STUDY OF MECHANICAL BEHAVIOR ON SINGLE USE BAGS WELDING UNDER GAMMA IRRADIATION

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Since a long time, biopharmaceutical industry utilizes more and more single use plastic bags due to its very easy use (long shelf-lives, mechanical properties), preparation, and storage properties (oxygen and water barriers). These plastic bags are composed of two welded multilayer polymer films. To ensure the function of the closure and the non-contamination from the external environment, welding must answer to several parameters according to norm ("ISO 15747," 2018) and standard (F02 Committee, n.d.). In this present study, the behavior of weldings on Ethylene Vinyl Acetate (EVA) single use bags under gamma irradiation have been studied. Mechanical tests have been performed at several gamma irradiation doses (from 0 kGy to 270 kGy) and at different location of the bag (*Figure 1*). The first objective is to study the impact of gamma irradiation dose on the welding mechanical tensile behavior. The second objective is to evaluate the impact of the welding location on the welding tensile properties. Each tensile curve (*Figure 2*) has been decomposed in 6 characteristic points which were evaluated with Principal Component Analysis (PCA): Ultimate Tensile strength at break (UTS), Ultimate elongation or elongation at break, 1st Yield-Strength (Y1 Strength), 1st Yield-Strain (Y1 Strain), 2nd Yield-Strength (Y2 Strength), 2nd Yield-Strain (Y2 Strain). The study showed that weldings are never impacted during tensile testing: this evaluation reveals that *in fine* the film cracks before the welding modification. Its function of closure and bag content preservation from external environment is fully achieved whatever the gamma irradiation dose and the welding location. Only the multilayer film on both sides of the welding is altered after 100% elongation strain. The EVA bag showed no degradation up to 115 kGy whereas they become to be altered at 270 kGy. The welding location on EVA bag showed different film mechanical behavior correlated to the polymer film extrusion process orientation.

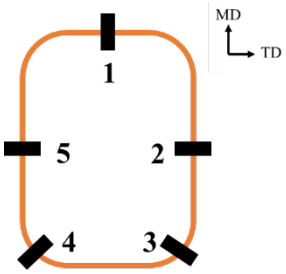

Figure 1: Five welding locations. Black lines correspond to welding samples (1-5). Orange lines correspond to welding.

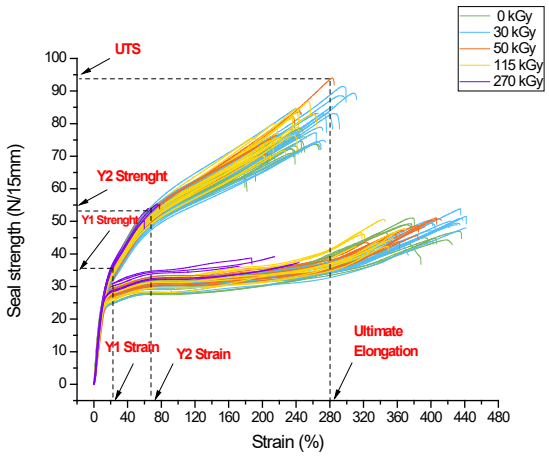

Figure 2: Strength-strain curves for each welding location (1-5) and each gamma doses (0-270 kGy) of EVA bag. Colors according to gamma doses.

REFERENCES

F02 Committee, n.d. Design and Evaluation of Primary Flexible Packaging for Medical Products (No. F 2097 – 08). ASTM International. ISO 15747, 2018.