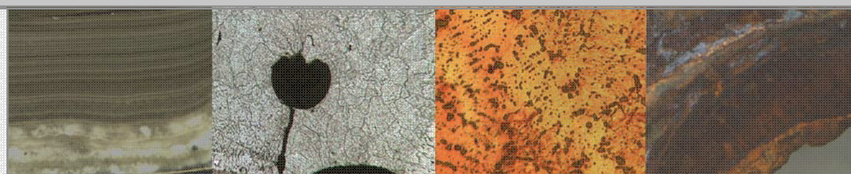
NUTS & BOLTS



Decontaminating biomedical and Pharmaceutical products

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Supplement Issue

New Hampshire MATERIALS LABORATORY, INC.
Your Problem Solving Partner

Welcome to New Hampshire Materials Laboratory

In the manufacturing of medical devices, contaminants are a source of aggravation. New Hampshire Materials Laboratory will often receive a request from a quality control manager for help to identify an unknown contaminant that was found during production.

In this Nuts & Bolts article, we'll share how our chemistry department helps our medical device customers find the answer to this problem.

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Laboratory Director

Decontaminating Biomedical and Pharmaceutical Products

The biomedical and pharmaceutical industries, understandably, require strict quality control for product manufacturing. Drug delivery packaging and equipment must be free of contaminants that will interfere with medication delivery. Implant manufacturers need to be sure that remnants of manufacturing process fluids – fluids which might cause rejection or reaction for the implant's recipient – don't remain on their final products after manufacturing is completed. Developers of medical and pharmaceutical devices need to be confident that the products they build won't fall apart – devices that have a tiny bit of manufacturing grease remaining in an area where adhesive is used to glue two parts together will often experience adhesion failure when doctors or patients try to actually use such devices. →

NHML's Chem Lab often sees clients coming in with challenges in these areas – where contaminants are a looming source of pain for quality assurance and control departments. Testing for our biomedical and pharmaceutical clients, as a result, is often focused on contaminants: Are they present in a manufactured product? What are they? Where did they come from? In this article, we'll share how NHML's Chem Lab answers these questions.

Testing technology

When confirming or identifying a contaminant, we use two main testing techniques: Fourier Transform Infrared spectroscopy (FTIR) and Energy Dispersive Spectroscopy (EDS). When we use one approach or the other depends entirely on the type of materials our clients' products use and the questions we need to answer about those materials.

FTIR - Fourier Transform Infrared Spectroscopy

We can use FTIR to 'fingerprint' almost any liquid, in addition to all organic (meaning carbon-based) solids. To describe how this works more fully, let's start with some basic chemistry. All molecules are made up of atoms that are bonded together. Different atoms and bond structures are what define one material or chemical as "different" from another. Every material we see around us has its own unique molecular bond structure. Some bonds between atoms are stronger, some weaker. Some materials are comprised of only a few elements (like water, which uses only hydrogen and oxygen) and some are highly complex blends of very high numbers of bonds and elements.

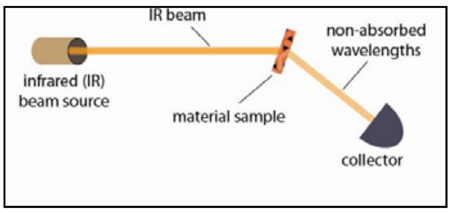

Figure 1: Simple diagram depicting FTIR process

In FTIR, an infrared (IR) beam of light is passed through either a liquid or solid sample of the material we're examining (for solids, the samples are sliced thin enough that the light does actually pass through them). As this beam passes through the sample, the energy in the infrared light interacts with and 'excites' the molecular bonds, causing the actual bonds to move like springs and vibrate. Different bonds absorb energy differently: some more strongly or more weakly, some have more energy absorption or less energy absorption. In FTIR, the IR energy that isn't absorbed by the bonds passes straight through the sample and is 'read' by a collector on the other side of the sample (see Figure 1). **This reading produces an absorption plot to view the plots and case history click here.**

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Where every material has its own particular molecular structure (i.e. atoms and bond structure), every material will absorb the infrared energy differently and uniquely, which means that every material will have its own unique absorption plot or 'fingerprint'. If you have an uncontaminated sample containing only the type of plastic which should be present in a pill bottle, for example, you can compare this ***control*** sample to a potentially contaminated ***test*** sample to see if the plots look the same or not. Identical plots would indicate that the ***test*** sample is identical to the ***control*** sample – not contaminated. Plots that don't look similar could indicate a contaminant and a quality control problem.

Even if we don't know exactly what the contaminant is at this point, FTIR can give us some information on what the contaminating material's molecular bond structure is like. If we have additional knowledge regarding what percentage of the contaminated sample is comprised by what elements (For example: 20% hydrogen, 30% oxygen, 5% carbon, etc.), combining this elemental data with the FTIR bond structure data can help us identify what an unknown contaminant material is. So how does NHML get this elemental data from a mysterious material sample? With EDS.

EDS - Energy Dispersive Spectroscopy

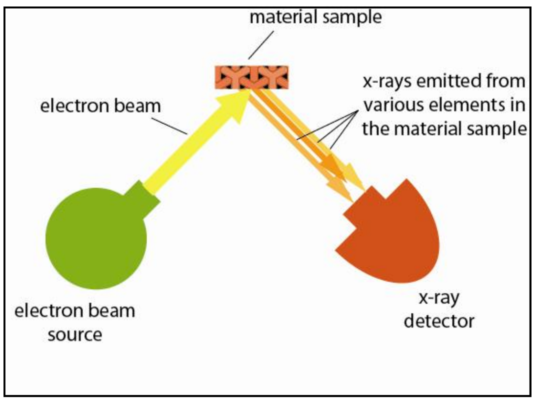

Figure 2: Simple diagram depicting the EDS process

EDS can be used to help identify what individual base elements are present in many materials: metals, plastics, polymers, elastomers. In EDS, a material sample is first bombarded by a beam of electrons. In response to this, the individual elements in the material sample emit x-rays (see Figure 3). Each element in the **periodic table** emits x-rays at its own specific frequency and intensity. EDS detects these individual intensities and measures how much of which elements are in the material sample. EDS can do this for all elements that are heavier than boron (starting with carbon) in the periodic table. The outcomes are a plot and elementary information data like that seen in an **EDS Spectra to view click here.** →

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As you can see, the data tells us exactly what elements are present, and it also gives us some information on how much of those elements are present in the material. EDS can be used for manufacturing quality control in a manner similar to the FTIR approach (using paired *control* and *test* material sample plots) and is often used to identify the inorganic (non-carbon based) contaminant materials, which the FTIR equipment can not identify.

Combined EDS & FTIR Testing

In some cases, we might pair EDS with FTIR to help diagnose what a specific contamination is or to help clients track down the source of a specific contaminant. For example, say we had a client come to us because they can see some kind of dark speck of material in their plastic, molded medical device. We can test the ‘speck’ using EDS to identify how much of which elements are present in the contaminant and pair that elemental information with FTIR data that tells us how the atoms are bonded together. From this, we can glean information about what kind of potential materials the ‘speck’ might be – rust, burnt plastic that has been overheated during a blow molding process, maybe a coating that is flaking off manufacturing equipment and falling into the manufacturing line, and so on.

Click here to find out where this testing is applicable and some cases where NHML’s lab can and has helped biomedical and pharmaceutical clients.

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