TECHNICAL AGREEMENT

1. SCOPE

This Technical Agreement between [CLIENT] and [CONTRACTOR] relates to the compliance with cGMPs (as hereinafter defined) in the contract testing of [PRODUCT].

The purpose of the Technical Agreement is to assign responsibilities among the parties so as to assure compliance with cGMPs. Nothing in this Technical Agreement shall limit a party's obligation to comply with cGMPs under applicable laws including, without limitation, the guidance and directives set forth in:

(i) requirements for current good manufacturing practices as contained in:
   a. PIC/S Guide to Good Manufacturing for Medicinal Products,
   b. The Rules Governing Medicinal Products in the European Union (EudraLex) – Volume 4 (conforms to EU Directive 2003/94/EC), the Clinical Trials Directive 2001/20/EC
   c. US Code of Federal Regulations, 21 CFR Parts 210, 211 and 312

(ii) applicable laws

This Technical Agreement takes the form of a detailed checklist of the activities associated with laboratory testing of medicinal product(s). Responsibility for each activity is assigned to either [CLIENT] and/or [CONTRACTOR] in the appropriate box in the Responsibilities Checklist that follows. For each responsibility listed, the respective party is required to put into effect all applicable procedures and to take all necessary actions to effectuate that responsibility in accordance with cGMPs, applicable laws, and the marketing authorisations (as appropriate).

Signature on this Technical Agreement indicates agreement to the responsibilities outlined in the Agreement as well as agreement that the Test Methods, Specifications, Procedures, Certificates and additional information as attached meet the recipient's requirements.

Two (2) original copies of this Agreement will be made and signed, one to be retained by each party. Both parties must agree on any future appendixes or modifications.

2. EFFECTIVE DATE OF TECHNICAL AGREEMENT

The effective date of the Agreement is the date of the final approval of the Agreement.

3. CONFIDENTIALITY

[CLIENT] and [CONTRACTOR] shall treat as confidential all data and information supplied by other parties in connection with the manufacturing/testing/ and/or packaging. None of the parties will disclose any data or information to a third party (other than the appropriate registration or health authority) without the permission of the other parties.

4. PRODUCT and TESTING PLAN

The list of test methods and standards are described in Appendix D.

5. SURVIVAL CLAUSE OF TECHNICAL AGREEMENT

Regulatory obligations shall survive the termination of the Technical Agreement.

6. KEY CONTACTS

All quality issues will be directed through the Quality Assurance for each company. See Appendix A for the contact list. Significant organization changes in roles and responsibilities are communicated through the company communication channel.

7. CHANGE CONTROL PROCESS

For changes to Technical Agreement:

Either party may propose updates, amendments, or supplements to this Technical Agreement.

All proposed changes to the Technical Agreement would only be approved by unanimous consent through formal documentation signed by both Parties.

No changes to the Technical Agreement will be valid or effective unless made in writing and signed by duly authorized officers of both Parties.

DEFINITIONS

Terms used in this Technical Agreement shall have the following definitions:

1. CONTRACT TESTING shall mean performing some aspect of testing on behalf of the original manufacturer.
2. MEDICINAL PRODUCTS shall mean any medicine or similar product intended for human use, which is subjected to control health legislation in the manufacturing or importing State.
3. QUALITY SYSTEMS shall mean an official compilation of specifications, analytical test methods/ monographs and standard operating procedures (SOPs) used to ensure the identity, quality, and purity of [PRODUCT].
4. APPLICABLE LAWS shall mean all laws, ordinances, rules, and regulations applicable to the manufacture/testing/and/or packaging of [PRODUCT] and the obligations of [CLIENT] or [CONTRACTOR], as the context requires under this Technical Agreement, including, without limitation,0 (i) all applicable states, and local laws and regulations; (ii) the cGMPs; and (iii) regulatory requirements.
5. cGMP shall mean current Good Manufacturing Practices as specified in 1 (i) as applied to the manufacture, testing, and quality control of medicinal products.
6. DEVIATION shall mean any departure from an approved instruction or established standard, to be investigated and documented according to SOPs.
7. PIC/S shall mean the Pharmaceutical Inspection Cooperation Scheme.
8. INVESTIGATION shall mean any documented inquiry resulting from a deviation, Out-of-Specification (OOS), or other event as applicable and as required by SOPs.

9. MAJOR DEVIATION shall mean any Out-of-Specification (OOS) result and/or any manufacturing, testing, packaging, labelling, storage, shipping, or qualification/validation deviation that has a significant impact on quality, safety, or identity.

10. OUT OF SPECIFICATION RESULT (OOS) shall mean any analytical test result or final test result which does not comply with the established analytical specifications.

11. QUALITY UNIT shall mean collectively the Quality Assurance and Quality Control Departments.

12. SPECIFICATIONS shall mean the approved analytical release testing criteria for materials.

13. STANDARD OPERATING PROCEDURES shall mean the standard operating procedures in effect at the time of manufacture/testing/and/or packaging applicable to [PRODUCT], which have been approved by the Quality Unit.

14. TEST METHOD shall mean the established analytical procedure or set of procedures that is used to ascertain whether or not a test material is in compliance with the established analytical specification.

Agreement Number:XXX/XX

RESPONSIBILITIES CHECKLIST

	RESPONSIBILITIES	CLIENT	CONTRACTOR
1.0 General Requirements			
1.0.1	Test in accordance with applicable regulatory requirements and/or relevant guidelines. This may be applicable to activities such as sample management (including methods, testing, sample storage, laboratory standards, reagents and solution and sample retention), method validation and equipment qualification. Each party shall refrain from activities that could adversely affect the quality of the product or outcome of the results.		X
1.02	Ensure an adequate number of personnel qualified by appropriate education, training and/or experience to perform and supervise the testing of samples.		X
1.0.3	Training programs shall be regularly conducted by qualified individuals. The training shall cover at a minimum the particular operations that the employee performs as they relate to the employee's function. Training needs to be properly documented.		X
1.0.4	Maintain Standard Operating Procedures for all testing activities.		X
1.0.5	Maintain all test information related to the testing operations and samples. Ensure that testing requirements are met by the work performed.		X
1.0.6	Control the quality of all laboratory standards, reagents and solutions according to specification by the application of approved analytical methods.		X
1.0.7	Maintain all testing documentation for a minimum of X years and supply all such records to [CLIENT] on request.		X
1.0.8	Review and approve all test data, worksheets, and any other documentation associated with the testing of the samples.		X
1.0.9	Make no changes to the test method and test specification without prior written agreement.		X
1.0.10	Document and inform [CLIENT] of any changes in the defined procedures. This may include a change in the procedural sequence, or any other changes which cause the revised procedures to differ from the original procedures. Notification is required and shall be in the form of a written document e.g. a memorandum. The revised methods/procedures shall be implemented only upon review and approval from [CLIENT]		X
1.0.11	Provide [CLIENT] with the investigation details and corrective actions taken.		X
1.13	Document and notify any analytical or laboratory deviations from defined procedures, including approval by relevant personnel where appropriate as defined in the **Investigation Report** procedure. The investigation procedure shall define: ▪ System for reporting deviations to [CLIENT] ▪ Details of deviation ▪ Follow-up, and close investigations with specified timeline ▪ Completion of corrective action commitments resulting from investigation closure		X
1.14	Notify [CLIENT] in writing, within three (3) business days, of any **deviations** (for example out of specifications – OOS) affecting a test outcome.		X
1.15	Permit **audits** of all relevant premises, procedures and documentation by [CLIENT], and permit inspection by the Regulatory Authorities.		X

	RESPONSIBILITIES	CLIENT	CONTRACTOR
1.16	Not to subcontract any of the testing to a **third party** without prior written agreement.		X
1.17	Obtain and provide copies, when requested, of audit reports for any **Third Party** Testing facility, (if any).		X
1.18	Obtain and provide copies, when requested, of validation documentation performed by **Third Parties**, (if any).		X
1.19	Obtain and provide copies, when requested, of specifications and analytical methods for the products. This also includes product tested at **Third Parties**, (if any).		X
1.20	A **Calibration** Program will be maintained for analytical equipment/instruments.		X
1.21	A **Preventive Maintenance** Program will be maintained for analytical equipment/instruments.		X
1.22	Provisions for [CLIENT] to receive copies of the regulatory inspection reports or regulatory compliance observations, edited to exclude any proprietary information to [CLIENT].		X
1.23	Ensure all equipment and instruments are properly **qualified** prior to use.		X
1.24	**(If method validation/qualification is performed by [CONTRACTOR]** Provide method validation/qualification package to [CLIENT] for all non-compendial test methods.	X	

RESPONSIBILITIES		[CLIENT]	XXX
2.0 Testing and Release Results			
2.0.1	Clean the premises and equipment thoroughly, prior to use in testing, in accordance with Standard Operating Procedures		X
2.0.2	Written procedures/methods are in place for the preparation of standards, reagents and solutions. Each standard, reagent and solution must be labelled with date of preparation, date of expiration and signature/initial of the analyst.		X
2.0.3	Laboratory standards used during a testing must be documented for full traceability, ensuring that all information pertaining to the solution / reagents is included, or referenced to a logbook with raw data records or it could be referenced to another sample.		X
2.0.4	Maintain compliance with all applicable laws with respect to environmental, occupational and safety issues.		X
2.0.5	Laboratory samples may be disposed after approved test results are released to [CLIENT].		X
2.0.7	Destroy (and dispose) the samples in a secure and legal manner that ▪ prevents unauthorised use or diversions ▪ complies with all applicable environmental laws and ▪ maintains destruction records.		X
3.0 Storage and Transportation of Samples and Analysed Samples			
3.0.1	Ensure that samples shall be in clean containers with no visible contamination on the outer surfaces of the sample containers.		X
3.0.2	If visible contamination is observed on the outer surface of the sample container(s), it is agreed that [CONTRACTOR] may dispose the suspect sample container(s) immediately without testing. [CONTRACTOR] must then inform [CLIENT] so that replacement samples, if warranted, are made available to [CONTRACTOR].		X
3.0.3	Ensure suitable storage of sample from receipt to the point of testing and throughout the duration of the test at [CONTRACTOR] site.		X
3.0.4	Ensure that suitable storage of samples at [CONTRACTOR] from the end of test.		X
3.0.5	Disposal of special waste; e.g., toxic waste, solvents, samples, etc.		X

Agreement Number:XXX/XX
APPROVAL SIGNATURES

IN WITNESS WHEREOF, the parties hereto have caused this Technical Agreement to be executed by their duly authorized representatives as of the EFFECTIVE DATE (as noted on the Cover Page of this Agreement).

[CLIENT]	**[CONTRACTOR]**
Signature: _____	Signature: _____
Name: _____	Name: _____
Position: _____	Position: _____
Date: _____	Date: _____

Agreement Number:XXX/XX

ATTACHMENTS

ATTACHMENT A – Routine Communication Contacts

[CLIENT]:

Name	Title	Contact Number	E-mail Address

[CONTRACTOR]:

Name	Title	Contact Number	E-mail Address

ATTACHMENT B - Examples of MAJOR Changes Requiring Prior Notice and Approval

A. Packaging

1. Changes to packaging components, materials, or packaging designs.

B. Special Transportation and/or Special Storage Conditions

1. Change in packaging.
2. Modifications to special storage criteria (e.g. temperature, humidity, light, etc).

C. Material Specifications and Analytical Methods/Monographs

1. Change in specifications.
2. Analytical test methodology.

ATTACHMENT C - Requirements for Certificates of Analysis

A **Certificate of Analysis** will include the following:

- Name, address, and contact phone number of the [CONTRACTOR] facility where product was tested;
- Product Name;
- Product Identification Number;
- Date of Analysis;
- A list of each test performed, the acceptance limits as indicated in the monographs/ specifications, and the results obtained;
- The Certificate of Analysis should document actual values, where specifications are quantitative, and maintain the significant figures defined in the specifications.

Agreement Number:XXX/XX

ATTACHMENT D – List of Test Standards and Method(s)