

Single-Use Bioprocessing Systems Definitions

AAMI

Association for the Advancement of Medical Instrumentation

ANSI

American National Standards Institute

ASTM

American Society for Testing and Materials

Bacterial Endotoxin

USP <85>, Bacterial Endotoxins Test – Estimates the concentration of the bacterial endotoxins that may be present in or on the sample of the test article by using the Limulus Amebocyte Lysate (LAL) method.

Brittleness Temperature

ASTM D 746, Standard Test Method for Brittleness Temperature of Plastics and Elastomers by Impact – To determine the temperature at which plastics and elastomers exhibit brittle failure under specified impact conditions.

ASTM D 1790, Standard Test Method for Brittleness Temperature of Plastic Sheeting by Impact – To determine the temperature at which plastic sheeting 1mm or less in thickness exhibits a brittle failure under specified impact conditions.

cGMP

Current Good Manufacturing Practice – The basic principles, procedures and resources required to ensure an environment suitable for manufacturing products of an acceptable quality. These regulations govern the standards of design, operation, practice and sanitization set forth by the Federal Government of the US which outline general requirements that manufacturers of medical devices must follow to assure the highest quality attainable.

CO₂ Transmission Rate

ASTM F 2476, Standard Test Method for Carbon Dioxide Gas Transmission Rate Through Barrier Materials Using and Infrared Detector – To determine the steady-state rate of transmission of carbon dioxide gas through plastics in the form of film, sheeting, laminates, coextrusions, or plastic-coated papers or fabrics. Carbon dioxide permeability was measured at 23C with 0% relative humidity on both sides of the film.

Cytotoxicity – MEM Elution

USP <87>, Biological Reactivity Tests, In Vitro – To determine the biological reactivity of mammalian cell cultures following contact with the elastomeric plastics and other polymeric materials with direct or indirect patient contact or of specific extracts prepared from the material under test.

Density

ASTM D 1505, Standard Test Method for Density of Plastics by the Density-Gradient Technique – To determine the density of solid plastics by observing the level to which a test specimen sinks in a liquid column exhibiting a density gradient, in comparison with standards of known density.
ASTM D 792, Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement – To determine the specific gravity (relative density) and density of the film.

Elongation

ASTM D 882, Standard Test Method for Tensile Properties of Thin Plastic Sheeting – To determine the tensile properties of plastics in the film. This test method covers the determination of tensile properties of plastics in the form of thin sheeting, including film (less than 1.0 mm in thickness).

EP

European Pharmacopoeia

European Pharmacopoeia

Established in 1964, the European Pharmacopoeia was set up to harmonize medical standards to make drugs safer for the consumers. The harmonization, with the implied national requirements, also has the advantage of facilitating imports and exports of medicines. The European pharmacopoeia, in collaboration with the EU, is mainly concerned with the quality aspect of European medicines policy and covers all phases from composition, manufacturing, marketing and quality control.

EP <3.2.2.1>, Plastic Containers for Aqueous solutions for Parenteral Infusion – To confirm the compatibility of the container and the contents and to ensure that there are no changes detrimental to the quality of the preparation, various tests are carried out such as verification of the absence of changes in physical characteristics, assessment of any loss or gain through permeation, detection of pH changes, assessment of changes caused by light, chemical tests and, where appropriate, biological tests.

FDA

Food and Drug Administration. The FDA is a federal agency responsible for protecting public health by assuring the safety, efficacy and security of human and veterinary drugs, foods and cosmetics.

FTMS

Federal Standard Test method

Hemolysis

ISO 10993-4, Selection of Tests for Interactions with Blood

– It describes a classification of medical and dental devices that are intended for use in contact with blood, based on the intended use and duration of contact as defined in ISO 10993-1, the fundamental principles governing the evaluation of the interaction of devices with blood and the rationale for structured selection of tests according to specific categories, together with the principles and scientific basis of these tests.

ISO

International Organization for Standardization

ISTA

International Safe Transit Association

JP

Japanese Pharmacopoeia

Japanese Pharmacopoeia Provides the official Japanese standard for the description and quality of drug substances and products.

JP <61>, Test methods for plastic containers: Polyethylene or polypropylene containers for aqueous injections – A set of tests that may be used for designing and quality assurance of plastic containers.

Modulus at 100% Elongation

ASTM D 1004, Standard Test Method for Initial Tear Resistance of Plastic Film and Sheeting – To determine the tear resistance of flexible plastic film and sheeting at very low rates of loading. Designed to measure the force to initiate tearing. The specimen geometry of this test method produces a stress concentration in a small area of the specimen. The maximum stress, usually found near the onset of tearing, is recorded as the tear resistance in Newtons.

O₂ Transmission Rate

ASTM D 3985, Standard Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using a Coulometric Sensor – To determine the steady-state rate of transmission of oxygen gas through the film. Oxygen permeability was measured at 23C with 0% relative humidity on both sides of the film.

Physicochemical

USP <661>, Containers: Physicochemical Tests – Plastics – The tests are designed to determine physical and chemical properties of plastics and their extracts and are based on the extraction of the plastic material.

Puncture Resistance

FTMS 101C Method 2065.1, Puncture Test – Measurement of the load required to puncture film. It is used to simulate everyday puncture failure or as a quality control method on film.

Tear Resistance

ASTM D 1004, Standard Test Method for Initial Tear Resistance of Plastic Film and Sheeting – To determine the tear resistance of flexible plastic film and sheeting at very low rates of loading. Designed to measure the force to initiate tearing. The specimen geometry of this test method produces a stress concentration in a small area of the specimen. The maximum stress, usually found near the onset of tearing, is recorded as the tear resistance in Newtons.

Tensile Strength

ASTM D 882, Standard Test Method for Tensile Properties of Thin Plastic Sheeting – To determine the tensile properties of plastics in the film. This test method covers the determination of tensile properties of plastics in the form of thin sheeting, including film (less than 1.0 mm in thickness).

USP

United States Pharmacopoeia

USP Class VI

Designed primarily as a means of evaluating plastics used in drug packaging, "USP Class VI" refers to a battery of biological tests defined in USP XXIII, part 88. Any food-grade material which means most silicones that has passed this test series can be designated USP Class VI. The series is a four-part evaluation involving animal (mouse and rabbit) testing of extracts of saline, vegetable oil, alcohol, and polyethylene glycol along with a 5-day rabbit intramuscular implantation test. While this level of testing is widely used and accepted in the medical products business, the significance of the results and their level of safety assurance for medical devices are limited. For example, it would be possible for a material to pass USP Class VI while still showing up as cytotoxic, mutagenic, hemolytic, or sensitizing in other biological testing.

USP <88>, Biological Reactivity Tests, In Vivo – To determine the biological response of animals to elastomers, plastics and other polymeric material with direct or indirect patient contact, or by the injection of specific extracts prepared from the material under test. The tests are applied to materials, if there is a need for classifications of plastics on in vivo biological reactivity testing.

Water Vapor Transmission Rate

ASTM F 1249, Standard Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor – To determine the rate of water vapor transmission through flexible barrier materials. Water vapor permeability was measured at 23C with 0% relative humidity on the outside of the film and 100% relative humidity on the inside of the film.