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#### GAMMA RADIATION EFFECTS IN PACKAGING FOR STERILIZATION OF HEALTH PRODUCTS AND THEIR CONSTITUENTS PAPER AND PLASTIC FILM

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#### ABSTRACT

The integrity of materials containing packaging (natural or synthetic polymers) is essential to keep the aseptic condition of commercialized products (health care products, food and pharmaceuticals). The objective of this paper was to study gamma radiation effects (25 kGy, 40 kGy and 50 kGy) on the main properties of paper and multilayer films (polyester and polyethylene). Paper and multilayer films are components of packaging (pouches) for radiation sterilization containing medical equipment or products. Paper was the more radiation sensitive among the studied materials and radiation effects were more pronounced at brightness, pH, tearing resistance, bursting strength and tensile strength. Concerning plastic film, no pinholes were induced by radiation and the effects on the tensile strength were not significant. Although the seal strength packaging (pouches) decreased according to increasing dose, the sealing integrity was preserved.

#### Keywords

gamma radiation, mechanical properties, packaging, paper, multilayer plastic film.

#### **1 INTRODUCTION**

Radiation sterilization is a common technology for microbial inactivation for different products. Although 25kGy is the recommended dose for sterilization of healthcare products, it is possible and sometimes necessary to use doses higher than this. Dose and dose uniformity requirements for the intended items are among the criteria to be achieved and the compatibility of packaging material is necessary for safety reasons.

Another issue is the variation of doses during radiation processing in commercial plants. What variation of dose is safe? International standards for radiation sterilization ask for evidences of a minimum dose of 25kGy. On the other hand, in order to ensure the safety of sterile products many authors performed their experiments extrapolating the doses from 25kGy up to 60kGy or higher (Dermetzis at al., 1999; IAEA, 2008 and Porto, 2013).

The evaluation of packaging materials is also very important for a safety application of radiation for healthcare products sterilization. The effects of gamma irradiation on compositional changes in plastic films were reported by Demertzis and co-authors, who applied 44 kGy at several polymers. Since the late fifties radiation effects on polymers were studied and the relative stability of twelve types of plastics were published in 1961 (Krasnansky et al., 1961). They found that containing conjugated ring systems, ionic bounds and chlorine in side groups were the most stable polymers. Random degradation of polymers (cellulose) was carefully demonstrated by Ershov, using the molecular mass distribution factor (Ershov, 1998).

It is well known that polymers can be cross-linked when exposed to radiation or chain scission as the opposite effect. Regarding packaging, there is a lot of interest since irradiation

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