

# CONTROLLED EXTRACTION STUDY ON POLYPROPYLENE TEST ARTICLE

Lisa Bavis, Laura Stubbs, Diane Paskiet, Andrea Straka

WEST MONARCH Analytical Laboratories, West Pharmaceutical Services, Inc., Maumee, OH 43537



## ABSTRACT

A qualitative and quantitative study was performed following PORI's Leachable and Extractable Working Group's Experimental Protocol for Controlled Extraction Studies on Plastic Test Articles. The Working Group obtained a polypropylene resin of known ingredients for the purpose of this study. The project entailed three phases:

- 1) Qualitative Controlled Extraction (Profile)
- 2) Quantitative Controlled Extraction
- 3) Validation

Phase one included an analytical survey to determine the following: if the known ingredients could be detected, if other species not predicted would be extracted, and if the analytical techniques were appropriate. The second phase of the study was the quantitative controlled extraction. Three target analytes were selected to be analyzed by High Performance Liquid Chromatography (HPLC) based on the results obtained in the profile study (qualitative). The third phase, validation of the HPLC method, was performed using a specific validation procedure.

This presentation summarizes results for both qualitative and quantitative extractables from the polypropylene test article.

## PROFILE METHODOLOGY

### Solvents

Solvents were selected by the Working Group to represent a range of polarities and boiling points.

- 2-Propanol
- Hexane
- Methylene Chloride

### Extraction Techniques

Extractions were accomplished using typical laboratory equipment.

- Soxhlet
- Sonication
- Reflux

### Analytical Techniques

A variety of analytical techniques were used to detect a wide range of analytes.

- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography/Mass Spectrometry (LC/MS)
- Gas Chromatography/Mass Spectrometry (GC/MS)
- Non-volatile residue (NVR)
- Fourier Transform Infrared Spectroscopy (FTIR)
- Optical Microscopy/Electron Microprobe (OM/EM)

## SYSTEM SUITABILITY

The Working Group recommended standard reference materials to be used with certain analytical techniques to ensure system suitability. The reference materials and concentrations are listed in Table 1.

Reference Material	Concentration	Technique	Target Concentration (µg/g)
2-Propanol	1000 µg/g	HPLC	1000
Hexane	1000 µg/g	HPLC	1000
Methylene Chloride	1000 µg/g	HPLC	1000
Stearic Acid	1000 µg/g	GC/MS	1000
Calcium Chloride	1000 µg/g	GC/MS	1000
Calcium Nitrate	1000 µg/g	GC/MS	1000
Calcium Sulfate	1000 µg/g	GC/MS	1000
Calcium Hydroxide	1000 µg/g	GC/MS	1000
Calcium Oxide	1000 µg/g	GC/MS	1000
Calcium Phosphate	1000 µg/g	GC/MS	1000
Calcium Silicate	1000 µg/g	GC/MS	1000
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