow{\text{Cholesterol esterase}} \text{Cholesterol} + \text{fatty acids}$$

$$\text{Cholesterol} \xrightarrow{\text{Cholesterol oxidase}} \text{Cholest-4-en-3-one} + H_2O_2$$

$$2H_2O_2 + \text{Phenol} + \text{4-Aminoantipyrine} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + 4H_2O$$

Reagents and Apparatus

1. Cholesterol buffer solution (Cholesterol kit, 100 mL) - phenol 132 mg, NaH2PO4 0.78g, NaH2PO4 0.71 g
2. Enzyme reagent (Cholesterol kit, 100 mL dilution) - cholesterol oxidase 12 unit, cholesterol esterase 3.5 unit, peroxidase 6700 unit, 4-aminoantipyrine 17.0 mg/dL
3. Cholesterol standard solution (Cholesterol kit) - 300mg/dL
4. Human serum sample
5. D.I water
6. Water bath
7. LAMBDA 465 (UV/Vis Spectrophotometer)
8. UV Lab software
9. Cuvettes (10 mm pathlength)

Procedure

1. Prepare an enzyme solution by dissolving the enzyme reagent to 100 mL in the cholesterol buffer solution.
2. Prepare the mixture as shown in Table 2.
3. Place in a water bath at 37°C for five minutes.
4. Measure blank solution.
5. Measure standard solution.
6. Measure sample solution.
   (Perform the measurement quickly, within one hour).

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Table 1. Common blood tests and measurable parameters using UV/Vis spectrophotometer.

Common Blood Tests	Tests using UV-Vis Spectrophotometer
WBC, RBC, Hb, HCT, MCV, MCH, MCHC, Platelet, GOT, SGPT, ALP, y-GTP, Total protein, Albumin, Total bilirubin, BUN, Creatinine, Uric acid, Total cholesterol, Triglyceride, LDH, CPK, Amylase, Glucose, VDRL, anti-HIV, HBs Ag, HBs Ab, Fe, P, Ca, Mg	Hb, SGOT, SGPT, ALP, y-GTP, Total protein, Albumin, Total bilirubin, Creatinine, Uric acid, Total cholesterol, Triglyceride, LDH, Amylase, Glucose, Fe, P, Ca, Mg

Table 2. Mixture preparation for measurement.

Common Blood Tests	Blank	Standard	Sample
Enzyme sol.	3	3	3
D.I Water	0.02		
Cholesterol std.		0.02	
Serum Sample			0.02

Result

Figure 2 shows the spectra of cholesterol. The absorbance values and cholesterol level of serum sample are shown in Table 3. The determined cholesterol level in serum is 253.84 mg/dL calculated using Equation 1.

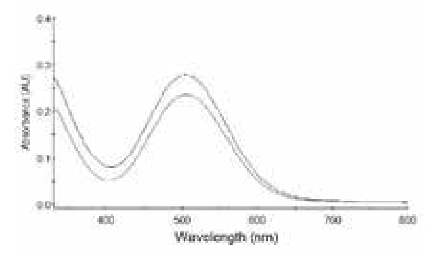


Figure 2. Absorption spectra of cholesterol by enzymatic colorimetric method.

Table 3. Cholesterol level in human serum.

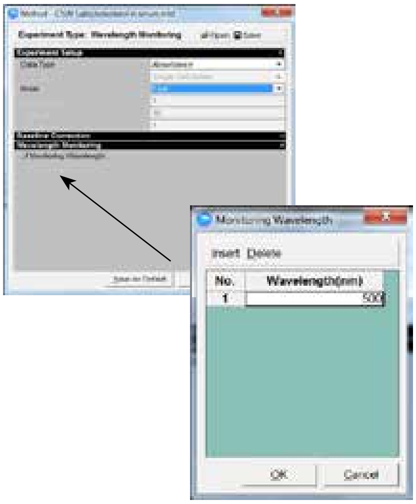
Name	AU(500 nm)	Concentration (mg/dL)
Standard	0.2775	300
Serum Sample	0.2348	253.84

Instrument Parameters

The LAMBDA 465 instrument parameters are as follows. Figure 1 shows experimental method.

Experiment Setup

Data type: Absorbance
Sampling: Single cell
Mode: Scan no. : 30; Integration no. : 1



Experiment Type: Wavelength Monitoring

Monitoring Wavelength

No.	Wavelength(nm)
1	500

Figure 1. Experimental method.

Conclusion

The determination of cholesterol level in human serum by enzymatic colorimetric method was performed using the LAMBDA 465 UV/Vis spectrophotometer and the UV Lab software. After the reaction, the measurement time was minimized using the LAMBDA 465, enabling us to collect data quickly over the full wavelength range from 190 to 1100 nm. Data processing was performed effectively by the powerful and easy to use software. The calculated cholesterol level by Equation 1 was slightly higher than the normal expected range (130 - 250 mg/dL).

*This application note is for research purpose only.

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Food Testing

Expanding Food Testing Capabilities further with Perten Instruments

We are very pleased to announce that PerkinElmer Inc. has entered into definitive agreement to acquire Perten Instruments Group AB, based in Stockholm, Sweden. By adding Perten's analysis platforms, along with its leading food quality calibration database to the existing portfolio of analytical instruments, we are now holistically equipped to firmly assist our customers in addressing rigorous regulations for food quality control, import/export product testing and the need to preserve the integrity of global supply chains.

Perten is a leading global supplier of advanced analytical instruments for quality of food, grain, flour and feed. Typical offerings include:

1. NIR Analyzers (Lab, On-line and In-line)
2. Falling Number System
3. Lab Mills
4. Texture Analyzer
5. Glutomatic System
6. Food Viscosity Analyzer

Inexpensive sample modules with quick changeover and minimal clean-up.

The new DA 7250 NIR analyzer is the third generation diode array NIR instrument from Perten, designed specifically for analysis in the food and agri industries. The DA 7250 comes pre-calibrated for a wide range of applications, and determines following:

Parameters: Moisture/Dry Matter, Protein, Fat/Oil, Ash, Fiber, Starch, Amino Acids, Fatty Acids, Sugars, Brix, Lactose, and more.

Samples: Grains, Pellets, Powders, Pastes, Slurries, Liquids and more, the DA 7250 excels in dusty, dirty and otherwise challenging environments.

- Minimal or no sample preparation
- No moving optical components
- Rapid and Non-Contact analysis in seconds
- Factory calibrations available for wide range of applications
- Global database of more than 100,000 samples
- IP 65 certified for dust and water resistance
- Lab, In-Line and At-Line versions

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News and Event Update

Asia Pharma Expo and DTG-2016, Dhaka, Bangladesh | 28-31st Jan, 2016

This year we participated in Asia Pharma Expo and Textile & Garment Machinery Exhibition to connect with professionals from pharmaceutical and textile industry, which are priority sectors in Bangladesh with textile contributing to 80% of exports earnings and pharma industry gearing up for investments in their manufacturing and testing infrastructure for exploring regulated markets.

IAIA - Anacon Seminar Series, Vapi, Gujarat | Environmental Monitoring and Analysis | 27th Feb, 2016

This was the 1st of planned seminar from series and the topic was much suited to current issues for Vapi industrial area where chemical industries are the main cause of pollution. Eminent speakers from various industries and organizations presented the concerns and solutions related to environment. We discussed solutions for monitoring RoHS to all the industries and our day to day appliances disposal with emphasis on unique speciation capabilities.

ICEFN-16, Kumaun University, Nainital and ICNANO-2016 @ VTU, Bangalore

We sponsored two international conferences on Nanotechnology which is widely discussed due to its range of applications, but as with any new technology, nanotechnology has also raised many concerns about toxicity and environmental impact of nanomaterials. Our focus was on application capabilities of SP-ICPMS, to identify and measure nano-particles (ENP's, Ag, TiO2 etc.) in waste water, cosmetics, dietary supplements etc.

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NCL, Pune Service and PU, Chandigarh UV Vis and FTIR Workshop | April, 2016

Recently, we organized service camp in National Chemical Laboratory, Pune for instrument health checkup, to discuss the concerns and recommend preventive steps to end-users for instrument maintenance. Team also suggested suitable consumables and importance of AMC/CMC for longer instrument life and minimal downtime.

Sophisticated Analytical Instrumentation Facility (SAIF), Panjab University, conducted a week long workshop on spectroscopy techniques participated by 70 faculty members and SRF's from PU, SLIET, IACS etc. Since we have UV Vis-Lambda 750 and FTIR + FIR-Spectrum 400 installed in PU, so we supported them with two days hands on application and troubleshooting training session, executed by Pratik Deshmukh and Amarinder Singh with Sales and Marketing support.

Enhancing Analytical Capabilities Seminar, Visakhapatnam | 29th April, 2016

Last year we started with "Enhancing Analytical Capabilities" seminar series with an objective of:

- Updating our customers with instrumentation and application capabilities of existing analytical techniques and new technological advancements for enhanced applications, through 30-35 min presentation each on key technologies.
- To give an overview on addressing regulatory challenges using existing and advanced analytical techniques

Continuing with same this year, seminar was conducted in Visakhapatnam on 29th April, 2016 evening at Hotel Fortune Inn Sree Kanya. We had around 130 attendees from pharmaceutical organizations in Vizag, followed by interaction with cross functional teams (application, consumable, sales, service) over dinner.

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