European Pharmacopoeia/ICH Q3(M) Class 2 Mix A, Revised

(6 components)
- 2-ethylhexanol 160µg/mL
- ethylene glycol 620
- formamide 220
- 2-methoxyethanol (methyl Cellosolve) 50
- In dimethyl sulfoxide, 1mL/ampul

Prepared in water:dimethyl sulfoxide (80:20), 1mL/ampul

EP 2.4.22 Composition of Fatty Acids by GC Mix 1

(6 components)
- methyl arachidate (C20:0) 40
- methyl docosanoate (C22:0) 5
- methyl myristate (C14:0) 5

100mg total

No data pack available.

EP 2.4.22 Composition of Fatty Acids by GC Mix 2

(5 components)
- methyl caprate (C10:0) 10
- methyl caprate (C12:0) 10
- methyl myristate (C14:0) 40

100mg total

No data pack available.

ASTM Method D6042-96 (Plastic Container Testing)

American Society for Testing and Materials (ASTM International) Method D6042-96—Test Method for Determination of Phenolic Antioxidants and Erucamide Slip Additives in Polypropylene Homopolymer Formulations Using Liquid Chromatography—is a “consensus” or “referee” method used among plastic manufacturers and the pharmaceutical companies that purchase plastic containers. Plastic container manufacturers use this test to ensure the quality of their product to their pharmaceutical customers. Pharmaceutical companies also specify this test and provide their own lists of target compounds and concentration limits in purchase agreements.

This test calls for isopropanol extraction, HPLC separation, and UV detection. Restek offers a variety of reversed phase HPLC columns suitable for these separations. Restek also designed an analytical reference material to validate this method. This mixture contains the common antioxidants and slips listed in ASTM D6042-96, along with BHT.

ASTM D6042-96 Calibration Mix

<table>
<thead>
<tr>
<th>Material</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>BHT</td>
<td>51.8µg/mL</td>
</tr>
<tr>
<td>Irganox L314</td>
<td>1000 µg/mL</td>
</tr>
<tr>
<td>Irganox 1035</td>
<td>200 µg/mL</td>
</tr>
<tr>
<td>Irganox L64</td>
<td>200 µg/mL</td>
</tr>
<tr>
<td>Irganox L109</td>
<td>100 µg/mL</td>
</tr>
<tr>
<td>Irganox L1134</td>
<td>100 µg/mL</td>
</tr>
<tr>
<td>Irganox L1010</td>
<td>100 µg/mL</td>
</tr>
<tr>
<td>Irganox L1076</td>
<td>100 µg/mL</td>
</tr>
</tbody>
</table>

No data pack available.

ASTM D6042-96 Internal Standard Mix

<table>
<thead>
<tr>
<th>Material</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tinuvin P</td>
<td>51.8µg/mL</td>
</tr>
</tbody>
</table>

No data pack available.

Other Additives—Available from Restek as Custom Formulations

Similar methods for extractables in plastic pharmaceutical containers are cited in the United States Pharmacopeia (USP), British Pharmacopoeia (BP), European Pharmacopoeia (EP), and Japanese Pharmacopoeia (JP). Customers may also have formulation-specific or product-specific test mixtures. Please contact us for a custom mixture. Our current inventory of raw materials includes these popular antioxidants. We have many more not listed and can obtain most compounds you may need.

- Ethanox 323
- Ethanox 210
- Ethanox 702
- Ethanox 703
- Ethanox 106
- Ethanox 157

No data pack available.

At Risk for Melamine

Meet new FDA guidance for melamine contamination in at-risk pharmaceutical components.

Melamine Analysis Kit.......

(see page 535)

Detect melamine and related compounds by GC/MS with a complete analysis kit. Consistent with FDA procedure and new guidance for at-risk pharmaceutical components.

Keep up with advances in melamine analysis at www.restek.com/melamine