

pH EVOLUTION IN SOLUTION AFTER CONTACT WITH MULTILAYER FILMS AFTER DIFFERENT γ -IRRADIATION DOSES AND THUS RECONCILIATION OF pH AND TOC WITH CARBOXYLIC ACIDS DETECTED BY ION CHROMATOGRAPHY

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For a number of various uses (storage, mixing, freezing, transportation, formulation, and filling) biopharmaceutical solutions are stored in sterile single-use plastic bags. Material transfers can then occur between containers and contents. These migrations, of different types, depend on the physicochemical characteristics of the material (composition, pH, solubility, viscosity, molecular weight, etc.), the nature of the product (solid, semi-solid and liquid) and the conditions of the material utilization. In the case of single-use polymers, γ -irradiation sterilization of the polymer is often carried out. The interactions could be therefore influenced by the dose and the contact time between the container and the contents.

γ -sterilization of single-use systems initiates chemical reactions and complex modifications inside the plastic material. In this study, γ -irradiation doses investigated are up to 270 kGy in order to emphasize the γ -irradiation effect and to better investigate the modifications of commercial PE(Polyethylene)/EVOH(Ethylene Vinyl Alcohol)/PE-film and commercial EVA(Ethylene Vinyl Acetate)/EVOH/EVA film. This study is a part of a global investigation on γ -irradiation on multilayer films Non-specific (TOC, pH, conductivity) or specific (e.g. chromatographic, spectroscopic, gravimetric) analytical methods can be used. several approaches were used to study the impact of γ -irradiation on multilayer films, as ion chromatography to detect and quantify the ionic species, and as pH and conductivity measurements to observe the consequences of the chemical modifications.. There are few references available on the leaching of carboxylic acid species impacting aqueous solutions used in biopharmaceutical applications in contact with plastic single-use systems [1]. Stability studies under accelerated or real-time degradation conditions make it possible to define the shelf life and storage conditions in order to guarantee the quality of the product. The aim of the study is to identify and quantify the acid compounds that can be released from the container under normal conditions of use of the materials: the extractables.

[1] D. Jenke, D and V.J. Barge. Factors affecting the release of extractable acetic acid from multi-layered plastic films containing ethylene vinyl acetate (EVA) and polyethylene (PE) layers. Pharm Outsourcing. 15 (2014) 56-59.