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GAMMA RADIATION APPLIED FOR STERILIZATION OF SPECIAL HEALTH CARE PRODUCT PACKAGES

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ABSTRACT

Ionizing radiation is one of the possibilities for the sterilization of packaging systems for health products. In the sterilization process it is fundamental to maintain the properties of the packaging materials. In this study, 25kGy was applied (gamma cell radiation) at two different packaging systems (pouches built by paper and multilayer film - “polyester + polyetilene” and “polyester + polypropylene”, for health products protection) in order to determine its effect, especially in the mechanical properties of the packaging materials. It was observed a decrease in the following properties: tensile strength (8.5 % - 11.7%); sealing resistance (2.0 % - 20.1%); bursting strength (10.9 % - 18.2 %); tearing resistance (19.4 %- 21.3 %). Although these parameters decreased after being submitted to gamma radiation, they still attend the requirements of the ABNT NBR 14990-3:2010 and ABNT NBR 14990-8:2004 standards, applied for compliance analysis of the studied packaging system. The pouch made of paper and multilayer film (“polyester + polyetilene”) showed the best performance.

Key words: gamma rays, health product sterilization, packaging.

1. INTRODUCTION

The packaging application for the protection of food and medical products requires compatibility between both product and packaging. Important technology has been developed worldwide in accordance to the needs of packaging systems. Part of the packaging systems projected for radiation sterilization of products has envelope (pouch) or tube shape. Both shapes are made of paper (side 1) and thermoplastic film (side 2), as a multilayer film. The combined polymers offer a suitable transparence for packaging made of “polyester + polypropylene” or by “polyester + polyetilene”.

The packaging system requirements for medical products are: a) protection of the item during transportation, storage and handle; b) provide identification of the packaged material; c) guarantee the sterility required level and serve as a microbial barrier; d) be resistent to violation (flexibility and impermeability to micro-particles and microorganisms); e) allow asseptic opening and make easy to get the product; f) not interact to the items inside it (Pinter, 2000; ABNT NBR 14990-8, 2004). All these properties must be maintained after the packaging and packing material being subjected to the sterilization process.

Sterilization, by gamma radiation and/or electron beam, is already an industrial process, specially for packaging systems containing medical equipments or products. Approximatelly 50% of disposable healthcare products are sterilized by gamma radiation worldwide (CBE Embrarad, 2010). Gamma radiation diminishes the microbiological contamination by direct and indirect action of ionizing radiation. Several types of damages to the cells are very well described by Sonntag (1987).

On a industrial scale, ionizing radiation has been sucessfully applied on polymers to promote reticulation and cure, as well as to sterelize medical and biomedical items (O'Donnell & Sangster, 1970). Polymers modification depends on several parameters: type and amount of dose radiation, dose rate, radiation atmosphere, use of chemicals during irradiation (such as solvents, aditives and others). Degradation and reticulation of polymers are the main effects of radiation into polymers as described by Spinks and Woods, 1990.

It is of fundamnental importance the knowledge of the radiation effect on the packaging systems and on its materials. The integrity of materials (natural or sinthetic polymers) is essential to keep the asseptic condition of produts (food and pharmaceutical products) (Haji-Saeid, 2007). The paper used to manufacture packaging systems for items on sterility conditions is called *surgical grade paper*. There is a brazilian standard document that brings the specifications required for these type of packaging system and its material, the "ABNT NBR 14990 – Sistemas e materiais de embalagem para esterilização de produtos para saúde".

The objective of this paper is to study gamma radiation effects (25 kGy) on the main physical properties of surgical grade paper and multilayer films (polyester + polyethylene and polyester + polypropylene). Surgical grade paper and multilayer films are components of packaging system for radiation sterelization containing medical equipments or products.

2. METHODOLOGY

Packaging system in pouch shape is the focus of this study (**Figure 1**). Two samples were used: one of them is composed of surgical paper and polyester + polyethylene multilayer film and the second is made of surgical paper and polyester + polypropylene multilayer film.

The gammacell irradiator was the radiation source and all samples were irradiated together under a dose rate = 1.71 kGy/h. Irradiation took few hours until the samples receive 25 kGy. The irradiation was carried out at Radiation Technology Center (CTR), IPEN-CNEN/SP.

The samples were analyzed before and after irradiation. The test items to be analyzed were taken from the samples in a way to avoid interference related with sample composition variation. The conducted tests are listed bellow and they are usually carried out during approval process for this type of packaging system.

In the packaging:

- Sealing resistance (standard method ABNT NBR 14990-8:2004).

In the paper of the packaging:

- Diffuse blue reflectance factor – ISO brightness (ABNT NBR 14990-3:2010);
- Grammage (ABNT NBR 14990-3:2010);
- Air permeance (ABNT NBR 14990-3:2010);
- Bursting strength (ABNT NBR 14990-3:2010);
- Tensile strength (ABNT NBR 14990-3:2010);
- Tearing resistence (ABNT NBR 14990-3:2010).

For the multilayer film of the packaging:

- Micro roles (ABNT NBR 14990-8:2004);
- Tensile strength (ABNT 14990-8:2004).

The tests were conducted at the Pulp and Paper Laboratory, Institute for Technological Research – IPT.

Figure 1. Type of packaging (pouch) studied

3. RESULTS AND DISCUSSION

All the obtained results were organized at Table 1, which represent the results obtained from the packaging, paper and multilayer film before and after irradiation with 25 kGy, for two types of packaging. The numbers of determinations which gave the average of presented results are especified below:

- ten determinations for the tests of brightness and pores diameter;
- nine determinations for the tests of tensile strength paper and of the top of the package;
- five determinations for the tests of bursting strength, grammage and air permeance Bendtsen;
- six determinations for the tests of tearing resistance, multilayer film of the right side and left side.

Also in Table 1, the right and left sides refer to the packaging with the multilayer film facing up towards opening of the sealing (Figure 1) and in Sample 1 the multilayer film is formed by polyester and polyethylene and in Sample 2 is formed by polyester and polypropylene.

The results in Table 1 show, for both samples, that paper grammage, air permeance and diameter of pores are very little affected by radiation, while the parameters for bursting and tensile strength, tearing resistance and brightness resulted in considerably decreased after radiation.

The tearing resistance is a property that depends essentially on the integrity of the fiber, while the tensile stregth depends more on the paper fibrous arrangement. Once the variation on tearing for both samples (~18%) was higher than the variantion on tensile strength (~11%), it is possible to deduce that the applied sterilization process by gamma radiation affected specially the cellulosic fiber. The bursting strength is a characteristc of the fiber integrity and the paper fibrous arrangement. For both samples, the low difference obtained for the air permeance and diameter of pores parameters, before and after radiation, confirms that it is possible to consider that the paper fibrous arrangement was unaffected.

As it was expected, paper brightness was affected by this treatment as a possible effect of sterilization process (D'Almeida et al., 2009). This was probably because of chromophore groups formation. The yellowing of the paper could be noticed with bare eyes.

For the multilayer film, the analysed parameters were unaffected in both samples.

Concerning the packagings, sample 2 presented a significant decrease on the sealing resistance. But it is well known that it is usually not recommended sterilization by irradiation for packaging system formed by the composition of multilayer film of sample 2. This sample is formed by polyester and polypropylene multilayer film and is recomended for items to be sterilized by vapour or by ethylene oxide. On the other hand, the sample 1, formed by polyester + polyethylene is the recomended material for items to be processed by gamma radiation.

Table 1 – Influence of 25 kGy at parameters related to material resistance

PAPER				
Assays	Sample 1		Sample 2	
	before	after	before	after

		sterilization	sterilization	sterilization	sterilization
Paper grammage, g/m^2		62.9 (0.2)	63.3 (0.4)	69.9 (1.0)	70.4 (0.7)
Bursting strength, kPa - Side A - Side B		358.1 (37.8) 384.4 (17.4)	319.0 (26.3) 330.0 (16.1)	448.8 (35.7) 389.4 (67.0)	367.1 (43.6) 318.8 (27.6)
Tensile strength, kN/m - machine direction - cross direction		7.28 (0.44) 3.79 (0.12)	6.66 (0.30) 3.38 (0.14)	7.77 (0.24) 4.02 (0.20)	6.88 (0.43) 3.55 (0.13)
Tearing resistance, mN - machine direction - cross direction		601.7 (20.3) 686.7 (32.8)	484.0 (40.5) 555.9 (29.5)	673.6 (295) 797.9 (32.0)	549.4 (0.00) 627.8 (0.00)
Air permeance – *Bendtsen* method, µm/Pa.s		10.41 (0.34)	10.72 (0.14)	9.53 (0.44)	9.53 (0.63)
Diameter of pores, µm		28.2 (3.0)	27.6 (3.1)	22.8 (3.3)	22.6 (4.1)
Diffuse blue reflectance factor – ISO brightness (Elrepho 3300 – Datacolor equipment), %	without UV filter	86.04 (0.11)	79.77 (0.09)	85.36 (0.04)	80.11 (0.05)
	with UV filter	85.68 (0.11)	79.42 (0.09)	85.09 (0.04)	79.82 (0.05)
MULTILAYER FILM					
Assays		Sample 1		Sample 2	
		before sterilization	after sterilization	before sterilization	after sterilization
Multilayer film grammage, g/m^2		56.3 (0.5)	56.1 (0.6)	52.8 (0.5)	53.2 (0.5)
Micro roles		Absents	absents	absents	absents
Multilayer film tensile strength, N - machine direction - cross direction		49.99 (1.21) 37.78 (1.19)	49.74 (2.30) 39.92 (2.03)	36.63 (2.52) 41.68 (2.18)	37.97 (2.19) 41.89 (2.09)
PACKAGING					
Assays		Sample 1		Sample 2	
		before sterilization	after sterilization	before sterilization	after sterilization
Sealing resistance, N	Top	7.59 (0.70)	7.43 (0.96)	8.00 (0.23)	6.39 (0.35)
	Right side	5.01 (0.38)	4.82 (0.23)	6.85 (1.00)	5.54 (0.66)
	Left side	5.09 (0.50)	4.92 (0.53)	5.80 (0.37)	5.15 (0.32)

Table 2 summarizes the effects of 25kGy radiation dose on the two types of packaging material analysed and the main affected parameters were pointed out in order to facilitate further comparison.

Table 2 – Relative grade of radiation induced effects (25kGy)

A s s a y s	**Paper**
Paper grammage, g/m^2	0
Bursting strength, kPa	+++
Tensile strength, kN/m	++
Tearing resistance, mN	+++
Air permeance – *Bendtsen* method, µm/Pa.s	0
Diameter of pores, µm	0
ISO brightness	+
A s s a y s	**Multilayer film**
Multilayer film grammage, g/m^2	0
Multilayer film tensile strength, N	0
A s s a y s	**Packaging**
Sealing resistance, N	0 (polyester and polyethylene multilayer film) +++ (polyester and polypropylene multilayer film)

Notes:
(0) not affected or very little affected by gamma radiation
(+) litlle affected by gamma radiation
(++) medium affected by gamma radiation
(+++) highly affected by gamma radiation

4. CONCLUSION

After 25kGy radiation dose, applied in the conditions specified in this study, it was obtained: a decrease in the sealing resistance of the packaging, when the multilayer film was polyester and polypropylene; a decrease in the mechanical properties of the paper (bursting strenght, tensile strength and tearing resistance) and a yellowing of the paper. Gamma radiation did not affect the properties of the analysed multilayer film. The examined properties in this sudy were those usually employed for the health products packaging considered.

The analysed parameters were affected by the applied radiation dose but they are still in accordance with the specification standards for medical products packaging considered in this study (ABNT NBR 14990-3:2010). Comparing the two samples the one with the multilayer film made of "polyester + polyetilene" (Sample 1) showed the best performance.

Future studies will include different radiation doses and monitoring their effects in the main physical properties of surgical grade paper and multilayer films (polyester + polyethylene and polyester + polypropylene) which are components of packaging system for radiation sterelization containing medical devices.

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