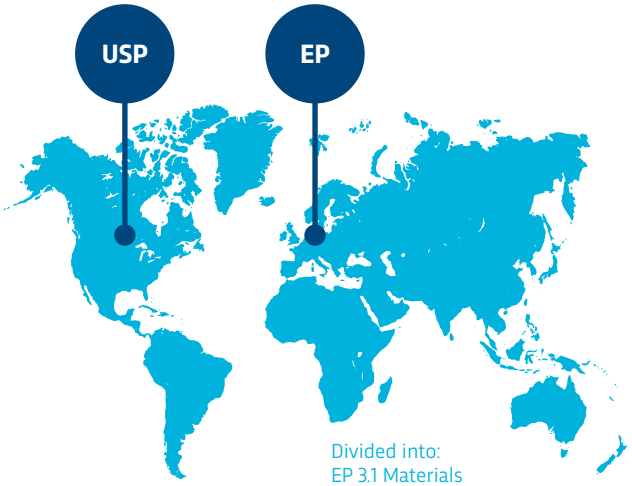
Does your polymeric material qualify as pharmaceutical packaging material?

The quality and safety of final drug products is continuously monitored and evaluated for example by means of quality control on production batches. But also the interaction with their (primary / immediate) packaging systems is thoroughly investigated and controlled. Only packaging materials of a known and consistent quality can be used. Therefore, even the raw materials used in the manufacturing of these packaging materials are strictly regulated. These raw materials are further converted into polymeric containers by a number of subsequent processes.

Both the raw materials and the containers made from these materials have to be tested against predefined pharmacopoeia standards to meet regulatory requirements. There are no global compendia which can be applied in all regions. The European and the United States Pharmacopeia (USP, EP) are best known, however also other regional Pharmacopoeias exist like Japanese, Chinese, Russian or Indian Pharmacopoeias. The tests under USP and EP are further subdivided into different chapters according to the type of material used. These are called monographs.



Divided into:
USP 661.1 Materials
USP 661.2 Packaging Systems
Plastic Packaging Systems

Divided into:
EP 3.1 Materials
EP 3.2 Containers
EP 3.3 Containers for human blood and blood components, and materials used in their manufacture, transfusion sets and materials used in their manufacture, syringes.
Materials for containers
Containers

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The table below summarizes the polymeric materials covered by different monographs.

United States Pharmacopeia USP	
USP <661>	Plastic packaging systems & their materials of construction *
USP <661.1>	Plastic materials of construction • Cyclic olefins (CO) • Polyamide 6 (PA) • Polycarbonate (PC) • Polyethylene (PE) • Polyethylene terephthalate (PET/PETG) • Poly(ethylene-vinyl acetate) (EVA) • Polypropylene (PP) • Polyvinyl chloride (PVC)
USP <661.2>	Plastic packaging systems for pharmaceutical use
USP <381>	Elastomeric components in injectable pharmaceutical product packaging/delivery systems

* USP <661> is valid until 2025, after this deadline polymeric materials need to comply to USP <661.1>

European Pharmacopeia or EP	
EP <3.1.3>	Polyolefins (PO)
EP <3.1.4>	Polyethylene (PE) without additives for containers
EP <3.1.5>	Polyethylene (PE) with additives for containers
EP <3.1.6>	Polypropylene (PP) for containers and closures
EP <3.1.7>	Poly(ethylene-vinyl acetate) (EVA) for containers and tubings
EP <3.1.9>	Silicone elastomer for closures and tubing
EP <3.1.10>	Non-plasticised PVC materials for non-injectable solutions
EP <3.1.11>	Non-plasticised PVC materials for solid dosage forms (oral)
EP <3.1.14>	Plasticised PVC materials for intravenous solutions
EP <3.1.15>	Polyethylene terephthalate (PET) for containers
EP <3.2.2>	Plastic containers and closures for pharmaceutical use
EP <3.2.8>	Sterile-single use plastic syringes
EP <3.2.9>	Rubber closures for containers
EP <3.3.2>	Materials based on plasticised poly (vinyl chloride) for containers for human blood and blood components
EP <3.3.3>	Materials based on plasticised poly (vinyl chloride) for tubing used in sets for transfusion of blood and blood components
EP <3.3.8>	Sterile single-use plastic syringes

How Nelson Labs can help you

Thanks to our thorough understanding of the different compendial standards, we can assist you in defining a complete compendial test plan that matches your product launch plans. Regardless of whether you are planning a regional or a global product launch, we can help you secure a stressless regulatory approval.

About Nelson Labs

Nelson Labs, A Sotera Health company, is the leading, global provider of lab testing and expert advisory services. We perform microbiological and analytical laboratory tests across the medical device, pharmaceutical, and tissue industries. The company is regarded as a best-in-class partner with a strong track record of collaborating with customers to solve complex problems. We have over 700 scientists, technicians, and service specialists who diligently perform more than 700 rigorous tests in 13 global laboratory locations.

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