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ANALYSIS OF EXTRACTABLES PROFILE FOR SINGLE-USE BIOPROCESS BAGS

Approved by SGS Life Science Service

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1 Introduction

Extractables and leachables (E&L) issues represent some of the most significant challenges for a pharmaceutical product development team. Foreign organic or inorganic chemical entities may migrate from a pharmaceutical construct, for instance the contact material that is contacted by a therapeutic substance during its synthesis, formulation, production, storage, or delivery. The foreign chemical entities may cause product purity, efficacy, or even safety concern. Regulatory organizations encourage manufacturers to evaluate the risk through properly designed E&L studies.

National Medical Products Administration (NMPA)¹ has published guidelines² on the compatibility studies of parenteral drug product with plastic, pharmaceutical glass, and elastomer packaging materials or containers since 2012. Meanwhile, Product Quality Research Institute (PQRI) published guidelines titled "Safety Thresholds and Best Practices for Extractables and Leachables in Orally Inhaled and Nasal Drug Products" in 2006, and continued to work on a best practice for the E&L studies on Parenteral and Ophthalmic Drug Product (PODP). SGS approaches to E&L in alignment with these publications and USP<665> & USP<1665> resulted from accomplished chemists, toxicologists, renowned pharmaceutical companies, and governmental organizations.

SGS has been approached by ZHEJIANG JYSS BIOENGINEERING CO.,LTD to evaluate the extractables profiles of Single-use Bioprocess bags under ISO 17025 quality system.

2 Definitions

Extractables

Extractables are organic and inorganic chemical entities that are released from a pharmaceutical packaging/delivery system, packaging component, or packaging material of construction and into an extraction solvent under laboratory conditions. Depending on the specific purpose of the extraction study, these laboratory conditions (e.g., solvent, temperature, stoichiometry, etc.) may accelerate or exaggerate the normal conditions of storage and use for a packaged dosage form. Extractables themselves, or substances derived from extractables, have the potential to leach into a drug product under normal conditions of storage and use and thus become leachables.³

Leachables

Leachables are foreign organic and inorganic chemical entities that are present in a packaged drug product because they have leached into the packaged drug product from a packaging/delivery system, packaging component, or packaging material of construction under normal conditions of storage and use or during accelerated drug product stability studies. Because leachables are derived from the packaging or delivery system, they are not related to either the drug product itself or its vehicle and ingredients. Leachables are present in a packaged drug product because of the direct action of the drug product on the source of the leachable. Thus, leachables are typically derived from primary and secondary packaging, as the primary and secondary packaging can serve as a barrier between the packaged drug product and other potential sources of foreign chemical entities (such as tertiary packaging and ancillary components). In certain circumstances, packaging may directly contact the patient under typical clinical conditions of use (for example, the mouthpiece of a metered dose inhaler). As a result of this contact, patients may be exposed

¹ Originally called China Food and Drug Administration.

² The guidelines have considered publications from the China Food and Drug Administration, European Medicine Agency, United State Food and Drug Administration, United States Pharmacopeia, International Conference on Harmonisation, Product Quality Research Institute, and academic publications etc.

³ Cited from reference 2.

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to leachables from the packaging without the action of the drug product. Leachables are typically a subset of extractables or are derived from extractables.

3 Samples

Samples were assigned unique SGS Assignment ID (14A1906975) and Sample ID (Table 1) and stored at room temperature prior to analysis. Information of packaging materials was listed in Table 1.

Table 1 Packaging Materials Information

Name	Batch number	Manufacturer	Sample ID
Single-use Bioprocess bags ⁴	20191007	ZheJiang JYSS Bioengineering Co.,Ltd	14S19026114

4 Limit(s) and Analytical Evaluation Threshold (AET)

Permitted daily exposure (PDE) per "Guideline for Elemental Impurities Q3D"⁵ publicized by International Conference on Harmonisation (ICH) and "Guideline for the Compatibility Study of Pharmaceutical Glass Container for Parenteral Drug Products" by NMPA are shown in Appendix II.

Evaluations of organic compounds are based on AET concept per "Safety Thresholds and Best Practices for Extractables and Leachables in Orally Inhaled and Nasal Drug Products" by PQRI and "Guideline for the Compatibility Study of Chemical Drug Products and Elastomer Seals"⁶. AET is an analytical threshold at or above which the chemical should be identified, quantified, reported, and evaluated by a toxicologist if necessary. AET is derived from Safety Concern Threshold (SCT) or Threshold of Toxicological Concern (TTC), product's administration route, dosage, frequency, and treatment durations, etc. The SCT and TTC concepts were developed to define an acceptable intake for any unstudied chemical below which poses a negligible risk of carcinogenicity or other toxicity.

In the extractable study, 0.01 µg/mL is set as AET_{extraction solution} which confirmed by customers.

5 Extractables study – Sample preparation

The properties of drug product must be carefully considered during the selection of extraction solvents and proper extend of exaggeration of extracting conditions. Meanwhile, the choice of extraction solvents should be compatible to the analytical instruments.

5.1 Controlled extraction process

5.1.1 Overview of extraction process

The extraction solvents, extraction method and instruments used in the extractable study, referenced to guidance about analysis of extractables in elastomers and vials by PQRI⁷. The overview of the extractables study was listed in Table 2.

⁴ It is abbreviated as bags in the following context.

⁵ Reference 6.

⁶ Reference 4.

⁷ Reference 1.

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Table 2 Overview of the extractable study

Sample	Extraction solvent	Extraction technique	ICP-MS ICP-OES	UPLC- DAD-MS	GC- MS/FID	HS-GC- MS
Bags	Purified water	40°C for 28 days	X ⁸	X	X	X
	pH3.0 potassium chloride solution		X	X	X	X
	pH10.0 phosphate solution		X	X	X	X
	50% ethanol solution		N/A ⁹	X	X	X
	0.5N sodium hydroxide solution		X	X	X	X

5.1.2 Extraction solvents

- **Extraction solvent A:** Purified water.
- **Extraction solvent B:** Potassium chloride aqueous solution which was adjusted to pH 3.0±0.1
- **Extraction solvent C:** Phosphate aqueous solution which was adjusted to pH10.0±0.1.
- **Extraction solvent D:** 50% (V/V) ethanol aqueous solution.
- **Extraction solvent E:** 0.5N sodium hydroxide aqueous solution

5.1.3 Extraction solutions

- **Extraction solution A:** 300mL of extraction solvent A was transferred into 2 bags (inner surface area: 1800cm²/bag), which were then shaken at 40°C for 28 day after sealed.
- **Extraction solution B:** 300mL of extraction solvent B was transferred into 2 bags (inner surface area: 1800cm²/bag), which were then shaken at 40°C for 28 day after sealed.
- **Extraction solution C:** 300mL of extraction solvent C was transferred into 2 bags (inner surface area: 1800cm²/bag), which were then shaken at 40°C for 28 day after sealed.
- **Extraction solution D:** 300mL of extraction solvent D was transferred into 2 bags (inner surface area: 1800cm²/bag), which were then shaken at 40°C for 28 day after sealed.
- **Extraction solution E:** 300mL of extraction solvent E was transferred into 2 bags (inner surface area: 1800cm²/bag), which were then shaken at 40°C for 28 day after sealed.
- **Blank extraction solutions** were prepared in the same way with inert containers.

5.2 Testing Sample preparation

5.2.1 Analysis of 29 elements by Inductively Coupled Plasma - Mass Spectrometry (ICP-MS)

- **Sample solution-1:** extraction solution A, B, C, E¹⁰ and blank extraction solutions 4mL each were transferred into separate volumetric flasks, to which was added 20μL of 100μg/mL Au standard solution. Diluent¹¹ was used to adjust volume to 20mL.
- **Sample solution-2 (only for Ni, Cu):** extraction solution E and blank extraction solution 2mL each were transferred into separate volumetric flasks, to which was added 20μL of 100μg/mL Au standard solution. Diluent was used to adjust volume to 20mL.

⁸ "X" means the test was performed.⁹ N/A means not available.¹⁰ 5 times of additional dilution because of the result of B in extraction solution E is beyond the linear range.¹¹ Diluent: Transferred 100 mL of nitric acid, diluted to 1000 mL with purified water, mixed well.

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- **LOQ solution** (1.0µg/L): 1mL of 50µg/L element mixture standard solution and 50µL of 100µg/mL Au solution were transferred into a volumetric flask. Diluent was used to adjust volume to 50mL.
- 5.2.2 Analysis of 5 elements by Inductively Coupled Plasma-Optical Emission Spectrometry (ICP-OES)
- **Sample solution:** extraction solution A, B, C, E and blank extraction solutions 4mL each were transferred separately into separate 20mL volumetric flasks. Diluent was used to adjust volume to 20mL.
 - **LOQ solution** (0.05µg/mL): 1.25mL of 2.0µg/mL element mixture standard solution was transferred into a 50mL volumetric flask. Diluent was used to fill to the meniscus.
- 5.2.3 Analysis of non-volatile compounds by Ultra-Performance Liquid Chromatography - Diode Array Detector - Mass Spectrometry (UPLC-DAD-MS)
- **Sample solution-1:** 25mL of each extraction solution B, C and blank extraction solutions were transferred into different separational funnels. Three aliquots of 7mL (3 X 7mL) dichloromethane (DCM) were used to extract and DCM layers were combined, respectively. Each DCM extract was concentrated to dryness under nitrogen flow. The residue was reconstituted with 0.5mL 50% acetonitrile aqueous solution.
 - **Sample solution-2:** 25mL of each extraction solution A and blank extraction solution were transferred into different separational funnels, 5mL of 1mol/L sodium chloride aqueous solution and 10mL of ethanol aqueous solution were added to each funnel. Three aliquots of 7mL (3 X 7mL) dichloromethane (DCM) were used to extract and DCM layers were combined, respectively. Each DCM extract was concentrated to dryness under nitrogen flow. The residue was reconstituted with 0.5mL 50% acetonitrile aqueous solution.
 - **Sample solution-3:** 25mL of each extraction solution D and blank extraction solution were transferred into different separational funnels, 5mL of 1mol/L sodium chloride aqueous solution was added to each funnel. Three aliquots of 7mL (3 X 7mL) dichloromethane (DCM) were used to extract and DCM layers were combined, respectively. Each DCM extract was concentrated to dryness under nitrogen flow. The residue was reconstituted with 0.5mL 50% acetonitrile aqueous solution.
 - **Sample solution-4:** 25mL of each extraction solution E and blank extraction solution were transferred into different separational funnels, 25mL of 0.5N hydrochloric acid aqueous solution was added to each funnel. Three aliquots of 7mL (3 X 7mL) dichloromethane (DCM) were used to extract and DCM layers were combined, respectively. Each DCM extract was concentrated to dryness under nitrogen flow. The residue was reconstituted with 0.5mL 50% acetonitrile aqueous solution.
 - **System Suitability Test (SST) solution:** 10µg/mL of Bisphenol M (BPM) and Irganox 1035 solution was injected directly.
 - **Extracted system suitability (ESS) solution-1:** 25mL of each extraction solvent B, C were transferred into different separational funnels, and 0.5mL of 10µg/mL BPM and Irganox 1035 solution was added to each funnel. Three aliquots of 7mL (3 X 7mL) dichloromethane (DCM) were used to extract and DCM layers were combined, respectively. Each DCM extract was concentrated to dryness under nitrogen flow. The residue was reconstituted with 0.5mL 50% acetonitrile aqueous solution.
 - **ESS solution-2:** 25mL of each extraction solvent A was transferred into different separational funnels. 0.5mL of 10µg/mL BPM and Irganox 1035 solution, 5mL of 1mol/L sodium chloride aqueous solution and 10mL of ethanol aqueous solution were added to each funnel. Three aliquots of 7mL (3 X 7mL) dichloromethane (DCM) were used to

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extract and DCM layers were combined, respectively. Each DCM extract was concentrated to dryness under nitrogen flow. The residue was reconstituted with 0.5mL 50% acetonitrile aqueous solution.

- **ESS solution-3:** 25mL of each extraction solvent D was transferred into different separational funnels. 0.5mL of 10µg/mL BPM and Irganox 1035 solution, 5mL of 1mol/L sodium chloride aqueous solution were added to each funnel. Three aliquots of 7mL (3 X 7mL) dichloromethane (DCM) were used to extract and DCM layers were combined, respectively. Each DCM extract was concentrated to dryness under nitrogen flow. The residue was reconstituted with 0.5mL 50% acetonitrile aqueous solution.
- **ESS solution-4:** 25mL of each extraction solvent E was transferred into different separational funnels. 25mL of 0.5N hydrochloric acid aqueous solution and 0.5mL of 10µg/mL BPM and Irganox 1035 solution were added to each funnel. Three aliquots of 7mL (3 X 7mL) dichloromethane (DCM) were used to extract and DCM layers were combined, respectively. Each DCM extract was concentrated to dryness under nitrogen flow. The residue was reconstituted with 0.5mL 50% acetonitrile aqueous solution.
- **Mix standard solution:** 2µg/mL of Bisphenol A (BPA), Mono(2-ethylhexyl) phthalate (MEHP), Bis (2-ethylhexyl) phthalate (DEHP), and Trioctyl Trimellitate (TOTM) solution was injected directly.
- **LOQ solution:** 0.5µg/mL of BPM and Irganox 1035 solution was injected directly.

5.2.4 Analysis of semi-volatile and volatile compounds by Gas Chromatography - Flame Ionization Detector / Mass Spectrometry (GC-FID/MS)

- **Sample solution-1:** 25mL of extraction solution A, B, C, E and blank extraction solutions were transferred into different separational funnels. Two aliquots of 10mL (2 X 10mL) DCM were used to extract and the DCM layers were combined, respectively, and dried over anhydrous sodium sulphate. Each solution was concentrated to less than 0.5mL by nitrogen flow and dilute to 0.5mL by DCM.
- **Sample solution-2:** 25mL of extraction solution D and blank extraction solution were transferred into different separational funnels, and 40mL of purified water was added to each funnel. Two aliquots of 10mL (2 X 10mL) DCM were used to extract and the DCM layers were combined, respectively, and dried over anhydrous sodium sulphate. Each solution was concentrated to less than 0.5mL by nitrogen flow and dilute to 0.5mL by DCM.
- **SST solution:** 10µg/mL of 2-fluorobiphenyl (2-FBP) solution was injected directly.
- **ESS solution-1:** 25mL of extraction solvent A, B, C, E were transferred into different separational funnels, and 0.5mL of 10µg/mL 2-FBP solution was added to each funnel. Two aliquots of 10mL (2 X 10mL) DCM were used to extract and the DCM layers were combined, respectively, and dried over anhydrous sodium sulphate. Each solution was concentrated to less than 0.5mL by nitrogen flow and dilute to 0.5mL by DCM.
- **ESS solution-2:** 25mL of extraction solution D was transferred into different separational funnels, and 0.5mL of 10µg/mL 2-FBP solution, 40mL of purified water were added to the funnel. Two aliquots of 10mL (2 X 10mL) DCM were used to extract and the DCM layers were combined, respectively, and dried over anhydrous sodium sulphate. Each solution was concentrated to less than 0.5mL by nitrogen flow and dilute to 0.5mL by DCM.
- **Mix standard solution:** 10µg/mL of Grob mix solution¹² was injected directly.
- **LOQ solution:** 0.5µg/mL of 2-FBP solution was injected directly.

¹² Grob mix solution is a DCM solution containing 2-octanone, n-decane, 1-octanol, n-undecane, 2,6-dimethylphenol, 2,6-dimethylaniline, n-dodecane, and n-tridecane.

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- 5.2.5 Analysis of volatile compounds by Headspace-Gas Chromatography - Mass Spectrometry (HS-GC-MS)
- **Sample solution:** Extraction solution A, B, C, D, E and blank extraction solutions 10mL each were transferred into separate 20mL vials. The vial was sealed with Teflon septum caps immediately.
 - **SST solution:** 10mL of toluene aqueous solution of 0.1µg/mL was transferred into a 20 mL vial. The vial was sealed with Teflon septum caps immediately.
 - **LOQ solution:** 10mL of toluene aqueous solution of 0.01µg/mL was transferred into a 20 mL vial. The vial was sealed with Teflon septum caps immediately.
- 5.2.6 Analysis of 9 radicals by ion chromatograph (IC)
- Sample solution: Transferred a certain amount of extraction solution A and blank extraction solution to be tested after filtration.
- 5.2.7 Analysis of Total Organic Carbon (TOC)
- Sample solution: Transferred a certain amount of extraction solution A and blank extraction solution to be tested.
- 5.2.8 Analysis of Nonvolatile Residue (NVR)
- Sample solution: Transferred a certain amount of extraction solution D and blank extraction solution to be tested.
- 5.2.9 Analysis of pH
- Sample solution: Transferred a certain amount of extraction solution A, B, C and blank extraction solution to be tested.
- 5.2.10 Analysis of conductivity
- Sample solution: Sample tubes were filled with extraction A and blank extraction solution respectively to be tested.

6 Extraction Study - Analysis and results

6.1 Analysis of 29 elements by ICP-MS

6.1.1 Method

29 elements were analysed by Agilent ICP-MS and the method was listed in **Table 3**. A serial of standard solutions with concentrations of 0 µg/L, 5 µg/L, 10 µg/L, 20 µg/L, and 50 µg/L were also analysed to establish calibration curves.

Table 3 Method of ICP-MS

Element	Mass	ISTD	He Flow Rate (mL/min)	Tune Mode
Li	7	45	0.0	No Gas
B	11	45	0.0	No Gas
Al	27	45	4.2	He
Ti	47	45	4.2	He

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Element	Mass	ISTD	He Flow Rate (mL/min)	Tune Mode
V	51	45	4.2	He
Cr	52	45	4.2	He
Mn	55	45	4.2	He
Co	59	45	4.2	He
Ni	60	45	4.2	He
Cu	63	45	4.2	He
Zn	66	45	4.2	He
As	75	115	4.2	He
Se	78	115	4.2	He
Mo	95	115	4.2	He
Ru	101	115	4.2	He
Rh	103	115	4.2	He
Pd	105	115	4.2	He
Ag	107	115	4.2	He
Cd	111	115	4.2	He
Sn	118	159	4.2	He
Sb	121	159	4.2	He
Ba	137	159	4.2	He
W	182	159	4.2	He
Os	189	159	4.2	He
Ir	193	159	4.2	He
Pt	195	159	4.2	He
Hg	201	159	4.2	He
Tl	205	159	4.2	He
Pb	208	159	4.2	He

Element	Mass	He Flow Rate (mL/min)	Tune Mode
Sc (ISTD)	45	0.0	No Gas
Sc (ISTD)	45	4.2	He
In (ISTD)	115	4.2	He

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Element	Mass	He Flow Rate (mL/min)	Tune Mode
Tb (ISTD)	159	4.2	He

6.1.2 LOQ

According to USP-NF, when the recovery of a standard solution of a certain concentration fulfils the requirement of 70% to 150%, the standard solution can be used as the minimum concentration of quantitation solution. The LOQ was calculated by equation below:

$$LOQ \left(\frac{\mu g}{mL} \right) = \text{the minimum concentration of quantitation} \left(\frac{\mu g}{L} \right) \times \text{dilution ratio} \div 1000 \left(\frac{mL}{L} \right)$$

$$LOQ \left(\frac{\mu g}{cm^2} \right) = \text{the minimum concentration of quantitation} \left(\frac{\mu g}{L} \right) \times \text{dilution ratio} \times \text{extraction volume (mL)} \div \text{Inner surface area (cm}^2\text{)} \div 1000 \left(\frac{mL}{L} \right)$$

Results of the LOQ were listed in Table 4.

Table 4 Results of the LOQ for ICP-MS¹³

Element	Theoretical concentration(μg/L)	Actual concentration(μg/L)	Recovery (%)	LOQ	
				μg/mL	μg/cm ²
Li	1	1.044	104	0.0050	0.00083
B	1	1.128	113	0.0050	0.00083
Al	1	1.276	128	0.0050	0.00083
Ti	1	1.125	113	0.0050	0.00083
V	1	1.062	106	0.0050	0.00083
Cr	1	1.031	103	0.0050	0.00083
Mn	1	0.966	97	0.0050	0.00083
Co	1	0.973	97	0.0050	0.00083
Ni	1	1.015	102	0.0050	0.00083
Ni-1	1	0.968	97	0.010	0.0017
Cu	1	1.017	102	0.0050	0.00083
Cu-1	1	0.961	96	0.010	0.0017
Zn	1	1.084	108	0.0050	0.00083
As	1	1.001	100	0.0050	0.00083
Se	1	0.941	94	0.0050	0.00083
Mo	1	1.014	101	0.0050	0.00083

¹³ The result of Ni-1 & Cu-1 is results of the LOQ in Extraction solution E.

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Element	Theoretical concentration($\mu\text{g/L}$)	Actual concentration($\mu\text{g/L}$)	Recovery (%)	LOQ	
				$\mu\text{g/mL}$	$\mu\text{g/cm}^2$
Ru	1	1.004	100	0.0050	0.00083
Rh	1	1.061	106	0.0050	0.00083
Pd	1	1.014	101	0.0050	0.00083
Ag	1	1.010	101	0.0050	0.00083
Cd	1	1.002	100	0.0050	0.00083
Sn	1	1.009	101	0.0050	0.00083
Sb	1	0.993	99	0.0050	0.00083
Ba	1	1.036	104	0.0050	0.00083
W	1	1.058	106	0.0050	0.00083
Os	1	1.076	108	0.0050	0.00083
Ir	1	1.048	105	0.0050	0.00083
Pt	1	1.006	101	0.0050	0.00083
Hg	1	1.094	109	0.0050	0.00083
Tl	1	1.064	106	0.0050	0.00083
Pb	1	1.056	106	0.0050	0.00083

6.1.3 Results

Concentrations of 29 elemental impurities were quantified via calibration curves of standard reference material solutions. The concentrations of elemental impurities that appeared in the blank extraction solution was subtracted from the concentration detected from extraction solutions. Results are listed in Table 5.

Table 5 Extractable study-results of the 29 elemental impurities

Element	Extraction solution A		Extraction solution B		Extraction solution C		Extraction solution E	
	$\mu\text{g/mL}$	$\mu\text{g/cm}^2$	$\mu\text{g/mL}$	$\mu\text{g/cm}^2$	$\mu\text{g/mL}$	$\mu\text{g/cm}^2$	$\mu\text{g/mL}$	$\mu\text{g/cm}^2$
Li	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
B	<0.0050	<0.00083	<0.0050	<0.00083	0.011	0.0018	0.42	0.071
Al	<0.0050	<0.00083	<0.0050	<0.00083	0.0088	0.0015	0.20	0.034
Ti	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
V	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Cr	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Mn	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Co	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083

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Element	Extraction solution A		Extraction solution B		Extraction solution C		Extraction solution E	
	µg/mL	µg/cm ²	µg/mL	µg/cm ²	µg/mL	µg/cm ²	µg/mL	µg/cm ²
Ni	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.010	<0.0017
Cu	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.010	<0.0017
Zn	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
As	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Se	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Mo	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Ru	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Rh	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Pd	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Ag	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Cd	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Sn	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Sb	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Ba	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
W	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Os	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Ir	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Pt	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Hg	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Tl	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083
Pb	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083	<0.0050	<0.00083

6.2 Analysis of 5 elements by ICP-OES

6.2.1 Method

Samples were analysed by PerkinElmer ICP-OES with method parameters listed in **Table 6**. A series of elemental reference standard solution at 0 µg/mL, 0.1 µg/mL, 0.5 µg/mL, 1.0 µg/mL and 2.0 µg/mL were also analysed to establish calibration curves.

Table 6 Method of ICP-OES

Element	Wavelength (nm)	Plas (L/min)	Aux (L/min)	Neb (L/min)	Power Watts	View Dist	Plasma View
Fe	238.204	12	0.3	0.70	1300	15.0	Radial
Au	267.595						

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Element	Wavelength (nm)	Plas (L/min)	Aux (L/min)	Neb (L/min)	Power Watts	View Dist	Plasma View
Mg	279.077						
Si	288.158						
Ca	396.847						

6.2.2 LOQ

According to USP-NF, when the recovery of a standard solution of a certain concentration fulfils the requirement of 70% to 150%, the standard solution can be used as the minimum concentration of quantitation solution. The LOQ was calculated by equation below and results of the LOQ is listed in **Table 7**.

$$\text{LOQ} \left(\frac{\mu\text{g}}{\text{mL}} \right) = \text{the minimum concentration of quantitation} \left(\frac{\mu\text{g}}{\text{mL}} \right) \times \text{dilution ratio}$$

$$\text{LOQ} \left(\frac{\mu\text{g}}{\text{cm}^2} \right) = \text{the minimum concentration of quantitation} \left(\frac{\mu\text{g}}{\text{mL}} \right) \times \text{dilution ratio} \times \text{extraction volume (mL)} \div \text{Inner surface area (cm}^2\text{)}$$

Table 7 Results of the LOQ for ICP-OES

Element	Theoretical concentration (μg/mL)	Actual concentration-1 (μg/mL)	Recovery-1 (%)	Actual concentration-2 (μg/mL)	Recovery-2 (%)	LOQ	
						μg/mL	μg/cm ²
Fe	0.05	0.044	88	0.046	92	0.25	0.042
Au	0.05	0.051	102	0.055	110	0.25	0.042
Mg	0.05	0.045	90	0.047	94	0.25	0.042
Si	0.05	0.045	90	0.049	98	0.25	0.042
Ca	0.05	0.054	108	0.056	112	0.25	0.042

6.2.3 Results

Concentrations of 5 elements were quantified with calibration curves of standard reference material solutions. The concentration of element that appears in the blank extraction solution was subtracted. Results are listed in **Table 8**.

Table 8 Extractable study-results of 5 elemental impurities

Element	Extraction solution A		Extraction solution B		Extraction solution C		Extraction solution E	
	μg/mL	μg/cm ²	μg/mL	μg/cm ²	μg/mL	μg/cm ²	μg/mL	μg/cm ²
Fe	<0.25	<0.042	<0.25	<0.042	<0.25	<0.042	<0.25	<0.042
Au	<0.25	<0.042	<0.25	<0.042	<0.25	<0.042	<0.25	<0.042
Mg	<0.25	<0.042	<0.25	<0.042	<0.25	<0.042	<0.25	<0.042
Si	<0.25	<0.042	<0.25	<0.042	0.44	0.073	5.39	0.90
Ca	<0.25	<0.042	<0.25	<0.042	<0.25	<0.042	<0.25	<0.042

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6.3 Analysis of non-volatile compounds by UPLC-DAD-MS

6.3.1 Method

Samples were analysed by Agilent UPLC-DAD-MS and the method listed **Table 9**.

Table 9 Method of UPLC-DAD-MS

Parameters	Details
Column	C18, 100 × 2.1 mm, 3.5 μm
Column temp (°C)	40
Injection volume (μL)	20
Mobile phase A	10 mM Ammonium Acetate
Mobile phase B	Methanol
UV/Vis range (nm)	190-400
Ionization mode	ESI; Positive and Negative
Drying gas flow (L/min)	10.0
Nebulizer pressure (psig)	45
Drying gas temp (°C)	350
Capillary voltage (V)	Pos 4000, Neg 4000
Mass range	80-1200
Fragmentor	100

Gradient			
Time (min)	Flow rate (mL/min)	A (%)	B (%)
0	0.5	95	5
1	0.5	95	5
20	0.5	1	99
30	0.5	1	99
30.1	0.5	95	5
35	0.5	95	5

6.3.2 Results

Several groups of common additive agents were used as authentic reference standards and were analyzed with the same method. Both Diode Array Detector (DAD), preferred if applicable, and Mass Selective Detector (MSD) responses of these authentic reference standards were used for qualification or semi-quantification of the corresponding chemical. The concentration of any reported substance was calculated by subtracting its concentration in a sample solution with that in the corresponding blank extraction solution. 68 authentic reference standards were used. The report unit is μg/mL and μg/cm². Results

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and chromatograms were shown in Table 10-Table 14 and Figure 1-Figure 5, respectively.

Table 10 Results of non-volatile compounds in Extraction solution A

No.	RT min	Name	CAS#	Concentration		Note
				µg/mL	µg/cm ²	
1	13.6	3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionic acid	20170-32-5	0.021	0.0035	N/A
2	18.5	2,4-bis(1,1-dimethylethyl)phenol phosphate	69284-93-1	0.15	0.025	N/A

Table 11 Results of non-volatile compounds in Extraction solution B

No.	RT min	Name	CAS#	Concentration		Note
				µg/mL	µg/cm ²	
1	13.6	3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionic acid	20170-32-5	0.015	0.0025	N/A
2	18.5	2,4-bis(1,1-dimethylethyl)phenol phosphate	69284-93-1	0.027	0.0045	N/A

Table 12 Results of non-volatile compounds in Extraction solution C

No.	RT min	Name	CAS#	Concentration		Note
				µg/mL	µg/cm ²	
1	18.5	2,4-bis(1,1-dimethylethyl)phenol phosphate	69284-93-1	0.27	0.045	N/A
2	17.5	Myristic acid	544-63-8	0.014	0.0023	N/A
3	18.1	Pentadecanoic acid	1002-84-2	0.021	0.0035	N/A
4	18.6	Palmitic acid	57-10-3	0.14	0.024	N/A
5	18.9	Elaidic acid & Oleic acid	112-79-8 & 112-80-1	0.015	0.0025	N/A
6	19.4	Stearic acid	57-11-4	0.061	0.010	N/A

Table 13 Results of non-volatile compounds in Extraction solution D

No.	RT min	Name	CAS#	Concentration		Note
				µg/mL	µg/cm ²	
1	13.6	3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionic acid	20170-32-5	0.038	0.0064	N/A
2	13.8	Decanoic acid	334-48-5	0.011	0.0019	N/A
3	15.0	Undecanoic acid	112-37-8	0.011	0.0018	N/A
4	17.5	Myristic acid	544-63-8	0.011	0.0018	N/A
5	18.1	Pentadecanoic acid	1002-84-2	0.014	0.0024	N/A
6	18.6	Palmitic acid	57-10-3	0.24	0.041	N/A
7	18.8	Elaidic acid & Oleic acid	112-79-8 & 112-80-1	0.017	0.0029	N/A

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No.	RT min	Name	CAS#	Concentration		Note
				µg/mL	µg/cm ²	
8	19.4	Stearic acid	57-11-4	0.10	0.017	N/A

Table 14 Results of non-volatile compounds in Extraction solution E

No.	RT min	Name	CAS#	Concentration		Note
				µg/mL	µg/cm ²	
1	12.6	Bisphenol A	80-05-7	0.071	0.012	N/A
2	15.0	Undecanoic acid	112-37-8	0.011	0.0018	N/A
3	17.5	Myristic acid	544-63-8	0.014	0.0024	N/A
4	18.1	Pentadecanoic acid	1002-84-2	0.018	0.0030	N/A
5	18.6	Palmitic acid	57-10-3	0.17	0.028	N/A
6	18.9	Elaidic acid & Oleic acid	112-79-8 &112-80-1	0.017	0.0028	N/A
7	18.9	Heptadecanoic acid	506-12-7	0.022	0.0036	N/A
8	19.4	Stearic acid	57-11-4	0.057	0.010	N/A

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6.3.3 Chromatogram

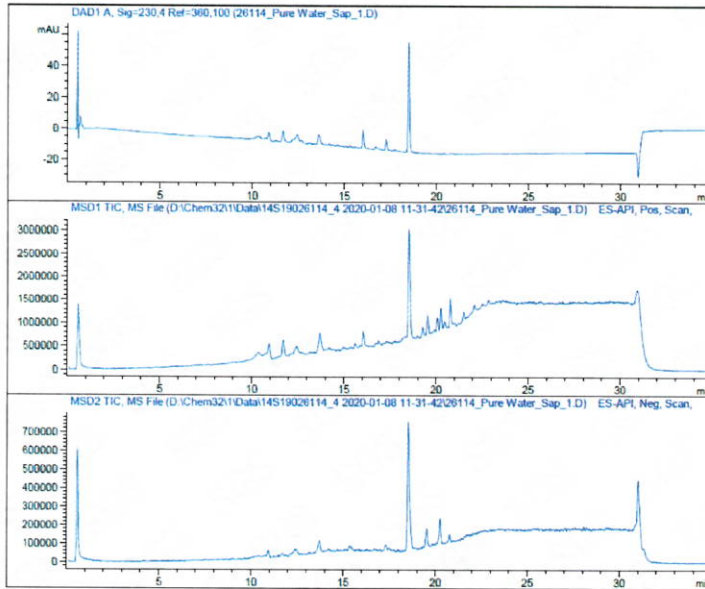


Figure 1 UV and TIC chromatogram of Extraction solution A

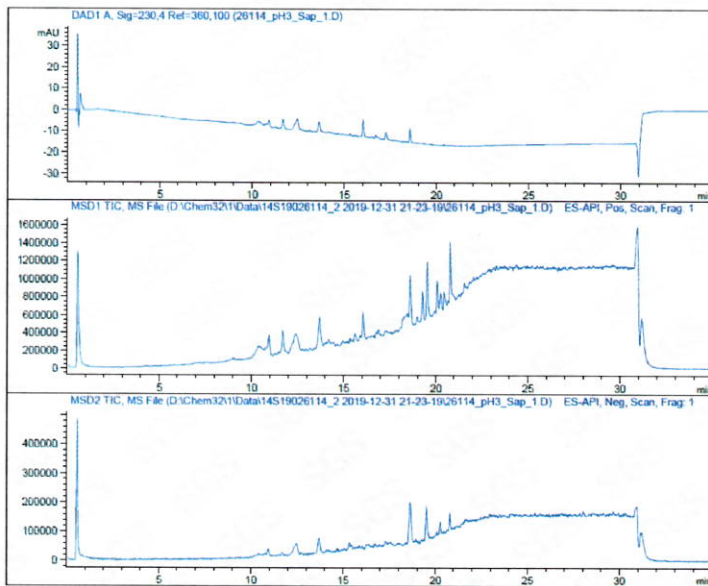


Figure 2 UV and TIC chromatogram of Extraction solution B

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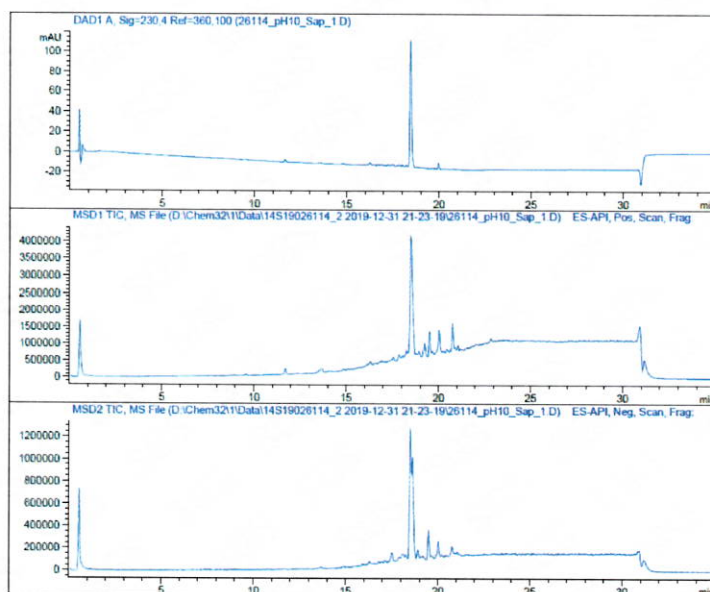


Figure 3 UV and TIC chromatogram of Extraction solution C

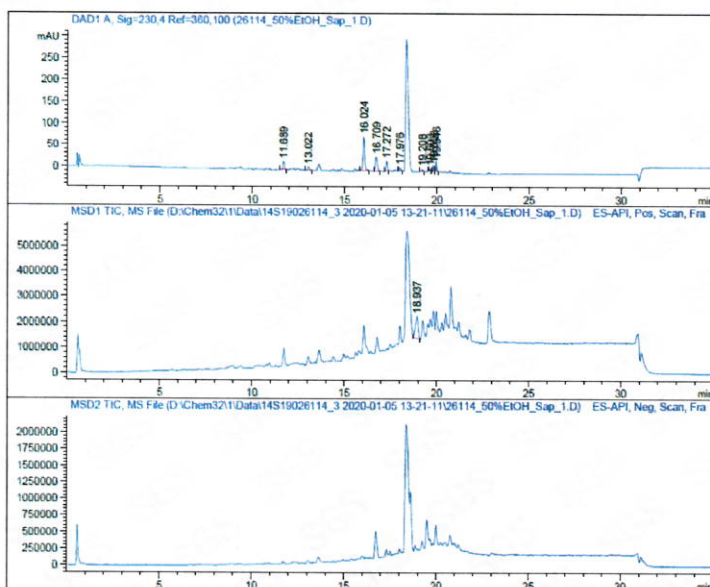


Figure 4 UV and TIC chromatogram of Extraction solution D

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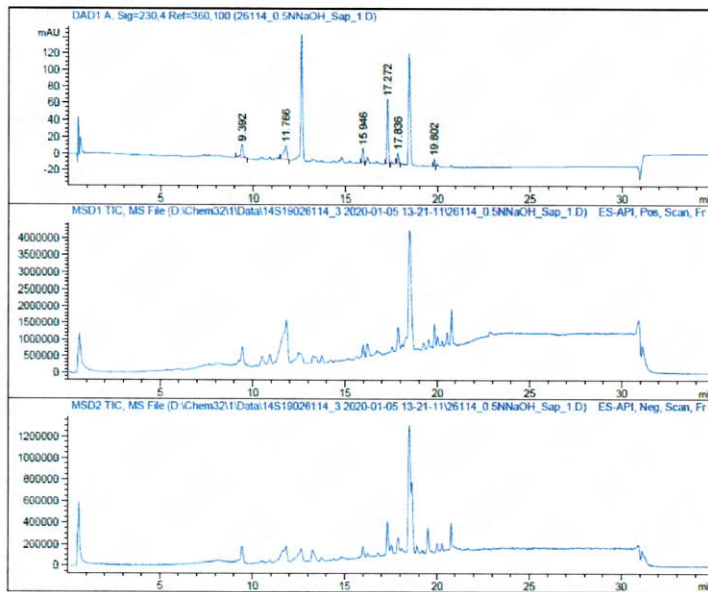


Figure 5 UV and TIC chromatogram of Extraction solution E

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6.4 Analysis of semi-volatile and volatile compounds by GC- FID/MS

6.4.1 Method

The samples were analysed by Agilent GC- FID/MS and the method listed in **Table 15**.

Table 15 Method of GC-MS/FID

Parameters	Details
Column	DB-5HT (30 m × 0.25 mm, 0.1 µm)
Oven program	40 °C hold 1 min, ramp to 280 °C at 10 °C/min, hold 2min, ramp to 310 °C at 15 °C/min, hold 10 min
Inlet	300 °C
Carrie gas	He
Flow rate	1.0 mL/min
Injection mode	Pulsed Split (2:1)
Injection volume	1.5 µL
MS Source	230 °C
MS Quad	150 °C
Scan range	25-650 amu
FID temp.	320 °C

6.4.2 Results

Several groups of common additive agents were used as authentic reference standards and were analyzed with the same method. Both Flame Ionization Detector (FID), preferred if applicable, and Mass Selective Detector (MSD) responses of these authentic reference standards were used for qualification or semi-quantification of the corresponding chemical. The concentration of any reported substance was calculated by subtracting its concentration in a sample solution with that in the corresponding blank extraction solution. 95 authentic reference standards were used. The report unit is µg/mL and µg/cm². Results and chromatograms were shown in **Table 16-Table 20** and **Figure 6-Figure 10**, respectively.

Table 16 Results of semi-volatile and volatile compounds in Extraction solution A

No.	RT min	Name	CAS#	Concentration		Note
				µg/mL	µg/cm ²	
1	13.6	2,4-Di-tert-butylphenol	96-76-4	0.033	0.0055	N/A

Table 17 Results of semi-volatile and volatile compounds in Extraction solution B

No.	RT min	Name	CAS#	Concentration		Note
				µg/mL	µg/cm ²	
1	13.6	2,4-Di-tert-butylphenol	96-76-4	0.019	0.0032	N/A

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Table 18 Results of semi-volatile and volatile compounds in Extraction solution C

No.	RT min	Name	CAS#	Concentration		Note
				µg/mL	µg/cm ²	
1	13.6	2,4-Di-tert-butylphenol	96-76-4	0.033	0.0055	N/A

Table 19 Results of semi-volatile and volatile compounds in Extraction solution D

No.	RT min	Name	CAS#	Concentration		Note
				µg/mL	µg/cm ²	
1	13.6	2,4-Di-tert-butylphenol	96-76-4	1.61	0.27	N/A

Table 20 Results of semi-volatile and volatile compounds in Extraction solution E

No.	RT min	Name	CAS#	Concentration		Note
				µg/mL	µg/cm ²	
1	13.6	2,4-Di-tert-butylphenol	96-76-4	0.58	0.097	N/A

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6.4.3 Chromatogram

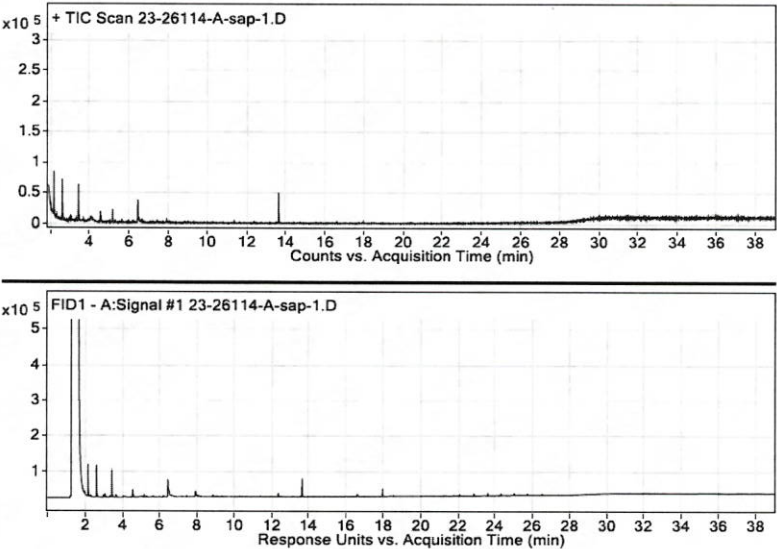


Figure 6 TIC and FID chromatogram of Extraction solution A

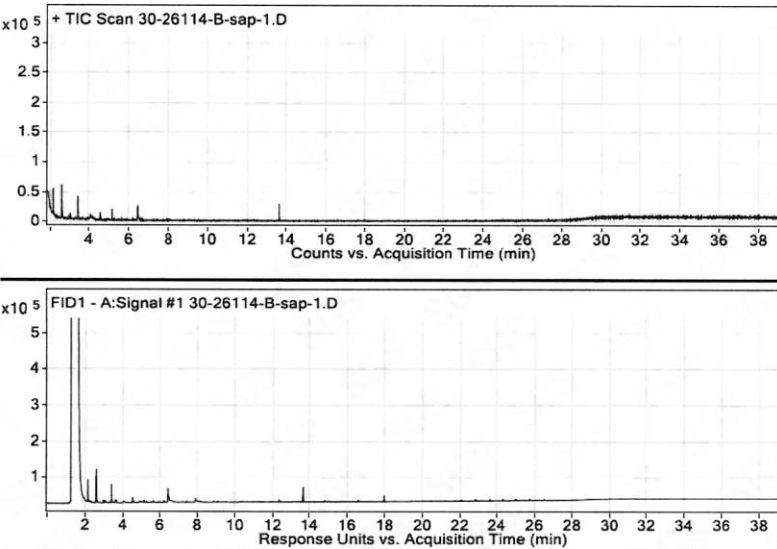


Figure 7 TIC and FID chromatogram of Extraction solution B.

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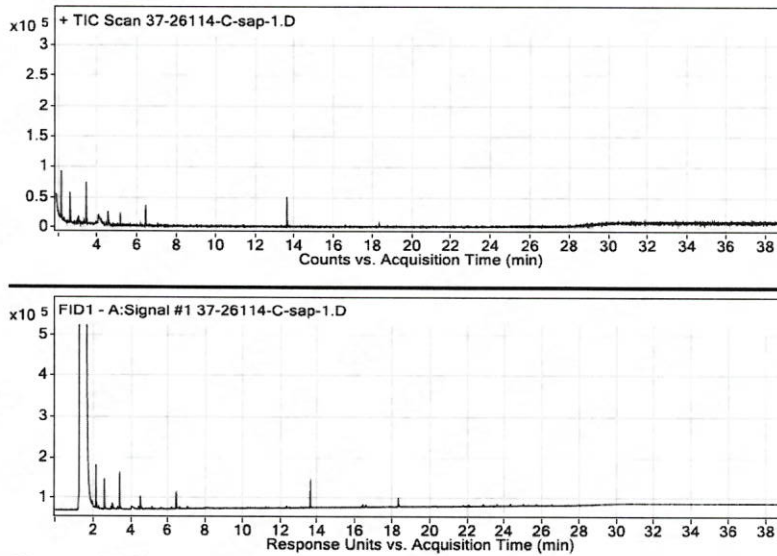


Figure 8 TIC and FID chromatogram of Extraction solution C

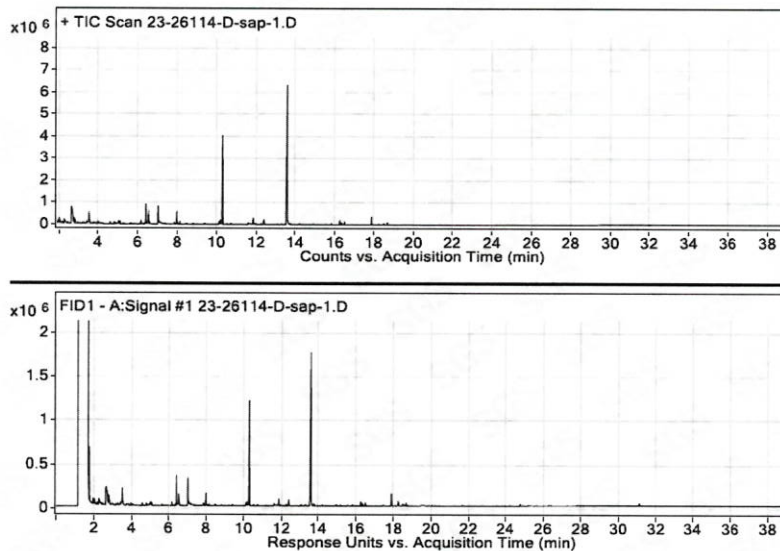


Figure 9 TIC and FID chromatogram of Extraction solution D

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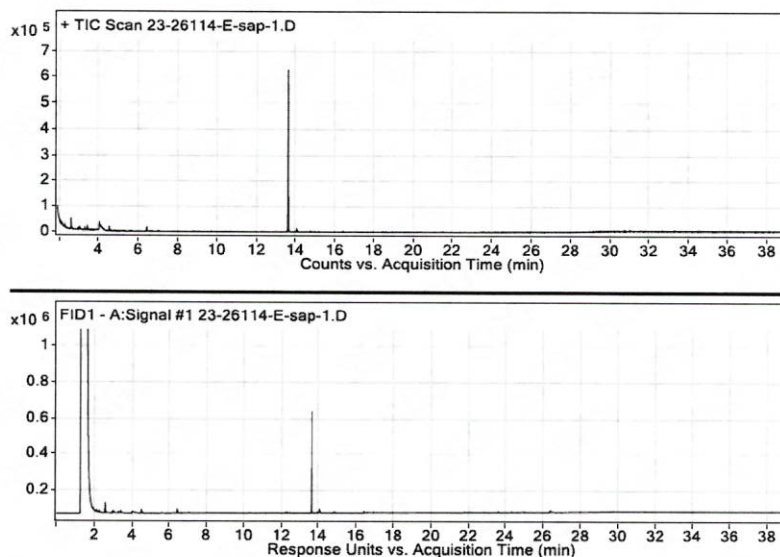


Figure 10 TIC and FID chromatogram of Extraction solution E

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6.5 Analysis of volatile compounds by HS-GC-MS

6.5.1 Method

The samples were analysed by HS-GC-MS and the method listed in **Table 21**.

Table 21 Method of HS-GC-MS

Parameters	Details
Oven Temperature	80 °C
Loop Temperature	120 °C
Transfer Line Temperature	120 °C
Carrier Gas	He at 1.5 mL/min, Pulsed Split (1:1)
Equilibrium Time	30 min
Injection Duration	0.5 min
Column	DB-624 30 m×0.32 mm, 1.8 µm film
Temperature Program	40°C, hold 1 min, ramp to 200 °C at 7 °C/min, ramp to 250 °C at 20 °C/min, hold 3 min
MSD Transfer line temperature	250 °C
MS Source	230 °C
MS Quad	150 °C
MS Range	29-650 amu

6.5.2 Results

Several groups of common additive agents were used as authentic reference standards and were analyzed with the same method. Mass Selective Detector (MSD) responses of these authentic reference standards were used for qualification or semi-quantification of the corresponding chemical. The concentration of any reported substance was calculated by subtracting its concentration in a sample solution with that in the corresponding blank extraction solution. 41 authentic reference standards were used. The report unit is µg/mL and µg/cm². Results and chromatograms were shown in **Table 22-Table 26** and **Figure 11-Figure 15**, respectively.

Table 22 Results of volatile compounds in Extraction solution A

No.	RT (min)	Name	CAS	Concentration		Note
				µg/mL	µg/cm ²	
No compound was detected with a concentration greater than or equal to AET						

Table 23 Results of volatile compounds in Extraction solution B

No.	RT (min)	Name	CAS	Concentration		Note
				µg/mL	µg/cm ²	
No compound was detected with a concentration greater than or equal to AET						

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Table 24 Results of volatile compounds in Extraction solution C

No.	RT (min)	Name	CAS	Concentration		Note
				µg/mL	µg/cm ²	
No compound was detected with a concentration greater than or equal to AET						

Table 25 Results of volatile compounds in Extraction solution D

No.	RT (min)	Name	CAS	Concentration		Note
				µg/mL	µg/cm ²	
1	4.4	Methylcyclopentane	96-37-7	0.036	0.0060	N/A
2	5.2	Cyclohexane	110-82-7	0.070	0.012	N/A
3	8.4	n-Octane	111-65-9	0.013	0.0021	N/A
4	19.9	1,3-bis(1,1-dimethylethyl)-benzene	1014-60-4	0.035	0.0059	N/A

Table 26 Results of volatile compounds in Extraction solution E

No.	RT (min)	Name	CAS	Concentration		Note
				µg/mL	µg/cm ²	
No compound was detected with a concentration greater than or equal to AET						

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6.5.3 Chromatogram

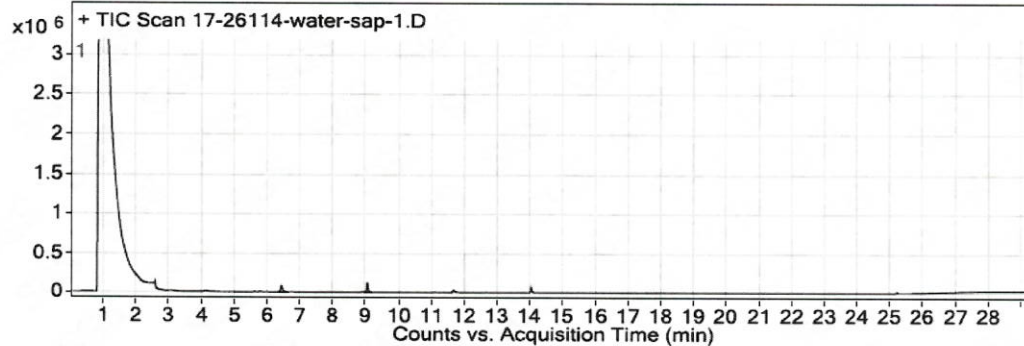


Figure 11 TIC chromatogram of Extraction solution A

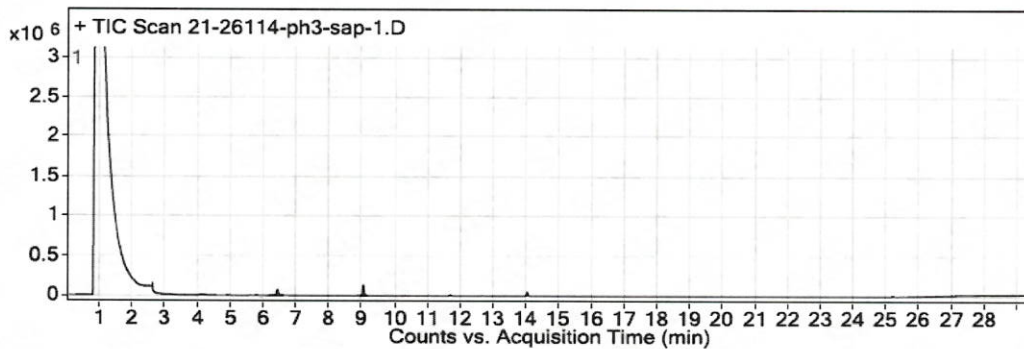


Figure 12 TIC chromatogram of Extraction solution B

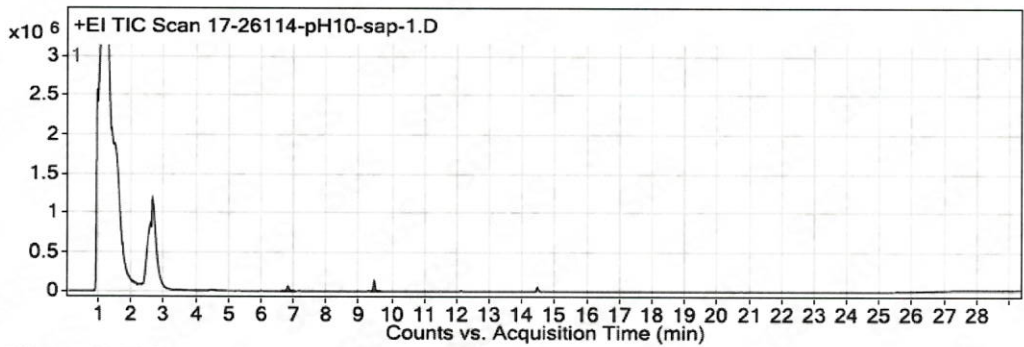


Figure 13 TIC chromatogram of Extraction solution C

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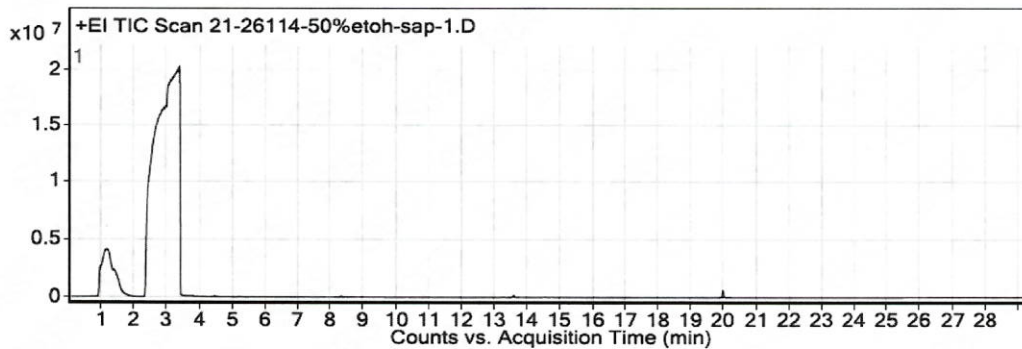


Figure 14 TIC chromatogram of Extraction solution D

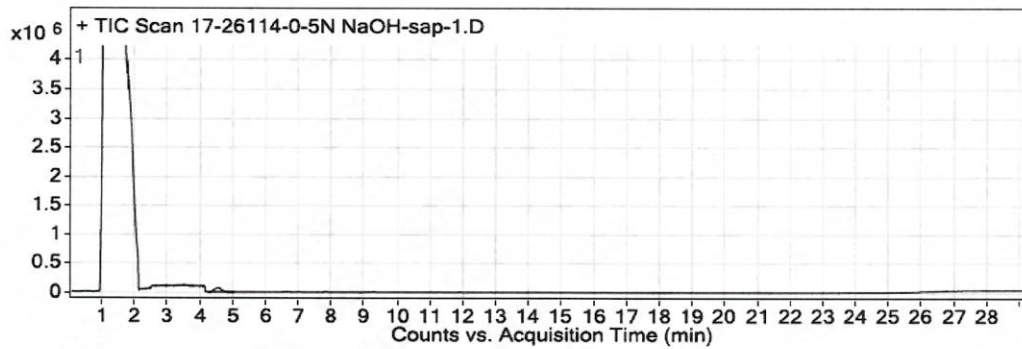


Figure 15 TIC chromatogram of Extraction solution E

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6.6 Analysis of 9 radicals by IC

6.6.1 Method

Samples were analysed by Thermo IC with method parameters listed in **Table 27**.

Table 27 Method of IC

Parameters	Details
Pre-column	Dionex IonPac AG19 (50×4mm, 4μm)
Column	Dionex IonPac AS19 (250×4mm, 4μm)
Column temp	30°C
Detector	conductivity detector (35°C)
Current	75mA
Suppressor	ASRS 300×4mm
KOH Generator	Dionex EGC III KOH

Gradient		
Time (min)	Flow rate (mL/min)	KOH (mM)
0	1.0	3
15	1.0	3
40	1.0	30
50	1.0	30
50.1	1.0	3
60	1.0	3

6.6.2 Result

Concentrations of 9 radicals were quantified with calibration curves of standard reference material solutions. The concentrations of radicals that appeared in the blank extraction solution were subtracted from the concentration detected from extraction solution. Results are listed in **Table 28**.

Table 28 Results of 9 radicals in the extractables study

Radical	Sample		LOQ	
	μg/mL	μg/cm ²	μg/mL	μg/cm ²
Fluorine	<0.010	<0.0017	0.010	0.0017
Acetate	1.49	0.25	0.020	0.0033
Formate	0.26	0.044	0.020	0.0033
Chloride	0.025	0.0042	0.010	0.0017
Nitrite	<0.020	<0.0033	0.020	0.0033
Bromide	<0.050	<0.0083	0.050	0.0083

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Radical	Sample		LOQ	
	µg/mL	µg/cm ²	µg/mL	µg/cm ²
Nitrate	<0.050	<0.0083	0.050	0.0083
Sulfate	<0.050	<0.0083	0.050	0.0083
Phosphate	<0.050	<0.0083	0.050	0.0083

6.7 Analysis of TOC

6.7.1 Method

Samples were analysed by GE TOC with mode of autoreagent (M9).

6.7.2 Result

The results of TOC are listed in **Table 29**.

Table 29 Results of TOC in the extractables study

Extraction solution	Blank (µg/L)	Sample (mg/L)	Result after subtracting the blank (mg/L)
A	<0.03	3.97	3.97

6.8 Analysis of NVR

6.8.1 Method

Transferred 50.0mL of extraction solution D and blank extraction solution into different constant weight evaporating dishes, which had been acid cleaned, and evaporate them in water bath. Placed the above dried evaporating dishes at 105°C for 1 hours, weighed after cooling down.

6.8.2 Result

The results of NVR are listed in **Table 30**.

Table 30 Results of NVR in the extractables study

Extraction solution	Blank (mg)	Sample (mg)	Result after subtracting the blank (mg)
D	0.03	1.01	1

6.9 Analysis of pH

6.9.1 Method

Extraction solution A, B, C and blank extraction solutions were placed in 25 °C water bath and tested after the temperature was stabilized.

6.9.2 Result

The results of pH are listed in **Table 31**.

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Table 31 Results of pH in the extractables study

Extraction solution	Blank	Sample
A	6.5	4.4
B	3.0	3.0
C	9.8	9.8

6.10 Analysis of Conductivity

6.10.1 Method

Extraction solution A and blank extraction solution were filled the sample tube and capped tightly. They were placed in 25 °C water bath and kept at a constant temperature. then tested after the temperature was stabilized.

6.10.2 Result

The results of conductivity are listed in **Table 32**.

Table 32 Results of conductivity in the extractables study

Extraction solution	Blank (μS/cm)	Sample (μS/cm)
A	0.827	10.25

7 Summary of extractables study

7.1 Elemental impurities

ICP-MS and ICP-OES analysis show that the B, Al were > 0.0050μg/mL and Si > 0.25μg/mL. Results are listed in **Table 5, Table 8**.

The PDE values from ICH Q3D and the Guideline for the Compatibility Study of Pharmaceutical Glass Container for Parenteral Drug Products were listed in **Appendix II**.

7.2 Organic compounds

In the extractables study, there were 17 compounds detected with a concentration greater than or equal to 0.01μg/mL. Results are listed **Table 10-Table 14, Table 16-Table 20, Table 25**.

8 Reference

- 1) Jenke, D.; Castner, J.; Egert, T.; Feinberg, T.; Hendrick, A.; Houston, C.; Hunt, D. G.; Lynch, M.; Shaw, A.; Nicholas, K.; Norwood, D. L.; Paskiet, D.; Ruberto, M.; Smith, E. J.; Holcomb, F., Extractables Characterization for Five Materials of Construction Representative of Packaging Systems Used for Parenteral and Ophthalmic Drug Products, *PDA Journal of Pharmaceutical Science and Technology* **2013**, 67, 448.
- 2) USP<1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems.
- 3) USP<1664>Assessment of Drug Product Leachables Associated with Pharmaceutical Packing Delivery Systems.
- 4) Safety Thresholds and Best Practices for Extractables and Leachables In Orally Inhaled and Nasal Drug Products. Recommendations submitted to the PQRI Drug Product Technical Committee, PQRI Steering Committee, and U.S. Food and Drug Administration by the PQRI Leachables and Extractables Working Group in September 2006.

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- 5) Guideline on the Limits of Genotoxic Impurities, EMEA/CHMP/QWP/251344/2006
- 6) Guideline for Elemental Impurities, ICH Q3D Final version
- 7) Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk, ICH M7 Current Step 4 version
- 8) USP<1665> Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products.
- 9) USP<665>Polymeric Components and Systems Used in the Manufacturing of Pharmaceutical and Biopharmaceutical Drug Products.

9 Revision History

Version	Date	Change History
01	2020.06.01	First issue

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Appendix I Abbreviation and Definition

Abbreviation	Definition
AET	Analytical Evaluation Threshold
DCM	Dichloromethane
FID	Flame Ionization Detector
GC-MS/FID	Gas Chromatographic-Mass Selective/Flame Ionization Detector
HS-GC-MS	Headspace-Gas Chromatographic-Mass Selective
ICP-MS	Inductively Coupled Plasma-Mass Spectrometer
ICP-OES	Inductively Coupled Plasma Optical Emission Spectrometer
NLT	Not Less Than
NMT	Not More Than
PDE	Permitted Daily Exposure
SCT	Safety Concern Threshold
TIC	Total Ion Current
TTC	Toxicological Threshold of Concern
UPLC-DAD-MS	Ultra-Performance Liquid Chromatographic-Diode Array Detector
UV	Ultraviolet
RT	Retention time

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Appendix II Limits for element impurities

No.	Element	PDE (µg/day)
1	Li	250
2	V	10
3	Cr	1100
4	Co	5
5	Ni	20
6	Cu	300
7	Zn	1300
8	As	15
9	Se	80
10	Mo	1500
11	Ru	10
12	Rh	10
13	Pd	10
14	Ag	10
15	Cd	2
16	Sn	600
17	Sb	90
18	Ba	700
19	Os	10
20	Ir	10
21	Pt	10
22	Hg	3
23	Tl	8
24	Pb	5
25	Fe	1300
26	Au	100

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Appendix III Non-volatile compounds

No.	Compound name	CAS No.
1	Mono(2-ethylhexyl)phthalate (MEHP)	4376-20-9
2	Bis(2-ethylhexyl)phthalate (DEHP)	117-81-7
3	Tris(2-Ethylhexyl) trimellitate (TOTM)	3319-31-1
4	Biphenol M (BPM)	13595-25-0
5	Bisphenol A (BPA)	80-05-7
6	Tetramethylthiuram disulfide	137-26-8
7	Benzoyl Peroxide	94-36-0
8	Hexadecanamide	629-54-9
9	Citric acid, triethyl ester	77-93-0
10	Triphenylphosphine oxide	791-28-6
11	3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionic acid	20170-32-5
12	Octadecanamide	124-26-5
13	Erucamide	112-84-5
14	2,2'-Methylenebis[4-Methyl-6-tert-butylphenol]	119-47-1
15	2,4,6-Trimethyl Benzoyl Diphenylphosphine oxide	75980-60-8
16	Tris(butoxyethyl) phosphate	78-51-3
17	Tinuvin 770	52829-07-9
18	Irganox 1076	2082-79-3
19	Irganox 245	36443-68-2
20	Irganox 1035	41484-35-9
21	Antioxidant 168	31570-04-4
22	Irganox 330	1709-70-2
23	Antioxidant 3114	27676-62-6
24	Irganox 1010	6683-19-8
25	UV 531	1843-05-6
26	2,4-bis(1,1-dimethylethyl)phenol phosphate	69284-93-1
27	Oleamide	301-02-0
28	Di-Trimethylolpropane tetra acrylate	94108-97-1
29	2-Methyl-4-(methylthio)-2-morpholinopropiophenone	71868-10-5

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No.	Compound name	CAS No.
30	Nonylphenol	84852-15-3
31	Octanoic acid	124-07-2
32	Decanoic acid	334-48-5
33	Undecanoic acid	112-37-8
34	Lauric acid	143-07-7
35	Tridecanoic acid	638-53-9
36	Myristic acid	544-63-8
37	Myristoleic acid	544-64-9
38	Pentadecanoic acid	1002-84-2
39	10-Pentadecenoic acid	84743-29-3
40	Palmitic acid	57-10-3
41	Palmitoleic acid	373-49-9
42	Heptadecanoic acid	506-12-7
43	10-Heptadecenoic acid	62528-80-7
44	Stearic acid	57-11-4
45	Elaidic acid	112-79-8
46	Oleic acid	112-80-1
47	Linoelaidic acid	506-21-8
48	Linoleic acid	60-33-3
49	Arachidic acid	506-30-9
50	Gamma linolenic acid	506-26-3
51	11-Eicosenoic acid	5561-99-9
52	Linolenic acid	463-40-1
53	Heneicosanoic acid	2363-71-5
54	11,14-Eicosadienoic acid	2091-39-6
55	Behenic acid	112-85-6
56	Homogamma linolenic acid	7324-41-6
57	Erucic acid	112-86-7
58	11,14,17-Eicosatrienoic acid	2091-27-2
59	Arachidonic acid	506-32-1
60	Tricosanoic acid	2433-96-7
61	Docosadienoic acid	7370-49-2

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No.	Compound name	CAS No.
62	Lignoceric acid	557-59-5
63	Eicosapentaenoic acid	25378-27-2
64	Nervonic acid	506-37-6
65	Docosahexaenoic acid	6217-54-5
66	Docosapentaenoic acid	24880-45-3
67	Docosatetraenoic acid	28874-58-0
68	Docosapentaenoic acid	25182-74-5

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Appendix IV Volatile and semi-volatile compounds

No.	Name	CAS No.
1	2-(5H)-Furanone	497-23-4
2	Aniline	62-53-3
3	Phenol	108-95-2
4	N,N-dimethyl Propenamide	2680-03-7
5	1-Nitrosopyrrolidine	930-55-2
6	Benzyl alcohol	100-51-6
7	Caprolactam	105-60-2
8	N-Nitrosopiperidine	100-75-4
9	2-Butoxyethanol	111-76-2
10	2,6-dimethyl Phenol	576-26-1
11	2,3-dimethyl Phenol	526-75-0
12	N-cyclohexylformamide	766-93-8
13	N,N-Dimethylcyclohexylamine	98-94-2
14	Benzothiazole	95-16-9
15	N,N-Dimethylbenzylamine	103-83-3
16	2-Phenyl-2-propanol	617-94-7
17	p-Tert-butyl phenol	98-54-4
18	N-Nitrosodibutylamine	924-16-3
19	Tetrachloroethylene	127-18-4
20	Diphenylamine	122-39-4
21	Diphenyl oxide	101-84-8
22	Dimethyl terephthalate	120-61-6
23	2,4-Di-tert-butylphenol	96-76-4
24	2,6-Di-tert-butylphenol	128-39-2
25	2,6-Di-tert-butyl-p-benzoquinone	719-22-2
26	Nonylphenol	84852-15-3
27	Cyclotrisiloxane, hexamethyl-	541-05-9
28	Dibutyl fumarate	105-75-9
29	1-Pentadecanol	629-76-5
30	2,6,10,14-tetramethyl-pentadecan	1921-70-6

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No.	Name	CAS No.
31	1-Chlorooctadecane	3386-33-2
32	Cyclotetrasiloxane, octamethyl-	556-67-2
33	1-Eicosanol	629-96-9
34	2,2'-Methylene bis(4-ethyl-6-tert-butylphenol)	88-24-4
35	Squalene	111-02-4
36	Ethynylcyclohexanol	78-27-3
37	1-Hexyn-3-ol, 3,5-dimethyl-	107-54-0
38	BHT	128-37-0
39	Cyclopentasiloxane, decamethyl-	541-02-6
40	4-tert-Octylphenol	140-66-9
41	1,4-Diacetylbenzene	1009-61-6
42	n-Nonane	111-84-2
43	n-Decane	124-18-5
44	n-Undecane	1120-21-4
45	n-Dodecane	112-40-3
46	n-Tridecane	629-50-5
47	n-Tetradecane	629-59-4
48	n-Pentadecane	629-62-9
49	n-Hexadecane	544-76-3
50	n-Heptadecane	629-78-7
51	n-Octadecane	593-45-3
52	n-Nonadecane	629-92-5
53	n-Eicosane	112-95-8
54	n-Heneicosane	629-94-7
55	n-Docosane	629-97-0
56	n-Tricosane	638-67-5
57	n-Tetracosane	646-31-1
58	n-Pentacosane	629-99-2
59	n-Hexacosane	630-01-3
60	n-Heptacosane	593-49-7
61	n-Octacosane	630-02-4
62	n-Nonacosane	630-03-5

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No.	Name	CAS No.
63	n-Triacontane	638-68-6
64	n-Hentriacontane	630-04-6
65	n-Dotriacontane	544-85-4
66	n-Tritriacontane	630-05-7
67	n-Tettriacontane	14167-59-0
68	n-Pentatriacontane	630-07-9
69	n-Hexatriacontane	630-06-8
70	n-Heptatriacontane	7194-84-5
71	n-Octatriacontane	7194-85-6
72	n-Nonatriacontane	7194-86-7
73	n-Tetracontane	4181-95-7
74	Dimethyl phthalate (DMP)	131-11-3
75	Bis(2-methoxyethyl)phthalate (DMOEP)	117-82-8
76	Bis(2-ethoxyethyl)phthalate (DEOEP)	605-54-9
77	Diethyl phthalate (DEP)	84-66-2
78	Diphenyl phthalate (DPhP)	84-62-8
79	Butyl benzyl phthalate (BBP)	85-68-7
80	Bis(2-butoxyethyl)phthalate (DBOEP)	117-83-9
81	Di-n-butyl phthalate (DNBP)	84-74-2
82	Diisobutyl phthalate (DIBP)	84-69-5
83	Diamyl phthalate (DNPP)	131-18-0
84	Dicyclohexyl phthalate (DCHP)	84-61-7
85	Bis(4-methyl-2-pentyl)phthalate (mixture of isomers) (DIHP)	146-50-9
86	Di-n-hexyl phthalate (DNHP)	84-75-3
87	Bis(2-ethylhexyl)phthalate (DEHP)	117-81-7
88	Di-n-octyl phthalate (DNOP)	117-84-0
89	Di-nonyl phthalate (mixture of isomers) (DINP)	84-76-4
90	2-Fluorobiphenyl (2-FBP)	321-60-8
91	o-Hydroxybiphenyl	90-43-7
92	Phenol, 4-(1,1-dimethylpropyl)-	80-46-6
93	2,6-Di-tert-butyl-4-hydroxy-4-methylcyclohexa-2,5-dien-1-one	10396-80-2

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No.	Name	CAS No.
94	3,5-di-tert-Butyl-4-hydroxybenzaldehyde	1620-98-0
95	Ethanone, 1-[4-(1-hydroxy-1-methylethyl)phenyl]-	54549-72-3

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Appendix V Volatiles

No.	Name	CAS No.
1	Isothiocyanic acid, ethyl ester	542-85-8
2	Cyclohexanone	108-94-1
3	2-Methylvaleraldehyde	123-15-9
4	N-Nitrosodiethylamine	55-18-5
5	Benzaldehyde	100-52-7
6	Acetophenone	98-86-2
7	Dicyclopentadiene	77-73-6
8	Benzaldehyde, 2,5-dimethyl-	5779-94-2
9	Hexane	110-54-3
10	Heptane	142-82-5
11	Octane	111-65-9
12	Methylcyclopentane	96-37-7
13	1,1-Dichloroethene	75-35-4
14	1,1,1-Trichloroethane	71-55-6
15	Carbon Tetrachloride	56-23-5
16	Benzene	71-43-2
17	1,2-Dichloroethane	107-06-2
18	Methylene Chloride	75-09-2
19	trans-1,2-dichloroethene	156-60-5
20	cis-1,2-dichloroethene	156-59-2
21	Tetrahydrofuran	109-99-9
22	Cyclohexane	110-82-7
23	Methylcyclohexane	108-87-2
24	1,4-Dioxane	123-91-1
25	Toluene	108-88-3
26	Chlorobenzene	108-90-7
27	Ethylbenzene	100-41-4
28	m-Xylene and p-Xylene	108-38-3/ 106-42-3
29	o-Xylene	95-47-6
30	Cumene	98-82-8

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No.	Name	CAS No.
31	Chloroform	67-66-3
32	1,2-Dimethoxyethane	110-71-4
33	Trichloroethylene	79-01-6
34	Methyl butyl ketone	591-78-6
35	Pyridine	110-86-1
36	Tetralin	119-64-2
37	Pentane, 2-methyl-	107-83-5
38	Pentane,3-methyl-	96-14-0
39	2-Butanone	78-93-3
40	Styrene	100-42-5
41	1,3-bis(1,1-dimethylethyl)-Benzene	1014-60-4

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