SiO2 MATERIALS SCIENCE℠

The Effect of Ionizing Radiation on Cyclic Olefin Polymer (COP) Color

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INTRODUCTION

The objective of this study was to determine the effect of ionizing radiation on the color of cyclic olefin polymer (COP) vials. An evaluation of the color intensities produced by varying electron beam (e-beam) radiation doses was performed. A study was performed to determine the visual degree of color dissipation at different e-beam doses over the course of three months.

METHODS & MATERIALS

10 mL SiO2 Medical Products (SMP) COP Vials (i.e., trilayer coated vials) were used to evaluate the effect of e-beam sterilization on color. The COP polymer is 690R grade and manufactured by ZEON, Inc. The single tubs of 10mL coated vials were exposed to e-beam radiation doses of 0kGy, 12kGy, and 18kGy. Reference tubs of coated vials were not exposed to any radiation. Photographic evidence of each vial was collected at 1 week and 12 weeks post-sterilization.

RESULTS

Vial Color after E-beam Exposure

1 week post-sterilization

Expected Dose Range

Control

Minimum

Dosage = 13.4 – 14.4 kGy

Target Dose = 12 kGy

Maximum

Dosage = 19.1 – 20.6 kGy

Target Dose = 18 kGy

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6 weeks post-sterilization

Expected Dose Range

Control

Minimum

Dosage = 13.4 – 14.4 kGy

Target Dose = 12 kGy

Maximum

Dosage = 19.1 – 20.6 kGy

Target Dose = 18 kGy

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12 weeks post-sterilization

Expected Dose Range

Control

Minimum

Dosage = 13.4 – 14.4 kGy

Target Dose = 12 kGy

Maximum

Dosage = 19.1 – 20.6 kGy

Target Dose = 18 kGy

RESULTS & DISCUSSION

The photographs of COP vials show that the color changes from a clear white before ionizing radiation to a clear greenish hue after sterilization. The color change is caused by a chemical reaction that forms organic quinones, which are a yellowish green color. Due to their natural volatility some of this color tends to dissipate with time.

It is generally believed that the color observed in irradiated plastics is due to trace color bodies and reaction products of the antioxidants. Phenolic antioxidants, which are used to protect the COP during its storage, processing, and general long term thermal stability, are susceptible to forming colored species and a number of studies have identified quinone dimers, oxidation products of the phenol stabilizer, as the main mechanism of color formation. This color fades with time as seen in the photographs. This has been cited in the literature as a function of the recombination of the radicals that were formed during the irradiation process. This fading may not be completely reversible depending on the radiation dosage received. In addition, it is known that trace metals, in combination with other conjugated color bodies (phenolic antioxidant oxidation products), further enhance color in plastics. It is also well known that there is always some trace level of metal impurities in almost all plastics. Upon examination of trace metals by ICP/OES, the concentrations were found to be below the detection limit or in the low ppb level in the SiO2 plasma coated COP containers.

CONCLUSION

E-beam sterilization up to a target dose of 18 kGys imparts a transparent greenish hue to COP vials. The color, however, dissipates with time and practically disappears completely after 12 weeks of storage at room temperature. The impact of e-beam exposure on COP color is completely reversible up to this dose and is further diminished at lower dose.