SiO2 MATERIALS SCIENCE℠

Impact of Barrier Coating Technology on Polymer Additive Extractables in Parenteral Vials

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PURPOSE

Testing was conducted to compare the concentration of Irganox 1076 extracted into a solvent filled into cyclic olefin polymer (COP) vials and barrier coating system COP vials.

BACKGROUND

One of the shortcomings of parenteral containers composed of plastic materials is the potential for chemical compounds leaching from the container into liquid drug formulation. The leachable compounds can contaminate the drug and ultimately injected into the patient. Similarly, there are known cases of organic compounds from label adhesives on polymer container migrating through the plastic and leaching into the drug formulation.

SiO2 Materials Science (SMS), Inc. addresses this problem with leachables from cyclic olefin polymer (COP) plastic containers by depositing an amorphous silicate glass (SiOx) coating on the inside surface of the plastic container. This coating technology offers an additional safeguard against potential leachables compromising the drug product.

Irganox 1076 is a low molecular weight (Figure A) additive that is compounded into plastics to provide antioxidant stability. It was chosen as an extraction candidate for its low molecular weight and high polarity, and thus high migratory rate to the surface of olefin plastics. If the SMS coatings could inhibit extraction of Irganox 1076, it was reasoned that higher molecular weight additives and degraded polymer oligomers, if present, would be at least as effectively inhibited.

Method

1% by mass of Irganox 1076 was compounded with Zeonex 690R COP resin from Zeon Inc. and extruded into pellets comprising one percent weight/weight Irganox 1076. Compounded pellets were then injection-stretch molded into five milliliter (mL) vials.

A barrier coating system consisting of an adhesion layer followed by a barrier layer was deposited on a set of COP vials. Plasma enhanced chemical vapor deposition was used to deposit the barrier coating system.

Both sets (uncoated and coated) of vials were charged with 15 percent volume/volume cyclohexane in isopropanol solvent, sealed with aluminum foil, and heated to 65 °C for 24 hours. High performance liquid chromatography (HPLC) was used to quantify the amount of Irganox 1076 extracted into the solvent. The lower detection limit of the HPLC instrument for Irganox 1076 was 0.1 microgram per milliliter.

RESULTS

Figure B indicates that almost 1.5 ppb of Irganox 1076 was extracted from the uncoated COP vial. No Irganox 1076 was quantified above the detection limit in the coated COP vials.

CONCLUSION

The coating system provides an effective extractables barrier to the additive Irganox 1076, even at concentrations 5-10x higher than typical additive concentrations in ordinary plastic articles. Leachables would be expected to be as low or lower based on this study.

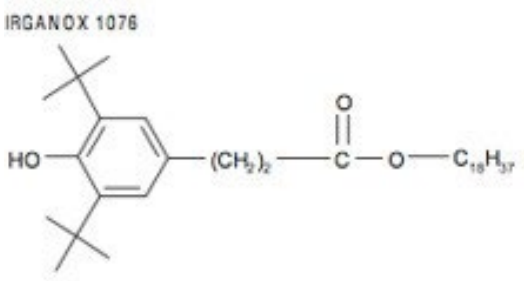

Figure A. Structure of Irganox 1076

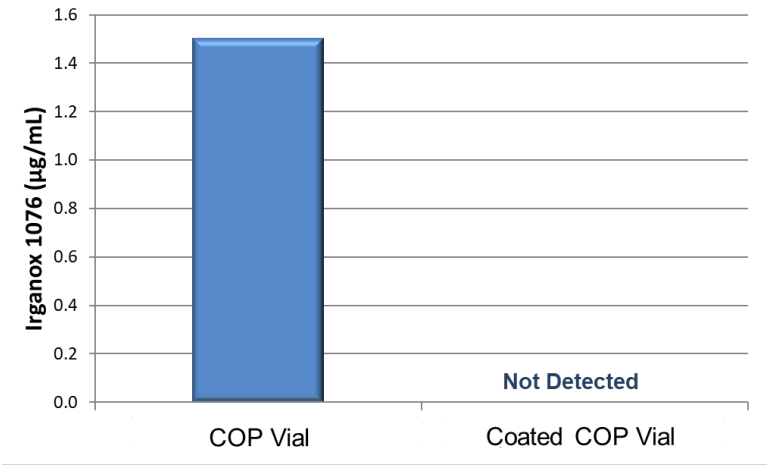

Figure B. Irganox 1076 extractables on uncoated COP and coated COP vials.