Introduction

A controlled extraction study has been conducted on polycarbonate employing organic and aqueous solvents in combination with different extraction techniques. Extracts were analyzed by ICP-MS, Headspace GC/MS, LC/MS, and GC/MS before and after derivatisation.

Material

Polymer Synthesis and Structure:

Applications:

Polycarbonate is a strong, rigid, transparent plastic material amenable to sterilization by multiple means: ethylene oxide (EO), irradiation (both gamma and electron beam), and steam autoclaving.

It was chosen for the PODP protocol because of its use in intravenous (IV) bag ports and connectors.

A key concern with polycarbonate as a material is its potential to leach the monomer Bisphenol A.

Composition

Functionality:

• Polycarbonate resin Base polymer

• Irganox 1076, 0.05% Primary antioxidant

• Irgafos 168, 0.01% Secondary antioxidant

Solvent / Extraction Map

Elemental Analysis (ICP-MS)

Extractables from Solvent Extraction – Gas Chromatography

Extractables from Headspace GC

Extractables from Solvent Extraction – Liquid Chromatography

VWD1 A, Wavelength=205 nm (JUL10/0727B-27.D)

VWD1 A, Wavelength=205 nm (JUL10/0727B-08.D)

Observations and Results

The anticipated additives were detected:

Common oxidative (oxidized phosphate form of Irgafos 168) and hydrolytic (2,4-dihydroxybutyl) phenol transformation products of Irgafos 168 were also observed.

Under aqueous conditions, a key extractable is bisphenol A (BPA), one of the monomers:

Extraction of BPA is highly pH dependent. At pH ~9.5, an order of magnitude more BPA is extracted from polycarbonate than pH 2.5. This is particularly important to note for high pH aqueous formulations.

Sorption, a low temperature extraction technique, was significantly less efficient than sealed vessel. Sorption at pH 9.5 failed to produce detectable BPA.

Isopropanol, a solvent of intermediate polarity between water and hexane, was the most successful solvent for the antioxidants and related substances, extracting an order of magnitude more of each than hexane. This underscores the value of running multiple solvents, trying to ‘bracket’ with water and hexane would have yielded very few significant extractables.

No significant volatiles (headspace GC) or metals (ICP MS) were detected.