



Graver Technologies

Technical Brief

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Understanding USP, FDA and NSF

Filters used in food, beverage and pharmaceutical applications, should comply with relevant guidelines and standards for those industries. In order to comply, the filter must typically be tested according to standard test methods, or the components must be tested as prescribed by a recognized entity. This guidance is set forth by several organizations that include the US Food and Drug Administration (FDA), the United States Pharmacopeia (USP) or NSF International.

USP

The United States Pharmacopeia (USP) is a non-governmental, not-for-profit public health organization that is an official public standards-setting authority for all prescription and over-the-counter medicines and other health care products manufactured or sold in the United States. The USP also establishes standards for food ingredients, dietary supplements and materials that come in contact with food during the manufacturing process or as packaging materials. The reference standards are updated in official monographs in the USP-NF, and these standards and procedures are enforceable by the U.S. Food and Drug Administration (FDA). Since 2002, the standards have been published annually although prior to that, it was as infrequent as every 10 years.

For filters composed primarily of plastic parts, the relevant portion of the USP monograph is Chapter 88, *Biological Reactivity Tests, In Vivo Classification of Plastics* (Class 1 to VI). The testing consists of three parts, intravenous systemic injection, intracutaneous test and implantation test. The first portion of the test requires an extraction in saline, alcohol in saline, polyethylene glycol and cottonseed oil which is then injected in mice and rabbits to determine if there is a reaction as compared to a blank. The last portion of the test is to implant the filter material under the skin of a rabbit and again determine if there is a reaction. A negative response on all of the tests

signifies the material is suitable for contact with parenteral preparations, use in medical devices, implants and other systems. Customers in the pharmaceutical and biotech businesses will typically look for filters that meet USP guidelines.

FDA

FDA, an agency within the US Department of Health and Human Services, is responsible for ensuring that foods, cosmetics and electronic products are safe, and that human and veterinary drugs, biological products, and medical devices are safe and effective. FDA also ensures that these products are honestly and accurately represented to the public. While filters and filter manufacturing is not monitored by the FDA, the processes in which they are used may fall under FDA review. Since filters come into contact with food and pharmaceuticals, there are standards that are relevant.

The Code of Federal Regulations (CFR) is a set of general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration. Each title (or volume) of the CFR is revised once each calendar year.

For filters utilized in the manufacturing of food and beverage products, Parts 174, *Indirect Food Additive - General*, and Part 177, *Indirect Food Additives - Polymer* are relevant. These sections describe the materials that are permissible to be utilized for food contact as well as the methods for determining the characteristics of the materials. Filters composed of materials other than polymers may fall under different sections between Parts 170 and 189, thus other references may be referenced in filter product literature or certificates of conformance. Note that FDA does not test filters, nor do they approve filters for use. Instead, a filter is deemed FDA compliant if

it is composed entirely of materials of construction that are listed in the appropriate CFR. End users in the food and beverage and pharmaceutical markets will demand products that consist of all FDA listed materials of construction.

21 CFR 314.420 also provides for the Drug Master File (DMF). This is a submission to the Food and Drug Administration (FDA) that may be used to provide confidential or detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storage of a human drug. The submission of a DMF is not required by law or FDA regulation, and does not impose mandatory requirements nor is it approved or disapproved by the FDA. Rather, the DMF is generally created to allow a party, other than the holder of the DMF, to reference material without disclosing to that party the contents of the file. The information contained in the DMF may be used to support an Investigational New Drug Application (IND), a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), another DMF, an Export Application, or amendments and supplements to any of these. Much of the information included in the DMF would be highlighted in a validation guide that is generally available with filters used in pharmaceutical applications.

NSF

NSF International is a not-for-profit, non-governmental organization that sets the standards for development, product certification, education, and risk-management for public health and safety for food, water, indoor air, and the environment. NSF standards describe minimum performance requirements as well as methodology for evaluating products. For filtration purposes, these standards typically come into play when addressing the filtration of municipal water, for residential water

treatment systems and for filtration of bottled water. The three standards that most commonly apply to process filters are NSF 42, NSF 53 and NSF 61. Customers involved with municipal drinking water, residential water treatment and food and beverage manufacturing will sometimes request NSF certified products.

NSF/ANSI Standard 42, *Drinking Water Treatment Units - Aesthetic Effects* covers point-of-use (POU) and point-of-entry (POE) systems designed to reduce specific aesthetic or non-health-related contaminants (chlorine, taste, odor, and particulates) that may be present in public or private drinking water. While this standard is typically applied to residential systems, the testing utilized for extraction is similar to that in NSF 61 and thus has relevance to a process filter.

NSF/ANSI Standard 53, *Drinking Water Treatment Units - Health Effects* addresses point-of-use (POU) and point-of-entry (POE) systems designed to reduce specific health-related contaminants, such as *Cryptosporidium*, *Giardia*, lead, volatile organic chemicals (VOCs), and MTBE (methyl tertiary-butyl ether), that may be present in public or private drinking water. Most often this standard is referenced to document the capabilities of filters to remove cysts.

NSF/ANSI Standard 61, *Drinking Water System Components - Health Effects* establishes minimum health effect requirements for the chemical contaminants and impurities that may be indirectly imparted to drinking water. The standard provides the criteria used to evaluate the public health safety of materials, components, products, or systems that contact drinking water, drinking water chemicals, or both. The extraction methods utilized in this standard are similar to that of NSF 42.

For more information on USP, FDA and NSF standards and guidelines, use the following links:

www.nsf.org

www.usp.org

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm