Austin Journal of Analytical and Pharmaceutical Chemistry

Open Access

Austin Publishing Group

Short Communication

# Infrared Spectroscopy - A Boon to Medical Device Characterization

**Amarjit Luniwal***
Medical Research Manager, NAMSA, 6750 Wales Rd, Northwood, Ohio 43619, USA

***Corresponding author:** Amarjit Luniwal, Medical Research Manager, NAMSA, 6750 Wales Rd, Northwood, Ohio 43619, USA

**Received:** February 13, 2017; **Accepted:** February 17, 2017; **Published:** February 20, 2017

## Short Communication

In the year 2016, the Federal Drug Administration finalized the guidance document to help medical device industry and to provide clear expectations on the utilization of International Standard ISO 10993-1, "Biological evaluation of medical devices – part 1: Evaluation and testing within a risk management process." The guidance document stipulates FDA's expectations and recommendations for biological safety and biocompatibility evaluation of medical devices in preparing Premarket Applications (PMAs), Humanitarian Device Exceptions (HDEs), Investigational Device Applications (IDEs), Premarket Notifications (510(k)s), and de novo request for medical devices that come into indirect or direct contact with the human body. These evaluations are required to establish a risk for an intolerable adverse biological reaction resulting from contact of the component material of the device with the body.

Medical Devices are typically made using a variety of materials and processing agents and undergo numerous complex manufacturing processes. Risk for the intolerable adverse biological response from the components of devices to the body comes these potential extractables and leachables chemical entities. Per the ISO-10993 and US FDA guidance recommends a device is extracted in a polar such as saline and a non-polar such as sesame oil extraction medium under exaggerated clinical use conditions. The new FDA guidelines put special emphasis on the conditions of the extracts and require that if particulates be characterization if observed.

There are several factors that may contribute to the formation of particulates during extractions. The ISO 10993 guidelines recommend that a device be subdivided into small pieces so that the test sample can be fully submerged during extraction process. The process of subdivision has potential for generation of particulates. A stainless steel based device may lead to corrosion during extraction especially in saline (0.9% Sodium chloride solution) extraction as presence of salt facilitates the process of corrosion under typical extraction conditions which are typically 50°C for 72 hours. If physical and chemical characteristics of a device permit then the extraction conditions can be performed at 70°C for 24 hours or 121°C for 1 hour. The process of corrosion causes formation of iron oxides particulates as extraction is typically performed under atmospheric conditions. Additionally, particulates can also form due to precipitation of leached extractable and leachable due to cooling of extracts at room temperature. However, most predominant source of particulates in a plastic device is use of various adhesive to join different components together. Typically adhesives used in manufacturing of devices are acrylate based that solidify upon curing.

FTIR (Fourier Transform Infrared) Spectroscopy has turned out to be a technique of choice for characterization of particulates formed during extraction process of medical devices. That is mainly because a wide range of samples such as solids, liquids, and gases can be qualitatively identified using IR techniques. The technique of Attenuated Total Reflectance (ATR) has in recent years revolutionized solid and liquid sample analyses because it has significantly simplified sample preparation. Almost no sample preparation is required to obtain high quality spectrum using this technique. That's why this technique has special use in characterization of particulates formed during extraction as an isolated particulate can be directly analyzed.

Recently, we were able to use this technique for qualitative identification of a methyl acrylate based adhesive used in the manufacturing of a device. The device was subdivided for extraction and white particulates were observed during extraction. The IR library database was utilized to find a matching spectra and the identification was confirmed using a representative reference spectra.




**Citation:** Luniwal A. Infrared Spectroscopy - A Boon to Medical Device Characterization. Austin J Anal Pharm Chem. 2017; 4(1): 1081.