

REQUEST FOR QUOTE

**Extractables Study for**

**Elastomer Vial Stoppers (Coated and Uncoated)**

July 8, 2025

Extractables and Leachables Safety Information Exchange (ELSIE) Consortium

Request for Quote

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# Introduction

## About the ELSIE Consortium

The Extractables and Leachables Safety Information Exchange Consortium (ELSIE) is a leading industry voice and scientific resource on extractables and leachables (E&L), comprised of pharmaceutical, biotechnology, and medical device companies. ELSIE‘s objectives are to reduce duplicative safety studies across companies, streamline development projects, and to help advance the practice and science of extractables, leachables and materials evaluation. ELSIE members participate in collaborative Working Groups and Subteams that address key knowledge gaps, support members’ daily work, and advance the state of E&L risk management. ELSIE also has regular interactions with the regulatory agencies and industry stakeholders to discuss current and emerging E&L issues. ELSIE achieved an important milestone launching a next generation Knowledge Base in 2024.  The Knowledge Base is a valuable resource for members that will store toxicological safety information and extractables study results on raw materials, single-use products, drug packaging and delivery systems, and medical devices.

## Request for Quote

Publication of this Request for Quote (RFQ) is the first step by ELSIE to identify a laboratory to conduct an ELSIE-sponsored extractables study on Elastomer vial stoppers.

## Disclaimer

The contents and information provided in this RFQ are meant to provide general information to parties interested in performing this ELSIE-sponsored extractables study on Elastomer vial stoppers. The successful respondent selected by ELSIE will be required to supply a Statement of Work (SOW) describing the work to be performed and execute an Agreement that will govern the terms of the project. When responding to this RFQ, please note the following:

* This RFQ is not an offer or a contract
* Responses submitted in response to this RFQ become the property of ELSIE
* Respondents will not be compensated or reimbursed for any costs incurred as part of the RFQ process
* If ELSIE receives and responds to questions from RFQ respondents, ELSIE reserves the right to anonymize the questions and make the questions and ELSIE’s responses available to all respondents via our website
* ELSIE is not obligated to contract for any of the products or services described in this RFQ
* ELSIE reserves the right to:
	+ Accept or reject any or all proposals
	+ Waive any anomalies in proposals
	+ Negotiate with any or all bidders
	+ Modify or cancel this RFQ at any time

## RFQ Contact Information

All questions and inquiries regarding this RFQ

be directed to:

Ms. Mary Kate Bielinski

ELSIE Secretariat

c/o Faegre Drinker Biddle & Reath, LLP

1500 K St NW

Washington DC, 20005-1209

414.207.4189

info@elsiedata.org

<https://www.elsiedata.org>

## Anticipated Time Frames for Evaluation and Selection Process\*

Issue RFQ July 8, 2025

Responses to RFQ due July 25, 2025

*\*Dates subject to change without notice*

***Please submit your response electronically to the above address. Responses received after July 25, 2025*** ***will not benefit from full consideration and may be excluded from the selection process.***

## Project Scoping and Project Execution

ELSIE project sponsors will work with the selected laboratory to define the project scope and work to finalize a Statement of Work (SOW) for the project which describes project timelines, milestones, budget, deliverables, etc. The scoping exercise will be conducted via email and/or web-meetings.

The ELSIE Secretariat will work with the selected laboratory to negotiate and finalize a contract.

# Project Information

## Description

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| ELSIE members have identified a common need to conduct an extractables study on Elastomer stoppers.**Test articles:**  Elastomer vial stoppers (coated and uncoated)**Test protocol:** 1. **Introduction**

The purpose of this protocol is to outline the steps and procedures for conducting an extractables study on the test articles (elastomeric stoppers) used. Extractions will be conducted so that the stoppers are submerged in the extraction solvents. Testing will be conducted with the whole formed vial stopper. The study plan and testing matrix is outlined in Table 1. A minimum of three different batches of the two types of vial stoppers (coated and uncoated) will be used in the extractables study.1. **Study Plan and Testing Matrix**

Table 1

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Group** | **Solvent** | **Temperature** | **GC-MS** | **LC-UV-MS (positive and negative)** | **ICP-MS¹** | **SH-GC-MS** |
| 1 | 50% aqueous IPA, oven extractionfor 100 days at: | 40°C | Yes | Yes |  |  |
| 2 | Acidic solution, pH 3,oven extraction for 100 days at: | 40°C | Yes | Yes | Yes |  |
| 3 | Basic solution, pH 10,oven extraction for 100 days at: | 40°C | Yes | Yes |  |  |
| 4 | Neutral solution, pure water, oven extraction for 100 days at: | 40°C | Yes | Yes |  |  |
| 5 | 50% aqueous IPA, oven extractionfor 50 days at: | 50°C | Yes | Yes |  |  |
| 6 | Acidic solution, pH 3,oven extraction for 50 days at: | 50°C | Yes | Yes | Yes |  |
| 7 | Basic solution, pH 10,oven extraction for 50 days at: | 50°C | Yes | Yes |  |  |
| 8 | Neutral solution, pure water, oven extraction for 50 days at: | 50°C | Yes | Yes |  |  |
| 9 | Direct Analysis | n/a |  |  |  | Yes |

Acidic solution represents worst case in terms of elemental extractables. ICP analysis should be qualified to match the pH 3 matrix.A reporting threshold of 0.1 mcg/mL in the extract will be applied to the chromatographic analysis.A reporting threshold of 0.05 mcg/mL in the extract will be applied to the ICP analysis. 1. **Analytical Details**

Filled sample extraction: A suitable vessel, e.g., a glass vial, will be filled with the required volume of solvent. Once filled, the vessel will be closed with the test sample and placed under the required extraction temperature for the required test period. The stoppers will be submerged fully in the extraction solvent.Control (blank) samples will be prepared for each of the extraction solvents and conditions used. **3.1 Analysis of Volatile Extractables**Static Headspace Gas Chromatography Mass Spectrometry (SH GC-MS) to detect low molecular weight extractables including residual solvents.**3.2 Analysis of Semi-Volatile Extractables**Direct injection Gas Chromatography Mass Spectrometry (GC-MS) analysis to detect low molecular weight initiators, antioxidants, UV absorbers, lubricants, process aids, plasticisers, anti-static agents, modifiers and oligomers.**3.3 Analysis of Non-Volatile Extractables**Analysis by Liquid Chromatography with Mass Spectrometric detection (LC-MS) will be done to detect medium to high molecular weight substances including antioxidants, UV absorbers, plasticisers, lubricants process aids and heat stabilisers. Mass spectrometry analysis will be conducted using positive and negative ionization modes for LC. All detection modes will be reported.**3.4 Peak Identification and Semi-Quantification SH GC-MS, GC-MS and LC-UV-MS**Peak identification will be provided by reference to a commercial mass spectral library (Wiley or NIST) and internal libraries. An external standard containing a number of reference compounds will be used to estimate the level of extractables. This study may detect substances (chromatographic peaks) which cannot be assigned to a specific compound or compound class and would therefore be reported as “unknown.” We expect follow-up investigation/analysis if required to identify peaks that are initially “unknown.”**3.5 Analysis of Elemental Extractables**Elemental extractables will be determined by Inductively Coupled Plasma Mass Spectrometry (ICP-MS). The elements that will be assessed are those shown in USP <232> and ICH Q3D.1. **Additional Details**

The test articles will be provided by ELSIE to the selected laboratory.The results of the extractables study must be provided to ELSIE in an agreed upon report format along with all the raw analytical data files generated during the study to allow additional analysis by ELSIE members as needed. It is ELSIE’s intention to include the results from this extractable study in the ELSIE Knowledge Base. The selected laboratory will be required to provide the information contained in the extractables report in our custom Excel-based templates to enable direct upload into the ELSIE Knowledge Base. ELSIE will provide software, instructions, and support for the laboratory to generate these templates.  |

## Timeline

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| Anticipated Time Frames for Process and Study\*Select Laboratory Sept 5, 2025Laboratory to provide SOW Oct 3, 2025ELSIE and Laboratory executes Agreement Nov 7, 2025Laboratory initiates study Nov 24, 2025Data provided to consortium by end 1Q 2026*\*Dates subject to change without notice* |

## Study Requirements

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| * Study conducted according to protocol described in Table 2.1
* All raw data and spectra generated will be provided to ELSIE in its native, electronic format for import into scientific software. Static images, screenshots, Excel tables, Word Documents, etc., are not acceptable for providing raw data.
* Study results provided both in a mutually agreed upon report format and in ELSIE templates.
* All data and results generated by the study will be owned by ELSIE. The Laboratory will not have a license to use the data or sell the extractable report to other customers
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## Criteria for Evaluation

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| ELSIE will evaluate all responses to this RFQ based upon the respondent’s ability to meet the requirements outlined in this document, demonstration of domain expertise, interest to work with ELSIE on this joint study project, and any additional capabilities that may differentiate their response from others received. The laboratory will be selected for this study based on the following criteria:CostAvailability to complete the study in short timeframe Analytical equipment availableCalibration protocol with reference standards (multi-point calibration required)Ability to provide raw data files and spectra Ability to provide information on findings of anything above the LOQ* Ability to provide extractable study report
* Ability to provide study results in templates using software provided by ELSIE
* Expertise and experience in conducting E&L studies

Please note that due to the volume of responses received, ELSIE only provides general updates related to the status of the review process and will not provide individualized feedback as to why a particular proposal was not selected by ELSIE. |

# Respondent Profile

*(To be completed by respondent)*

Please provide information to the following:

## Company/Organization Information

|  |  |
| --- | --- |
| Company/Organization Name |  |
| Address |  |
| City |  |
| State |  |
| Country |  |
| Zip Code |  |
| Website |  |

## Primary Contact Person

|  |  |
| --- | --- |
| Name |  |
| Title |  |
| Email address |  |
| Phone Number |  |

## Company/Organization Overview

Provide a brief overview of your company/organization including number of years in business, number of employees, nature of business, description of clients, and related products developed and commercialized to date.

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## Parent Corporation and/or Subsidiaries

Identify any parent corporation and or subsidiaries, if appropriate.

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## Summary of Expertise

Give a brief description of your company/organization’s expertise in the area/field related to this RFQ. Include any experience working on projects with Consortia/Associations.

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## Standards Certifications

List any certifications currently held, including date received, duration, and renewal date.

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## Miscellaneous

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# Company/Organization Response to RFQ (*to be completed by RFQ respondent)*

## Description of Services

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## Estimated Timeline

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## Estimated Project Cost

Participating ELSIE members will provide resources in the form of funding and subject matter expertise to support this extractable study.  While ELSIE will entertain all proposals received, regarding funding from ELSIE, please consider the following:

* Costs should be provided as **fixed-costs in US Dollars;**
* Costs to complete individual tasks should be itemized.
* Any additional work and associated costs suggested by the laboratory to enhance the study are welcome but should be clearly labeled as “optional” in the itemized price list.

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**Regarding the estimated project cost, please specify the following:**

* Does the price quoted included evaluation of all peaks observed? If not, please provide details as to what the price includes (e.g., number of peaks, peaks above certain threshold, etc.)

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* Does the price quoted include review of the protocols and reports by ELSIE prior to finalization? If not, please provide details as to what the price includes (e.g., number of rounds of review)

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* Does the price quoted include providing the raw and analyzed data to ELSIE in a ready-to-use electronic format such as native file, comma delimited, Excel, JSON, etc. which will allow for additional analysis by ELSIE? **Note**: PDF and Word documents are not acceptable formats for this purpose.

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* Does the price quoted include conducting recovery experiments with the reference standards?

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## Protocol Details

**General**

Please describe your process for ELSIE review and finalization of protocols, including any limits on the number of rounds of review.

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Which elements do you include in ICP testing?

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**Reference Standards and Calibration Curves**

What is the status of method qualification / validation for reference standards?

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How many reference standards do you use per method?

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How many unique data points and repeats are measured to make the calibration curve for each reference standard?

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How do you choose the most appropriate reference standard for semi-quantification?

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Do you perform recovery experiments with the reference standards?

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**Analytical Equipment and Detector Information**

Please provide the LODs and LOQs per method without sample concentration.

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Please provide details on what analytical equipment will be used including all available detectors.

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**Extractables Identification**

Please state how you identify and quantify peaks per method.

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What is your average rate of unidentifiable extractables (in %)?

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What is your average rate of unidentifiable extractables (in %)?

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Please confirm that you report the % match with library matches, will report alternative compounds if there are various matches, and indicate what match in % you start reporting. *To clarify: Each lab will compare the spectrum with some sort of library. You may get a 100% match, but this is very rare. Normally, you get around 70%. The question is, does your lab have some sort of cut-off for example, it must be a match above 50%...how do you choose the most appropriate match if various compounds are possible?)*

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For compound identification, what is your governing procedure/approach for determining Confirmed, Confident, and Tentative ID?

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Do you have an MS expert on staff to review software predictions/identifications?

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Is there a workflow template/example that can be provided for ID investigation?

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## Deliverables

Please confirm CAS numbers will be provided for all identified compounds.

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Please confirm SMILES codes will be provided for all identified compounds.

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Please confirm raw and analyzed data (i.e., chromatograms, MS spectra, UV spectra, etc.) including MS data will be provided to ELSIE in a ready-to-use electronic format such as native format, comma delimited, Excel, JSON, etc. which will allow for additional analysis by ELSIE and upload into the ELSIE Knowledge Base.
Note: PDF and Word documents are not acceptable formats for this purpose.

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Please describe your process for ELSIE review of reports prior to finalization, including any limits on the number of rounds of review.

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Will you provide a governing SOP or validation report for method validation/qualification that can be shared to support regulatory submissions?

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## Opportunities for Additional Studies Beyond this Project

The overarching goal of ELSIE is to share safety and chemistry information within member companies in order to reduce redundant studies. Aligned with that goal, ELSIE members are looking to sponsor future joint-study projects which will result in results and data that will be added to the ELSIE Knowledge Base so that the information may be shared among all member companies.

Please describe your interest (if any) to work with ELSIE on future studies. Include in your response, any cost savings gained by performing extractable studies in parallel on multiple test articles with the same study protocol (e.g., USP protocols, other) vs. the same studies conducted one at a time, in series.

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