

POLYMERS USED IN PHARMACEUTICALS PACKAGING

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Introduction. Synthetic and natural-based polymers have found their way into the pharmaceutical and biomedical industries and their applications are growing at a fast pace. Understanding the role of polymers as ingredients in drug products is important for a pharmacist or pharmaceutical scientist who deals with drug products on a routine basis.

Aim. This thesis will provide the basis for understanding pharmaceutical polymers, polymer properties, types of polymers, polymers in pharmaceutical industries.

Materials and methods. Depending on their applications, polymers may be classified as rubbers, plastics, fibers, adhesives, and coatings. Each application requires a polymer to possess certain properties.

Results and discussion. Rubbers have unique elongation properties, they can be stretched without failure, and they can be loaded with static and dynamic loads under very severe conditions. Different rubbers offer different properties. Those with double bonds (e.g., isoprene, butadiene) offer resiliency but are very susceptible to oxidation and ozonation. Those without double bonds (e.g., ethylene-propylene rubber) are very durable against weathering conditions. Some are very resistant to oil (e.g., chloroprene and nitrile) and some have excellent impermeability (e.g., isobutylene-isoprene rubber). Silicone is a very inert rubber with almost no affinity to any material. Therefore, silicone rubber is an excellent candidate for very durable parts such as implants in biomedical applications. Rubbers in general are not very strong in their raw form but they have a potential to be cross-linked and cured. Rubber is loaded with certain chemicals (curing agents) and is cured or cross-linked at high pressure and temperature.

Plastics on the other hand possess completely different properties. Plastic parts are manufactured by techniques such as injection molding, extrusion, and thermoforming that require the plastic to be in its molten state. Plastics that are used in general applications such as packaging are generally cheap and are structurally weak. Polymers such as polyethylene, polypropylene, and polystyrene have only carbon in their backbone. The other groups of plastics which are used in engineering applications are required to be impact resistant, weather resistant, solvent resistant, and so on and so forth. These are generally heterogeneous plastics, which have elements other than carbon such as N, Si, and O in their backbone. Polyesters, polyamides, and polyacetals are engineering plastics with very high intermolecular forces and hence high melting point.

Polymers for fibrous products are required to have a crystalline structure with a very sharp melting point. For this application, polymers need to be meltable and spinnable.

Examples of fiber-forming materials are cellulose acetate, rayon, polypropylene, nylon, polyester, polyamide, and polyacrylonitrile.

The required properties of polymers for adhesive and coating applications are tackiness and adhesiveness. Structurally speaking, the cohesive forces within a polymer can be modulated by changing its molecular weight, crystallinity, or addition of a second material such as plasticizers or oils. The adhesive

intended for a nonpolar adherent should be nonpolar as well. On the other hand, very polar adhesive materials such as epoxy and cyanoacrylate are suggested for very polar adherents including metals.

Like plastics, adhesives can be categorized as general and engineering (structural). The difference is the level of intermolecular forces within the adhesive structure. Cyanoacrylate-based adhesives or silicone adhesives are generally cured by absorbing moisture from the air. Epoxy adhesives are generally supplied as two components and cured in the presence of a third component (primary, secondary, and tertiary amines). Polyester adhesives are cured using peroxides and catalyzed by amines. The curing process increases the cohesive forces at the expense of adhesive forces. Since an adhesive should possess a balance of cohesive and adhesive properties, the curing process should also be optimized. Coating and adhesive applications rely on similar concepts. A successful adhesive or coating process requires that the matrix onto which the adhesive is applied to be fully covered by the polymer material, which is generally applied in an emulsion form.

Coatings are used for protection purposes. A successful adhesive application requires careful understanding of the properties of the adhesive and adherents since an adhesive is generally trapped in between two or more materials. For coating applications, the coating polymer is generally exposed to a second environment such as air, oxygen, water, stomach fluid, intestinal fluid, solvents, and so on and so forth. This requires a thorough understanding of the coated matrix, coating material, as well as the service environment in which the material is expected to serve. Examples of coating materials are poly (vinyl acetate), acrylate esters, ethyl cellulose, and so on and so forth.

Conclusion. The thesis continues with a variety of polymer products including rubbers, plastics, fibers, adhesives, and coatings, and also highlights important properties of each group.

INDICATORS OF STERILIZATION OF MEDICAL PRODUCTS

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Introduction. Providing of the medicines and medical devices sterility is one of the most important tasks in creation of products of the required quality. For a number of different reasons, such as non-compliance with the sterilization mode or breakage of the device, the material being sterilized can remain contaminated. Sterilization indicators are used in order to control the quality of the process.

Aim. The aim of this research is to analyze the current range of merchandising sterilization indicators on the Ukrainian market.

Materials and methods. For the study of the topic were used Internet data (official websites of manufacturers, regulatory documents) and the results of own studies.

Results and discussion. To date, there is no universal indicator of sterilization, which could provide control of the sterilization effectiveness for all types of equipment. Control can be carried out by physical, chemical and biological methods. In the physical control method ampoules with a crystalline substance are inserted into the device together with the material to be sterilized, which under certain parameters melts or changes the consistency. With the chemical method, when the desired temperature is reached, the indicator changes color. Currently, to monitor the parameters of the operating modes of steam and air sterilizers are used special paper thermochemical indicators for single use. Paper strips are laid in different places with sterilized material and after the end of the cycle, the color change of the indicator is compare with standard. In the biological method bottles are placed in the device with napkins or paper disks soaked in a suspension of a heat-resistant spore-forming microbe and after sterilization disks are incubated in a meat-peptone broth. At proper sterilization the clear broth should not be muddy. Only the biological method and biological indicators can be reliable for determining the effectiveness of sterilization. Physical and chemical tests are designed for operational control and allow to monitor compliance with the parameters