

## **Extractables and Leachables Screening Standard in Methanol**

Art. ID	WAT-186008063
Unit	1,5 mL
Deliverydetails	ADR Excepted Quantity (EQ) / AIR Excepted Quantity (EQ) UN1230 (6.1) II E2

### Description

Description: The Extractables & Leachables Screening Standard is a 1.5 mL mixture of 18 common polymer additives and preservatives dissolved in methanol // Intended Use: This standard is used to evaluate and benchmark high resolution LC-MS systems.

INTRODUCTION: The safety of pharmaceuticals, foodstuffs and cosmetics may be compromised by chemical compounds in the food contact materials (FCMs) and other packaging that is in direct contact with the consumer product. These chemical compounds are typically categorized as:

Extractables - Compounds which are extracted from packaging or device components under controlled extraction conditions.

Leachables - Compounds which migrate from the packaging into the product during its normal shelf life.

Non-Intentionally Added Substances (NIAS) - Impurities and reaction and breakdown products from starting substances used to produce food contact plastics.

Due to continuously increasing global regulations, the characterization of packaging and FCMs has become more critical than ever for the manufacturers that supply the pharmaceutical, food and cosmetics industries. To ensure regulatory compliance, avoid product recalls and protect their brands, these organizations must carefully control and monitor their products to eliminate the potential risks associated with extractable, leachable and NIAS compounds.

Text/Information	Analyte/Parameter	CAS number	Concentration/Value	Unit	Method	Source
Ionization: -	Methylparaben (4-Hydroxybenzoic acid-methyl ester)	[99-76-3]	0,1	µg/mL		
Ionization: -	Propylparaben (4-Hydroxybenzoic acid-propyl ester)	[94-13-3]	0,1	µg/mL		
Ionization: +	Diethyl phthalate	[84-66-2]	0,1	µg/mL		
Ionization: +	2-(2-Hydroxy-5-methylphenol)-benzotriazin (Tinuvin P)	[2440-22-4]	1	µg/mL		
Ionization: +	Di-n-butyl sebacate	[109-43-3]	0,1	µg/mL		
Ionization: +	Phthalic acid, bis-phenyl ester (Bis-phenyl phthalate)	[84-62-8]	0,1	µg/mL		
Ionization: +	2-Hydroxy-4-octyloxy benzophenone (Uvinul 3008)	[1843-05-6]	0,1	µg/mL		
Ionization: +/-	Tri-p-cresyl phosphate (Tinuvin 327)	[3864-99-1]	1	µg/mL		
Ionization: +	Tris(p-cresyl) phosphat	[78-32-0]	0,1	µg/mL		

	e (TCP)			
Ionization: +	2,5-Bis(5-tert-butylbenzoxazol-2-yl)thiophene (BBOT) (Uvitex OB)	[7128-64-5]	0,1	µg/mL
Ionization: +/-	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (Cyasorb 2908)	[67845-93-6]	0,1	µg/mL
Ionization: +/-	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (Irganox 1076)	[2082-79-3]	1	µg/mL
Ionization: +/-	3,3'-Bis(3,5-di-tert-butyl-4-hydroxyphenyl)-N,N'-hexamethylenedipropionamide (Irganox 245)	[36443-68-2]	0,1	µg/mL
Ionization: +/-	3,3'-Bis(3,5-di-tert-butyl-4-hydroxyphenyl)-N,N'-hexamethylenedipropionamide (Irganox 1098)	[23128-74-7]	0,1	µg/mL
Ionization: +/-	Tinuvin 360 (Bisotrizole)	[103597-45-1]	1	µg/mL
Ionization: +/-	2,2',2,6,6'-Hexa-tert-butyl-4,4',4'-[(2,4,6-trimethyl-1,3,5-benzenetriyl)trismethylene]triphenol (Ethanox 330, Irganox 1330)	[1709-70-2]	1	µg/mL
Ionization: +	2-Propenoic acid,2-cyano-3,3-diphenyl-,2,2-bis(2-cyano-1-oxo-3,3-diphenyl-2-propenyl)oxymethyl-1,3-propanediyl ester (Uvinul 3030)	[178671-58-4]	0,1	µg/mL
Ionization: +/-	Pentaerythrityl tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate] (Irganox 1010)	[6683-19-8]	1	µg/mL

