EB STERILIZATION OF MEDICAL DEVICES: DEVELOPMENT OF RADIATION RESISTANT POLYMER COMPOUNDS IN MALAYSIA

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The medical devices sector is one of the priority sectors identified for promotion and further development, given the growing demand for medical products in Malaysia. There is a strong presence of established supporting industries ranging from sterilization services, sterile medical packaging, precision engineering and tool and die making to contract molding and assembly and machinery fabrication in Malaysia. The availability of the supporting industries positions Malaysia as an ideal location for the manufacture of medical devices with the potential to be developed into a medical device hub in Asia. The rapid growth of polymers in the medical market reflects the suitability and need of these materials to meet the ongoing requests from today's healthcare industry. Radiation sterilization is a well-established technique that has several advantages compared to heat and ethylene oxide. Polymers can be sterilized using radiation which is nontoxic, efficient and cost effective, thus solving the problem of environmental contamination with mutagenic and toxic ethylene oxide and its residue caused by the use of Ethylene Oxide (ETO) gas. However, ionizing radiation sterilization known to cause detrimental effect on polymers that can cause substantial changes in the properties. Polymers that can be cross-linked by electron beam irradiation (EB) processing include polyethylene (PE), ethylene-vinyl acetate copolymers (EVA), butyl rubber, natural rubber and latex, polyvinylidene fluoride (PVDF), and many others. Some polymers that undergo degradation upon EB processing include polytetrafluoroethylene (PTFE), polypropylene (PP), cellulosic, and natural cellulose.

This paper briefly outlines the development of radiation resistant polymer compounds for EB sterilization with emphasis on rubber gloves, PVC compounds and, polypropylene (PP) and Ethylene Propylene Diene monomer rubber (EPDM) rubber based thermoplastic elastomers(TPE). The respective compounds were irradiated by using a 3.0 MeV at doses ranging from 0 -100 kGy in air and room temperature. The changes in tensile strength, modulus at 100% elongation, elongation at break, gel fraction, morphological and properties of the samples were investigated. In view of surgical rubber gloves, the tensile strength, elongation at break and modulus were evaluated as function of dose range 20±100 kGy minimum dose, dose uniformity ratio, 3.1, and both, accelerated and normal aging, were used to study the stability of the irradiated gloves after irradiation [1]. Attempts on hydrogel coating of rubber film by EB Irradiation were also made [2]. With respect to development of EB sterilizable PVC, various PVC formulations were compounded and subjected to electron beam irradiation [3]. The changes in yellowness index, tensile strength and elongation at break were used to measure the stability of the material on EB irradiation and on storage following irradiation. The effect of EB radiation on various ethylene-propylene diene terpolymer (EPDM)/ polypropylene (PP) compounds were studied as an attempt to develop EB radiation sterilizable PP/EPDM blends suitable for medical devices [4]. The influence of additives on the radiation stability of the polymers with the addition of stabilizers, antioxidants and multi-functional monomers will also be reported.

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