



**RETURN BIDS TO:
RETOURNER LES SOUMISSIONS À:**

**Bid Receiving
PWGSC
33 City Centre Drive
Suite 480C
Mississauga
Ontario
L5B 2N5
Bid Fax: (905) 615-2095**

**REQUEST FOR PROPOSAL
DEMANDE DE PROPOSITION**

**Proposal To: Public Works and Government
Services Canada**

We hereby offer to sell to Her Majesty the Queen in right of Canada, in accordance with the terms and conditions set out herein, referred to herein or attached hereto, the goods, services, and construction listed herein and on any attached sheets at the price(s) set out therefor.

**Proposition aux: Travaux Publics et Services
Gouvernementaux Canada**

Nous offrons par la présente de vendre à Sa Majesté la Reine du chef du Canada, aux conditions énoncées ou incluses par référence dans la présente et aux annexes ci-jointes, les biens, services et construction énumérés ici sur toute feuille ci-annexée, au(x) prix indiqué(s).

Comments - Commentaires

Title - Sujet Dissolutions System	
Solicitation No. - N° de l'invitation H4004-173786/A	Date 2018-01-10
Client Reference No. - N° de référence du client H4004-173786	
GETS Reference No. - N° de référence de SEAG PW-\$TOR-009-7462	
File No. - N° de dossier TOR-7-40134 (009)	CCC No./N° CCC - FMS No./N° VME
Solicitation Closes - L'invitation prend fin at - à 02:00 PM on - le 2018-02-20	Time Zone Fuseau horaire Eastern Standard Time EST
F.O.B. - F.A.B. Plant-Usine: <input type="checkbox"/> Destination: <input checked="" type="checkbox"/> Other-Autre: <input type="checkbox"/>	
Address Enquiries to: - Adresser toutes questions à: Holvec, Monique	Buyer Id - Id de l'acheteur tor009
Telephone No. - N° de téléphone (905) 615-2062 ()	FAX No. - N° de FAX () -
Destination - of Goods, Services, and Construction: Destination - des biens, services et construction: DEPARTMENT OF HEALTH ONTARIO REGL OFFICE 2301 MIDLAND AVE Toronto Ontario M1P4R7 Canada	

Instructions: See Herein

Instructions: Voir aux présentes

Vendor/Firm Name and Address

**Raison sociale et adresse du
fournisseur/de l'entrepreneur**

Issuing Office - Bureau de distribution

Public Works and Government Services Canada
Ontario Region
33 City Centre Drive
Suite 480
Mississauga
Ontario
L5B 2N5

Delivery Required - Livraison exigée See Herein	Delivery Offered - Livraison proposée
Vendor/Firm Name and Address Raison sociale et adresse du fournisseur/de l'entrepreneur	
Telephone No. - N° de téléphone Facsimile No. - N° de télécopieur	
Name and title of person authorized to sign on behalf of Vendor/Firm (type or print) Nom et titre de la personne autorisée à signer au nom du fournisseur/ de l'entrepreneur (taper ou écrire en caractères d'imprimerie)	
Signature	Date

TABLE OF CONTENTS

PART 1 - GENERAL INFORMATION	3
1.1 SECURITY REQUIREMENTS	3
1.2 REQUIREMENT	3
1.3 DEBRIEFINGS	3
1.4 TRADE AGREEMENTS	3
PART 2 - BIDDER INSTRUCTIONS	3
2.1 STANDARD INSTRUCTIONS, CLAUSES AND CONDITIONS	3
2.2 SUBMISSION OF BIDS	3
2.3 ENQUIRIES - BID SOLICITATION	3
2.4 APPLICABLE LAWS	4
PART 3 - BID PREPARATION INSTRUCTIONS	4
3.1 BID PREPARATION INSTRUCTIONS	4
PART 4 - EVALUATION PROCEDURES AND BASIS OF SELECTION	5
4.1 EVALUATION PROCEDURES	5
4.2 BASIS OF SELECTION	6
PART 5 - CERTIFICATIONS AND ADDITIONAL INFORMATION	6
5.1 CERTIFICATIONS REQUIRED WITH THE BID	6
5.2 CERTIFICATIONS PRECEDENT TO CONTRACT AWARD AND ADDITIONAL INFORMATION	6
PART 6 - RESULTING CONTRACT CLAUSES	8
6.1 SECURITY REQUIREMENTS	8
6.2 REQUIREMENT	8
6.3 STANDARD CLAUSES AND CONDITIONS	8
6.4 TERM OF CONTRACT	8
6.5 AUTHORITIES	9
6.6 PAYMENT	9
6.7 INVOICING INSTRUCTIONS	10
6.8 CERTIFICATIONS AND ADDITIONAL INFORMATION	11
6.9 APPLICABLE LAWS	11
6.10 PRIORITY OF DOCUMENTS	11
6.11 SACC <i>MANUAL</i> CLAUSES	11
6.12 INSURANCE REQUIREMENTS	11
ANNEX "A"	12
REQUIREMENT	12
ANNEX "B"	17
BASIS OF PAYMENT	17
ANNEX "C"	19
ELECTRONIC PAYMENT INSTRUMENTS	19

Solicitation No. - N° de l'invitation
H4004-173786/A
Client Ref. No. - N° de réf. du client
H4004-173786

Amd. No. - N° de la modif.
File No. - N° du dossier
TOR-7-40134

Buyer ID - Id de l'acheteur
tor009
CCC No./N° CCC - FMS No./N° VME

ANNEX "D"	20
EVALUATION CRITERIA	20
ANNEX "E"	22
CERTIFICATION FORMS	22

PART 1 - GENERAL INFORMATION

1.1 Security Requirements

There is no security requirement applicable to the Contract

1.2 Requirement

The requirement is detailed under Article 6.2 of the resulting contract clauses.

1.3 Debriefings

Bidders may request a debriefing on the results of the bid solicitation process. Bidders should make the request to the Contracting Authority within 15 working days from receipt of the results of the bid solicitation process. The debriefing may be in writing, by telephone or in person.

1.4 Trade Agreements

The requirement is subject to the provisions of the North American Free Trade Agreement (NAFTA), and the Canadian Free Trade Agreement (CFTA).

PART 2 - BIDDER INSTRUCTIONS

2.1 Standard Instructions, Clauses and Conditions

All instructions, clauses and conditions identified in the bid solicitation by number, date and title are set out in the [Standard Acquisition Clauses and Conditions Manual](https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) (<https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual>) issued by Public Works and Government Services Canada.

Bidders who submit a bid agree to be bound by the instructions, clauses and conditions of the bid solicitation and accept the clauses and conditions of the resulting contract.

The [2003](#) (2017-04-27) Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation.

Subsection 5.4 of [2003](#), Standard Instructions - Goods or Services - Competitive Requirements, is amended as follows:

Delete: 60 days
Insert: 120 days

2.1.1 SACC Manual Clauses

[B3000T](#) (2006-06-16), Equivalent Products

2.2 Submission of Bids

Bids must be submitted only to Public Works and Government Services Canada (PWGSC) Bid Receiving Unit by the date, time and place indicated on page 1 of the bid solicitation.

2.3 Enquiries - Bid Solicitation

All enquiries must be submitted in writing to the Contracting Authority no later than ten (10) calendar days before the bid closing date. Enquiries received after that time may not be answered.

Bidders should reference as accurately as possible the numbered item of the bid solicitation to which the enquiry relates. Care should be taken by Bidders to explain each question in sufficient detail in order to enable Canada to provide an accurate answer. Technical enquiries that are of a proprietary nature must be clearly marked "proprietary" at each relevant item. Items identified as "proprietary" will be treated as such except where Canada determines that the enquiry is not of a proprietary nature. Canada may edit the question(s) or may request that the Bidder do so, so that the proprietary nature of the question(s) is eliminated, and the enquiry can be answered to all Bidders. Enquiries not submitted in a form that can be distributed to all Bidders may not be answered by Canada.

2.4 Applicable Laws

Any resulting contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario, Canada.

Bidders may, at their discretion, substitute the applicable laws of a Canadian province or territory of their choice without affecting the validity of their bid, by deleting the name of the Canadian province or territory specified and inserting the name of the Canadian province or territory of their choice. If no change is made, it acknowledges that the applicable laws specified are acceptable to the Bidders.

PART 3 - BID PREPARATION INSTRUCTIONS

3.1 Bid Preparation Instructions

Canada requests that Bidders provide their bid in separately bound sections as follows:

Section I: Technical Bid - Two (2) hard copies

Section II: Financial Bid - One (1) hard copy

Section III: Certifications - Two (2) hard copies

Prices must appear in the financial bid only. No prices must be indicated in any other section of the bid.

Canada requests that Bidders follow the format instructions described below in the preparation of their bid:

- (a) use 8.5 x 11 inch (216 mm x 279 mm) paper;
- (b) use a numbering system that corresponds to the bid solicitation.

In April 2006, Canada issued a policy directing federal departments and agencies to take the necessary steps to incorporate environmental considerations into the procurement process [Policy on Green Procurement](http://www.tpsgc-pwgsc.gc.ca/ecologisation-greening/achats-procurement/politique-policy-eng.html) (<http://www.tpsgc-pwgsc.gc.ca/ecologisation-greening/achats-procurement/politique-policy-eng.html>). To assist Canada in reaching its objectives, Bidders should:

- 1) use 8.5 x 11 inch (216 mm x 279 mm) paper containing fibre certified as originating from a sustainably-managed forest and containing minimum 30% recycled content; and

- 2) use an environmentally-preferable format including black and white printing instead of colour printing, printing double sided/duplex, using staples or clips instead of cerlox, duotangs or binders.

Section I: Technical Bid

In their technical bid, Bidders should explain and demonstrate how they propose to meet the requirements and how they will carry out the Work.

Section II: Financial Bid

Bidders must submit their financial bid in accordance with the Basis of Payment.

3.1.1 Electronic Payment of Invoices – Bid

If you are willing to accept payment of invoices by Electronic Payment Instruments, complete Annex “C” Electronic Payment Instruments, to identify which ones are accepted.

If Annex “C” Electronic Payment Instruments is not completed, it will be considered as if Electronic Payment Instruments are not being accepted for payment of invoices.

Acceptance of Electronic Payment Instruments will not be considered as an evaluation criterion.

3.1.2 Exchange Rate Fluctuation

[C3011T](#) (2013-11-06), Exchange Rate Fluctuation

Section III: Certifications

Bidders must submit the certifications and additional information required under Part 5.

PART 4 - EVALUATION PROCEDURES AND BASIS OF SELECTION

4.1 Evaluation Procedures

- (a) Bids will be assessed in accordance with the entire requirement of the bid solicitation including the technical and financial evaluation criteria.
- (b) An evaluation team composed of representatives of Canada will evaluate the bids.

4.1.1 Technical Evaluation

4.1.1.1 Mandatory Technical Criteria

See Annex “D” Evaluation Criteria

4.1.2 Financial Evaluation

The bidder must submit firm unit or firm lot prices excluding GST/HST in accordance with the Basis of Payment at Annex “B”.

The price of the bid will be evaluated in Canadian dollars, Applicable Taxes excluded, FOB Destination, Canadian customs duties and excise taxes included.

The evaluated price will be calculated using the Bidder's proposed Firm lot price multiplied by the quantity as provided in Annex "B".

SACC Manual Clause [A0220T](#) (2014-06-26), Evaluation of Price - Bid

4.2 Basis of Selection

A bid must comply with all requirements of the bid solicitation to be declared responsive. The responsive bid with the lowest evaluated price will be recommended for award of a contract.

PART 5 – CERTIFICATIONS AND ADDITIONAL INFORMATION

Bidders must provide the required certifications and additional information to be awarded a contract.

The certifications provided by Bidders to Canada are subject to verification by Canada at all times. Unless specified otherwise, Canada will declare a bid non-responsive, or will declare a contractor in default if any certification made by the Bidder is found to be untrue whether made knowingly or unknowingly, during the bid evaluation period or during the contract period.

The Contracting Authority will have the right to ask for additional information to verify the Bidder's certifications. Failure to comply and to cooperate with any request or requirement imposed by the Contracting Authority will render the bid non-responsive or constitute a default under the Contract.

5.1 Certifications Required with the Bid

Bidders must submit the following duly completed certifications as part of their bid.

5.1.1 Integrity Provisions - Declaration of Convicted Offences

In accordance with the Integrity Provisions of the Standard Instructions, all bidders must provide with their bid, **if applicable**, the declaration form available on the [Forms for the Integrity Regime](http://www.tpsgc-pwgsc.gc.ca/ci-if/declaration-eng.html) website (<http://www.tpsgc-pwgsc.gc.ca/ci-if/declaration-eng.html>), to be given further consideration in the procurement process.

5.2 Certifications Precedent to Contract Award and Additional Information

The certifications and additional information listed below should be submitted with the bid, but may be submitted afterwards. If any of these required certifications or additional information is not completed and submitted as requested, the Contracting Authority will inform the Bidder of a time frame within which to provide the information. Failure to provide the certifications or the additional information listed below within the time frame provided will render the bid non-responsive.

5.2.1 Integrity Provisions – Required Documentation

In accordance with the section titled Information to be provided when bidding, contracting or entering into a real procurement agreement of the [Ineligibility and Suspension Policy](http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html) (<http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html>), the Bidder must provide the required documentation, as applicable, to be given further consideration in the procurement process.

5.2.2 Federal Contractors Program for Employment Equity - Bid Certification

By submitting a bid, the Bidder certifies that the Bidder, and any of the Bidder's members if the Bidder is a Joint Venture, is not named on the Federal Contractors Program (FCP) for employment equity "FCP Limited Eligibility to Bid" list available at the bottom of the page of the [Employment and Social Development Canada \(ESDC\) - Labour's](https://www.canada.ca/en/employment-social-development/programs/employment-equity/federal-contractor-program.html#) website (<https://www.canada.ca/en/employment-social-development/programs/employment-equity/federal-contractor-program.html#>).

Canada will have the right to declare a bid non-responsive if the Bidder, or any member of the Bidder if the Bidder is a Joint Venture, appears on the "FCP Limited Eligibility to Bid" list at the time of contract award.

5.3 OEM Certification

Any Bidder that is not the Original Equipment Manufacturer (OEM) for every item of hardware proposed as part of its bid is required to submit Annex "E" OEM's certification regarding the Bidder's authority to provide and maintain the OEM's hardware, which must be signed by the OEM (not the Bidder). No Contract will be awarded to a Bidder who is not the OEM of the hardware it proposes to supply to Canada, unless the OEM certification has been provided to Canada. Bidders are requested to use the OEM Certification Form included with the bid solicitation. Although all the contents of the OEM Certification Form are required, using the form itself to provide this information is not mandatory. For Bidders/OEMs who use an alternate form, it is in Canada's sole discretion to determine whether all the required information has been provided. Alterations to the statements in the form may result in the bid being declared non-responsive.

If the hardware proposed by the Bidder originates with multiple OEMs, a separate OEM certification is required from each OEM.

For the purposes of this bid solicitation, OEM means the manufacturer of the hardware, as evidenced by the name appearing on the hardware and on all accompanying documentation.

5.4 Software Publisher Certification and Software Publisher Authorization

If the Bidder is the Software Publisher for any of the proprietary software products it bids, Canada requires that the Bidder confirm in writing that it is the Software Publisher. Bidders are requested to use Annex "E" Software Publisher Certification Form included with the bid solicitation. Although all the contents of the Software Publisher Certification Form are required, using the form itself to provide this information is not mandatory. For bidders who use an alternate form, it is in Canada's sole discretion to determine whether all the required information has been provided. Alterations to the statements in the form may result in the bid being declared non-responsive.

Any Bidder that is not the Software Publisher of all the proprietary software products proposed in its bid is required to submit proof of the Software Publisher's authorization, which must be signed by the Software Publisher (not the Bidder). No Contract will be awarded to a Bidder who is not the Software Publisher of all of the proprietary software it proposes to supply to Canada, unless proof of this authorization has been provided to Canada. If the proprietary software proposed by the Bidder originates with multiple Software Publishers, authorization is required from each Software Publisher. Bidders are requested to use the Software Publisher Authorization Form included with the bid solicitation. Although all the contents of the Software Publisher Authorization Form are required, using the form itself to provide this information is not mandatory. For Bidders/Software Publishers who use an alternate form, it is in Canada's sole discretion to determine whether all the required information has been provided. Alterations to the statements in the form may result in the bid being declared non-responsive.

In this bid solicitation, "Software Publisher" means the owner of the copyright in any software products proposed in the bid, who has the right to license (and authorize others to license/sub-license) its software products.

PART 6 - RESULTING CONTRACT CLAUSES

The following clauses and conditions apply to and form part of any contract resulting from the bid solicitation.

6.1 Security Requirements

There is no security requirement applicable to the Contract.

6.2 Requirement

The Contractor must provide the goods in accordance with the Requirement at Annex "A".

6.3 Standard Clauses and Conditions

All clauses and conditions identified in the Contract by number, date and title are set out in the [Standard Acquisition Clauses and Conditions Manual](https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) (https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) issued by Public Works and Government Services Canada.

6.3.1 General Conditions

[2010A](#) (2016-04-04), General Conditions - Goods (Medium Complexity), apply to and form part of the Contract.

6.3.2 Supplemental General Conditions

[4001](#) (2015-04-01), Hardware Purchase, Lease and Maintenance
[4003](#) (2010-08-16), Software Development or Modification Services
[4004](#) (2015-04-01), Hardware Purchase, Lease and Maintenance

6.4 Term of Contract

6.4.1 Period of the Contract

The period of the Contract is from date of Contract Award to March 28, 2019.

6.4.2 Delivery Date – Firm Requirement

All the deliverables for the firm requirement must be received on or before March 29, 2018.

6.4.3 Delivery Date – Optional Requirement

All the deliverables for the optional requirements, if invoked, must be received on or before March 28, 2019.

6.4.3 Delivery Points

Delivery of the requirement will be made to delivery point(s) specified at Annex "A" of the Contract.

6.5 Authorities

6.5.1 Contracting Authority

The Contracting Authority for the Contract is:

Name: Monique Holvec
Title: Supply Specialist
Public Works and Government Services Canada
Directorate: Acquisitions Branch / Mississauga
Address: 33 City Centre Drive, Suite 480C
Mississauga, Ontario, Canada
L5B 2N5
Telephone: 905-615-2062
Facsimile: 905-615-2060
E-mail address: monique.holvec@pwgsc-tpsgc.gc.ca

The Contracting Authority is responsible for the management of the Contract and any changes to the Contract must be authorized in writing by the Contracting Authority. The Contractor must not perform work in excess of or outside the scope of the Contract based on verbal or written requests or instructions from anybody other than the Contracting Authority.

6.5.2 Project Authority

The Project Authority for the Contract is (To be completed at time of Contract Award):

Name: _____
Title: _____
Organization: _____
Address: _____
Telephone: _____
Facsimile: _____
E-mail address: _____

The Project Authority is the representative of the department or agency for whom the Work is being carried out under the Contract and is responsible for all matters concerning the technical content of the Work under the Contract. Technical matters may be discussed with the Project Authority, however the Project Authority has no authority to authorize changes to the scope of the Work. Changes to the scope of the Work can only be made through a contract amendment issued by the Contracting Authority.

6.5.3 Contractor's Representative

Name: _____
Title: _____
Organization: _____
Address: _____
Telephone: _____
Facsimile: _____
E-mail address: _____

6.6 Payment

6.6.1 Basis of Payment - Firm Price, Firm Unit Price(s) or Firm Lot Price(s)

In consideration of the Contractor satisfactorily completing all of its obligations under the Contract, the Contractor will be paid a firm lot price(s), as specified in Annex B – Basis of Payment for a cost of \$ _____ insert the **amount at contract award**). Customs duties are included and Applicable Taxes are extra.

Canada will not pay the Contractor for any design changes, modifications or interpretations of the Work, unless they have been approved, in writing, by the Contracting Authority before their incorporation into the Work.

6.6.2 Limitation of Price

SACC Manual clause [C6000C](#) (2017-08-17) Limitation of Price

6.6.3 Multiple Payment

SACC Manual clause [H1001C](#) (2008-05-12) Multiple Payment

6.6.4 Inspection and Acceptance

The Project Authority is the Inspection Authority. All reports, deliverable items, documents, goods and all services rendered under the Contract are subject to inspection by the Inspection Authority or representative. Should any report, document, good or service not be in accordance with the requirements of Annexes A and B and to the satisfaction of the Inspection Authority, as submitted, the Inspection Authority will have the right to reject it or require its correction at the sole expense of the Contractor before recommending payment.

6.6.5 Electronic Payment of Invoices – Contract

The Contractor accepts to be paid using any of the following Electronic Payment Instrument(s):

- a. Visa Acquisition Card;
- b. MasterCard Acquisition Card;
- c. Direct Deposit (Domestic and International);
- d. Electronic Data Interchange (EDI);
- e. Wire Transfer (International Only);
- f. Large Value Transfer System (LVTS) (Over \$25M)

6.7 Invoicing Instructions

1. The Contractor must submit invoices in accordance with the section entitled "Invoice Submission" of the general conditions. Invoices cannot be submitted until all work identified in the invoice is completed.
2. Invoices must be distributed as follows:
 - a. The original and one (1) copy must be forwarded to the address shown on page 1 of the Contract for certification and payment.
 - b. One (1) copy must be forwarded to the Contracting Authority identified under the section entitled "Authorities" of the Contract.

6.8 Certifications and Additional Information

6.8.1 Compliance

Unless specified otherwise, the continuous compliance with the certifications provided by the Contractor in its bid or precedent to contract award, and the ongoing cooperation in providing additional information are conditions of the Contract and failure to comply will constitute the Contractor in default. Certifications are subject to verification by Canada during the entire period of the Contract.

6.9 Applicable Laws

The Contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario, Canada.

6.10 Priority of Documents

If there is a discrepancy between the wording of any documents that appear on the list, the wording of the document that first appears on the list has priority over the wording of any document that subsequently appears on the list.

- (a) the Articles of Agreement;
- (b) the supplemental general conditions:
 - 4001 (2015-04-01), Hardware Purchase, Lease and Maintenance
 - 4003 (2010-08-16), Software Development or Modification Services
 - 4004 (2015-04-01), Hardware Purchase, Lease and Maintenance
- (c) the general conditions 2010A (2016-04-04) General Conditions - Goods (Medium Complexity);
- (d) Annex A, Requirement;
- (e) Annex B, Basis of Payment;
- (f) Annex C, Electronic Payment Instruments;
- (g) Annex E, Certifications;
- (h) the Contractor's bid dated _____

6.11 SACC Manual Clauses

SACC Manual clause [B7500C](#) (2006-06-16) Excess Goods
SACC Manual clause [B1501C](#) Electrical Equipment (2006-06-16)

6.12 Insurance Requirements

SACC Manual clause [G1005C](#) (2016-01-28) Insurance, No Specific Requirement

ANNEX "A"

REQUIREMENT

1. SCOPE

1.1. Introduction

The Ontario Health Products Laboratory has a requirement for the supply, delivery, installation and qualification of one (1) Dissolution System and Autosampler with an option to purchase one (1) additional Dissolution System and Autosampler within the next year. The equipment will be used by the Ontario Health Products Laboratory for analysis of the dissolution characteristics of health product samples.

1.2. Objective

The objective is for the Dissolution System and Autosampler to be purchased, delivered, installed, and qualified in the Ontario Health Products Laboratory. The instrument will then be operated by the Ontario Health Products Laboratory for the purpose of analyzing samples of health products in order to determine their dissolution characteristics.

1.3. Background

The Mission of the Ontario Health Products Laboratory is to provide its clients with reliable analytical results, along with scientific advice on those analyses, in order to support inspections, compliance verifications, border integrity activities, and investigations related to human drugs, natural health products, veterinary drugs, and medical devices. With this aim in mind, the laboratory performs routine analysis of various compounds in pharmaceutical products, natural health products, fraudulent samples, counterfeit health products, etc. The laboratory also develops new analytical procedures for special requests and other projects.

The dissolution characteristics of a health product in solid finished dosage form (e.g. tablets, capsules) are important quality parameters that determine when and how the product releases its active ingredients into the patient's system. The dissolution characteristics are subject to rigorous requirements which are stated in the approved finished product specifications, various international pharmacopeia listed in Schedule B of the Food and Drugs Act, and other regulatory authorities. The Ontario Health Products Laboratory has a mandate to measure the dissolution characteristics of health products, both as a reactive compliance verification activity in response to health product incidents and as a proactive activity as part of the Drug Quality Surveillance Program. The Ontario Health Products Laboratory has conducted dissolution testing of health products for the past several decades.

The Ontario Health Products Laboratory currently has two (2) Dissolution Apparatuses which were commissioned in 1995 and 1996. These systems are no longer supported by the manufacturer, and it is difficult to secure replacement parts for repairs. The existing equipment also falls short of current standards for dissolution systems, and no longer meets the minimum requirements for one of the laboratory's key projects (Collaborative Research Agreement with the United States Pharmacopeia).

The Ontario Health Products Laboratory requires one (1) new Dissolution Apparatus and Autosampler in order to continue to fulfil its mandate for dissolution testing of health products with an option to purchase one (1) additional Dissolution System and Autosampler within the next year.

1.4. Relevant Terms, Acronyms and Glossaries

Distek 2500 RTD – Distek Model 2500 RTD Dissolution System
Distek 5300 – Distek Eclipse 5300 Dissolution Autosampler
IQ/OQ – Installation Qualification and Operational Qualification
USP – United States Pharmacopeia

2. GENERAL REQUIREMENTS

2.1. Documentation

The Contractor must provide at the time of delivery, hard copy or electronic format, in English, after-sales services, the Maintenance and Operator Manuals containing the latest technical information related to the Dissolution System and Autosampler as follows:

- Maintenance Manual: must provide routine inspection and preventative maintenance for the Dissolution System and Autosampler.
- Operator Manual: must provide all necessary instructions for the safe operation of the equipment, including a detailed description of all available features and how to use them.
- After-sales services: must include specific warranty coverage details and contact information for service.

Note: A French version of the above documentation is desirable, but not mandatory.

2.2. Reporting Requirements

Upon conclusion of installation and IQ/OQ, the Contractor must provide a report detailing the qualification results. The qualification report must address all apparatus suitability and performance verification requirements stated in General Chapters <711> Dissolution and <724> Drug Release of the edition of the United States Pharmacopeia in effect at the time of installation.

2.3. On-Site End-User Training

The Contractor must provide familiarization training sufficient to allow a user who is already proficient in dissolution testing to operate the equipment. Training must be provided on-site either during or after the delivery and installation of the goods for primary equipment operators. Training to include start-up, safe operation, shut down procedures, daily/routine maintenance procedures and features to a maximum of three (3) personnel. Training must occur on the day of the installation or the following work day or any other time suitable to both parties.

2.4. Delivery and Installation

All deliverables must occur at the following address:

Ontario Health Products Laboratory
Regulatory Operations and Regions Branch, Health Canada
2301 Midland Avenue
Toronto, Ontario M1P 4R7

The Contractor must install the instrument and perform full Installation Qualification and Operational Qualification (IQ/OQ).

The Contractor must provide technical assistance services by trained technical personnel for a period of one (1) year from the date of installation and acceptance with support to be delivered on-site if necessary and at the expense of the Contractor.

2.5. Minimum Mandatory Technical Specifications

The Contractor must supply the following specific brand, make or model and/or part number for Dissolution System and Autosampler:

Make: _____ (to be determined at contract award)

Model: _____ (to be determined at contract award).

The system must be in accordance with each of the following specifications below under 2.5.1., 2.5.2. and 2.5.3.

The specifications are based on the Distek Model 2500 RTD Dissolution System (Distek 2500 RTD), or equivalent and the Distek Eclipse 5300 Dissolution Autosampler (Distek 5300) or equivalent.

2.5.1. Dissolution System

1. Must configure to perform testing as per each of the following requirements:
 - (a) United States Pharmacopeia (USP) Dissolution Apparatus 1 (Basket Apparatus)
 - (b) USP Dissolution Apparatus 2 (Paddle Apparatus)
 - (c) USP Drug Release Apparatus 5 (Paddle over Disk)
 - (d) USP Drug Release Apparatus 6 (Cylinder)
 - (e) Intrinsic dissolution.
2. Must have touch screen display.
3. Must have wireless temperature sensors.
4. Must have the functionality of continuously monitoring, displaying, and recording the in-vessel temperature of each vessel.
5. Must accommodate at least seven (7) vessels (volume: 500 mL and 1L).
6. Must have a self-priming circulator/heater.
7. Must have interchangeable stirring elements and automatic height adjustment to allow for transition between USP Dissolution Apparatus 1 and 2 configurations without removing the shaft.
8. Must have the functionality of user-programmable thermocirculator start-up and shutdown times.
9. Must have the functionality of different program modes supporting manual operation, automatic operation using pre-programmed methods, and Autosampler operation.
10. Must fully integrate operation with the specific Dissolution Autosampler quoted, with one system acting as the controller.
11. Must store at least 100 user-programmed methods.
12. Must meet the following performance requirements:
 - (a) RPM Control Range: 25 – 300 RPM or wider
 - (b) RPM Resolution: 0.1 RPM or less
 - (c) RPM Accuracy:
Maximum ± 1 RPM for speeds up to 100 RPM

Maximum $\pm 1\%$ for speeds greater than 100 RPM

- (d) Vessel Temperature Control: Ambient temperature to 55°C or greater
- (e) Temperature Resolution: 0.01°C or less
- (f) Temperature Accuracy: $\pm 0.3^\circ\text{C}$ or less
- (g) Shaft Wobble: Less than 0.010" / 0.254 mm (Total Indicator Runout).

2.5.2. Dissolution Autosampler

1. Must fully integrate operation with the specific Dissolution System quoted, with one system acting as the controller.
2. Must have touch screen display.
3. Must return unused media and replace the collected sample volume.
4. Must store at least 100 methods.
5. Must record an audit trail to track and report changes to methods.
6. Must have user-configurable settings for collection of at least 12 time points.
7. Must collect sample volumes ranging from 0.5 mL to 12 mL or wider.
8. Must collect samples with volumetric precision of ± 0.15 mL or less.
9. Must have flow rates ranging from 8 to 50 mL / min or wider.
10. Must have a capacity of 96 samples or more.
11. Must accept 2 ml vials for sample collection.
12. Must accept 12 mL glass test tubes for sample collection.

2.5.3. Power supply

The Dissolution Apparatus and Autosampler must operate with 115V electrical supply.

3. ADDITIONAL INFORMATION

3.1. Canada's Obligations

The Contractor will have accompanied access to the following laboratory for the installation, operation, and qualification of the equipment:

Ontario Health Products Laboratory
Regulatory Operations and Regions Branch, Health Canada
2301 Midland Avenue
Toronto, ON M1P 4R7

All Contractors will be accompanied at all times by a member of the laboratory staff during their work at 2301 Midland Avenue, Toronto (ON).

3.2. Contractor's Obligations

Solicitation No. - N° de l'invitation
H4004-173786/A
Client Ref. No. - N° de réf. du client
H4004-173786

Amd. No. - N° de la modif.
File No. - N° du dossier
TOR-7-40134

Buyer ID - Id de l'acheteur
tor009
CCC No./N° CCC - FMS No./N° VME

The Contractor must label all equipment/furnishings as being the property of Canada.

4. Delivery and On-Site Acceptance at the Project Authority Site

The overall system must be delivered to the location specified in Section 2.4 where it will undergo a full acceptance test carried out by the contractor under the supervision of the Project Authority or designated representative. Acceptance of the systems will only occur once all specifications have been met.

ANNEX "B"

BASIS OF PAYMENT

All inclusive, firm lot prices in Canadian funds, delivery and transportation included, FOB destination, Canadian Customs duties and excise taxes included. GST/HST extra if applicable.

1.0 FIRM REQUIREMENT

Item No.	Description	Qty.	Unit of Issue	Firm Unit Price	Extended Price
1.0	Dissolution System and Autosampler Manufacturer: _____ Model: _____	1	EA	\$	\$
2.0	Installation and Training on site at Health Canada (Midland, Ontario) for up to 3 persons in the use and maintenance of the Dissolution System for a minimum of 1 day. The Contractor is responsible for providing labour and covering their own travel expenses.	1 day Midland (Ontario)	1 Lot	\$_____ 1 day	\$
Total:					
\$ _____ (applicable taxes extra)					

Solicitation No. - N° de l'invitation
H4004-173786/A
Client Ref. No. - N° de réf. du client
H4004-173786

Amd. No. - N° de la modif.
File No. - N° du dossier
TOR-7-40134

Buyer ID - Id de l'acheteur
tor009
CCC No./N° CCC - FMS No./N° VME

2.0 OPTIONAL GOODS AND SERVICES – Date of Contract Award to March 28, 2019

Canada may purchase any or all of the optional good and services at any time during the period of the contract.

Item No.	Description	Qty.	Unit of Issue	Firm Unit Price	Extended Price
1.0	Dissolution System and Autosampler Manufacturer: _____ Model: _____	1	EA	\$	\$
Total: \$ _____ (applicable taxes extra)					

Solicitation No. - N° de l'invitation
H4004-173786/A
Client Ref. No. - N° de réf. du client
H4004-173786

Amd. No. - N° de la modif.
File No. - N° du dossier
TOR-7-40134

Buyer ID - Id de l'acheteur
tor009
CCC No./N° CCC - FMS No./N° VME

ANNEX "C"

ELECTRONIC PAYMENT INSTRUMENTS

The Bidder accepts any of the following Electronic Payment Instrument(s):

- VISA Acquisition Card;
- MasterCard Acquisition Card;
- Direct Deposit (Domestic and International);
- Electronic Data Interchange (EDI);
- Wire Transfer (International Only);
- Large Value Transfer System (LVTS) (Over \$25M)

ANNEX "D"

EVALUATION CRITERIA

1. Bidders must clearly demonstrate compliance with each mandatory technical criteria. Failure to demonstrate compliance will result in the offer being deemed non-responsive, and be given no further consideration.
2. It is the Bidders responsibility to ensure that the submitted supporting technical documentation provides detail to prove that the proposed product(s) meet the requirements detailed herein. If published supporting technical documents are not available, the Bidders must prepare a written narrative complete with a detailed explanation of how its offer demonstrates technical compliance.
3. Bidders must address any concerns with the performance specifications in written detail to the Contracting Authority before bid closing as outlined in the Request for Proposal (RFP) document.

Requirement	Manufacturer Offered	Model number offered#
Dissolution System		

Item #	Performance Specification	Cross Reference: In this column, Bidders should cross-reference where this performance specification is indicated in their supporting documents.
1.1	Dissolution system must configure to perform testing as per each of the following requirements: (a) United States Pharmacopeia (USP) Dissolution Apparatus 1 (Basket Apparatus) (b) USP Dissolution Apparatus 2 (Paddle Apparatus)	
1.2	Dissolution system must have touch screen display.	
1.3	Dissolution system must have wireless temperature sensors.	
1.4	Dissolution system must have the functionality of continuously monitoring, displaying, and recording the in-vessel temperature of each vessel.	
1.5	Dissolution system must accommodate at least seven (7) vessels.	
1.6	Dissolution system must have a self-priming circulator/heater.	

1.7	Dissolution system must have interchangeable stirring elements and automatic height adjustment to allow for transition between USP Dissolution Apparatus 1 and 2 configurations without removing the shaft.	
1.8	Dissolution system must have the functionality of user-programmable thermocirculator start-up and shutdown times.	
1.9	Dissolution system must store at least 100 user-programmed methods.	
1.10	Dissolution system must meet the following performance requirements: (a) RPM Control Range: 25 – 300 RPM or wider (b) RPM Resolution: 0.1 RPM or less (c) RPM Accuracy: Maximum ± 1 RPM for speeds up to 100 RPM Maximum $\pm 1\%$ for speeds greater than 100 RPM (d) Vessel Temperature Control: Ambient temperature to 55°C or greater (e) Temperature Resolution: 0.01°C or less (f) Temperature Accuracy: $\pm 0.3^\circ\text{C}$ or less (g) Shaft Wobble: Less than 0.010" / 0.254 mm (Total Indicator Runout).	
1.11	Dissolution system and dissolution autosampler must have the functionality of fully integrated operation, with one system acting as the controller.	
1.12	Dissolution system and dissolution autosampler must operate with 115V electrical supply.	
1.13	Dissolution autosampler must have touch screen display.	
1.14	Dissolution autosampler must return unused media and replace the collected sample volume.	
1.15	Dissolution autosampler must store at least 100 methods.	
1.16	Dissolution autosampler must record an audit trail to track and report changes to methods.	
1.17	Dissolution autosampler must have user-configurable settings for collection of at least 12 time points.	
1.18	Dissolution autosampler must collect sample volumes ranging from 0.5 mL to 12 mL or wider.	
1.19	Dissolution autosampler must collect samples with volumetric precision of ± 0.15 mL or less	
1.20	Dissolution autosampler must have flow rates ranging from 8 to 50 mL / min or wider.	
1.21	Dissolution autosampler must have a capacity of 96 samples or more.	
1.22	Dissolution autosampler must accept 2 ml vials for sample collection.	
1.23	Dissolution autosampler must accept 12 mL test tubes for sample collection.	

Solicitation No. - N° de l'invitation
H4004-173786/A
Client Ref. No. - N° de réf. du client
H4004-173786

Amd. No. - N° de la modif.
File No. - N° du dossier
TOR-7-40134

Buyer ID - Id de l'acheteur
tor009
CCC No./N° CCC - FMS No./N° VME

ANNEX "E"

CERTIFICATION FORMS

Form 1
OEM Certification Form

This confirms that the original equipment manufacturer (OEM) identified below has authorized the Bidder named below to provide and maintain its products under any contract resulting from the bid solicitation identified below.

Name of OEM _____

Signature of authorized signatory of OEM _____

Print Name of authorized signatory of OEM _____

Print Title of authorized signatory of OEM _____

Address for authorized signatory of OEM _____

Telephone no. for authorized signatory of OEM _____

Fax no. for authorized signatory of OEM _____

Date signed _____

Solicitation Number _____

Name of Bidder _____

Solicitation No. - N° de l'invitation
H4004-173786/A
Client Ref. No. - N° de réf. du client
H4004-173786

Amd. No. - N° de la modif.
File No. - N° du dossier
TOR-7-40134

Buyer ID - Id de l'acheteur
tor009
CCC No./N° CCC - FMS No./N° VME

Form 2
Software Publisher Certification Form
(to be used where the Bidder itself is the Software Publisher)

The Bidder certifies that it is the software publisher of all the following software products and components and that it has all the rights necessary to license them (and any non-proprietary sub-components incorporated into the software) on a royalty-free basis to Canada:

[bidders should add or remove lines as needed]

Form 3
Software Publisher Authorization Form
(to be used where the Bidder is not the Software Publisher)

This confirms that the software publisher identified below has authorized the Bidder named below to license its proprietary software products under any contract resulting from the bid solicitation identified below. The software publisher acknowledges that no shrink-wrap or click-wrap or other terms and conditions will apply, and that the contract resulting from the bid solicitation (as amended from time to time by its parties) will represent the entire agreement, including with respect to the license of the software products of the software publisher listed below. The software publisher further acknowledges that, if the method of delivery (such as download) requires a user to "click through" or otherwise acknowledge the application of terms and conditions not included in the bid solicitation, those terms and conditions do not apply to Canada's use of the software products of the software publisher listed below, despite the user clicking "I accept" or signalling in any other way agreement with the additional terms and conditions.

This authorization applies to the following software products:

[bidders should add or remove lines as needed]

Name of Software Publisher (SP) _____

Signature of authorized signatory of SP _____

Print Name of authorized signatory of SP _____

Print Title of authorized signatory of SP _____

Address for authorized signatory of SP _____

Telephone no. for authorized signatory of SP _____

Fax no. for authorized signatory of SP _____

Date signed _____

Solicitation Number _____

Name of Bidder _____