BioPhorum

GUIDE TO THE EXTRACTABLES TEST REPORT

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Contents

About BioPhorum

BioPhorum's mission is to create environments where the global biopharmaceutical industry can collaborate and accelerate its rate of progress, for the benefit of all.

Since its inception in 2004, BioPhorum has become the open and trusted environment where senior leaders of the biopharmaceutical industry come together to openly share and discuss the emerging trends and challenges facing their industry.

Growing from an end-user group in 2008, BioPhorum now comprises over 90 manufacturers and suppliers deploying their top 3,500 leaders and subject matter experts to work in seven focused Phorums, articulating the industry's technology roadmap, defining the supply partner practices of the future, and developing and adopting best practices in drug substance, fill finish, process development and manufacturing IT. In each of these Phorums, BioPhorum facilitators bring leaders together to create future visions, mobilize teams of experts on the opportunities, create partnerships that enable change and provide the quickest route to implementation, so that the industry shares, learns and builds the best solutions together.

1.0

Introduction

Over the last 2 years BioPhorum has been working with biomanufacturers and supply partners to refine the guidance on extractables testing for single use systems. Based on previous work the team was able to take a data driven approach to refining the protocol and has focused only on that testing which adds most value.

A second key element to realize the benefits from a standardized extractables protocol is making the data readily available and easy to leverage. To this end several key steps have been taken in the development of an extractables ecosystem. This ecosystem includes guidance on how data should be transferred, how data integrity should be maintained and how data should be formatted to facilitate its use. One element of this is completion of the BioPhorum Extractables Data Summary (BEDS) **https://www.biophorum.com/bpog-extractables-test-report-template-jan-2019/**

This document provides an overview of how to complete the BEDS document. It is important that this document is read in conjunction with the extractables protocol **https://www.biophorum.com/changes-to-biophorum-extractables-protocol/**

2.0

Guide to creating a BioPhorum Extractables Test Reports

Resulting extractables testing data should be compiled into an Extractables Test Report with summary tables of the results. The Extractables Test Report should include the amount and identity of each known compound and the estimated amount of each unknown compound. The Extractables Test Report should also include the study design, deviations, the analytical methods and associated method qualifications, data tables for each individual analysis technique, as well as a summary including any additional discussion necessary to provide enough context such that the results are readily interpretable by end-users.

It is not required to include chromatograms or spectra in the report, but these shall be made available upon request. Chromatographic data should then be presented using the total ion current (TIC). Presentation of spectra is primarily of interest for unknown compounds.

The standardized extractables testing protocol provides suppliers with a set of procedures agreed upon as representative of a comprehensive range of conditions by a broad group of companies. Suppliers can then prepare standardized Extractables Test Reports for SUS components including, but not limited to, films, tubing, tubing connectors and disconnectors, aseptic connectors and disconnectors, sterilizing-grade and process filters, tangential-flow filter cassettes, sensors, valves, chromatography columns, impellers, and filling needles.

The Extractables Test Report provides comprehensive information on the SUS component tested, including details of the testing setup, testing conditions and analytical methods applied, and identity and quantity of extracted compounds.

The Extractables Test Report should include, but is not limited to, the following information for each extractables study.

1. **Title page**
   The title page should include:
   a. Report title, study identity, report date, report revision
   b. Name and location of lab performing the testing and name and location of sponsor, if applicable
   c. Signatures

2. **Study summary**
   The Study summary for SUS components tested should consist of:
   a. Short description of background of testing
   b. Short description of the testing setup and experimental part
   c. Short summary of results and conclusion

3. **Study design**
   Outline of the study design information must follow the BioPhorum Extractables Data Summary (BEDS) spreadsheet template. It includes information on:
   a. Test article traceability
   b. Pre-treatment(s) of the test article
   c. Extraction conditions, solvents and time points
   d. Analytical information
   e. Supporting information on the test item

4. **Summary tables**
   One summary table for organic compounds and one summary table for elements should be included in the report. The formats of the summary tables must follow the BEDS spreadsheet template. In addition to including the summary tables in the Extractables Test Report, the summary tables need to be made available in BEDS spreadsheet format. It is optional to report structures of identified compounds.

5. **Results from analyses**
   Results from each individual analysis technique should be reported separately. It is highly recommended, but not mandatory, to follow the format provided in the BEDS spreadsheet template.

6. **Analytical methods**
   Information on each individual analysis technique should be reported separately. It is highly recommended, but not mandatory, to follow the format provided in the BEDS spreadsheet template. Information on analytical methods shall include:
   d. Method traceability
   e. Instrument settings
   f. Method qualification
   g. System suitability test (SST)
   h. Sample preparation
   i. Approaches for quantification and identification

7. **Deviations**
   Any deviations observed during the study needs to be documented.

8. **Terminology**
   Acronyms used in the Extractables Test Report need to be explained.

9. **Revision history**
   Revision history of the report needs to be included, describing changes made to the Extractables Test Report after initial release.

   The final reporting should be within the oversight of the company's quality management system and can be in one of the following formats (or a combination):

   - Signed pdf print-out of the BEDS document+ BEDS document provided as a spreadsheet file

     The generated pdf can be issued as final report. The title page can be modified to align with company branding and requirements for signatures etc. It is also allowed to add additional pages to the report that are not part of the BEDS template.

   - Signed pdf report + Summary tables provided as BEDS document

     This reporting option can be used by suppliers / labs that prefer to report the information and data in text format. It is mandatory to use the format dictated by the BEDS template for the summary tables and the study design information. All other information can be entered in a format of your choice, as long as all information required by the BEDS template is provided in the report.

The table below lists what content in the BEDS spreadsheet template:

- is mandatory to provide or optional to provide
- must follow the prescribed format or when template formatting is not descriptive
- must be provided in BEDS spreadsheet format or in pdf format

BEDS file	pdf file	Name of tab	Note
		Title page	Title page tab can be designed to comply with company guidelines and quality management system (QMS) requirements
		Study summary	Key content should be included in the report, but formatting not descriptive.
		Study design	Supplier data should follow the exact table format to provide standard work approach for reviewing overall study design.
		Summary table organics	Supplier data should follow the exact table format. Additional columns can be added to the right of the fixed template if supplier wants to include supplemental information.
		Summary table elements	Supplier data should follow the exact table format.
		Structures	Optional to provide
		HS-GC-MS	Format in template is recommended best practice. Key content should be included in the report, but formatting and organization may vary.
		GC-MS	Format in template is recommended best practice. Key content should be included in the report, but formatting and organization may vary.
		LC-UV-MS	Format in template is recommended best practice. Key content should be included in the report, but formatting and organization may vary.
		ICP-MS	Format in template is recommended best practice. Key content should be included in the report, but formatting and organization may vary.
		TOC	Optional to provide.
		pH	Optional to provide.
		NVR	Optional to provide.
		Analytical methods	Format in template is recommended best practice. Key content should be included in the report, but formatting and organization may vary.
		Deviations	Deviations from e.g. study plan or SST acceptance criteria must be properly documented, but formatting not descriptive.
		Chromatograms / spectra	Optional to provide. Tab(s) can be added at the end of the BEDS template. Formatting not descriptive. Should be kept on file and provided on request. May be appropriate to include supporting data of any unknowns of significant abundance.

Key:

Content MUST follow the prescribed format | Content MUST be included but format may vary | Optional to provide

It is allowed to add additional tabs to the spreadsheet as well as remove tabs not used.

Below is guidance on how to fill in the spreadsheet.

Tab 1: Title Page

The format and layout of title page can be edited /replaced by a design of your own choice e.g. to include company logotype, disclaimers etc. At a minimum, the below information should be included:

Study report title **Study report number(s)** **Study report revision** **Date**	Use a descriptive title of the extractables study Use a unique identifier for each study Fill in revision and approval date of the report
Sponsor **Sponsor reference No** **Sponsor contact** **Sponsor address**	For 3rd party labs: fill in information on the sponsor ordering the study. Note N/A or remove if the study is conducted in-house.
Testing laboratory **Testing laboratory contact** **Testing laboratory address**	Fill in information on the lab performing the test. Fill in the location of the lab as many companies have a global presence. If multiple sites were used, list the lab with the main responsibility for issuing the study.
Signatures	The title page needs to be signed in agreement with quality management system (QMS) requirements of the company issuing the report. Revise the signature roles to comply with company QMS.

Tab 2: Study summary

Purpose of this section is to give a high-level summary of the study. By reading this page it should be clear what the study design was (test item, extraction solvents, time points, and analysis techniques), and what the main outcome was (e.g. if silicone tubing was analyzed the main outcome is most likely detection of a wide range of organosilicon compounds using the chromatographic techniques and Si being a dominating element in ICP-MS analysis).

The study summary from a 3rd party lab will mainly reflect on the analysis results, whereas the study summary from a component supplier / integrator can reflect on the results in relation to the materials of construction and intended use of the component.

Tab 3: Study design

Purpose of this tab is to provide a summary of the study design.

Test item information	
Test article name	Provide traceability information on the test item.
Test article part number	
Number of lots tested	
Test article lot number(s)	
Film thickness (mm)	Edit the text to the left to provide information relevant to the test item under investigation: **Bags:** Film thickness (mm) Volume capacity (L) **Tubing:** Wall thickness (mm) Internal diameter (mm) Length (mm) **Tubing connectors and aseptic connectors:** Internal diameter (mm) Length (mm) **Filling needles:** Internal diameter (mm) Deleted the rows if the test item is none of above listed component types
Volume capacity (L)	
Pretreatment of test article	
Gamma irradiation	Provide information related to gamma, autoclave or pre-flush. If not performed, note N/A or delete rows. If incubation of all test items is not started on the same day, please provide a range for time between gamma irradiation and extraction start e.g. 20-25 days. In the case other pre-treatments than the above listed were used, please specify.
Typical dose range during normal manufacturing (kGy)	
Received dose/dose range (kGy)	
Gamma date (DD-Month-YYYY)	
Time between gamma irradiation and extraction (Requirement is ≤ 8 weeks) (Days)	
2D and 3D bags only: Time between film manufacturing and gamma irradiation (Days)	
Autoclave	
Time, temperature, number of cycles (Minutes,°C, #)	
Pre-Flush	
Fluid identity, duration, temperature, volume (Name, min., °C, L)	
Other	
(Please specify)	

Tab 3: Study design (continued)

Extraction solvents	Solvent loss (%)
50% Ethanol	Adapt the list of solvents to reflect the study design (e.g. for reporting of non-BPOG studies). Provide information on solvent loss for each solvent included in the study. Provide average or a range.
0.5 N NaOH	
0.1 M H3PO4	
Water for injection (WFI)	
Other(s) Please specify Add rows as needed	
Time Points	**Extraction temperature (°C)**
T 24 hrs.	Adapt the list of time points to reflect the study design (e.g. for reporting of non-BPOG studies). For each time point, provide information on what temperature was used during incubation.
T 7 days	
T 21 days	
T 70 days	
Other(s) (Please specify) Add rows as needed	
Test Article Extraction Conditions	
Static or dynamic extraction	If dynamic extraction is used, provide information such as shaking conditions or circulating flow conditions.
Solvent start volume (mL)	If the volume of solvent used is not identical for each test item, provide general high-level information e.g. target volume or average volume or volume range of all items included in the study. Target weight of liquid can be used as an alternative to volume, as applicable.
Solvent contact surface area (EFA for filter) (cm2)	If the surface area is not identical for each test item, provide general high-level information on test item wetted surface area, e.g. target area or average area or area range of all items tested. For filters: provide effective filtration area (EFA). When the area is not known (e.g. small items of complex shape that are immersed during incubation) the weight can be noted instead of the surface area.
Surface area to volume ratio (cm2/mL)	If the surface area is not identical for each test item, provide general high-level information, e.g. target value or average value or range of values for all items included in the study. In the case the weight of the test item is used, provide information expressed as g/mL.

Description of extraction procedure

Provide a short description on how the test items were extracted, e.g.:

- Bags were filled with extraction fluid and incubated in a heating cabinet
- Coupons were immersed in extraction fluid in glass vessels and incubated in a heating cabinet
- Filters were extracted under circulating flow in a heating cabinet
- Filters were filled with extraction fluid and capped and incubated in a heating cabinet
- Coupons were reflux extracted

Provide information on any visual observations, e.g. color of extracts.

Tab 3: Study design (continued)

Analytical methods	Comment
HS-GC-MS	Adapt the list to reflect the study design (e.g. for reporting of non-BPOG studies). For each analytical method, note what solvents were analyzed, e.g. "Applied to all solvents" or "Applied to WFI".
GC-MS	
LC-UV-MS ESI	
LC-UV-MS APCI	
ICP-MS	
TOC	
pH	
NVR	
Other(s) (Please specify) Add rows as needed	

Tab 4: Summary table Organics

This tab summarizes the outcome of the analysis of organic compounds. For each solvent, the table combines the results from all organic analysis techniques.

Content in this tab must follow the prescribed format. The columns in the summary tab are fixed, so as to make it easy for end users to copy, paste, scale, and manipulate data in the way they require. Additional columns can be added to the right of the fixed template, if supplier wants to include supplemental information.

Solvent	List extraction solvents used for incubation. Acronyms can be used to save space if these are explained elsewhere.
Compound	The compounds are reported per solvent, i.e. compounds identified in multiple solvents will be listed multiple times. If a compound is detected in multiple analysis techniques in a solvent, only the highest result or result from most confident/relevant technique is reported. Use IUPAC name or other chemical name. Trade names or similar can be provided in brackets to simplify reading. Unknowns are reported as Unknown 1, Unknown 2 etc. Within each solvent, list the compounds in order of highest to lowest concentration.
CAS	Provide CAS registry number for the compound. If not available, note N/A.
ICH Q3C	If the compound is listed in ICH Q3C (latest revision at date of study reporting), state 1 or 2 or 3 dependent on what class the compound belongs to. If the compound is not listed in Q3C state N/A.
RT (min)	Provide information on retention time. As there is a variability in retention time in between chromatographic runs, select the retention time associated with the quantitative value reported, or other representative retention time of the compound.
ID level	To align nomenclature; use definitions outlined in USP <1663> **Confirmed:** Verified by authentic standard **Confident:** Most probable compound suggested from data match vs. literature spectrum or indicated by orthogonal technique **Tentative:** Data is consistent with class of compound or accurate mass and chemical composition data only is available. **Unknown:** Insufficient data to propose an identity
Standard used for quantification	Provide information on what type of standard was used for quantification: authentic standard, a surrogate standard (e.g. for compounds not commercially available), or internal standard (e.g. for unknowns). If a surrogate standard is used, please provide the name. There is no need to provide the names for internal standards as these are listed for each method in the method tab.
Method and detection mode	Indicate what analysis method and detection mode measured the highest amount. For compounds detected in several techniques/detection modes: in case the highest amount measured for a compound is not considered as confident/accurate as results from another technique/mode, please report the technique/mode giving the most reliable quantitative value.
T1 **T21** **T70**	Modify the columns to reflect the study design (e.g. T0, T1 only or T0, T1, T7 or non-BPOG data points). Add or delete columns as needed. Report the quantitative value expressed as µg/cm2 (or µg/g if weight is used in the study design). Report the highest value of all lots tested (or most confident/reliable quantitative value of all lots tested). Note" <RL", or "<DL", or "<0.01" or "-" as appropriate when a compound is not detected or detected below reporting limit.

Tab 5: Summary table elements

This tab summarizes the outcome of the analysis of elements. The results are reported per solvent. The mandatory elements are listed in alphabetical order within ICH Q3D class, from class 1 to class 3. In addition to the elements listed in ICH Q3D, it is requested by end-users to analyze Al, Fe, Mg, Zn as these elements may impact drug product quality. It is allowed to add additional elwements as needed.

In the summary, only quantitative values >20 ppb (µg/L) are reported. Elements not analyzed are reported as "N/A". Provide results in units µg/cm2 (or µg/g). Provide results from the longest incubation time only (modify the text in the table heading accordingly) and the highest results from all lots tested.

Element		ICH Q3D Class	Highest result of all lots tested (µg/cm²) (7, 21, or 70 days)					
			Water	0.1 M H_3PO_4	0.5 N NaOH	50% Ethanol	5 M NaCl	1% PS80
Arsenic	As	1	-	-	-	-	-	-
Cadmium	Cd	1	-	-	-	-	-	-
Mercury	Hg	1	-	-	-	-	-	-
Lead	Pb	1	-	-	-	-	-	-
Cobalt	Co	2A	-	-	-	-	-	-
Nickel	Ni	2A	-	-	-	-	-	-
Vanadium	V	2A	-	-	-	-	-	-
Silver	Ag	2B	-	-	-	-	-	-
Gold	Au	2B	-	-	-	-	-	-
Iridium	Ir	2B	-	-	-	-	-	-
Osmium	Os	2B	-	-	-	-	-	-
Palladium	Pd	2B	-	-	-	-	-	-
Platinum	Pt	2B	-	-	-	-	-	-
Rhodium	Rh	2B	-	-	-	-	-	-
Ruthenium	Ru	2B	-	-	-	-	-	-
Selenium	Se	2B	-	-	-	-	-	-
Thallium	Tl	2B	-	-	-	-	-	-
Barium	Ba	3	-	-	-	-	-	-
Chromium	Cr	3	-	-	-	-	-	-
Copper	Cu	3	-	-	-	-	-	-
Lithium	Li	3	-	-	-	-	-	-
Molybdenum	Mo	3	-	-	-	-	-	-
Antimony	Sb	3	-	-	-	-	-	-
Tin	Sn	3	-	-	-	-	-	-
Aluminum	Al	N/A*	-	-	-	-	-	-
Iron	Fe	N/A*	-	-	-	-	-	-
Magnesium	Mg	N/A*	-	-	-	-	-	-
Zinc	Zn	N/A*	-	-	-	-	-	-

*Requested by end-users as element may affect drug product quality

Tab 6: Analytical methods

There is one table for each method. All tables are populated in the same way but differ in pre-populated text regarding e.g. instrument settings and standards recommended in the protocol for the different methods.

HS-GC-MS method			
Method id and revision no	Provide a unique identification number and a revision number of the method		
Instrument settings			
Variable(s)	**Value(s)**		
Instrument description	Provide information on brand, model, and type of detectors		
Column stationary phase and dimensions	Provide stationary phase name (e.g. DB-624), column length, column diameter and stationary phase thickness		
Carrier gas	Provide information on method settings.		
Flow rate (mL/min)			
Temperature gradient range (°C)			
Injection volume (mL)			
Mass scan range (m/z)			
Other(s)	This row can be used to provide other relevant instrument related information not listed above. If no other information is added, this row can be deleted.		
Method qualification			
Standard(s)	List all compounds used as standards during method qualification. Provide name and CAS no for each compound.		
Internal standard(s)	Provide name and CAS no of any internal standard(s) used. If no internal standard(s) were used state N/A.		
Variable(s)	**Solvent(s)**	**Criteria**	**Value OR Pass/Fail**
Precision (provide name of standard used)	State the solvent used for determining precision, accuracy, and LOD. The BEDS template is pre-populated with recommended solvent(s) for each variable. Edit the solvent list to reflect the study design	State the pass/fail criteria. The BEDS template is pre-populated with recommended criteria. For LOD, there are no pass/fail criteria set in the protocol. List the resulting LOD of the standard.	Type value of outcome or state Pass or Fail dependent on outcome
Accuracy (provide name of standard used)			
Limit of detection (LOD) (provide name of standard used)			
System suitability test (SST)			
SST standard(s)	List the compounds used in the SST test. Provide name and CAS no.		
Internal standard(s)	Provide name and CAS no of any internal standard(s) used. If no internal standard(s) were used state N/A.		
Variable(s)	**SST spike**	**Criteria**	**Value OR Pass/Fail**
Precision	Provide information on compound used, spike concentration and matrix into which it is spiked. One compound per row. The BEDS template is pre-populated with recommended compounds and matrixes for each method.	State the SST criteria for each compound included in the SST test solution.	Type value of outcome or state Pass or Fail dependent on outcome
Sensitivity			
Retention time			

Tab 6: Analytical methods (continued)

Sample preparation	
Variable(s)	**Value(s)**
Dilution factor(s)	Provide information on sample preparations such as dilution(s), pre-concentration (e.g. liquid-liquid extraction), additions (e.g. salt, acid), pH adjustments etc.
Salt addition	
Other(s)	
Quantification and identification	
Variable(s)	**Value(s)**
Internal standard(s) and spike concentration	Provide name, CAS no, and spike concentration of any internal standard(s) used for spiking the controls and extracts. If no internal standard(s) was used, state N/A.
Peak evaluation threshold	There are several approaches for how to define what peaks to include in data evaluation. Provide information on peak evaluation threshold criteria. **Example**: Peaks ≥ 10% of the internal standard were included in data evaluation.
Peak reporting criteria	State what criteria was used for reporting peaks as extractables, e.g. peaks of concentration ≥ 0.1 ppm (µg/mL) and ≥ 3x control.
Type of quantification	Quantification can be performed in many ways. Provide information on how quantification was performed. **Example:** A relative response factor in relation the internal standard was used for quantification. When available, an authentic compound was used to generate the relative response factor. A surrogate compound was used when an authentic compound was not available. For unknowns, the response factor of the compound was assumed to be 1, i.e. equal to the internal standard.
Identification	Please provide a brief explanation of how identity was assigned to identified peaks. **Example:** Retention time and mass spectra were matched with an-in-house database. If no correlation could be found, their mass spectra were compared to the reference data in the NIST mass spectral library.

Tab 7-9: HS-GC-MS, GC-MS, LC-UV-MS

The results from organic compound analyses are reported on separate tabs for each analysis technique. See guidance for Tab 5 on how to populate the tables.

It is allowed to combine results from all five LC analyses (UV, ESI+, ESI-, APCI+, APCI-) into one summary tab for LC-UV-MS. It is also allowed to insert additional LC tabs to report results from each LC analysis mode separately.

Tab 10: ICP-MS

Raw data from ICP-MS analysis is provided in the ICP-MS tab.

ICH Q3D Class	If the compound is listed in ICH Q3D (latest revision at date of study reporting), state 1, 2A, 2B, or 3 dependent on what class the compound belongs to. If the compound is not listed in Q3D state N/A.
LOD (µg/L)	Provide limit of detection for each compound in each matrix. Express in unit µg/L.
LOQ (µg/L)	Provide limit of quantification for each compound in each matrix. Express in unit µg/L.
Control (µg/L)	Provide raw data from the measurements of control and extracts in unit µg/L.
Lot 1 (µg/L)	
Lot 2 (µg/L)	
Result Lot 1 (µg/L)	Subtract the control from the extracts and report the result in unit µg/L. In cases when: • the control is < LOD or < LOQ, no subtraction is performed • both control and sample are > LOQ but the calculated result is < LOQ the calculated number is reported
Result Lot 2 (µg/L)	
Result Lot 1 (µg/cm²)	Convert the result from µg/L to µg/cm².
Result Lot 2 (µg/cm²)	

Additional elements can be added as needed. These are added in alphabetical order in the ICH Q3D "N/A" group

Tab 11: TOC

Analysis of TOC is optional to perform.

Solvent	Name of extraction solvent
Lot	Lot 1, Lot 2 etc.
LOD (mg/L)	Provide limit of detection in each matrix. Express in unit mg/L.
LOQ (mg/L)	Provide limit of quantification in each matrix. Express in unit mg/L.
Control (mg/L)	Provide raw data from the measurements of control and extracts in unit mg/L.
Extract (mg/L)	
Result (mg/L)	Subtract the control from the extracts and report the result in unit mg/L. In cases when: • the control is < LOD or < LOQ, no subtraction is performed • both control and sample are > LOQ but the calculated result is < LOQ the calculated number is reported
Result (µg/cm²)	Convert the result from mg/L to µg/cm². Add or remove columns as needed to reflect the timepoints of the study design.

Tab 12: pH

Analysis of pH is optional to perform..

Solvent	Name of extraction solvent
Lot	Lot 1, Lot 2 etc.
Control pH	Provide raw data from the measurements of control and extracts.
Extract pH	
Result Δ pH	Subtract the control from the extracts and report the results. Add or remove columns as needed to reflect the timepoints of the study design.

Tab 13: NVR

Analysis of NVR is optional to perform.

Solvent	Name of extraction solvent
Lot	Lot 1, Lot 2 etc.
LOQ (mg/L)	Provide limit of quantification in each matrix. Express in unit mg/L.
Control (mg/L)	Provide raw data from the measurements of control and extracts in unit mg/L.
Extract (mg/L)	
Result (mg/L)	Subtract the control from the extracts and report the result in unit mg/L. In cases when: • the control is < LOQ, no subtraction is performed • both control and sample are > LOQ but the calculated result is < LOQ the calculated number is reported
Result (µg/cm²)	Convert the result from mg/L to µg/cm². Add or remove columns as needed to reflect the timepoints of the study design.

Tab 14: Structures

The information in this tab is optional. The tab can be used to provide structures of identified compounds (ID levels confirmed and confident). List the compounds in CAS registry number order from low to high numbers.

Tab 15: Deviations

This section lists any deviations observed during the study, e.g. deviations from the study protocol or failed system suitability testing.

Tab 16: Terminology

List and explain all acronyms used in Extractables Test Report.

Tab 17: Revision history

Revision history of the report needs to be included, describing changes made to the Extractables Test Report after initial release.