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Marketing Manager: Marisa A. O'Brien

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CHAPTER 54

Plastic Packaging Materials

Barrett E Rabinow, PhD
Theodore J Roseman, PhD

As defined by the American Society for Testing and Materials (ASTM), a plastic is a material that contains as an essential ingredient one or more polymeric organic substances of large molecular weight, is solid in its finished state and at some stage in its manufacture or processing into finished articles can be shaped by flow. The large-molecular-weight organic substance is called a polymer.

The use of plastics in the health care industry has grown at a very rapid rate since the 1960s. This phenomenal growth is due primarily to the wide flexibility in choice of properties offered by plastics. However, because of the wide range of properties of plastics, judicious selection must be made for the intended application.

Prior to the recognition of the potential use of plastics in health care practice, glass was the predominate material used in the primary packaging of pharmaceutical products. Glass has a definite advantage in being a relatively unreactive and an inert substance (although leachable aluminum and glass particles or delamination have occasionally posed problems). As such, it can be used in contact with many critical products, either dry or liquid. It provides excellent protection against water vapor and gas permeation, and it can withstand steam sterilization (autoclaving) without incurring physical distortion. Two definite disadvantages of glass in the field of packaging, however, are its fragility and weight. Because of these negative aspects, coupled with the many positive attributes of plastics, significant inroads for the use of plastic in pharmaceutical packaging have been made. Today, for example, plastics are being used in the following primary packaging areas, where in the 1960s only glass could be considered: syringes, bottles, vials, and ampules.

There are many other significant medical uses that, without the use of plastics, would never have been technically feasible. A few examples include indwelling catheters, prosthetic devices, tracheotomy tubes, unit dose packaging, and flexible containers for intravenous, irrigation, and inhalation solutions, as well as for the collection of blood. An additional use for plastics is in secondary container packaging (ie, packaging that is not in direct contact with the product itself). This particular use normally involves plastic films of various types and thicknesses used for tamper-proof overwrapping, whereas the previously mentioned devices normally are fabricated by molding or extrusion of the finished part.

Selection of the appropriate materials for a packaging application should be performed with an understanding of the intended overall design of the package. The requirements should be specified with regard to customer usage, regulatory approval, marketing presentation, toxicological considerations, manufacturability, sterility, and, very importantly, protection of the pharmaceutical product or device during transportation, storage, and use. These functional requirements then must be analyzed in terms of the stress requirements they impose on the material, permitting translation of those requirements into material properties. A target material profile is developed by assigning required values of design and performance properties that predict or correlate with the container functions. Likely candidate materials are determined by comparing their properties with the property profile derived from the functional requirements. A prototype is built and tested via functionally oriented tests such as maintenance of product stability, simulated usage and storage tests, and customer focus groups. These concepts are embodied in ISO 11607.[1] Material properties affecting functional performance are described below.

MATERIAL PROPERTIES

Mechanical Properties

Important mechanical properties in plastic packaging materials are:

Tensile strength—the maximum force needed to pull apart a specimen of material, divided by its cross-sectional area. Elongation is the percentage change over original length at breaking point and measures a film's ability to stretch.

Impact strength—a measure of the ability to withstand shock-loading, in which a specimen receives a blow from a swinging pendulum, for example. Fracture will occur if the impact force exceeds the limit of elasticity of the material. Glass, for example, has a much lower impact strength than many plastics, although it has appreciable tensile strength.

Tear strength—measured both as the force necessary to initiate a tear and force to propagate a tear. Propagation of tear is undesirable in shipping sacks but desirable in tear tapes. Orientation of the material can affect results, because the polymer chains can be aligned along a particular direction during manufacturing, thus conferring greater strength in that direction.

Stiffness—the resistance of bending where deflection against a load can be measured.

Flex resistance to the development of pinholing and fracture, when subjected to repeated flexing or creasing, is important in shipping applications. Unsupported aluminum foil, unless it is heavy gauge, is prone to this failure mode.

Coefficient of friction or *slip*—relates to the ease with which one material will slide over another. Passage of films through

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