

# Biocompatibility Testing and Definitions

Test Description	Test Standard	Definition
<b>USP Class VI</b> <ul style="list-style-type: none"> <li>Intramuscular Implantation</li> <li>Intracutaneous Toxicity</li> <li>Acute Systemic Injection</li> </ul>	USP <88>	<b>Biological Reactivity Tests, In Vivo</b> – To determine the biological response of animals to elastomerics, 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.
<b>Hemolysis</b>	ISO 10993-4	<b>Selection of Tests for Interactions with Blood</b> – 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.
<b>Cytotoxicity – MEM Elution</b>	USP <87>	<b>Biological Reactivity Tests, In Vitro</b> – 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.
<b>Bacterial Endotoxin</b>	USP <85>	<b>Bacterial Endotoxins Test</b> – 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.
<b>Physicochemical</b> <ul style="list-style-type: none"> <li>Non-Volatile Residue</li> <li>Residue on Ignition</li> <li>Heavy Metals</li> <li>Buffering Capacity</li> </ul>	USP <661>	<b>Containers: Physicochemical Tests – Plastics</b> – 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.

# Biocompatibility Testing and Definitions – Cont.

Test Description	Test Standard	Definition
<b>European Pharmacopoeia</b> <ul style="list-style-type: none"> <li>• Appearance</li> <li>• Initial Color of Solution</li> <li>• Acidity</li> <li>• Alkalinity</li> <li>• Absorbance</li> <li>• Reducing Substances</li> <li>• Transparency</li> </ul>	EP <3.2.2.1 >	<b>Plastic Containers for Aqueous solutions for Parenteral Infusion</b> – 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.
<b>Japanese Pharmacopoeia</b> <ul style="list-style-type: none"> <li>• Transparency</li> <li>• Appearance</li> <li>• Heavy Metals</li> <li>• Lead</li> <li>• Cadmium</li> <li>• Residue on Ignition</li> <li>• Foaming Test</li> <li>• pH</li> <li>• Reducing Substances</li> </ul>	JP <61 >	<b>Test methods for plastic containers: Polyethylene or polypropylene containers for aqueous injections</b> – A set of tests that may be used for designing and quality assurance of plastic containers.