

A woman with dark curly hair, wearing safety glasses and a dark blue lab coat, is focused on adjusting a piece of scientific equipment. The equipment has a green component and a black handle. The background is a blurred laboratory setting.

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Materials Characterization and Analytical Chemistry

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NAMSA Characterization Matrix

Materials characterization testing establishes a baseline fingerprint for a material so that the results of biological testing can be firmly linked to a specific formulation. The identifying characteristics of this formulation can then be used as a manufacturing specification for the device.

Our characterization matrix provides general guidance in determining which tests should be performed, relative to the end use of a device or material. The degree of characterization performed on a device should reflect the type and condition of its exposure to human tissue and fluids.

Our chemistry laboratories provide analytical support for the development and a quality audit of medical devices, reagents, and excipients. Most of our work in this area is instrumental analysis of

polymers and other product components for purity, uniformity, composition, sterilant residues, and general extractables. Results characterize the material, giving it identity and reproducibility in product manufacturing.

GUIDELINES AND STANDARDS REFERENCE

Our materials characterization testing follows these guidelines and standards:

- U.S. FDA Blue Book Memorandum GP#95-1
- ISO Standard 10993-1, "Biological Evaluation of Medical Devices"
- ISO Standard 10993-18, "Chemical Characterization of Materials"
- FDA Guidance Document, "Container Closure Systems for Packaging Human Drugs and Biologics"

PHYSICOCHEMICAL TESTS

Used to determine the presence of both water-soluble (aqueous extraction) and solvent-soluble (non-aqueous extraction) substances, physicochemical tests are used to characterize and compare polymeric materials to one another or to audit materials.

EXHAUSTIVE EXTRACTION

Used for implants to determine the amount of water soluble and solvent soluble substances that equal $\geq 90\%$ of the total extractables, on a gravimetric basis.

FTIR

Fourier transform infrared spectroscopy (FTIR) is useful for identifying, characterizing, or "fingerprinting" organic chemical structures, and illustrating the vibrational features of all sample components.

HPLC

High-performance liquid chromatography (HPLC) is a form of liquid chromatography used for separating compounds in a solution.

MS

Mass spectrometry (MS) is an analytical detection method that measures the mass-to-charge ratio (M/Z) of ionized atoms or molecules. This technique is used to separate these atoms and molecules from one another.

GC

Gas chromatography (GC) is the separation of vaporizable chemical substances and particles by differential movement through a two-phase absorption system.

ICP

Inductively coupled plasma spectrometry (ICP) is a multi-element analysis technique that dissociates the sample into its constituent atoms or ions, exciting them to a level where they emit light of a characteristic wavelength.

PHYSICAL and MECHANICAL (INSTRON)

Tensile strength data are usually gathered on plastic formulations or

molded plastic parts in order to avoid failures during the intended use of the device. Besides tensile strength, other physical data, such as elongation and Young's modules, are also obtained from tensile tests.

SPECIFIC GRAVITY

Specific gravity is the ratio of the weight of a substance to the weight of an equal volume of purified water at the same temperature. It is useful in characterizing the identity, purity, and concentration of a material.

DUROMETER HARDNESS

This ASTM method measures the hardness of plastic materials by using a durometer. This is an efficient test often used to check the uniformity of the fabricated material from lot to lot.

GPC

Gel-permeation chromatography (GPC), also known as gel-filtration or size-exclusion chromatography, is an analytical method used to analyze the molecular weight and molecular weight distribution in a plastic formulation to assure product uniformity.

VISCOSITY

In general, viscosity is defined as the resistance to or alteration of flow by any substance as a result of molecular cohesion. The term is most frequently applied to liquids as the resistance of a fluid to flow because of a shearing force.

SEM/XRD

Scanning electron microscopy (SEM) is a direct examination of surface topography that provides a unique understanding of a material's characteristics, appearance of interfaces, solvent bonds, surface finish, and particle sizing below the limits of light microscopy. X-ray diffraction (XRD) is commonly used to identify solid and liquid materials and to determine their composition.

DSC

Differential scanning calorimetry (DSC) is an analytical method that independently measures the rate of heat flow to a sample against a reference standard of the same temperature. DSC

E Extractable

An extract of the device is prepared and characterized, resulting in a fingerprint that can be interpreted as being bioavailable.

M Material

(Ceramics, Metals, and Polymeric Materials) In addition to extractables, materials are characterized and evaluated for their physical and mechanical properties, surface morphology, thermal properties, etc.

P Polymeric Material

The individual unaltered device component is used for characterization. Test procedures indicated with P are appropriate for polymeric materials only.

DEVICE CATEGORIES					CHEMICAL/MATERIAL CHARACTERIZATION TEST PROCEDURES												
BODY CONTACT	Exhaustive Extraction	Physicochemical	FTIR	Organic Additive Identification					ICP	Physical Tests			Mol. Weight		SEM/XRD	DSC	
				HPLC-MS	HPLC-IC	GC Headspace	GC-FID	GC-MS		Physical/Mechanical	Specific Gravity	Durometer Hardness	GPC	Viscosity			
SURFACE DEVICES	SKIN	E	E/M														
	MUCOSAL MEMBRANE	E	E/M														
	BREACHED OR COMPROMISED SURFACES	E	E/M														
EXTERNALLY COMMUNICATING DEVICES	BLOOD PATH, INDIRECT	E	E/M	E	E	E	E	E	E	E	M						P
	TISSUE/ BONE/DENTIN COMMUNICATING	E	E/M	E	E	E	E	E	E	E	M						P
	CIRCULATING BLOOD	E	E	E/M	E	E	E	E	E	E	M	M	P	P	P	M	P
IMPLANT DEVICES	TISSUE/BONE	E	E	E/M	E	E	E	E	E	E	M	M	P	P	P	M	P
	BLOOD	E	E	E/M	E	E	E	E	E	E	M	M	P	P	P	M	P

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We've worked with thousands of companies to date—bringing safe, effective, and compliant medical products to market. We are passionate about our people, our scientific integrity, and the breadth of solutions we offer our clients globally. And we're ready. Ready to take you to market.

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