USP Technical Guide

System suitability mixtures for chromatographic screening of organic extractables and leachables

Summary

Non-targeted screening for organic extractables and leachables (E&L) relies on complex chromatographic methods implemented by multiple laboratories using various instruments, operating parameters, and workflows.

This technical guide describes the use of standardized USP system suitability mixtures to verify the readiness and performance of widely used chromatographic screening methods for organic E&L. These mixtures enable laboratories to confirm that key performance attributes—such as chromatographic range, sensitivity, specificity, and precision—are achieved and maintained during E&L screening.

The system suitability mixtures described in this technical guide originate from concepts and proposals first introduced in a USP Stimuli Article on system suitability for non-targeted analysis of organic extractables and leachables. Following publication, stakeholder input was solicited and a multi-laboratory round robin study was conducted to evaluate the practical performance of the proposed mixtures across diverse instruments and analytical methods. Insights gained from this collaborative evaluation informed subsequent refinement and optimization of the suitability mixture compositions described in this technical guide. This technical guide translates that scientific foundation into practical guidance for routine laboratory use.

The system suitability approach described herein supports consistency, credibility, and comparability of screening data generated across laboratories, analytical runs, and analytical platforms.

Intended use and scope

This technical note guides laboratories in the **implementation and interpretation** of the USP E&L System Suitability Standards for organic E&L screening using:

- Direct injection gas chromatography with mass spectrometric detection (GC–MS)
- Headspace GC–MS
- Liquid chromatography with MS detection, (LC–MS), with atmospheric pressure chemical ionization (APCI), both positive and negative ionization
- LC–MS with electrospray ionization,(ESI), both positive and negative ionization

The system suitability mixtures help enable laboratories to confirm that a screening method has been properly set up and that the instrument being used operates properly and effectively. This technical guide is not an official USP standard.

BIO.1054

Why system suitability matters for E&L screening

E&L screening presents multiple challenges because:

- The population of potential analytes is large, diverse, and largely unknown prior to screening.
- Screening methods rely on complex chromatographic separations with sensitive and information rich detectors (e.g., mass spectrometry).
- Analytical methods and instruments vary across laboratories, even when similar techniques are employed.

While method qualification establishes that a method is suitable for its intended use, **system suitability testing establishes that the instrumental systems are performing** effectively during a given analytical run.

For E&L screening, system suitability should demonstrate that the setup:

- Covers the intended chromatographic range.
- Achieves sufficient sensitivity relative to reporting thresholds (e.g., analytical evaluation threshold, AET).
- Produces reproducible and specific responses for chemically diverse marker compounds.
- Maintains chromatographic performance throughout use.

These objectives are achieved with **chemically representative system suitability mixtures** rather than analyte specific standards.

Design principles of USP system suitability mixtures

Each system suitability mixture was purposefully designed to probe specific aspects of method performance using compounds that are representative of real-world E&L.

Format of system suitability mixtures. Click here to order.

Item Number	Item Name	Pack Size	Chemical Name and Concentration (~mg/ml)	Diluent
1800490	Extractable & Leachable System Suitability Standard: Direct GC-MS Mixture	1ml ampule	A mixture containing: 1.0 mg/ml 18-Pentatriacontanone; 0.4 mg/ml Cyclohexanone; 0.4 mg/ml Caprolactam; 0.2 mg/ml Methyl methacrylate; 0.2 mg/ml 2-Ethyl-1-hexanol; 0.2 mg/ml 2-Fluorobiphenyl; 0.2 mg/ml n-Nonadecane; 0.2 mg/ml n-Nonacosane; 0.2 mg/ml Irgafos 168 (USP Plastic additive 5); 0.2 mg/ml 2-Heptadecanone.	Dichloromethane (DCM)
1800491	Extractable & Leachable System Suitability Standard: Head Space GC-MS Mixture	1ml ampule	A mixture containing: 2 mg/ml Trimethylsilanol; 2 mg/ml Methylcyclopentane; 2 mg/ml Hexamethylcyclotrisiloxane; 2 mg/ml Cyclohexanone; 2 mg/ml 2-Octanone; 2 mg/ml n-Tetradecane; 1 mg/ml Dimethoxymethane; 1 mg/ml Toluene d8.	Acetonitrile (ACN)

Item Number	Item Name	Pack Size	Chemical Name and Concentration (~mg/ml)	Diluent
1800501	Extractable & Leachable System Suitability Standard: LC-MS-APCI Mixture	1ml ampule	A mixture containing: 0.2 mg/ml Aminobenzoic acid; 0.2 mg/ml Caprolactam; 0.2 mg/ml 2-Mercaptobenzothiazole; 0.2 mg/ml Propylparaben; 0.2 mg/ml Hostanox® 03 (USP Plastic additive 1); 0.2 mg/ml Erucamide (USP Plastic additive 13); 0.2 mg/ml Irgafos® 168 (USP Plastic additive 5); 0.2 mg/ml Glyceryl 1,3-Distearate; 0.2 mg/ml Irganox® PS802 (USP Plastic additive 10).	Isopropyl Alcohol (IPA)
1800493	Extractable & Leachable System Suitability Standard: LC-MS-ESI Mixture	1ml ampule	A mixture containing: 0.2 mg/ml N-Nitrosodimethylamine; 0.2 mg/ml Adipic acid; 0.2 mg/ml Caprolactam; 0.2 mg/ml Phthalic acid; 0.2 mg/ml 2-Mercaptobenzothiazole; 0.2 mg/ml Propylparaben; 0.2 mg/ml Stearic acid; 0.2 mg/ml Irganox 1076.	Isopropyl Alcohol (IPA)

Functional roles of compounds

Each mixture contains compounds serving the following roles:

Compound Role	Purpose	Performance Attribute Assessed
Anchor compounds	Establish breadth of chromatographic separation	Chromatographic range and method setup
Sensitivity compounds	Establish sensitivity of the instrument system	Detector readiness and sensitivity
Precision compounds	Establish repeatability	Injection-to-injection repeatability
Critical pairs	Establish resolving power of chromatographic separation	Resolution and peak deconvolution
Overlapping compounds	Establish that methods are orthogonal and overlapping	Orthogonal method coverage

Together, these compounds allow laboratories to assess method performance in a **holistic and application-relevant manner**. If ISTD is present, it may be used for quantitation purposes.

System suitability mixture composition

The composition of the mixtures and the purpose of each marker compound in each mixture are indicated as follows:
Direct injection GC–MS (semi-volatile extractables)

Compound	CAS No	Retention Times (~min)	Purpose
Methyl methacrylate	80-62-6	3.6	Early-eluting anchor compound
Cyclohexanone	108-94-1	8.1	Overlapping compound with Headspace GC–MS
2-Ethyl-1-hexanol	104-76-7	11.3	Sensitivity, precision and accuracy compound
Caprolactam	105-60-2	15.7	Overlapping compound with LC–MS (APCI)
2-Fluorobiphenyl	321-60-8	17.7	Internal standard
n-Nonadecane	629-92-5	25.3	Critical pair compound
2-Heptadecanone	2922-51-2	25.4	Critical pair compound
n-Nonacosane	630-03-5	35.7	Low response detectability marker
Irgafos 168	31570-04-4	41.7	Overlapping compound with LC-MS (APCI)
18-Pentatriacontanone	504-53-0	47.1	Late eluting anchor compound

Headspace GC–MS (volatile extractables)

Compound	CAS No	Retention Times (~min)	Purpose
Dimethoxymethane	109-87-5	6.8	Early eluting anchor and sensitivity compound
Trimethylsilanol	1066-40-6	9.1	Critical pair compound
Methylcyclopentane	96-37-7	9.3	Critical pair compound
Toluene-d8	2037-26-5	15.5	Internal standard
Hexamethylcyclotrisiloxane	541-05-9	16.6	Detectability compound
Cyclohexanone	108-94-1	23.1	Overlapping compound with GC–MS and accuracy compound
2-Octanone	111-13-7	26.0	Precision compound
n-Tetradecane	629-59-4	38.0	Late eluting anchor compound

LC–MS (APCI) (non-volatile extractables)

Compound	CAS No	Retention Times (~min)	Ionization	Purpose
Aminobenzoic acid	150-13-0	1.5	±	Early eluting anchor compound
Caprolactam	105-60-2	3.3	+	Overlapping compound with LC-MS ESI
2-Mercaptobenzothiazole	149-30-4	6.8	±	Sensitivity, precision and accuracy compound
Propylparaben	94-13-3	7.3	±	Critical pair and orthogonal compound
Hostanox® 03	32509-66-3	8.8	–	Chemical diversity compound
Erucamide	112-84-5	10.1	±	Chemical diversity compound
Irgafos® 168	31570-04-4	14.2	±	Overlapping compound with GC-MS; Late eluting Anchor compound, - ion
Glyceryl 1,3-distearate	504-40-5	16.5	+	Low response detectability compound
Irganox® PS 802	693-36-7	25.9	+	Late eluting anchor compound, + ion

LC–MS (ESI) (polar and ionic extractables)

Compound	CAS No	Retention Times (~min)	Polarity	Purpose
N-Nitrosodimethylamine (NDMA)	62-75-9	3.1	+	Early eluting anchor compound, + ion
Adipic acid	124-04-9	7.5	–	Early eluting anchor compound, - ion
Caprolactam	105-60-2	8.3	+	Overlapping compound with LC-MS (APCI) and accuracy compound
Phthalic acid	88-99-3	9.3	–	Negative mode critical pair
2-Mercaptobenzothiazole	149-30-4	15.1	±	Precision and orthogonal marker
Propylparaben	94-13-3	17.9	±	Sensitivity compound
Stearic acid	57-11-4	24.9	–	Late eluting anchor compound, - ion
Irganox 1076	2082-79-3	30.5	+	Late eluting anchor compound, + ion

Use cases for the Suitability System Mixtures

When to perform system suitability?

System suitability testing should be performed:

- Prior to the start of chromatographic runs.
- At defined points during extended analytical sequences (including end-of-run).
- After significant system changes (e.g., column replacement, instrument and detector maintenance).

Preparation and dilution of system suitability mixtures

- The USP system suitability mixtures are supplied as ready-to-use stock solutions. Prior to analysis, these mixtures should be appropriately diluted by the user to achieve concentrations that align with the intended application and analytical configuration.
- Dilution factors may be adjusted based on the specific analytical method, instrument type, desired detector sensitivity, and analytical purpose, such as qualitative screening, semi-quantitative assessment, or evaluation of system performance relative to reporting thresholds (e.g., at or below the AET).
- This flexibility allows laboratories to integrate system suitability testing into their established workflows while maintaining the core objective of these mixtures.

General workflow

1. Appropriately dilute the system suitability mixture.
2. Analyze the diluted mixture using the laboratory's established screening method.
3. Evaluate chromatographic and detector performance against acceptance criteria.
4. Confirm satisfactory system performance before proceeding with sample analysis.
5. Review end-of-run data to confirm that the analytical system was appropriately stable over the entire run.

Example instrumentation, analytical methods, and chromatograms

Example methods and chromatograms

The system suitability mixtures were evaluated using **chromatographic and mass spectrometric methods representative** of those commonly employed for organic extractables screening. The methods employed and the chromatograms resulting from the analysis of the system suitability mixtures are provided **for illustration only** to demonstrate typical E&L performance.

Note: The methods described below are **not prescriptive** and are **not intended to replace laboratory-specific, qualified screening methods**. Laboratories can adopt method parameters, instrumentation, and workflows as appropriate, provided that system suitability acceptance criteria are met.

"Certain commercial equipment, instruments or materials may be identified in this technical guide to specify adequately the experimental procedure. Such identification does not imply approval, endorsement, or certification by USP of a particular brand or product, nor does it imply that the equipment, instrument, or material is necessarily the best available for the purpose or that any other brand or product was judged to be unsatisfactory or inadequate."

Note: The chromatograms are illustrative examples only and were generated using representative instruments and methods. Laboratories are not expected to reproduce identical chromatographic profiles, provided that the acceptance criteria are met.

Note: The names of instruments and manufacturers are provided for the purpose of this technical guide. USP does not endorse the instruments nor the manufacturers.

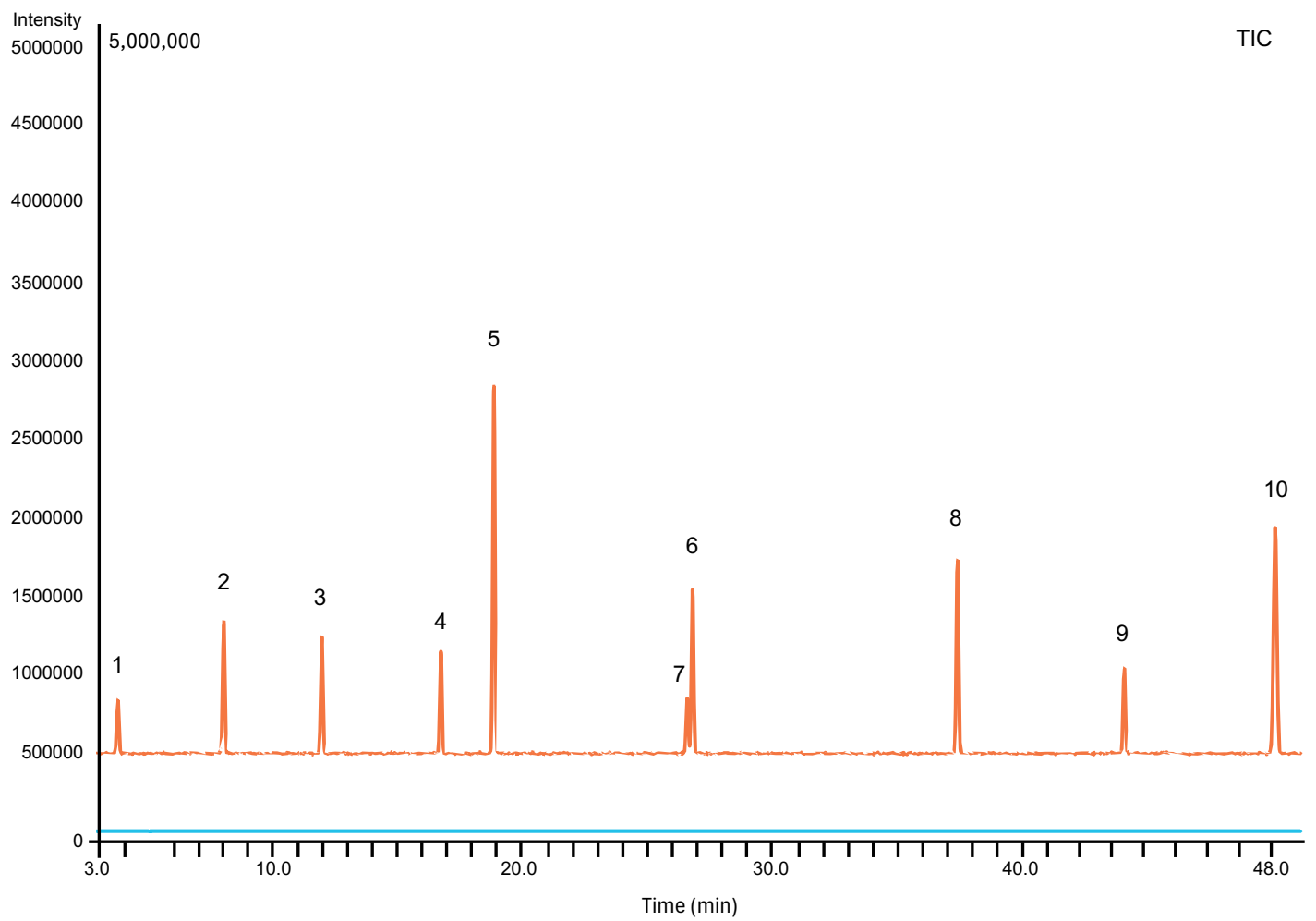
Direct injection GC–MS

Below is an example of Instrumentation and Method Operating Parameters:

Instrument	Shimadzu, GCMS-TQQ8050NX Gas chromatograph mass spectrometer and Nexis GC-2030 Gas chromatograph with AOC 20i Plus injector and AOC 20s Plus auto sampler			
Column	Agilent HP-5MS Ultra Inert (30-m x 0.250-mm x 0.25µm), Part No: 19091S-433UI			
Operating system	GCMS solutions			
Diluent	Dichloromethane			
Injector	Injection volume		1 µl	
GC Parameters	Inlet liner, Deactivated Insert with wool for Splitless (I.D 3.4mm O.D 5mm, Length 95mm), Part Number: 227-35008-01			
	Mode		Splitless	
	Carrier Gas		Helium	
	Inlet Temperature		270°	
	Sampling Time		1.00 min	
	Flow Control Mode		Column Flow	
	Total Flow		15 ml/min	
	Column Flow		1.0 ml/min	
	Average Linear Velocity		36.1 cm/s	
	Purge Flow		3.0 ml/min	
Column Oven Temperature Program	-	Rate (°/min)	Temperature (°)	Hold Time (min)
	Initial	-	40	4
	Rate-1	8	300	12
	Run time		48.50 min	
	Oven Equilibration time		2.0 min	

MS Parameters	Ionization Mode	Electron Impact
	Acquisition Mode	Full scan
	Ion source temperature	250°
	Interface temperature	250°
	Mass range (m/z)	35-700

Example Chromatogram



Methyl methacrylate[1], Cyclohexanone[2],2-Ethyl-1-hexanol[3], Caprolactam[4], 2-Fluorobiphenyl (ISTD)[5], n-Nonadecane[6], 2-Heptadecanone[7], n-Nonacosane[8], Irgafos® 168 (Plastic additive 5)[9], 18-Pentatriacontanone[10],

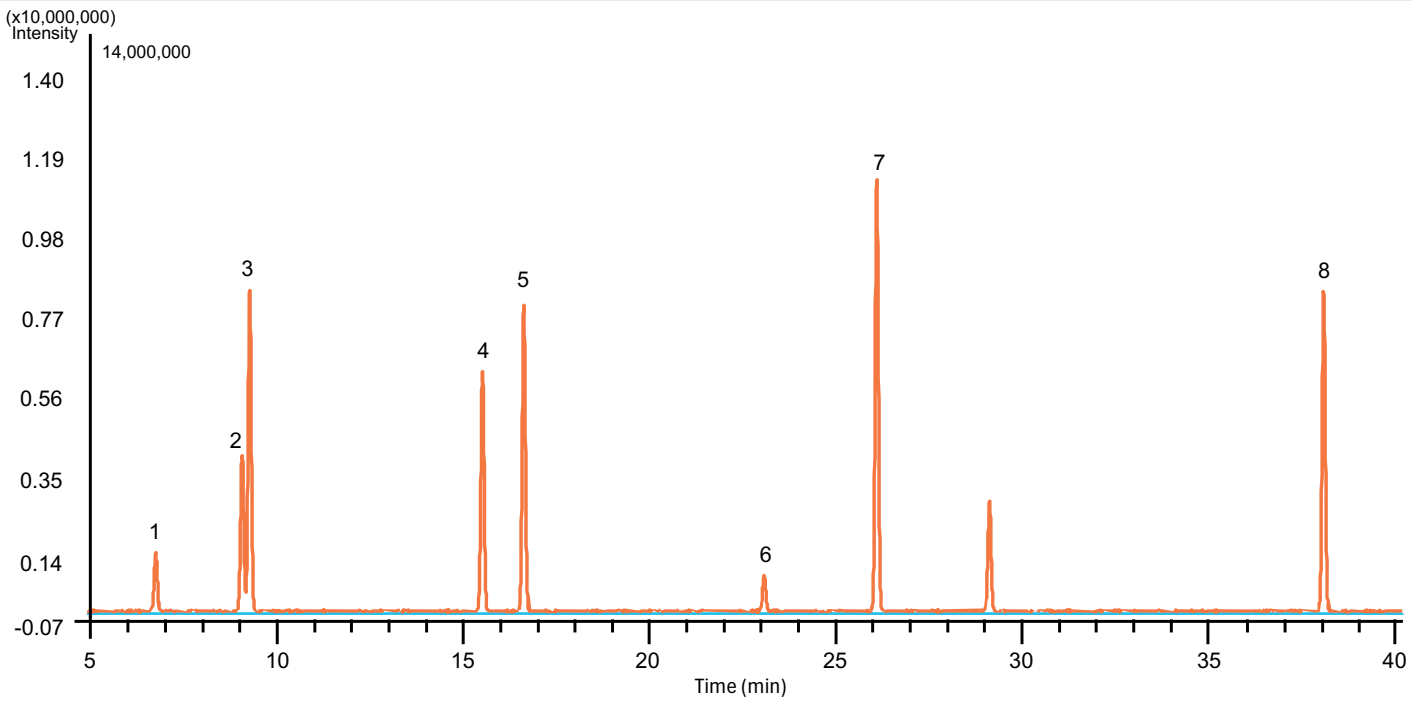
Headspace GC–MS

Example Instrumentation and Method Operating Parameters

Instrument	Shimadzu, GCMS-TQ8050NX Gas chromatograph mass spectrometer and Nexis GC-2030 Gas chromatograph with HS-20 Headspace sampler			
Column	Agilent DB-624 (60-m x 0.250-mm x 1.40µm), Part Number: 122-1364			
Operating software	GCMS solutions			
Diluent	Acetonitrile (ACN)			
GC Parameters	Carrier gas		Helium	
	Flow control mode		Column Flow	
	Constant flow		1.50 ml/min	
	Total flow		19.5 ml/min	
	Purge flow		3.0 ml/min	
	Average Linear Velocity		31.3 cm/s	
Column Oven Temperature Program	-	Rate (°/min)	Temperature (°)	Hold Time (min)
	Initial	-	45	3
	Rate-1	8	90	4
	Rate-2	5	200	3
	Rate-3	10	220	5.37
	Run time / Total program time		45 min	
	Oven Equilibration time		2.0 min	
Headspace Parameters	Oven temperature		85°	
	Sample line temperature		95°	
	Transfer line temperature		105°	
	Shaking level		1	
	Pressurizing gas pressure		50 kPa or 7 psi	
	Vial equilibration time		20 min	
	Vial pressurizing time		2 min	

	Pressure equilibration time	0.10 min
	Load time	2 min
	Load equilibration time	0.10 min
	Injection time	1 min
	Needle flush time	10 min
	GC cycle time	65 min
MS Parameters	Ionization mode	Electron impact
	Acquisition mode	Full scan
	Ion source temperature	250°
	Interface temperature	250°
	Mass range (m/z)	35-300

Example Chromatogram



Dimethoxymethane[1], Trimethylsilanol[2], Methylcyclopentane[3], Toluene-D8 (ISTD)[4], Hexamethylcyclotrisiloxane[5], Cyclohexanone[6] , 2-Octanone[7] , n-Tetradecane[8]

LC–MS (APCI)

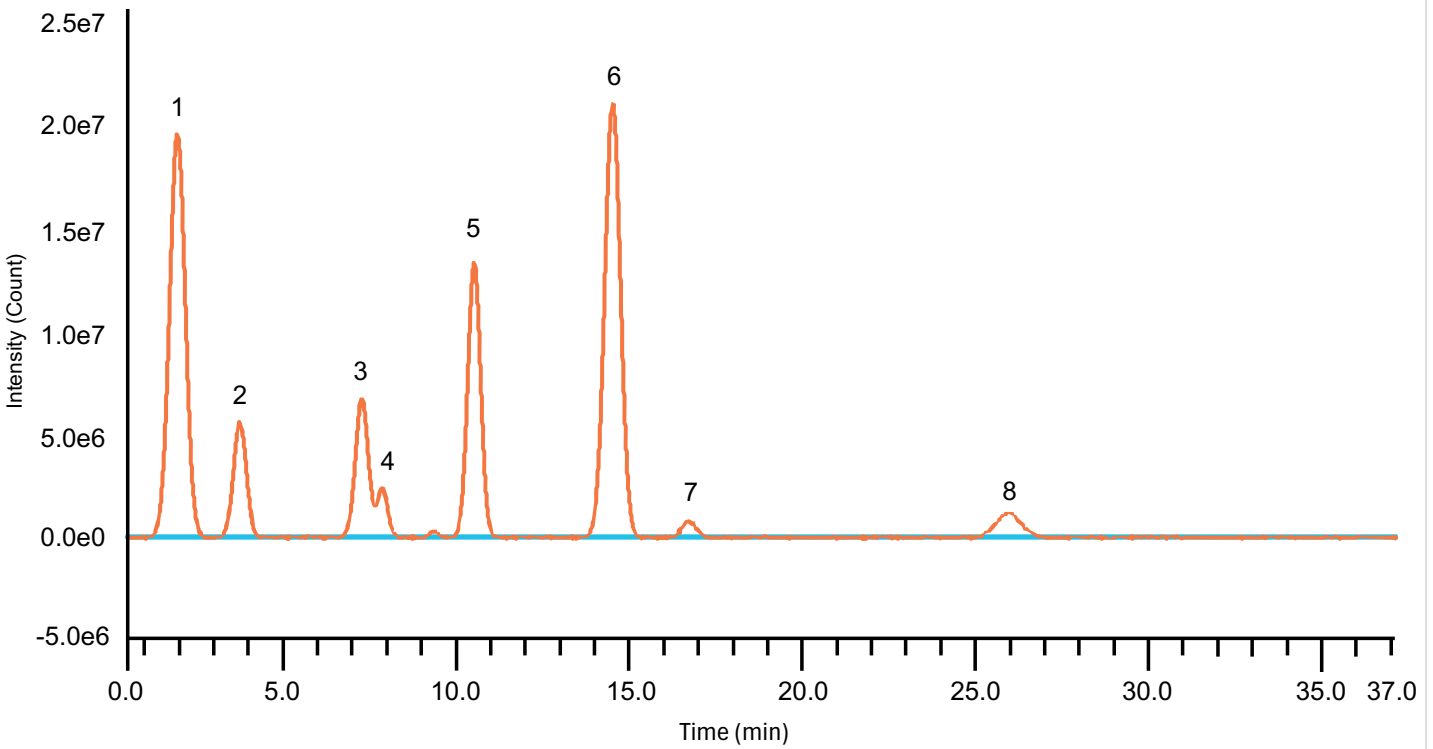
Example Instrumentation and Method Operating Parameters

Instrument	Thermo Fisher Scientific / Orbitrap Exploris 240 basic system w/IC			
Column	Waters Acquity CSH-C18 (100-mm x 3.0-mm x 1.7 µm, 130Å), Part No: 186005301			
Operating system	Chromeleon 7.3.2			
Diluent	Methanol: Water-98:2%v/v (Final diluent)			
Instrument operating Parameters	Column temperature		40º	
	Autosampler temperature		20º	
	Injection volume		3µl	
Gradient program	Time (min)	Flow Rate (µl/min)	Mobile phase-A (Ultra-pure water) (%)	Mobile phase-B (Methanol) (%)
	0	450	80	20
	2	450	80	20
	7	450	0	100
	32	450	0	100
	33	450	80	20
	37	450	80	20
	Run time		37 min	
MS Parameters	Ion source type		APCI	
	Acquisition Mode		Full scan	
	Spray current		Static	
	Positive ion discharge current (µA)		5	

	Negative ion discharge current (µA)	5
	Gas mode	Static
	Sheath gas (Arb)	35
	Aux gas (Arb)	10
	Sweep gas (Arb)	5
MS Parameters	Ion transfer tube temp (°)	300
	Vaporizer temp (°)	425
	APPI lamp	Not in use
	Use ion source settings from Tune	False
	FAIMS mode	Not installed
	RF lens (%)	70
	AGC target	Standard
	Maximum injection time mode	Auto
	Microscans	1
	Data type	Profile
	Polarity	Positive and Negative
	Scan Range (m/z)	90-1300 (Reported in XIC)
	Orbitrap resolution	120000

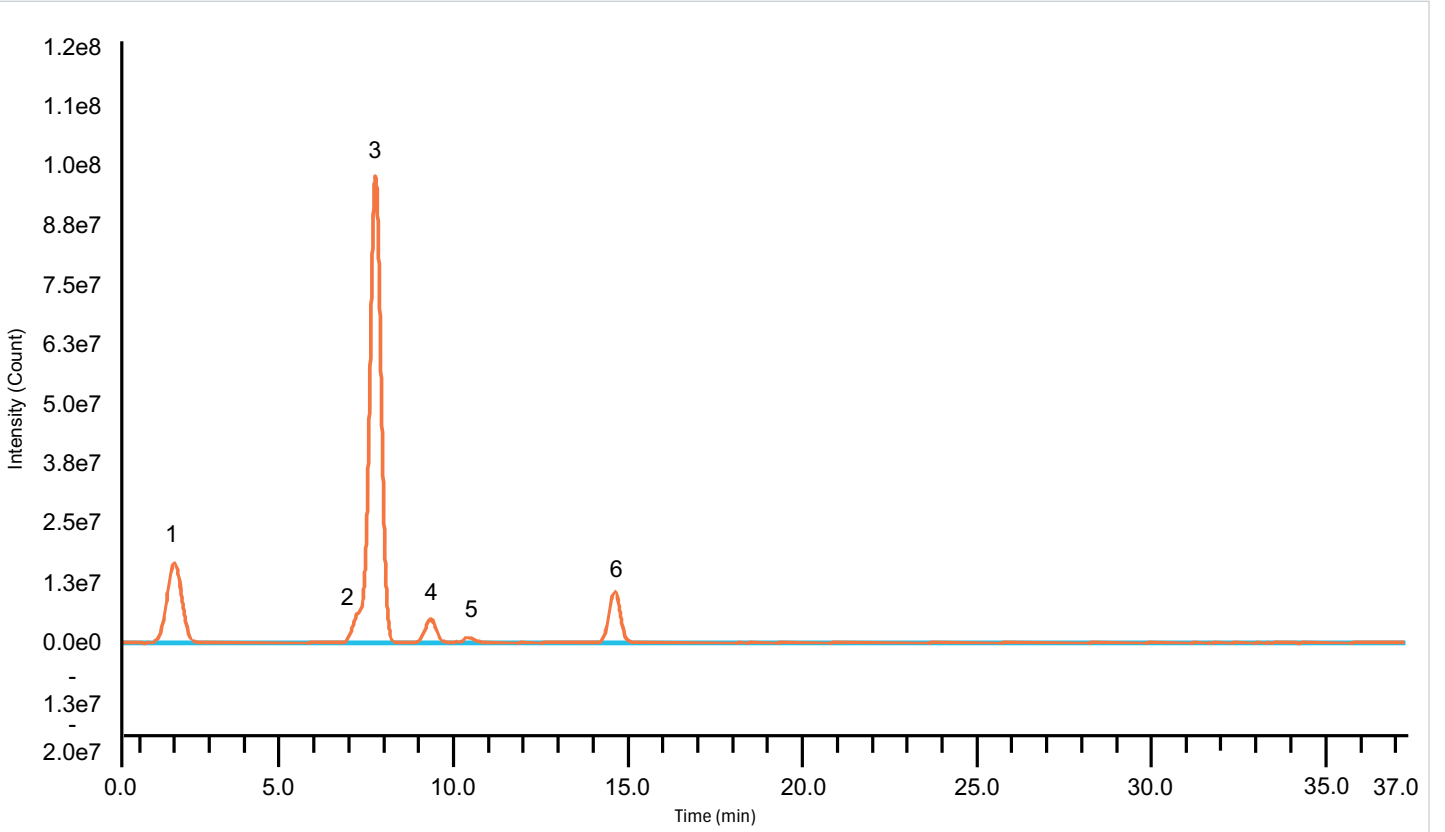
Example Chromatograms

Positive Ion



Aminobenzoic acid[1], Caprolactam[2], 2-Mercaptobenzothiazole[3], Propylparaben[4], Plastic additive[13] (Erucamide)[5], Plastic additive [5] (Irgafos® 168)[6], Glyceryl [1],3-Distearate[7], Plastic additive [10] (Irganox® PS802)[8]

Negative ion



Aminobenzoic acid[1], 2-Mercaptobenzothiazole[2], Propylparaben[3], Plastic additive-1 (Hostanox® 03)[4], Plastic additive-13 (Erucamide)[5], Plastic additive-5 (Irgafos® 168)[6]

LC–MS (ESI)

Example Instrumentation and Method Operating Parameters:

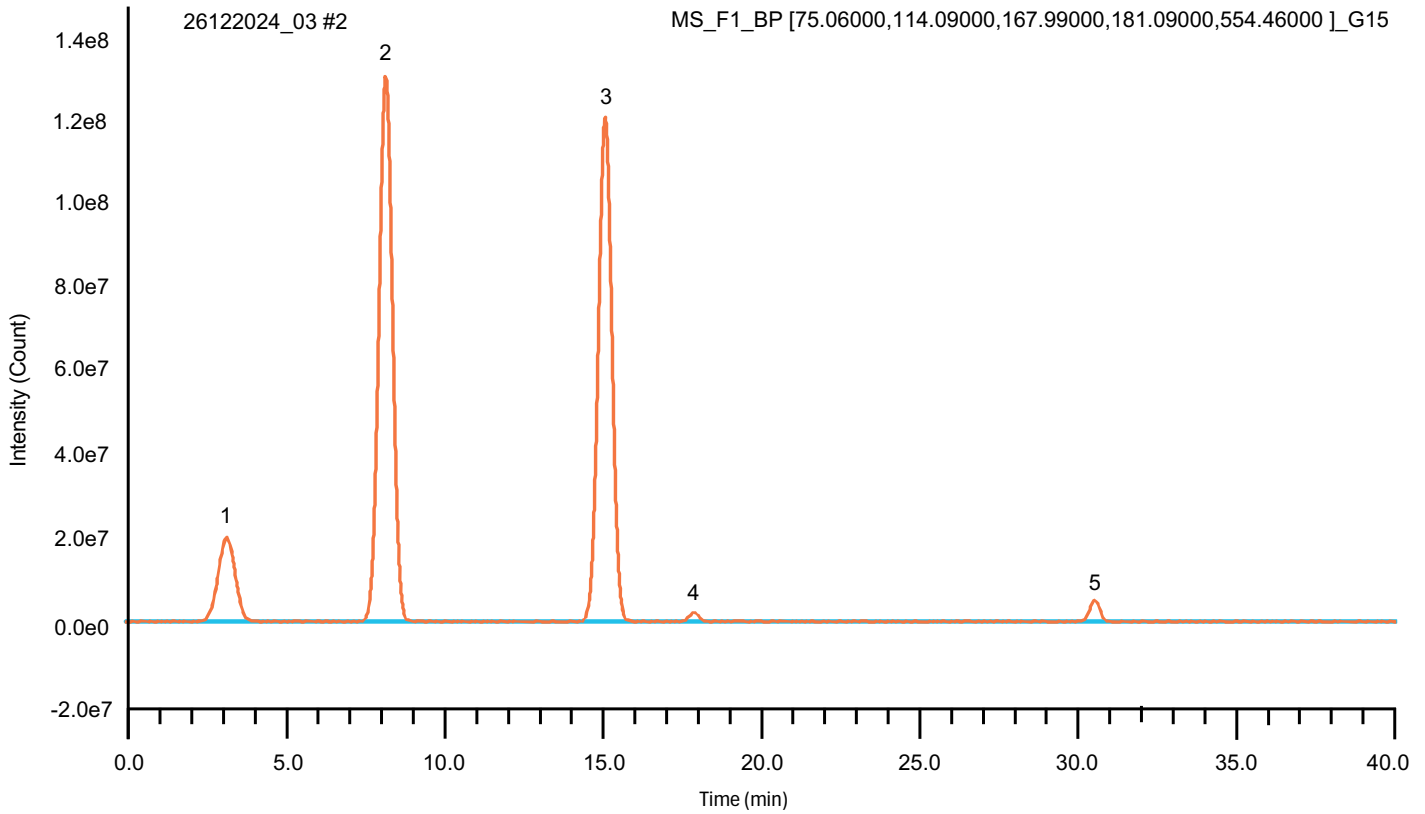
Instrument	Thermo Fisher Scientific / Orbitrap Exploris 240 basic system w/IC	
Column	Waters Acquity HSS-C18 (100-mm x 2.1-mm x 1.8 µm, 100Å), Part No: 186003533	
Operating system	Chromeleon 7.3.2	
Diluent	0.1% Formic acid in Methanol and Water (80:20 % v/v) was used as a diluent for final solution preparations.	
Instrument operating Parameters	Column temperature	40°
	Auto sampler temperature	5°
	Injection volume	3 µl

Gradient program	Time (min)	Flow Rate (µ/min)	Mobile phase-A (Ultra-pure water + 0.05% Formic acid) (%)	Mobile phase-B (Methanol + 0.05% Formic acid) (%)
	0	200	98	2
	15.5	200	35	65
	20	200	0	100
	32	200	0	100
	34	200	98	2
	40	200	98	2
	Run time		40 min	
MS Parameters	Ion source type		ESI	
	Acquisition Mode		Full scan and report as EIC	
	Spray voltage		Static	
	Positive ion (V)		3800	
	Negative ion (V)		3200	
	Gas mode		Static	
	Sheath gas (Arb)		30	
	Aux gas (Arb)		8	
	Sweep gas (Arb)		0	
MS Parameters	Ion transfer tube temp (°)		280	
	Vaporizer temp (°)		300	
	APPI lamp		Not in use	
	Use ion source settings from Tune		False	
	FAIMS mode		Not installed	
	RF lens (%)		70	
	AGC target		Standard	

	Maximum injection time mode	Auto
	Microscans	1
	Data type	Profile
	Polarity	Positive and Negative
	Scan Range (m/z)	60-900
	Orbitrap resolution	120000

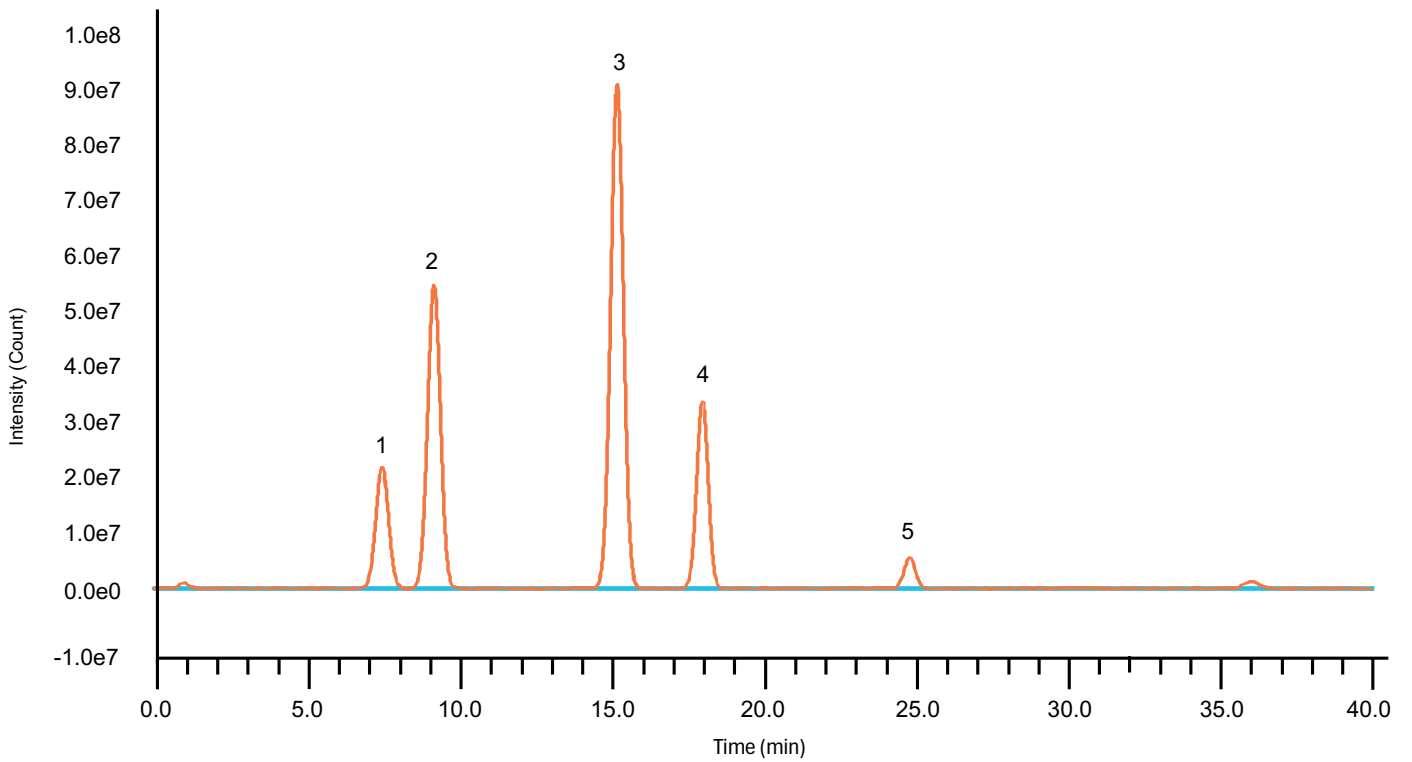
Example Chromatograms

Positive Ion



NDMA[1], Caprolactam[2], 2-Mercaptobenzothiazole[3], Propylparaben[4], Plastic additive 4 (Irganox® 1076)[5]

Negative ion



Adipic acid[1], Phthalic acid[2], 2-Mercaptobenzothiazole[3], Propylparaben[4], Stearic acid[5]

Acceptance criteria and interpretation

A screening method is performing as intended when **all applicable criteria below are met.**

Chromatographic performance

1. Anchor compounds are detected at the beginning and end of the chromatogram, confirming full analytical range.
2. Retention times are consistent across replicate injections (e.g., % RSD ≤ 2% at beginning of an analytical run, % RSD ≤ 5% over entire run).
3. Critical pairs demonstrate acceptable resolution (e.g., Rs ≥ 1.5), where applicable.

Interpretation guidance:

Failure to detect anchor compounds or significant retention time shifts may indicate issues with flow, temperature control, column condition, or gradient setup.

Sensitivity:

- Designated sensitivity compounds produce a recognizable response at or above the method's LOQ (e.g., S/N ≥ 10 or equivalent).

Interpretation guidance:

Failure to detect sensitivity compounds may indicate issues with tuning, ion source contamination, detector performance, or method sensitivity relative to intended use.

Precision:

- Peak areas for designated precision compounds across replicate injections meet the laboratory's acceptance criterion (e.g., %RSD ≤ 15% at the beginning of the run, % RSD ≤ 20% over entire run).

Interpretation guidance:

Poor precision may indicate injection issues, system instability, or contamination.

Accuracy:

- Identification accuracy: For each mix set, the designated accuracy compound shall be correctly identified based on its expected retention time and mass spectral characteristics.
- Concentration accuracy: For each mix set, the measured concentration of the designated accuracy compound shall be within 50–150% of the prepared concentration (or 70–130% where feasible).

Interpretation guidance:

- Failure to correctly identify the peak responsible for a marker compound generally suggests that there may be issues with the gradient setup such as using high organic content, column degradation, etc.,
- Failure to accurately quantify the marker compounds suggests that there may be issues related to detector response or standard preparations. The laboratory's quantitation process is flawed.

Optional Assessments:

At the user's discretion, additional assessments such as linearity may be employed.

What system suitability does and does not demonstrate

System suitability demonstrates that:

- The method was correctly implemented at time of use.
- The analytical instrumentation is operating properly.
- The analytical system is capable of generating screening-quality, semi-quantitative data throughout the analytical run.

System suitability does NOT demonstrate that:

- The method is fully qualified as suitable for its intended use.
- The method is applicable to a specific product, material, or circumstance.
- All potential extractables will be detected and identified.

Storage and stability

The stability of the system suitability mixture has been evaluated to support its intended use in routine analytical applications. Stability considerations relevant to users include long term storage (shelf life), handling after thawing, and use after dilution.

Shelf-life storage:

The system suitability mixtures are demonstrated to be stable for **up to one year when stored at –20 °C.** Ongoing stability studies are in progress, and the assigned shelf life may be extended as additional supporting data become available.

Storage after thawing (prior to use):

At present, no stability data is available to support extended storage of the system suitability mixtures after thawing and prior to use. Accordingly, it is recommended that thawed vials be used promptly (within 24 hours of thawing) and not subjected to repeated freeze–thaw cycles.

Use after dilution:

Once a vial is opened and the contents are diluted in the appropriate diluent for analysis, the resulting solution has been shown to be stable **up to 24 hours** under typical laboratory conditions. While preparation and handling of diluted solutions are the responsibility of the user, **USP recommends that diluted system suitability solutions be used within 24 hours** to ensure data integrity and method performance.

Conclusion

USP system suitability mixtures provide laboratories with a standardized and scientifically grounded tool to verify method performance for organic E&L screening. Their routine use supports consistent data quality, improved confidence in screening results, and greater comparability across laboratories and analytical platforms.

USP will continue to seek stakeholder feedback to support the ongoing evolution of these mixtures, consistent with evolving best practices in E&L analysis.

Acknowledgment of participating laboratories

USP gratefully acknowledges and thanks the laboratories and organizations that participated in the global round robin study, supporting the development of the E&L system suitability standards. Their collaboration, expertise, and timely execution of the study were essential to evaluating method performance across diverse instruments, workflows, and geographical regions. The study results, combined with participant feedback, informed additional method refinement and compound optimization, ultimately strengthening the proposed system suitability standards.

The round robin study included the following 15 participating locations across the following organizations:

- **Nelson Labs**
- **Boston Analytical**
- **USP–India**
- **Element**
- **Cytiva (3 locations)**
- **Solvias**
- **West Pharmaceutical Services**
- **Intertek**
- **Eurofins**
- **Shimadzu**
- **SGS (3 locations)**

Next Steps

The USP is committed to developing and procuring individual reference standards for extractables and leachables that are commonly encountered but not commercially available or readily obtainable. For example, USP currently offers several rubber oligomers as Analytical Reference Materials, including:

Item	CAS Number
1606221| Rubber Oligomer 1	63251-38-7
1606222 | Rubber Oligomer 2	63216-72-8
1606223 | Rubber Oligomer 3	2512216-71-4
1606224 | Rubber Oligomer 4	2446375-29-5
1606225 | Rubber Oligomer 5	2518227-14-8
1606226 | Rubber Oligomer 6	2514965-51-4
1606230 | Rubber Oligomer 10	NA

USP is now expanding this collection beyond rubber oligomers to include additional classes of oligomeric extractables currently under development, such as caprolactam oligomers, nylon oligomers, PET/PBT oligomers, and PES oligomers, to further support comprehensive E&L evaluations across a wide range of materials and applications. Furthermore, USP markets several Reference Standards that are also extractable and/or leachables, such as those target compounds present in the optimized System Suitability Mixtures.

For updates, visit: https://www.usp.org/impurities/extractables-and-leachables

Reference:

USP Stimuli Article Pharmacopeial Forum (PF) 49(4): Proposals for the Development, Composition, and Routine Use of System Suitability Standard Mixtures in Support of Chromatographic Screening for Organic Extractables and Leachables. https://doi.usp.org/USPNF/USPNF_S203084_10101_01.html

Resources:

- To explore the growing range of USP Reference Standards and Analytical Reference Materials* for E&L, including rubber oligomers, packaging components, etc., please visit USP store (click here).
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