SiO2 Medical Products™
SCIENCE INSIDE™

The Effect of Ionizing Radiation on Cyclic Olefenic 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 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.

Test Articles

10 mL SiO_2 Medical Products (SMP) COP Vials (trilayer coated vials)

Experimental

Single tubs of 10mL coated vials were exposed to Ebeam radiation doses of 0kGy, 12kGy, and 18kGy. Reference tubs of coated vials were not exposed to any radiation.

Photographic evidence of each time period was collected.

Results

Vial Color after E-beam Exposure

1 week post-sterilization

Expected Dose Range (Minimum – Maximum)

Control

Dosage = 13.4 – 14.4 kGy

Target Dose = 12 kGy

Dosage = 19.1 – 20.6 kGy

Target Dose = 18 kGy

6 weeks post-sterilization

Expected Dose Range (Minimum – Maximum)

Control

Dosage = 13.4 – 14.4 kGy

Target Dose = 12 kGy

Dosage = 19.1 – 20.6 kGy

Target Dose = 18 kGy

12 weeks post-sterilization

Expected Dose Range (Minimum – Maximum)

Control

Dosage = 13.4 – 14.4 kGy

Target Dose = 12 kGy

Dosage = 19.1 – 20.6 kGy

Target Dose = 18 kGy

Discussion and Summary

As seen in the exhibits provided above the color of the COP goes from a water white before ionizing radiation to a greenish hue after sterilization. Chemically this reaction is understood to be caused by the formation of 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 (see attached confirmation letter from resin supplier). 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 exhibits. 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 are always some trace level of metal impurities in almost all plastics. (Upon examination by ICP/OES most metals were found to be below the detection limit or in the low ppb level in the SiO_2 plasma coated COP containers). Further, the barrier properties of the PECVD (plasma enhanced chemical vapor deposition) silicon dioxide internal coating on the SiO_2 Medical Product's containers eliminate the migration of these species, as well as most gases and leachables. We have seen evidence of this behavior with other organic molecules purposefully added to the polymer and extracted in organic solvent (see TS-001/Impact of Free Radicals on Oxidation).