

# Physical Testing and Definitions

Test Description	Test Standard	Definition
Tensile Strength Elongation	ASTM D 882 ASTM D 882	<b>Standard Test Method for Tensile Properties of Thin Plastic Sheeting</b> – 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).
Tear Resistance Modulus at 100% Elongation	ASTM D 1004 ASTM D 1004	<b>Standard Test Method for Initial Tear Resistance of Plastic Film and Sheeting</b> – 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.
Puncture Resistance	FTMS 101C Method 2065.1	<b>Puncture Test</b> – Measurement of the load required to puncture film. It is used to simulate everyday puncture failure or as a quality control method on film.
Brittleness Temperature	ASTM D 746 ASTM D 1790	<b>Standard Test Method for Brittleness Temperature of Plastics and Elastomers by Impact</b> – To determine the temperature at which plastics and elastomers exhibit brittle failure under specified impact conditions. <b>Standard Test Method for Brittleness Temperature of Plastic Sheeting by Impact</b> – To determine the temperature at which plastic sheeting 1 mm or less in thickness exhibits a brittle failure under specified impact conditions.
Density	ASTM D 1505 ASTM D 792	<b>Standard Test Method for Density of Plastics by the Density-Gradient Technique</b> – 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. <b>Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement</b> – To determine the specific gravity (relative density) and density of the film.
O <sub>2</sub> Transmission Rate	ASTM D 3985	<b>Standard Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using a Coulometric Sensor</b> – To determine the steady-state rate of transmission of oxygen gas through the film. Oxygen permeability was measured at 23 C with 0% relative humidity on both sides of the film.
CO <sub>2</sub> Transmission Rate	ASTM F 2476	<b>Standard Test Method for Carbon Dioxide Gas Transmission Rate Through Barrier Materials Using and Infrared Detector</b> – 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 23 C with 0% relative humidity on both sides of the film.

# Physical Testing and Definitions – Cont.

Test Description	Test Standard	Definition
Water Vapor Transmission Rate	ASTM F 1249	<b>Standard Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor</b> – To determine the rate of water vapor transmission through flexible barrier materials. Water vapor permeability was measured at 23 C with 0% relative humidity on the outside of the film and 100% relative humidity on the inside of the film.
Sterility Assurance Level	ANSI/AAMI/ISO 11137	To determine the minimum irradiation dosage necessary to assure product sterility. Quarterly dose audits are performed to reaffirm the sterilization dosage of 25 - 45 kGy to achieve the sterility assurance level of 10 <sup>-6</sup> .
<b>Extractables</b> <ul style="list-style-type: none"> <li>• 1N NaOH</li> <li>• PBS, pH 7</li> <li>• Water for Injection</li> <li>• 1 N HCl</li> <li>• 20% Ethanol</li> </ul>	<b>Model Solvent</b>	<p><b>Model Solvent</b> – Simulates worst-case exposure and conditions. Use of solvents at low, neutral and high pH; increased temperatures; and specific surface area to solvent volume ratios.</p> <p><b>Leachables</b> – Migration of chemicals from packaging or other components into the solvent under normal conditions of use or during stability studies.</p> <p><b>Extractables</b> – Release of chemicals from a container or closure material into the solvent under exaggerated solvent, temperature and time conditions.</p>
Simulated Transit	ISTA, ASTM	Simulation testing for individual containers or unitized (palletized) loads. Data is used to evaluate the performance of the container and its contents as related to vibrations, shocks and other stresses normally encountered during handling and transportation. Tests can include vibration, drop, compression and incline-impact.