

a part of the drug development process. Soft-walled plastic containers of PVC are used to package intravenous solutions and blood for transfusion.

Sorption, a term used to indicate the binding of molecules to polymer materials, includes both adsorption and absorption. Sorption occurs through chemical or physical means due to the chemical structure of the solute molecules and the physical and chemical properties of the polymer. Generally, the un-ionized species of a solute has a greater tendency to be bound than the ionized species. Because the degree of ionization of a solute may be affected by the pH of a solution, the pH may influence the sorption tendency of a particular solute. Furthermore, the pH of a solution may affect the chemical nature of a plastic container so as to increase or decrease the active bonding sites available to the solute molecules. Plastic materials with polar groups are particularly prone to sorption. Because sorption depends on the penetration or diffusion of a solute into the plastic, the pharmaceutical vehicle or solvent used can also play a role by altering the integrity of the plastic.

Sorption may occur with active pharmacologic agents or with pharmaceutical excipients. Thus, each ingredient must be examined in the proposed plastic packaging to determine its tendency. Sorption may be initiated by the adsorption of a solute to the inner surface of a plastic container. After saturation of the surface, the solute may diffuse into the container and be bound within the plastic. The sorption of an active pharmacologic agent from a pharmaceutical solution would reduce its effective concentration and render the product's potency unreliable. The sorption of pharmaceutical excipients such as colorants, preservatives, or stabilizers would likewise alter the quality of the product. Methylparaben may be sorbed to some types of plastics, resulting in a decrease in the available concentration of the preservative; this may be reflected in a lowering of its preservative effectiveness.

Deformations, softening, hardening, and other physical changes in plastic containers can be caused by the action of the container's

contents or external factors, including changes in temperature and the physical stress placed upon the container in handling and shipping.

It is always good practice to dispense medication to patients in the same type and quality of container as that used by the manufacturer. In some instances, the original container may be used to dispense the medication.

Child-Resistant and Adult-Senior Use Packaging

The U.S. Consumer Product Safety Commission (CPSC) was created in 1972 through the Consumer Product Safety Act to protect "against unreasonable risks of injuries associated with consumer products." Today, the CPSC regulates the sale and manufacture of more than 15,000 different consumer products, including the packaging of legend and OTC medications. At present, all legend drugs intended for oral use must be dispensed by the pharmacist to the patient in a container having a child-resistant closure unless the prescriber or the patient specifically requests otherwise or unless the product is specifically exempt from the requirement.

The CPSC may propose exemption of certain drugs and drug products from the regulations based on toxicologic data or on practical considerations. For instance, certain cardiac drugs, such as sublingual tablets of nitroglycerin, are exempt from the regulations because of the importance of a patient's immediate access to the medication. Exemptions are also permitted in the case of OTC products for one package size or specially marked package to be available to consumers for whom safety closures are unnecessary or too difficult to manipulate. These consumers include childless persons, arthritic patients, and the debilitated. These packages must be labeled "This package for households without young children" or "Package not child-resistant."

A child-resistant container is defined as one that is significantly difficult for children under 5 years of age to open or to obtain a harmful amount of its contents within a reasonable time and that is not difficult for