QUALITY AGREEMENT

The following Agreement has been concluded between

LLC LABORATORIES
The **contract laboratory and service provider**
1625 Trinity Dr., Unit 11
Mississauga, Ontario
Canada L5T 1W9
Hereinafter referred to as **LLC Lab**

And

"INSERT COMPANY NAME"
The **Client**
"INSERT COMPANY ADDRESS"
Hereinafter referred to as **"INSERT COMPANY NAME"**

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1. INTRODUCTION

LLC Laboratories Inc. has its principle purpose of generating high quality data, utilizing analytical measurements that are accurate, reliable and meeting or exceeding client expectations. LLC Lab will operate in full compliance with current GMP requirements to meet its client's needs for quality analytical testing.

1.1 This Quality Agreement defines the expectations and responsibilities between LLC Lab as the contract laboratory and service provider and “INSERT COMPANY NAME” as service requestor.

1.2 Both LLC Lab and “INSERT COMPANY NAME” wish to ensure by this agreement that all services performed by LLC Lab are up to acceptable GMP standards set forth by the Health Canada Therapeutics Programme Directorate, through the current GMP Guidelines as defined under Division 1A, Part C of the Food and Drug Regulations; and by FDA, through 21 CFR Parts 210, 211 and 11.

1.3 On agreement to the expectations and responsibilities defined in this Agreement, this Agreement is considered as binding to all parties named in this Agreement and in effect at the time upon final signature approval, and thereafter, as may be amended in writing.

1.4 LLC Lab is currently approved by Health Canada (Establishment Licence No. 102202-A) to test drug, nutraceutical and device products. LLC Lab will maintain an Establishment License as per the Canadian Food and Drug regulations as a licensed testing laboratory. A current copy of Establishment Licence will be made available to “INSERT COMPANY NAME” upon written request. LLC Lab is responsible for informing “INSERT COMPANY NAME” without delay of any restriction to the regulatory licence for the products covered by the Agreement.

1.5 It is the responsibility of both LLC Lab and “INSERT COMPANY NAME” to maintain this Agreement in a current state and to ensure that this Agreement continues to cover the responsibilities and obligations of the parties as stated under Canadian GMP regulations. Any modifications to this agreement must be communicated and agreed to in writing prior to implementation.

1.6 Should , due to any change of the legal situation, the basis of this agreement be modified to such an extent that the part affected thereby cannot be reasonably expected to continue to perform under this Agreement, then the document will be modified accordingly and signed by both parties. The parties shall amicably try to find new rules.

1.7 “INSERT COMPANY NAME” shall ensure that LLC Lab is provided with the current testing procedures, columns (if unique or dedicated), and reference standards for all drug/device products to be tested by LLC Lab. In addition, “INSERT COMPANY NAME” shall be responsible for providing LLC Lab with the correct and current specifications and list of test methods for each lot of material to be tested.

2. BASIS FOR THE QUALITY AGREEMENT

2.1 This agreement addresses the technical and quality aspects relating to the product(s) which form(s) the basis of this agreement. It shall specify the respective responsibilities of LLC Lab and “INSERT COMPANY NAME” as generated by an appropriate and

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technically competent person(s) suitably knowledgeable in pharmaceutical technology, analysis and GMP.

2.2 LLC Lab is responsible for the testing of the product (s) and “INSERT COMPANY NAME” is responsible for release of the product (s).

2.3 LLC Lab (in the testing of all materials) and “INSERT COMPANY NAME” (in the release of all materials) must comply with the current regulatory requirements of Division 2, Part C of the Canadian Food and Drug Regulations (HPFB Inspectorate Good Manufacturing Practices Guidelines).

2.4 If “INSERT COMPANY NAME” wishes special provisions or guidelines to be followed that are not yet generally known or recognized, LLC Lab must be informed of that fact and agreement obtained in writing.

2.5 “INSERT COMPANY NAME” and LLC Lab are to designate responsible contacts to ensure responsible individuals are contacted for all technical matters. Attachment (I) is a listing of the persons named in the Company Contacts.

2.6 “INSERT COMPANY NAME” and LLC Lab agree to continually review the requirements of this Quality Agreement to ensure continued compliance with all such requirements.

2.7 Arrangements on prices and other commercial terms are reserved for a separate Commercial Agreement.

3. QUALITY SYSTEM

3.1 LLC Lab will ensure that all activities are in compliance with current Canadian regulatory requirements, current Good Manufacturing Practice regulations and “INSERT COMPANY NAME” quality specifications and requirements as outlined in this document.

3.2 LLC Lab shall have a written procedure for change control. Changes that may impact the testing of “INSERT COMPANY NAME” products will be done in consultation with “INSERT COMPANY NAME” prior to implementation of the change.

4. AUDITS and REGULATORY INSPECTION

4.1 LLC Lab shall maintain an internal audit or self-inspection program. A copy of the LLC Lab self-inspection schedule shall be provided to “INSERT COMPANY NAME” or the Regulatory Authorities upon request. If applicable to “INSERT COMPANY NAME” products, LLC Lab will notify immediately “INSERT COMPANY NAME” of any adverse finding.

4.2 LLC Lab permits “INSERT COMPANY NAME” GMP audits of all relevant premises, procedures, documentation annually.

4.3 LLC Lab shall permit Regulatory Authorities Inspections in relation to GMP certification and Establishment Licence renewal.

4.4 LLC LAB shall notify “INSERT COMPANY NAME” within twenty-four (24) hours of all regulatory agency inspections that are potentially connected to “INSERT COMPANY NAME” materials. Additionally, the respective inspection reports or observations that

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impact “INSERT COMPANY NAME” shall be provided to “INSERT COMPANY NAME” within three working days.

4.5 A copy of the audit report from Health Canada or the current Establishment License from Health Canada shall be provided to “INSERT COMPANY NAME” upon request to verify GMP compliance.

4.6 LLC Lab shall provide reasonable access to its premises, during normal working hours, at a time mutually agreed upon by “INSERT COMPANY NAME” and LLC Lab, to permit audits of the relevant documents and facilities by “INSERT COMPANY NAME” or the Regulatory Authorities.

4.7 LLC Lab will provide a copy of the most current local regulatory agency inspection reports along with the response to the report, if requested by “INSERT COMPANY NAME”. This information provides evidence of GMP compliance as required by Health Canada.

4.8 For each audit conducted by “INSERT COMPANY NAME”, LLC Lab agrees to provide, within 30 calendar days after receipt the audit report, a written response for each observation, provide corrective action, and the timeline for implementation of such corrective action, if applicable.

4.9 LLC Lab will be responsible for qualifying its supplier of services. The supplier qualification will be based on the latest Canadian GMP Guidelines and the frequency will be based on the CGMP's.

5. CHANGE CONTROL

5.1 LLC Lab will follow its internal procedures for Change Control documentation and maintain a log of any changes made to its policies, procedures and practices.

5.2 Changes to the test method, product specification, or other applicable written procedures must follow a documented Change Control system.

5.3 A copy of LLC Lab Change Control procedure will be provided to “INSERT COMPANY NAME” on LLC Lab’s site upon request.

5.4 “INSERT COMPANY NAME” agrees to notify LLC Lab of changes to test method, product specification, or other applicable written procedures if they are major or have an impact on a regulatory filing, prior to implementation.

5.5 LLC LAB agrees that any testing methods provided to LLC LAB by “INSERT COMPANY NAME” must be kept on file until “INSERT COMPANY NAME” provides LLC Lab with new versions of such methods. Once new documentation is received, LLC Lab agrees to archive or destroy the superseded documentation.

5.6 “INSERT COMPANY NAME” must authorize any changes to test method, product specification, or other applicable written procedures affecting “INSERT COMPANY NAME” products, prior to implementation.

6. DEVIATIONS, NON-CONFORMANCES OR INVESTIGATIONS OF OUT-OF SPECIFICATION RESULTS (OOS)

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6.1 When a test result falls outside the expected range, LLC Lab shall conduct an initial internal investigation and, upon confirmation of non-conformance, deviation, or OOS, LLC Lab shall notify "INSERT COMPANY NAME" within 24 hours.

6.2 "INSERT COMPANY NAME" is responsible to notify the appropriate authorities of a confirmed non-conformance by LLC Lab (i.e. FDA field alert report under 21 C.F.R. § 314.81(b) (1)).

6.3 A confirmed non-conformance result from a stability sample stored under accelerated conditions at 40°C/75%RH will trigger LLC Lab to remove a sample from the back-up condition (if present) and may result in "INSERT COMPANY NAME" requesting LLC Lab to initiate testing at a back-up accelerated storage condition (e.g. 30°C/65%RH) as per ICH Q1(R2). LLC Lab will only test sample from intermediate storage condition upon "INSERT COMPANY NAME" request.

6.4 Investigation of Out of Trend (OOT) results is "INSERT COMPANY NAME"'s responsibility unless otherwise specified in writing by "INSERT COMPANY NAME"

6.5 If the investigation findings results in laboratory error, LLC Lab will re-test the sample at no additional cost.

6.6 If there is an Out Of Specification result from a received batch and "INSERT COMPANY NAME" instructs LLC Lab to repeat the analysis using a different bottle of the same batch; passing the repeat testing does not lead to rejecting the initial result unless there is an assignable cause.

6.7 Unless otherwise instructed by "INSERT COMPANY NAME", LLC Lab shall be responsible for conducting and documenting any investigation into non-conformance, deviation, or OOS according to LLC Lab approved procedure (minimum requirement). Any investigation of non-conformance, deviation, or OOS shall not exceed 30 calendar days.

6.8 "INSERT COMPANY NAME" must review and approve any planned deviation that may have an impact on services for "INSERT COMPANY NAME", prior to implementation.

7. DOCUMENTATION

7.1 "INSERT COMPANY NAME" is responsible for providing LLC Lab with instructions on product testing, approved specifications, and method of analysis.

7.2 In circumstances where a "INSERT COMPANY NAME" test method is to be followed, the method will be provided in advance of the sample to allow LLC Lab adequate preparation time.

7.3 LLC Lab must review all documentation received and assure that it is thoroughly understood prior to implementation.

7.4 In the event that LLC Lab believes that the documentation is inadequate and/or in error, it is the responsibility of LLC Lab to communicate this to "INSERT COMPANY NAME".

7.5 If "INSERT COMPANY NAME" commissioned LLC Lab for validation and/or specific project, LLC Lab must ensure that the protocol of analysis is approved by "INSERT COMPANY NAME" prior to the execution of the protocol.

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7.6 No changes can be made to the documentation without prior written notification and approval of the other party.

7.7 All documentation supplied to LLC Lab by “INSERT COMPANY NAME” will be kept separate from documentation from other clients.

7.8 If methods, specifications or procedures are updated, it is the responsibility of “INSERT COMPANY NAME” to provide the most current copies of documentation to LLC Lab.

8. TRAINING

8.1 LLC Lab is responsible for assuring that all their personnel have an adequate combination of education, experience and training to perform the job functions.

8.2 Training shall be documented and GMP refresher training conducted annually at minimum.

9. SHIPPING, RECEIVING, STORAGE, AND DISPOSAL OF SAMPLES

9.1 “INSERT COMPANY NAME” is responsible for the sampling of all materials, and products sent to LLC Lab and will ensure that sufficient quantities are provided for the purpose of the testing.

9.2 During transportation “INSERT COMPANY NAME” shall ensure that all samples are properly packaged, labeled and protected from adverse environmental exposure.

9.3 “INSERT COMPANY NAME” will ensure that the sample is clearly labelled with the product name, lot number, testing required and any storage conditions.

9.4 All received samples must be accompanied by documentation clearly indicating the sample name, lot number, test method, testing required and contact information.

9.5 “INSERT COMPANY NAME” must inform LLC Lab of any potential risk to affect employee’s health and any hazardous material.

9.6 On receipt, integrity of the samples should be examined. LLC Lab must immediately advise “INSERT COMPANY NAME” for any physical damage and/or identification problem and/or missing documentation.

9.7 On receipt of samples, LLC Lab has the responsibility to keep the sample within required storage condition and to register sample immediately on receipt.

9.8 LLC Lab will maintain a system to assure proper identification and traceability of samples.

9.9 Any rejected/damaged drug/device product shall be segregated, clearly identified and returned to “INSERT COMPANY NAME” or destroyed if requested in writing by “INSERT COMPANY NAME”.

9.10 After analysis and final approval of data by LLC Lab, LLC Lab agrees to keep remaining samples for thirty (30) days within storage condition or longer if so directed by “INSERT COMPANY NAME”.

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9.11 LLC Lab is responsible for ensuring that all waste is disposed of in a manner consistent with local governmental and other applicable requirements and regulations.

9.12 LLC Lab will not receive samples on weekends and public holidays unless “INSERT COMPANY NAME” informs LLC Lab in advance.

10. TESTING AND DOCUMENTATION

10.1 “INSERT COMPANY NAME” is responsible for providing to LLC Lab instructions on product testing, approved specifications, and method of analysis.

10.2 If testing is to be carried out according to a pharmacopoeia such as; European Pharmacopoeia, the British Pharmacopoeia, the National Formulary, and/or the United States Pharmacopoeia, etc., only the most current edition will be used (including supplements), unless otherwise requested by “INSERT COMPANY NAME”.

10.3 If testing is to be performed using a “INSERT COMPANY NAME” test procedure, the test procedure shall be provided by “INSERT COMPANY NAME”.

10.4 LLC Lab agrees to conduct all “INSERT COMPANY NAME” analysis according to current Good Manufacturing Practices.

10.5 It is the client’s responsibility to initiate method transfer for noncompendial methods and method verification for compendial methods, as applicable. If “INSERT COMPANY NAME” commissioned LLC Lab for validation, technology transfer and/or specific project, LLC Lab must ensure that the protocol of analysis is approved by “INSERT COMPANY NAME” prior to execution.

10.6 Within 48 hours of sample receipt, LLC Lab is responsible to notify “INSERT COMPANY NAME” if the test execution will be delayed due to lack of required method of analysis, reagents, columns, equipment, and/or any other reason.

10.7 LLC Lab shall not sub-contract any analysis/test to another contract laboratory without “INSERT COMPANY Name’s” written agreement.

10.8 In the event that “INSERT COMPANY NAME” provide their own methods, “INSERT COMPANY NAME” is responsible to provide the most current copies to LLC LAB. “INSERT COMPANY NAME” is responsible to initiate any technological transfer of analytical methods. LLC Lab and “INSERT COMPANY NAME” must come to an agreement on who will be responsible for the writing of protocol and the transfer report before proceeding. “INSERT COMPANY NAME” must approve the protocol. LLC Lab is responsible for the execution of the technological transfer.

10.9 If the requested methods are not from official monographs, “INSERT COMPANY NAME” is responsible to provide to LLC Lab the respective methods (with validation of suitability of use demonstrated previously and on file at “INSERT COMPANY NAME”).

10.10 Any planned deviation from these procedures must be communicated to “INSERT COMPANY NAME” prior to execution of the method.

10.11 LLC Lab will perform “INSERT COMPANY NAME” tests with validated and calibrated equipment according to current Canadian Good Manufacturing Practices (GMP).

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10.12 If “INSERT COMPANY NAME” provides a standard, “INSERT COMPANY NAME” is responsible for the purity and expiry date of such items. LLC Lab will not test or otherwise qualify such standards unless expressed in written request of “INSERT COMPANY NAME”.

10.13 In the event that any standard, reagent, analytical column or other material required for analysis of “INSERT COMPANY NAME”’s samples is not routinely used by LLC Lab, “INSERT COMPANY NAME” is required to provide such item/s to LLC Lab or, alternatively, LLC Lab will purchase the item and invoice “INSERT COMPANY NAME” for its cost plus additional administrative fees. In this event, the item so purchased will be used only for testing “INSERT COMPANY NAME”’s sample and not for any other purpose.

10.14 LLC Lab shall ensure that they have the correct testing procedures and the latest revision on file, prior to initiating any testing on the drug or device product/s.

10.15 LLC Lab shall ensure that they use the correct reference standard to perform the testing and that the reference standard is not expired prior to use in any testing process.

10.16 LLC Lab shall give “INSERT COMPANY NAME” one month prior notice of the expiry reference standards in order for “INSERT COMPANY NAME” to ensure reordering of standards in a timely manner.

10.17 LLC Lab will complete testing and provide results to “INSERT COMPANY NAME” within 10 working days of receipt of the sample.

10.18 If LLC Lab cannot complete the testing in 10 working days, they will inform “INSERT COMPANY NAME” immediately stating the reason for the delay and the expected date of completion

NOTE: Exceptions to the 10 day turn around include method development and validation, technology transfer, stability studies, and out of specification investigations.

10.19 LLC Lab is responsible to review raw data generated and test results, and to issue a Certificate of Analysis (COA) approved by qualified personnel as stated in Canadian GMP.

10.20 LLC Lab will be responsible for faxing and/or e-mailing a completed Certificate of Analysis to “INSERT COMPANY NAME”. LLC Lab will ensure that the following documentation is provided to “INSERT COMPANY NAME” in a timely manner:

- The original copy of the Certificate of Analysis.
- Copies of all laboratory data recorded during testing.
- Copies of all records generated during testing (including chromatograms)
- Laboratory OOS investigation reports / non-conformance reports (if applicable).
- Any documentation and samples requested for return to “INSERT COMPANY NAME” (if applicable).

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- Narcotic documentation and sample not consumed by testing (if applicable).

NOTE: Unless otherwise requested by “INSERT COMPANY NAME”, all original raw data and results shall be stored at LLC Lab archive for a period of seven (7) years.

10.21 If any discrepancies are identified upon receipt of the paper work, “INSERT COMPANY NAME” will immediately inform LLC Lab and further action will be discussed and/or initiated.

10.22 LLC Lab will ensure that these records are available to “INSERT COMPANY NAME” upon request.

10.23 Stability samples maintained and tested at LLC LAB will be analyzed for “time zero” upon “INSERT COMPANY NAME”’s request or the results of time zero will be provided by “INSERT COMPANY NAME”.

11. CONFIDENTIALITY

11.1 Except if required by law including regulatory authorities, information contained in specifications, procedures, test methods, testing data, COA, etc., relating to “INSERT COMPANY NAME”’s test products is confidential (see signed Confidentiality Agreement with “INSERT COMPANY NAME”) and LLC Lab shall, under no circumstances, disclose this information to any other party without the written approval of “INSERT COMPANY NAME” or use the information in any manner other than for the purpose of this Agreement.

11.2 No unspecified testing or evaluation of any type of “INSERT COMPANY NAME” products is to be conducted without prior written consent of “INSERT COMPANY NAME”.

11.3 LLC Lab may be requested to sign a confidentiality agreement.

12. APPROVAL OF THE QUALITY AGREEMENT

We agree with the foregoing terms and conditions and, in testimony whereof, we have signed

LLC Laboratories	**“INSERT COMPANY NAME”**
Date:	Date:
_____	_____
Director of Operations	Name Title
Date:	Date:
_____	_____
Director of Quality	Name Title

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ATTACHMENT I

LLC LABORATORIES INC

LIST OF CONTACTS AND RESPONSIBLE PEOPLE

Director of Operation, head of lab testing
Phone: (905) 696-8715
Fax: (905) 696-9864
E-mail: jackchen@llclaboratories.com

Director of Director
Phone: (905) 696-8715
Fax: (905) 696-9864
E-mail: samsonlu@llclaboratories.com

"INSERT COMPANY NAME"

LIST OF CONTACTS AND RESPONSIBLE PEOPLE
(Title/Name/Phone/Fax/E-mail)

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