

European Pharmacopoeia Method *cont'd*

European Pharmacopoeia/ICH Q3C(M) Class 2 Mix C, Revised

(6 components)

2-ethoxyethanol	160µg/mL	N-methylpyrrolidone	530
ethylene glycol	620	sulfolane	160
formamide	220		

2-methoxyethanol
(methyl Cellosolve) 50

In dimethyl sulfoxide, 1mL/ampul
cat. # 36275 (ea.)

European Pharmacopoeia/ICH Class 2 Mix B, Revised



(10 components)

acetonitrile	410µg/mL	2-hexanone	50
chloroform	60	methanol	3,000
1,2-dimethoxyethane	100	nitromethane	50
N,N-dimethylacetamide	1,090	pyridine	200
1,4-dioxane	380	tetralin	100

Prepared in water:dimethyl sulfoxide (80:20), 1mL/ampul
cat. # 36270 (ea.)

European Pharmacopoeia/ICH Q3C(M) Class 2 Mix A, Revised

(14 components)

chlorobenzene	360µg/mL	methylene chloride	600
cyclohexane	3,880	tetrahydrofuran	720
cis-1,2-dichloroethene	1,870	toluene	890
N,N-dimethylformamide	880	trichloroethene	80
ethylbenzene	369	m-xylene	1,302
n-hexane (C6)	290	o-xylene	195
methylcyclohexane	1,180	p-xylene	304

In dimethyl sulfoxide, 1mL/ampul
cat. # 36274 (ea.)

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 (7 components)

BHT	Irganox 3114
erucamide slip	Irganox 1010
vitamin E	Irganox 1076
Irgafos 168	

50µg/mL each in isopropanol, 1mL/ampul
cat. # 31628 (ea.)

No data pack available.

ASTM D6042-96 Internal Standard Mix

Tinuvin P
51.8µg/mL in isopropanol, 1mL/ampul
cat. # 31629 (ea.)

No data pack available.

Composition of Fatty Acids by GC

EP 2.4.22 Composition of Fatty Acids by GC Mix 1

(6 components)

Description	% by Weight	Description	% by Weight
methyl arachidate (C20:0)	40	methyl oleate (C18:1[cis9])	20
methyl dodecanoate (C12:0)	5	methyl palmitate (C16:0)	10
methyl myristate (C14:0)	5	methyl stearate (C18:0)	20

100mg total
cat. # 35100 (ea.)



No data pack available.
Quantity discounts not available.

EP 2.4.22 Composition of Fatty Acids by GC Mix 2

(5 components)

Description	% by Weight	Description	% by Weight
methyl caproate (C6:0)	10	methyl dodecanoate (C12:0)	20
methyl caprylate (C8:0)	10	methyl myristate (C14:0)	40
methyl decanoate (C10:0)	20		

100mg total
cat. # 35101 (ea.)



No data pack available.
Quantity discounts not available.

Other Additives—Available from Restek as Custom Formulations

Similar methods for extractables in plastic pharmaceutical containers are cited in the United States Pharmacopoeia (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
- Irganox L64
- Ultrinox 626
- Vanlube PCX
- Ethanox 330
- Irganox L109
- Vanlube 81
- Vanlube SL
- Ethanox 702
- Irganox L134
- Vanlube 848
- Vanlube SS
- Ethanox 703
- Irganox L135
- Vanlube 7723
- Irganox L06
- Irganox 1035
- Vanlube AZ
- Irganox L57
- Santanox R
- Vanlube NA

At Risk for Melamine

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

Melamine Analysis Kit.....cat. # 33254

(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

