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## ACOMDIM APPLIED TO EVALUATE GAMMA IRRADIATION IMPACT ON MULTILAYER PE BASED FILMS

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### Abstract

The use of single-use systems is becoming increasingly common in the biopharmaceutical and biotechnology industries. These systems are manufactured from polymers such as polyethylene (PE) and ethylene vinyl acetate (EVA). For their future applications, these devices are sterilized by  $\gamma$ -irradiation with a dose between 25 and 45kGy. C. Artandi and W.V. Winkle<sup>i</sup> determined that 25kGy is the dose to be at 40% above the minimum needed to kill the most resistant microorganisms. The purpose of this study is to understand what happens on the surface of polymers after  $\gamma$ -sterilization. Optical spectroscopy are of great interest for chemical analysis and are used to obtain information on the composition of materials, such as polymers. The Fourier Transform Infrared (FTIR) spectroscopy provides information on the fundamental vibrations of the molecules using an excitation in the visible. The surface of films is analyzed after being sterilized with different radiation doses and after a natural ageing of few months to check their composition and stability by FTIR spectroscopy. As the number of data is important, the use of chemometric methods, like Principal Component Analysis (PCA) and AComDim (ANOVA Common Dimensions), has many advantages, such as identification of shift and intensity modification, detection and highlighting of the influential factors and interactions between several elements ( $\gamma$ -doses, aging, and film batches).

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<sup>i</sup> Guide to Irradiation and Sterilization Validation of Single-Use Bioprocess Systems, Bioprocess International, may 2008, p12.