

Services Agreement

THIS SERVICES AGREEMENT is made: ____/____/20__

BETWEEN THE PARTIES:

Company Name	[]		
Registered Office	[]		
Registration No.	[]	Country of Registration	[]

Henceforth known as the “Client”

Company Name	BUTTERWORTH LABORATORIES LIMITED		
Registered Office	54-56 Waldegrave Road, Teddington, Middlesex, TW11 8NY.		
Registration No.	01185121	Country of Registration	England & Wales

Henceforth known as “Butterworth”

WHEREAS

- A. The Client wishes to retain Butterworth to undertake Services.
- B. When the Client requires such Services, and Butterworth is able to provide them, Butterworth will issue a quotation and the parties will enter into a separate contract in accordance with the terms of this Services Agreement.
- C. Each contract will be subject to Butterworth’s Terms and Conditions as varied and supplemented by this Services Agreement.

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NOW IT IS HEREBY AGREED AS FOLLOWS

1. DEFINITIONS & INTERPRETATION

- 1.1. The definitions and rules of interpretation set out in Appendix B apply in this Services Agreement.

2. CONTRACT PROCESS

- 2.1. This Services Agreement governs the overall relationship of the parties in relation to the Services provided by Butterworth to the Client, and sets out:
- 2.1.1. the procedure for the Client to request the provision of Services from Butterworth under separate Call-off Contracts;
 - 2.1.2. in Appendix A Butterworth's Terms and Conditions which are varied and supplemented by this Services Agreement, which as such contains the terms for the Call-off Contract;
 - 2.1.3. certain ongoing obligations between the parties which are independent of any Call-off Contract.
- 2.2. The Client shall be entitled from time to time to request in writing the provision of Services from Butterworth.
- 2.3. Following a request for Services Butterworth shall either:
- 2.3.1. notify the Client that it is not able to provide the requested Services; or
 - 2.3.2. provide a Quotation.
- 2.4. The Call-off Contract will come into existence once the Quotation has been accepted in accordance with 2.2 of the Terms and Conditions, provided that as at the date the Call-off Contract is accepted, this Services Agreement has not been terminated.
- 2.5. Each Call-off Contract forms a separate contract between Butterworth and the Client.
- 2.6. Any amendments to this Services Agreement agreed by the Client and Butterworth in accordance with clause 14 (Variation) shall be deemed to apply to all future Call-off Contracts entered into after the date of such amendment.
- 2.7. There is no obligation on the Client under this Services Agreement to engage Butterworth to provide Services or provide any minimum amount of work and there is no obligation on Butterworth to accept requests to carry out Services.
- 2.8. Where the Client operates different divisions and a division is specified in Appendix D, then unless the Parties agree otherwise expressly in writing, this Services Agreement shall only apply in respect of Services which are requested from (or purport to be requested from) or to be supplied to that division.

3. CONFLICT

- 3.1. If there is an inconsistency between any of the provisions of this Services Agreement and either the provisions of any Call-off Contract or Butterworth's Terms and Conditions, the provisions of this Services Agreement shall prevail.

4. CONFIDENTIALITY

- 4.1. To the extent that there is an independent formal and written Confidentiality Agreement entered into by the Parties, condition 3 of Butterworth Terms and Conditions shall not apply.

5. REGULATORY

- 5.1. During the term of this Services Agreement Butterworth shall maintain its Quality Management System to ensure the Services can be performed to the following standards:
 - 5.1.1. UKAS Accreditation to ISO17025;
 - 5.1.2. Good Manufacturing Practice (GMP) as laid down in Directives 2001/20/EC, 2003/94/EC and 91/412/EEC and 21 CFR Parts 210 and 211 as they relate to Quality Control Laboratories;
 - 5.1.3. the Principles of Good Laboratory Practice (GLP) as laid down in Directive 2004/9/EC; and
 - 5.1.4. Good Clinical Practice (GCP) to EU Regulation No. 536/2014.
- 5.2. Either Party must inform the other as soon as reasonably practicable of:
 - 5.2.1. any material changes to their Regulatory Status; or
 - 5.2.2. where there has been a finding as a result of an inspection by a Regulator;in each case which has direct relevance and significance to the Service(s).
- 5.3. If either Party become aware of any circumstances or information which may potentially constitute a serious breach of the standards referred to in 5.1.1 to 5.1.4 where applicable, this shall be communicated immediately to the other Party. If appropriate this shall be communicated directly to the relevant Regulatory Authority.
- 5.4. The provisions of clause 5 apply only during the term of this Services Agreement and irrespective of whether any Call-off Contract has been entered into.

6. INFORMATION TO BE SUPPLIED BY & RESPONSIBILITIES OF THE CLIENT

- 6.1. Full disclosure must be made by the Client of all information and documentation which is required by Butterworth to provide a Quotation for the Service(s). A non exhaustive list of such information is:
 - 6.1.1. whether the Services are required to be carried out to the standards and regulations of Good Manufacturing Practice (GMP) as detailed in clause 5.1.2 or any other particular standard or regulation;
 - 6.1.2. sample matrix, numbers type(s) and frequency of Samples to be analysed;
 - 6.1.3. analyte(s) to be determined;
 - 6.1.4. methods and/or techniques to be used and if these are in the public domain a reference to their source and version number;
 - 6.1.5. protocols, study plans and any other document however named relating to work to be performed as part of the Service(s);
 - 6.1.6. where Samples are to be tested as part of a Clinical Trial, evidence of patient consent for the testing;
 - 6.1.7. details of any chemical or biological Health and Safety risks or environmental impact associated with the Service(s) to be performed including those relating to the Material and the methods to be employed. Examples include but are not limited to:
 - SDS/MSDS Sheets
 - Bio- safety containment level
 - Controlled drugs requiring Home Office Licences
 - 6.1.8. any special handling or storage conditions and requirements, including Sample stability;
 - 6.1.9. required time frames for the analysis;

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- 6.1.10. requirements for Method Validation or Verification prior to testing of Samples;
- 6.1.11. the purpose(s) for which the results of the analysis are to be used.
- 6.2. The Client is responsible for the selection of Samples, their packaging and transit, including temperature control, to Butterworth's Main Site and Laboratory Facility.
- 6.3. The Client is responsible for ensuring that sufficient quantities of Samples arrive at Butterworth's Main Site and Laboratory Facility in a condition which will not affect the validity of the Analysis and/or prevent the Service(s) being performed as agreed.
- 6.4. In addition to the information listed in 6.1, the Client shall provide the following at the time of or before receipt of Samples(s) by Butterworth:
 - 6.4.1. the signed Quotation;
 - 6.4.2. a Purchase Order stating all the necessary information for prompt payment of Butterworth invoices, such Purchase Order must reflect the charges and conditions detailed on the Quotation provided by Butterworth relating to the Service(s);
 - 6.4.3. information to uniquely identify each Sample to be tested or the Materials for each project to be carried out;
 - 6.4.4. the name and contact details of the Client's employee who is responsible for the Sample(s) and to whom Reports and additional communications relating to the Service(s) should be sent;
 - 6.4.5. information on the purity of any Reference Materials/Standards supplied by the Client;
 - 6.4.6. anything else requested by Butterworth to enable the correct performance of the Service(s);
 - 6.4.7. full, complete and current versions of all documentation required to provide the Service(s) such as methods and specifications. Authorised and controlled copies should be provided when available.
- 6.5. Butterworth reserve the right to refuse to undertake the Service(s) until the information required in 6.1 and 6.4 has been received from the Client or if the information in clause 6.1 and 6.4 has not been provided at the time of or in advance of receipt of the Samples by Butterworth.
- 6.6. The Client shall notify Butterworth forthwith of any changes to the information supplied relating to the Service(s) or the purpose of the Service(s) and any other information required by Butterworth to perform the Service(s). Butterworth reserves the right to refuse to undertake the Service(s) in the light of such changes.
- 6.7. The Client must immediately inform Butterworth of any withdrawal of consent from patients/subjects, to ensure that no further data is generated or collected from the specific Clinical Trial's patients/subjects.
- 6.8. The Client shall inform Butterworth in writing of any submission to a Regulatory Authority on which Butterworth is or will be named. Existing product, manufacturing or marketing licences/authorisations details are contained in Appendix F along with reference to all Methods, SOPs, specifications and other documentation required by Butterworth to carry out the Service(s). Butterworth must also be informed of any changes and/or amendments to applications to a Regulatory Authority on which Butterworth are named.
- 6.9. Subject to condition 7.1 of Butterworth's Terms and Conditions:
 - 6.9.1. Butterworth will not be liable to the Client for failure in providing the correct Service(s) if it is a consequence of the Client not providing full disclosure of information required to be provided by it as detailed in this Services Agreement;
 - 6.9.2. Butterworth shall bear no duty of care or contractual liability to the Client or any Third Party in respect of any purposes that results of the Services are to be used which have not been disclosed in writing prior to commencement of the Service(s).

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- 6.10. The Client shall indemnify Butterworth in respect of any liability, loss, expense or claim incurred by Butterworth arising from the Client's failure to make the disclosures as referred to in this clause 6.
- 6.11. The Client must respond to queries and information requests by Butterworth within a reasonable timeframe.
- 6.12. Butterworth are not responsible for final release or acceptance of any products based upon any Service(s) provided by Butterworth and Butterworth does not provide the services of a Qualified Person (QP). It is the responsibility of the Client to ensure that the Service(s) meet the Client's quality and compliance requirements including any needed for manufacturing or marketing authorisations.

7. INFORMATION TO BE SUPPLIED BY & RESPONSIBILITIES OF BUTTERWORTH

- 7.1. Upon the request of the Client, Butterworth will provide a Quotation detailing the Service(s). The Quotation will provide information detailed in clause 8.
- 7.2. Unless requested by the Client at the time of Sample submission, Butterworth will not provide the Client with confirmation of receipt of Sample(s).
- 7.3. Where Butterworth notice that Sample(s) have not been transported under correct conditions or where they have been received in a condition which might impact on the validity of test results, Butterworth will inform the Client.
- 7.4. Butterworth will ensure that samples are stored under any conditions stated in the Quotation or otherwise agreed in writing with the Client.
- 7.5. Whilst Butterworth aims to achieve or better the estimated turn round times set out in the Quotation (see clause 8), the Client understands and agrees that this is only an estimate and that time is not of the essence.
- 7.6. Butterworth shall inform the Client of all Planned and Unplanned Deviations, OOS results and Change Controls.
- 7.7. Reports will be in the form as described in clause 10.
- 7.8. Butterworth will not subcontract any of the work covered by this agreement without prior written consent of the Client

8. QUOTATIONS

- 8.1. Quotations issued by Butterworth will contain the following information:
 - 8.1.1. a unique identifier;
 - 8.1.2. date of issue and expiry;
 - 8.1.3. a descriptive title;
 - 8.1.4. a list of deliverables and charges;
 - 8.1.5. any important information such as:
 - minimum quantity of sample required by Butterworth to perform the test;
 - estimated turn round times (see clause 7.5);
 - identification of the quality regulation to be applied to the Service(s) and/or identification of UKAS Accredited Tests;
 - planned Deviations.
- 8.2. Butterworth reserves the right to revise estimated completion dates and charges for the Service(s) if:
 - 8.2.1. the Client fails to comply with the requirements of clause 6 or provide the minimum quantity of Sample(s) requested in the Quotation;
 - 8.2.2. the Sample(s) differs from the description or information supplied by the Client in compliance with clause 6.1 above;

- 8.2.3. events outside of Butterworth's control prevent the originally estimated timescales from being met such as where the method does not perform as expected or unavailability of reference standards;
- 8.2.4. the Client changes their requirements after the issue of the Quotation.

9. SAMPLES & TESTING

- 9.1. Unless requested by the Client when supplying information pursuant of clause 6.1, Butterworth shall use current versions of published Methods.
- 9.2. Where pharmacopoeial or standard published methods are employed for the testing of Samples, variations or adjustments documented as permissible within the method or publication (including the USP Pharmaceutical Forum for USP Monographs) may be applied. These variations or adjustments shall not be detailed on the Report.
- 9.3. Where Butterworth do not hold the relevant licences for the purchasing, handling, storage or disposal of Sample(s), Reference Standard(s), reagent(s) or hazardous waste(s) related to the testing of Sample(s), Butterworth may charge for the acquisition of such licences or return the Sample(s) to the Client.
- 9.4. Compendial Methods are not revalidated/verified by Butterworth, unless specifically requested by the Client. It is assumed that parameters such as system suitability or positive/negative controls inherent in the test provide sufficient evidence of the Contract Acceptor's capability to perform the test. Where the Client requires Butterworth to provide validation, verification or proof of competence for Compendial Methods, it shall be the responsibility of the Client to provide full written instructions prior to any analysis being performed.
- 9.5. Where Butterworth has performed a method verification for the Client, Butterworth will issue an in-house client specific method of the procedure to be followed. When the Compendial Method has been revised by a pharmacopeia post validation/verification the Client will be contacted for instructions on further validation/verification and revision of the in-house method.

10. RAW DATA, RESULTS & REPORTS

- 10.1. All dates will be recorded in UK format unless clearly stated otherwise i.e. dd/mm/yy or dd/mmm/yyyy
- 10.2. Figures will be rounded up or down at the final stage of calculations. When rounding is required, only one digit in the decimal place is considered. If the digit is smaller than 5, it is eliminated and the preceding digit is left unchanged. If the digit is equal to, or greater than 5, it is eliminated and the preceding digit is increased by one.
- 10.3. On completion of the Service(s) a copy of the Data Pack will be transferred to the Client for archiving/retention in accordance with 11.4.
- 10.4. Reports shall include:
 - 10.4.1. a unique report reference number;
 - 10.4.2. clear identification of any Sample(s) and dates when they were received;
 - 10.4.3. reference to the Client and Butterworth's unique Sample reference numbers;
 - 10.4.4. date the analysis was performed;
 - 10.4.5. all valid results obtained;
 - 10.4.6. references to any deviations;
 - 10.4.7. reference to any attached documentation such as Raw Data Packs and copies of OOS investigations;
 - 10.4.8. reference to the Method used or developed – including the issue/revision number;
 - 10.4.9. identification of tests accredited by UKAS to ISO17025.

- 10.5. In addition to this list, the following other information may also be included in a Report:
- 10.5.1. for GMP analysis, a statement of pass or failure of samples to meet the required specifications;
 - 10.5.2. results and findings from any Validation or Verification work performed;
 - 10.5.3. details of stability conditions used to store samples;
 - 10.5.4. statistical analysis of Results.
- 10.6. Results and findings in Reports only relate to the Sample(s) tested by Butterworth on an "as received" basis.
- 10.7. Reports are checked and signed by personnel who are approved by the Butterworth Quality Assurance department. Certificates of Analysis are not routinely signed by Butterworth Quality Assurance personnel.
- 10.8. Where factual errors and omissions in a Data Pack have been identified and agreed by mutual consent between the Parties, Butterworth shall provide a corrected version of the Data Pack at no extra charge.
- 10.9. Other changes and requests for additional information to the Data Pack may be requested by the Client provided these do not impact on the scientific or regulatory interpretation of the Results. This will incur an additional charge. Furthermore, Butterworth reserves the right to refuse any changes to Data Pack(s) where, in their opinion, the scientific integrity is compromised or where such changes may result in an incorrect conclusion or interpretation to be drawn from the Raw Data.

11. QUALITY

11.1. Quality Assurance & Standard of Work

- 11.1.1. The Service(s) shall be carried out only by suitably qualified and appropriately trained employees of Butterworth (as determined solely by Butterworth), in accordance with the terms of this Services Agreement.
- 11.1.2. Butterworth will perform the analysis of the Sample(s) supplied by the Client in accordance with Butterworth's QMS.
- 11.1.3. So that Butterworth can provide Service(s) in compliance with the required quality standard, the Client must detail whether the Analysis is to be carried out to either one or more of the following regulation(s)/standards which can be met by the Butterworth QMS:
 - GLP
 - GCP
 - GMP
 - ISO17025
- 11.1.4. Compliance to the required quality standard or regulation can only be met if the Client has supplied all relevant information as detailed in clause 6 and 11.1.3 prior to commencement of the Service(s). As a default the Service(s) shall be performed in accordance with the general quality requirements of the Butterworth QMS only.
- 11.1.5. Butterworth shall use its reasonable endeavours to ensure results are free from error, using its own procedures for quality control, review and approval of results.
- 11.1.6. Butterworth will monitor the performance of their QMS by the use of an internal self improvement programme which includes internal auditing and will seek continual improvement by the use of corrective or preventive actions.

11.2. Facilities, Equipment & Materials

- 11.2.1. Butterworth shall only use instruments, equipment and facilities which are both appropriate to the Service(s) and have been suitably qualified, validated and/or calibrated in accordance with the Butterworth QMS.

- 11.2.2. Qualification of computerised systems shall follow the principles of GAMP 5 and current Data Integrity requirements.
- 11.2.3. Butterworth shall ensure that the testing facilities and equipment are maintained in a manner and procedures exist which minimise the chances of contamination or mix up of Samples.
- 11.2.4. Butterworth's sites have adequate security to resist unauthorised access.
- 11.2.5. Unless agreed otherwise, Butterworth will be responsible for supplying all Reagents and Materials needed to perform the Service(s). Such Materials will be both appropriate and suitable and are of an equal or superior quality than that specified in the Method.
- 11.2.6. Materials will only be purchased from suppliers approved by Butterworth and, where appropriate to their use, will be accompanied by a Certificate of Analysis/Conformity to verify quality and enable Traceability.

11.3. Validation of Methods

- 11.3.1. It is the responsibility of the Client to identify any requirements for validation, verification or proof of competence for Client supplied or requested methodologies including compendia methodologies. Where there is such a requirement, the Client must provide Butterworth with a written request including their full requirements and criteria prior to the testing of Samples.
- 11.3.2. Methods developed by Butterworth will be validated in accordance with Butterworth's policy which is based on ICH Guidelines. A validation plan will be produced and agreed by both Parties prior to work being commenced.
- 11.3.3. Save for clause 11.3.2 pharmacopoeial methods are not validated or verified by Butterworth. It is assumed that parameters such as system suitability or positive/negative controls inherent in the test provide sufficient evidence of Butterworth's capability to perform the test.

11.4. Archiving & Record Retention

- 11.4.1. Electronic records shall be retained within Butterworth's internal computer network. The Data Pack and other records shall be retained at Butterworth's Archive facility located at the site identified in Appendix D.
- 11.4.2. Responsibilities for the Retention of records are detailed in the table below:

Record type	Responsibility	Retention Period
Data Pack	Client	As required
Original Electronic Raw Data	Butterworth	10* years
Supporting documentation including Controlled Documents, SOP's, instrument records, Method Validation data, analyst training records.	Butterworth	25 years
Electronic copies of all records, data and reports sent to the Client	Butterworth	10* years
* Whilst records will be retained for 10 years, a risk assessment by our IT Department has concluded that we cannot guarantee recovering the document in a readable format after 5 years		

- 11.4.3. The Retention Periods listed refer to a period of time after the date of completion of the Service(s).
- 11.4.4. Following the Retention Period Butterworth will destroy hard copy records in a secure and confidential manner without reference to the Client.
- 11.4.5. GLP & GCP Studies will be archived in accordance with their individual plans.

11.5. Out of Specification (OOS) Results

- 11.5.1. OOS investigations shall only be performed for Service(s) carried out to GMP compliance. An OOS result is one which is found to fail the prescribed specification once routine QC checking has been completed and where discovered the Client shall be notified by Butterworth within one (1) Business Day.

- 11.5.2. All other results failing to meet expectations shall be investigated in accordance with clauses 11.6 and 11.7 as appropriate.
- 11.5.3. Butterworth shall start their OOS investigation within one (1) Business Day of the Client's confirmation that the result is OOS. Butterworth will aim to complete the OOS investigation within ten (10) Business Days from the start of the investigation.
- 11.5.4. OOS investigations shall be conducted in accordance with Butterworth's own procedures which are based on MHRA and FDA guidance with an aim to determine the cause of the OOS result and are designed to prevent testing into compliance. Such investigations must be carried out independently, unhindered and outside the influence of the Client and/or any third party other than a Regulatory body.
- 11.5.5. Butterworth may identify re-testing of the Sample(s) as a necessary part of their investigation. No re-testing of the Sample(s) shall be carried out without the Client's permission. Where the Client does not provide their permission for re-testing they must provide a full justification why the investigation cannot continue. This justification must be documented with the OOS investigation report.
- 11.5.6. Save for clause 11.5.4, the investigation may also follow the requirements of the Client's own procedures provided that this has been agreed in writing prior to commencement of the investigation and that this does not conflict with Butterworth's own procedures which will always take precedence. Resulting additional work (both administrative and analytical) will be charged by Butterworth to the Client on the final invoice.
- 11.5.7. Where Butterworth's investigation has found clear evidence demonstrating that a laboratory error has caused the OOS result(s), the original results may be invalidated and the test repeated. Only valid results shall be detailed on the Report which shall be accompanied by a copy of the investigation along with the associated Raw Data. Once completed, changes to Butterworth OOS investigations will only be made at Butterworth's discretion where there is a clear error which has been agreed between the Parties. Additional information and findings which come to light after completion of the investigation must be appended to the original report.
- 11.5.8. After the completion of Butterworth's investigation, should the Client require a full scale investigation requiring further laboratory testing, the Client must detail their full requirements in writing, preferably providing a testing plan. Butterworth will co-operate with the Client to perform this testing and reserve the right to charge in accordance with clause 11.5.9 below.
- 11.5.9. Where the OOS result(s) is a consequence of a defective, incorrect or out of specification Sample or incorrect information supplied by the Client, the Client shall be invoiced for the investigation and any repeat analysis in accordance with the provisions of condition 5.5 of Butterworth's Terms and Conditions.
- 11.5.10. All samples and solutions should be retained until the OOS has been closed, where practicable.

11.6. Non-Conforming Work & Deviations

- 11.6.1. Non-Conforming Work (NCW) and Deviations shall be categorised, managed and communicated to the Client in accordance with Butterworth's in-house procedures.
- 11.6.2. Planned and Unplanned Deviations affecting the Service(s) shall be communicated to the Client. In the case of Unplanned Deviations, these shall be communicated within one (1) Business Day of discovery.
- 11.6.3. Planned Deviations affecting the Services(s) will not be implemented without the Client's approval.
- 11.6.4. Unplanned Deviations categorised as "Major" or "Critical" where the validity of the Service(s) have been or may have been affected require client approval prior to the release of results. Where necessary and appropriate, preventive actions will be applied to reduce the risk of reoccurrence.

11.7. Non-Conforming & Out of Trend Results

- 11.7.1. It is the responsibility of the Client to identify any Non-Conforming Results.

- 11.7.2. Should the Client require an investigation into the potential causes of Non-Conforming Results, this must be communicated to Butterworth within 30 days of the completion of the Service(s). Provided this requirement has been met, Butterworth shall co-operate with the Client in the investigation of any potential causes. Should this investigation confirm that the Non-Conforming Result is due to an error on behalf of Butterworth, the testing shall be repeated and no extra charge shall be made to the Client for the investigation and additional testing. Should the investigation fail to prove that the Non-Conforming Result is due to an error on behalf of Butterworth, Butterworth shall charge for the investigation and any additional testing.
- 11.7.3. Should the Client fail to notify Butterworth of a Non-Conforming Result within 30 days of the Completion of the Service(s), Butterworth reserve the right to charge for any investigation and additional testing performed at the request of the Client.

11.8. Change Control

- 11.8.1. Butterworth shall notify the Client of all proposed changes to methods and procedures specifically written for the Client to support the Service(s) in accordance with clause 7.6. No planned changes will be made without the Clients approval.
- 11.8.2. Any change which is found to have a direct and negative impact on the quality of results provided as part of the Service(s) shall be communicated to the Client in writing.
- 11.8.3. The Client will ensure that Butterworth is informed promptly of any changes to any of the information supplied to Butterworth under clauses 6.1 and 6.4 or otherwise which might affect Butterworth's ability to adequately perform the Service(s). This includes any updates or changes to methodologies and/or specifications supplied by the Client.

11.9. Audits

- 11.9.1. The Client may, having given at least two weeks' notice, perform a one day quality audit of Butterworth's sites and facilities used to perform the Service(s). Butterworth will use reasonable endeavours to comply with all requested dates for audits.
- 11.9.2. Butterworth, having been given reasonable written notice by the Client, will permit access by representatives of Regulatory Authorities to inspect and audit the sites and facilities used to perform the Service(s) supplied to the Client. Butterworth shall also permit access by personnel belonging to the Client during such inspections. Costs relating to such inspections shall be borne by the Client.
- 11.9.3. Butterworth shall promptly notify the Client of any planned inspection by a Regulatory Authority in connection with the Service(s). Butterworth shall permit access to personnel belonging to the Client during such inspections. Should any such inspection take place without notice, Butterworth shall inform the Client as soon as reasonably practicable.
- 11.9.4. Butterworth have no obligation to inform the Client of any Regulatory Authority inspection not specifically related to the Service(s) supplied to the Client. If however the inspection results in negative findings specific and directly related to the Service(s) supplied to the Client, Butterworth shall notify the Client and provide details on the findings and any proposed corrective and/or preventative actions.

11.10. Complaints

- 11.10.1. If either party wishes to make a formal complaint to the other, this should be done in writing to the named contact in clause 23.3. Acknowledgement of the complaint must be made by the receiving party within two (2) Business Days and Butterworth aim to complete the investigation and produce a report within ten (10) Business Days of receipt.

12. TERM & TERMINATION

- 12.1. This Services Agreement shall continue for two (2) years from the date of signature by both Parties unless terminated earlier in accordance with its terms. At the end of two (2) years this Services Agreement may be extended by both Parties using a Services Agreement Extension form which once signed by both Parties can be appended to this document.

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- 12.2. Either Party may terminate this Services Agreement by immediate written notice at any time if the other Party is in material breach of its obligations under this Services Agreement or compounds with or executes an assignment for the benefit of its creditors or commits any act of bankruptcy or being a company enters into voluntary or compulsory liquidation or suffers a receiver, administrative receiver or administrator to be appointed over all or any part of its assets or takes or suffers any similar action in consequence of debt or becomes insolvent or should the other Party have reasonable cause to believe that any of these events is likely to occur.
- 12.3. If either Party materially breaches any terms or conditions of this Services Agreement, the other (i.e., non-breaching) party may terminate this Services Agreement upon thirty (30) days' written notice to the breaching Party specifying the material breach, unless within such thirty (30) day period all material breaches identified therein shall have been remedied.
- 12.4. On termination (or expiry) of this Services Agreement, howsoever arising, each Call-off Contract then in force at the date of such termination shall continue in full force and effect for the remainder of the term of such Call-off Contract, unless terminated earlier in accordance with the terms of such Call-off Contract.
- 12.5. The termination of any Call-off Contract shall not affect any other Call-off Contracts or this Services Agreement.
- 12.6. On termination of this Services Agreement, those clauses which form part of any Call-off Contract in existence shall continue to apply to such Call-off Contract.
- 12.7. Termination of this Services Agreement shall not affect any rights, remedies, obligations or liabilities of the parties that have accrued up to the date of termination, including the right to claim damages in respect of any breaches of the agreement which existed at or before the date of termination.
- 12.8. In the event of termination of a Call-off Contract, Butterworth shall be entitled to:
 - 12.8.1. payment forthwith of all monies due to Butterworth in respect of the Service(s) which have been completed and invoiced;
 - 12.8.2. payment forthwith of all monies due to Butterworth in respect of Service(s) which have been completed by the date of termination subject to submission of an invoice;
 - 12.8.3. in respect of a Service which has only been part completed at the date of termination, Butterworth shall submit an invoice for such sum as represents the proportion of work actually completed bears to the total work to be undertaken for that Service and the Client will pay such invoice forthwith.
- 12.9. On termination of a Call-off Contract for whatsoever reason, Butterworth shall return all unused quantities of Sample(s) to the Client, or destroy them at the request of the Client. Any accompanying documentation not required to be archived for regulatory/legal reasons shall also be returned to the Client, or destroyed at the request of the Client.
- 12.10. Termination of a Call-off Contract shall not release either Party from any liability or right or action, which at the time of termination has already accrued to either Party or which may thereafter accrue in respect of any act or omission prior to such termination. Such rights shall include but not be limited to the recovery of any monies due hereunder.

13. RELATIONSHIP OF PARTIES

- 13.1. Nothing in this Services Agreement and no action taken by the Parties pursuant to this Services Agreement shall constitute or be deemed to constitute a partnership between the Parties, or shall constitute either Party as the agent, employee or representative of the other.

14. VARIATIONS

- 14.1. No variation of or amendment to this Services Agreement shall bind either party unless made in writing and signed by both parties hereto. Both Parties shall at all times remain willing to discuss possible contractual variations that have been prompted by technical or other factors, although neither party shall have any obligation to agree to any such variation proposed.

15. WAIVERS

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- 15.1. Failure of either Party to enforce or exercise, at any time or for any period, any term of this Services Agreement, does not constitute, and shall not be construed as, a waiver of such term and shall not affect the right later to enforce such term or any other term herein contained.

16. RESTRAINT

- 16.1. During the term of this Services Agreement and for a period of six months following its termination (howsoever caused) the Client (and any of its Associated Companies) shall not either directly or indirectly offer employment to or otherwise entice away from Butterworth any employee of Butterworth who:

- 16.1.1. at the date upon which such offer of employment was made or enticement advanced was employed by Butterworth at a level of Analytical Chemist or above; and

- 16.1.2. is or has been engaged as an employee of Butterworth in the provision of Services under a Call-off Contract.

17. LAW & JURISDICTION

- 17.1. This Services Agreement, and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by, and construed in accordance with the law of England and Wales.

- 17.2. Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with this Services Agreement or its subject matter or formation.

18. SEVERABILITY

- 18.1. The invalidity or unenforceability of any term of or any right arising pursuant to this Services Agreement shall not adversely affect the validity or enforceability of the remaining terms and rights.

- 18.2. If any provision of this Services Agreement is declared by any judicial or other competent authority to be voidable, illegal or otherwise unenforceable this shall not affect the remainder of the Services Agreement, which shall continue in full force and effect. Any such provisions as shall be declared to be voidable, illegal or otherwise unenforceable shall be amended so that the amended provision achieves the intention of the parties.

19. ENTIRE AGREEMENT

- 19.1. This Services Agreement constitutes the entire and integrated agreement and understanding between the Parties with respect to its subject matter and supersedes any prior agreement, understanding or arrangement between the parties, whether oral or in writing.

20. SURVIVAL

- 20.1. Provisions of this Services Agreement which either are expressed to survive its termination or from their nature or context it is contemplated that they are to survive such termination shall remain in full force and effect notwithstanding such termination.

21. COUNTERPARTS

- 21.1. This Services Agreement may be executed in any number of counterparts, each of which when executed shall constitute a duplicate original, but all the counterparts together constitute the one agreement.

22. RIGHTS OF THIRD PARTIES

- 22.1. This Services Agreement does not give rise to any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Services Agreement.

23. NOTICES

- 23.1. Any notice or other communication given to a party under this Services Agreement shall be in writing, addressed to that party at its address stated in clause 23.3 below, or such other address as that party may have specified to the

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other party in writing in accordance with this clause 23, and shall be delivered personally, or sent by pre-paid first class post or other next working day delivery service, commercial courier, fax or email.

- 23.2 A notice or other communication shall be deemed to have been received: if delivered personally, when left at the address referred to in clause 23.3; if sent by pre-paid first class post or other next working day delivery service, at 10.00 am on the second Business Day after posting; if delivered by commercial courier, on the date and at the time that the courier's delivery receipt is signed; or, if sent by fax or email, one (1) Business Day after transmission.

23.3

Company Name	Butterworth Laboratories Limited
Address	54-56 Waldegrave Road, Teddington Middlesex TW11 8NY UK
Contact Name	Associate Director - Business Operations - John Welch
Contact Details	Email: john.welch@butterworth-labs.co.uk

Company Name	[]
Address	[]
Contact Name	[]
Contact Details	Email: []

23.4 The provisions of this clause 23 shall not apply to the service of any proceedings or other documents in any legal action.

24. SIGNATURES

The following signatures confirm acceptance of this Services Agreement

Signed for and on behalf of: Butterworth Laboratories Limited (Butterworth)	
Signature	Signature
Name John A S Welch	Name Stuart Davey
Position Associate Director - Business Operations	Position Head of Quality Assurance
Date	Date

Signed for and on behalf of: [] (Client)	
Signature	Signature
Name []	Name []
Position []	Position []
Date []	Date []

APPENDIX – A BUTTERWORTH TERMS & CONDITIONS

1 INTERPRETATION

- 1.1 **Advance Payment Invoice:** an invoice payable before the completion of the Services to which it relates;
- 1.2 **Business Day:** a day (other than a Saturday, Sunday or public holiday in England or any day falling in the period between Christmas Day and the New Years Day);
- 1.3 **Butterworth:** Butterworth Laboratories Limited (Company no. 1185121), 54/56 Waldegrave Road, Teddington, Middlesex, TW11 8NY;
- 1.4 **Client:** the company or firm who purchases Services from Butterworth;
- 1.5 **Client Materials:** all documents, information, Samples, items, substances and material which are provided by the Client to Butterworth in connection with the Services;
- 1.6 **Conditions:** these terms and conditions as amended from time to time;
- 1.7 **Contract:** the contract between Butterworth and Client for the supply of Services in accordance with these Conditions;
- 1.8 **Intellectual Property Rights:** all patents, rights to inventions, utility models, copyright and related rights, trademarks, service marks, trade, business and domain names, rights in trade dress or get-up, rights in goodwill or to sue for passing off, unfair competition rights, rights in designs, rights in computer software, database rights, topography rights, moral rights, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications for and renewals or extensions of such rights, and all similar or equivalent rights or forms of protection in any part of the world;
- 1.9 **Order:** the Client's order for Services as set out in the Client's written acceptance of a Quotation, or the Client's purchase order form, or completed sample submission form/instruction, as the case may be;
- 1.10 **Quotation:** the cost for the Services and scope of the Services, as provided in writing by Butterworth;
- 1.11 **Raw Data:** A documented record of the original observations and activities relating to the Service(s). This may be in the format of hand written notes and calculations, instrument print-outs or as electronic records;
- 1.12 **Report:** the document signed on behalf of Butterworth by any authorised signatory containing results and outcomes relating to the Service(s). Reports may be in the form of a certificate of analysis, a validation report or such other form as Butterworth determines unless stated in the Quotation or agreed between the parties in writing;
- 1.13 **Samples:** goods, substances or materials provided by the Client to enable the Services to be performed;
- 1.14 **Service(s):** any analytical testing or consulting provided by Butterworth for the Client.

2 BASIS OF CONTRACT

- 2.1 The Quotation constitutes an offer by Butterworth to provide the Services in accordance with these Conditions.
- 2.2 The Quotation shall only be deemed to be accepted when the first of the following occurs:
 - 2.2.1 the Client signs the Quotation and it is received by Butterworth;
 - 2.2.2 the Client provides the Order and it is received by Butterworth; or
 - 2.2.3 Butterworth receives the Samples;at which point and on which date the Contract shall come into existence.
- 2.3 The Contract constitutes the entire agreement between the parties. The Client acknowledges that it has not relied on any statement, promise or representation made or given by or on behalf of Butterworth which is not set out in the Contract.
- 2.4 Any descriptive matter or advertising issued by Butterworth, are issued for the sole purpose of giving an approximate idea of the Services described in them. They shall not form part of the Contract or have any contractual force.
- 2.5 These Conditions apply to the Contract to the exclusion of any other terms that the Client seeks to impose or incorporate, or which are implied by trade, custom, practice or course of dealing.
- 2.6 Where the Client and Butterworth have entered into a contract in writing signed by the Client and Butterworth and that contract governs the supply of Services as part of an ongoing arrangement for the provision of services by Butterworth and has not terminated or expired, then the terms of that contract shall apply to the exclusion of these Conditions save where that contract expressly adopts these Conditions, whether with or without variation, in which case these Conditions shall apply subject to such variation (if any).
- 2.7 Any Quotation given by Butterworth is only valid for the period stated on the Quotation.
- 2.8 Butterworth shall make all reasonable efforts to supply the Services by any provisional completion date but Butterworth do not guarantee such a date, which is given by way of estimate only. Time shall not be of the essence of the Contract in relation to the performance of the Services.

3 CONFIDENTIALITY

- 3.1 Subject to any independent formal and written confidentiality agreement entered into by the parties and condition 3.2:
 - 3.1.1 each party undertakes that it shall not at any time disclose to any person any confidential information concerning the business, products, processes, trade secrets, know how, finances, affairs, customers, clients or suppliers of the other party;
 - 3.1.2 the Client agrees to treat the Report as confidential and not to make it public nor disclose it to any third party without Butterworth's consent, save to the extent that disclosure is made to those third parties referred to in condition 13.4 (provided that the Client requests that those third parties treat the Report as confidential).
- 3.2 Each party may disclose the other party's confidential information:

- 3.2.1 to its employees, officers, representatives, subcontractors or advisers who need to know such information for the purposes of carrying out the party's obligations under the Contract. Each party shall ensure that its employees, officers, representatives, subcontractors or advisers to whom it discloses the other party's confidential information comply with this condition 3; and
- 3.2.2 as may be required by law, a court of competent jurisdiction or any governmental or regulatory authority.
- 3.3 Neither party shall use the other party's confidential information for any purpose other than to perform its obligations or exercise its rights under the Contract.

4 THE ANALYTICAL SERVICES & REPORTS

- 4.1 Contracts to perform Services are accepted by Butterworth on the basis that full disclosure is made by the Client of all information and documentation which may affect Butterworth's ability to correctly perform the Services in a safe manner and that Butterworth will not be liable to the Client for any delay, failure to perform or for defective Services unless such full disclosure has been made.
- 4.2 If the results of the Services are to be used for litigation or possible litigation this must be made known to Butterworth when requesting a Quotation. Butterworth employees will not act as expert witnesses, nor enter into discussions nor offer opinions on the application or consequence of the results provided in the supply of the Services.
- 4.3 If the Client requires Butterworth to perform the Services in a shorter time than that specified in the Quotation, it is the responsibility of the Client to negotiate whether this is possible with Butterworth. If Butterworth (in its absolute discretion) agrees a shorter time Butterworth will issue a revised Quotation to incorporate the changes to the Services. The Client should not assume such revision can be accommodated without accepting the revised Quotation.
- 4.4 The Client must inform Butterworth of hazards of any kind relating to Samples when requesting a Quotation. Samples submitted should be labelled with the appropriate hazard labels and safety data sheets; failure to do so may result in a delay in the start of Services and an additional handling charge.
- 4.5 Where hazards are not universally known as inherent in the Sample or advised in writing to Butterworth prior to the issue of the Quotation, Butterworth may raise an additional charge for handling or disposing of any Sample as appropriate.
- 4.6 Work carried out by Butterworth will be in accordance with the description set out in the Quotation and Butterworth shall be entitled to test any Samples to destruction. All Samples remaining following analysis will be disposed of by Butterworth no earlier than one month following the date of the Report. If requested in writing, all Samples remaining after analysis will be returned by courier and charged to the Client at cost plus Butterworth's standard administration charge in force at that time.
- 4.7 Any Report issued by Butterworth will be factual and will relate only to the Samples in respect of which the Services have been performed and not to the bulk from which the Samples analysed may have been selected. All results reported will relate to the Samples on an 'as received' basis, unless otherwise instructed in writing, or documented in an agreed methodology.
- 4.8 The Client is responsible for the transportation and delivery of Samples to Butterworth and Butterworth accept no responsibility for Samples received in a condition which may affect the Services or the results or outcome contained in any Report. If any Sample is received in a damaged condition, Butterworth reserve the right to charge for the time taken to dispose of the Sample in a safe manner.
- 4.9 Butterworth reserves the right to withdraw provision of the Services to the Client after their acceptance of a Quotation but prior to commencement of the Services, in which case Butterworth will (save as provided by condition 4.5) at its own cost return any Samples to the Client and neither party will have a claim against the other.

5 QUALITY ASSURANCE, METHODOLOGY AND ARCHIVING

- 5.1 Unless stated otherwise in the Quotation, Butterworth shall perform the Services in compliance with its Quality Management System (details of which are available on request).
- 5.2 Requirements for the Service to be performed to any specific regulations or standards must be requested by the Client at the time of requesting a Quotation
- 5.3 Methods forming part of Butterworth's ISO17025 Accreditation Schedule which are to apply to the Services will be clearly indicated in the Quotation.
- 5.4 Applicable administration charges associated with Services performed in compliance with GCP or GLP will be detailed in the Quotation.
- 5.5 Butterworth shall be entitled to charge for additional work, whether at the Client's request or not, which is carried out:
 - 5.5.1 in performing investigations in respect of results which are out of specification, out of trend or unexpected; and/or
 - 5.5.2 in repeating analysis of a Samplein each instance where such additional work is a consequence of a defective, incorrect or out of specification Sample or incorrect information supplied by the Client.
- 5.6 Butterworth are not responsible for final release or acceptance of any products based upon any Service(s) provided by Butterworth and Butterworth does not provide the services of a Qualified Person (QP). It is the responsibility of the Client to ensure that the Service(s) meet the Client's quality and compliance requirements including any needed for manufacturing or marketing authorisations.

5.7 The test specific Raw Data, or in the case of electronically generated records, certified hard copies, will be sent to the Client with the Report. Electronic Raw Data and electronic copies of Raw Data and certified copies will be stored in Butterworth's archives in accordance with Butterworth's archiving policy, after which they will be destroyed.

6 INVOICE AND PAYMENT

- 6.1 In the case of supplying the Client with the Service(s) for the first time and in cases where Butterworth considers the Client to be a credit risk or which has a late payment history, Butterworth reserves the right to require payment in advance. In this case an Advance Payment Invoice will be submitted to the Client before the Service(s) are commenced. The Report will not be issued until the Advance Payment Invoice has been paid.
- 6.2 In all cases not falling within condition 6.1 and subject to condition 6.12 Butterworth will submit an invoice to the Client in respect of the Service(s) on completion of the Service(s).
- 6.3 For invoices submitted by Butterworth in accordance with conditions 6.2 or 6.12 the Client shall pay the invoice no later than the end of the month following the month in which the invoice is dated, or such other date as specified in the Quotation.
- 6.4 All amounts payable by the Client under the Contract are exclusive of amounts in respect of value added tax chargeable for the time being (VAT). Where any taxable supply for VAT purposes is made under the Contract by Butterworth to the Client, the Client shall, on receipt of a valid VAT invoice from Butterworth, pay to Butterworth such additional amounts in respect of VAT as are chargeable on the supply of the Services at the same time as payment is due for the supply of the Services.
- 6.5 If the Client fails to make any payment due to Butterworth under the Contract by the due date for payment, then the Client shall pay interest on the overdue amount at the rate of 4% per cent per annum above Bank of England's base rate from time to time. Such interest shall accrue on a daily basis from the due date until actual payment of the overdue amount, whether before or after judgment. The Client shall pay the interest together with the overdue amount.
- 6.6 The Client shall pay all amounts due under the Contract in full without any set-off, counterclaim, deduction or withholding (except for any deduction or withholding required by law).
- 6.7 If the Client requests any change in the specification of the Service(s) or any additional Service(s) and Butterworth agrees to such changed or additional Service(s) being supplied, those Service(s) will be invoiced at Butterworth's then current standard charges unless they have been the subject of a further Quotation.
- 6.8 Additional Services including (but not limited to) further copies of the Report, or Raw Data, will be subject to an additional charge as detailed in a separate Quotation.
- 6.9 Butterworth reserves the right to make an appropriate charge to the Client for Service(s) which are cancelled by the Client after receipt of Samples, for whatever reason.
- 6.10 All payments by the Client shall be in £ GBP, unless payment in € Euro or \$ USD has been previously agreed in writing by Butterworth or where the Quotation is in such currency. Payment shall be by way of electronic funds transfer to such account as Butterworth may notify the Client.
- 6.11 If the Client pays any amount to Butterworth without apportioning it between specific debts or liabilities it shall be apportioned as Butterworth thinks fit.
- 6.12 In instances where the Services may take longer than one month to complete, Butterworth shall have the right to produce interim invoices either after the completion of a distinct phase of the work or at the end of each month and calculated on a work performed basis.
- 6.13 Butterworth reserves the right to withhold Reports and to discontinue provision of the Service(s) at any time or during any period during which any amounts are owed by the Client to Butterworth and are overdue. Butterworth accept no responsibility for the consequences of withholding Reports or discontinuing work in such circumstances.
- 6.14 Butterworth shall provide such co-operation and assistance to the Client as Butterworth in its absolute discretion considers reasonable in matters relating to the Service(s), the Reports and Raw Data up to 30 days after completion of the Service(s), but otherwise Butterworth reserves the right to charge for any additional consultation which will be subject to its current standard charges in force from time to time or otherwise agreed with the Client in writing.

7 LIABILITIES

- 7.1 Nothing in the Contract shall limit or exclude either party's liability for:
- 7.1.1 death or personal injury caused by its negligence, or the negligence of its employees, agents or subcontractors;
 - 7.1.2 fraud or fraudulent misrepresentation; or
 - 7.1.3 breach of the terms implied by section 2 of the Supply of Goods and Services Act 1982 (title and quiet possession) or any other liability which cannot be limited or excluded by applicable law.
- 7.2 Subject to condition 7.1, Butterworth shall not be liable to the Client, whether in contract, tort (including negligence), for breach of statutory duty, or otherwise, arising under or in connection with the Contract for:
- 7.2.1 loss of profits;
 - 7.2.2 loss of sales or business;
 - 7.2.3 loss of use or corruption of software, data or information;
 - 7.2.4 loss or damage to goodwill; and
 - 7.2.5 any indirect or consequential loss.
- 7.3 Subject to condition 7.1 and 7.7, each party's total liability to the other, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, arising under or in connection with the Contract shall be limited to £1,000,000.

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- 7.4 The terms implied by sections 3 to 5 of the Supply of Goods and Services Act 1982 are, to the fullest extent permitted by law, excluded from the Contract.
- 7.5 Butterworth shall not be liable for any costs or losses sustained or incurred by the Client arising directly or indirectly from Butterworth's failure or delay in providing the Services, where such failure or delay is caused by the Client's failure to perform any of its obligations under the Contract.
- 7.6 The Client shall indemnify and hold Butterworth harmless from any and all losses, claims, actions, damages, liabilities, costs and expenses, (including reasonable legal fees and court costs) (collectively "Losses") that arise as a result of:
- 7.6.1 the Client supplying incomplete, inaccurate or incorrect information concerning the Sample;
 - 7.6.2 any use of Samples, where full disclosure of all information and documentation referred to in condition 4.1 has not been made which may affect such use;
 - 7.6.3 any Sample received by Butterworth from or at the direction of the Client which is not clearly labelled with the correct hazardous nature of the Sample or accompanied by a Safety Data Sheet (SDS).
- 7.7 The indemnity in condition 7.6 shall:
- 7.7.1 not be subject to the terms of condition 7.3; and
 - 7.7.2 include (without limitation) any losses incurred because Butterworth is obliged (or it is otherwise prudent) to quarantine or shut down part or the whole of its premises or curtail normal operations or the use of any instrumentation as a result of the circumstances referred to in condition 7.6.1 to 7.6.3.
- 7.8 This condition 7 shall survive termination of the Contract.

8 DEFECTS AND TIME LIMITS

- 8.1 Butterworth's policy is to retain Samples for no longer than one month after completion of the Services. Accordingly the Client agrees to give Butterworth notice of any defects in the Services in writing within one month after completion of the Services or as soon as is reasonably practicable after it becomes aware of any such defects.

9 FORCE MAJEURE

- 9.1 Neither party shall be liable for any delay in performing or for failure to perform its obligations under the Contract if the delay or failure results from any cause or circumstance whatsoever beyond its reasonable control, (hereinafter "event of force majeure"), provided the same arises without the fault or negligence of such party. If an event of force majeure occurs, the date(s) for performance of the obligation affected shall be postponed for as long as is made necessary by the event of force majeure, provided that if any event of force majeure continues for a period of or exceeding three (3) months, either party shall have the right to terminate the Contract forthwith by written notice to the other party. Each Party shall use its reasonable endeavours to minimise the effects of any event of force majeure.

10 TERMINATION

- 10.1 Should the Client make default in any payment due to Butterworth or otherwise be in breach of its obligations under these Conditions or under any other contract with Butterworth or compound with or execute an assignment for the benefit of its creditors or commit any act of bankruptcy or being a company enter into voluntary or compulsory liquidation or suffer a receiver, administrative receiver or administrator to be appointed over all or any part of its assets or take or suffer any similar action in consequence of debt or become insolvent or should Butterworth have reasonable cause to believe that any of these events is likely to occur, Butterworth may, by notice in writing to the Client and without prejudice to any other rights forthwith suspend or cancel the whole or part of the Services or require payment in advance or satisfactory security for further delivery of the Services or otherwise terminate the Contract with immediate effect.
- 10.2 On termination of the Contract:
- 10.2.1 the Client shall immediately pay to Butterworth all of its outstanding unpaid invoices and interest and, in respect of Services supplied but for which no invoice has been submitted, Butterworth shall submit an invoice, which shall be payable by the Client immediately on receipt;
 - 10.2.2 the accrued rights, remedies, obligations and liabilities of the parties as at expiry or termination shall not be affected, including the right to claim damages in respect of any breach of the Contract which existed at or before the date of termination or expiry; and
 - 10.2.3 conditions which expressly or by implication have effect after termination shall continue in full force and effect.

11 DATA PROTECTION

- 11.1 In the course of its dealings with clients, Butterworth receives and processes information about Clients including:
- 11.1.1 contact details of the Client;
 - 11.1.2 credit references;
 - 11.1.3 name and contact details of the person requesting the Services;
 - 11.1.4 details of the Client's requirements for the Services.
- 11.2 All such information will be retained in confidence (subject to condition 3.2) and will only be used for the following purposes:
- 11.2.1 for proper performance of the Services and exercising Butterworth's rights under the Contract;
 - 11.2.2 to assess whether and how the Services be provided and at what cost;
 - 11.2.3 to report to the Client on the Services;
 - 11.2.4 to forward to the Client information regarding services provided by Butterworth and general marketing material;

- 11.2.5 to share the information with associated and group companies and professional advisers for administrative purposes;
- 11.2.6 disclosure to a transferee (or proposed transferee) of the whole or a material part of Butterworth's business;
- 11.2.7 to retain a record of the supply of the Services; and
- 11.2.8 to comply with any law or regulatory requirement.

In consenting to these terms the Client consents to this use of such information.

- 11.3 In all other respects the information will not be shared without the Client's prior consent unless required or permitted by law.
- 11.4 Butterworth's full Privacy Policy (which may otherwise be referred to as a Privacy Statement) can be found on the website: www.butterworth-labs.co.uk/company-privacy-policy/.

12 LAW AND JURISDICTION

- 12.1 The Contract, and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by, and construed in accordance with the law of England and Wales.
- 12.2 Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with the Contract or its subject matter or formation.

13 INTELLECTUAL PROPERTY

- 13.1 In relation to the Client Materials, the Client:
 - 13.1.1 and its licensors shall retain ownership of all Intellectual Property Rights in the Client Materials; and
 - 13.1.2 grants Butterworth a fully paid-up, non-exclusive, royalty-free, non-transferable, revocable, limited licence to copy and modify the Client Materials for the term of the Contract solely for the purpose of providing the Services and associated Report to the Client. The Client warrants that the receipt and use of the Client Materials in the performance of the Contract by Butterworth, its agents, subcontractors or consultants shall not infringe the rights, including any Intellectual Property Rights, of any third party.
- 13.2 All Intellectual Property Rights in the Report, any development or method conceived or reduced to practice by Butterworth, written statements and other information provided by Butterworth in connection with the Services (other than the Client Materials) shall be owned by Client.
- 13.3 Butterworth name and logos are trademarked and therefore cannot be used or reproduced without permission
- 13.4 The Client agrees not to publish any Report or results without Butterworth's written consent, which will not be unreasonably withheld.

14 NOTICES

- 14.1 Any notice or other communication given to a party under or in connection with the Contract shall be in writing, addressed to that party at its address stated in the Quotation, in the Order (in the case of the Client) or registered office (if applicable) or such other address as that party may have specified to the other party in writing in accordance with this condition 14, and shall be delivered personally, or sent by pre-paid first class post or other next working day delivery service, commercial courier, fax or email.
- 14.2 A notice or other communication shall be deemed to have been received: if delivered personally, when left at the address referred to in condition 14.1; if sent by pre-paid first class post or other next working day delivery service, at 10.00 am on the second Business Day after posting; if delivered by commercial courier, on the date and at the time that the courier's delivery receipt is signed; or, if sent by fax or email, one Business Day after transmission.
- 14.3 The provisions of this condition 14 shall not apply to the service of any proceedings or other documents in any legal action.

15 ASSIGNMENT & SUBCONTRACTING

- 15.1 The Client shall not, without the prior written consent of Butterworth, assign, transfer, mortgage, charge, subcontract, declare a trust over or deal in any other manner with any or all of its rights or obligations under the Contract.
- 15.2 Butterworth will notify the Client in advance if the whole or any part of the Services is to be sub-contracted by Butterworth.

16 MISCELLANEOUS

- 16.1 Under no circumstances will any terms introduced by the Client (whether in the Order or otherwise) take priority over these Conditions unless Butterworth agrees in writing.
- 16.2 The failure by Butterworth to enforce at any time any one or more of these Conditions shall not amount to a waiver by Butterworth of its right subsequently to enforce such Conditions.
- 16.3 The Contract does not give rise to any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of the Contract.
- 16.4 If any provision of these Conditions is declared by any judicial or other competent authority to be voidable, illegal or otherwise unenforceable this shall not affect the remaining Conditions, which shall continue in full force and effect. Any such provisions as shall be declared to be voidable, illegal or otherwise unenforceable shall be amended so that the amended provision achieves the intention of the parties.
- 16.5 No variation of the Contract shall be effective unless it is in writing and signed by the parties (or their authorised representatives).

APPENDIX – B

GLOSSARY OF TERMS AND ABBREVIATIONS

Below are terms and abbreviations used within this Services Agreement. A full Glossary of Terms employed by Butterworth can be supplied upon request.

Accreditation	Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.
Accuracy	The accuracy of an analytical Method is the closeness of test results obtained by that Method to the true value. Accuracy is a measure of the exactness of the analytical Method.
Analysis	The process, using both physical and chemical techniques, used to identify components of a Material, to identify proportions of those components and/or their concentrations.
Analytical Data	The Raw Data produced from the analysis of Samples.
Analytical Equipment	A piece of scientific apparatus used in the analysis of Samples.
Analytical Instrument	A piece of Analytical Equipment used for the analysis of Samples and which produces, collects and/or manipulates Analytical Data.
API	Active Pharmaceutical Ingredient
Archive	Records retained specifically by an appointed Archivist; See Record Retention
Associated Companies	Any holding or intermediate holding Company and any Company over which control is exercised (either alone or in conjunction with any connected person) within the meaning of Section 840 of the Income and Corporation Taxes Act 1988.
Business Day	has the meaning given in Butterworth's Terms and Conditions.
Butterworth Terms & Conditions	means the terms and conditions contained in Appendix A.
Calibration	The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements.
Call-off Contract	A contract for the provision of the Services by Butterworth in accordance with clause 2.1.1.
Certificate of Analysis (CofA)	A type of Report containing the results of the scientific tests carried out on Sample(s) and where specifications have been set, compliance or otherwise to those limits.
Certified Copy	A paper or electronic copy of the original record that has been verified (eg by a dated signature) or has been generated through a validated process to produce an exact copy having all the same attributes and information as the original.
Change Control	A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect the validated status of facilities, systems, Analytical Instruments/Equipment or processes.
Clinical Trial	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms Clinical Trial and Clinical Study are synonymous.

Complaint	Where either Party formally and in writing claims that the conduct by the other Party does not meet the required level of adherence to any Agreement, Contract or agreed Terms & Conditions, or where the other Party has not acted in an acceptable and professional manner. A Complaint may also be made by a Third Party against the conduct of either the Client or Butterworth.
Data Integrity	The extent to which all Analytical Data is complete, consistent and accurate throughout the data life cycle.
Data Pack	The Original analytical Raw Data and Certified Copies relating to the services detailed in the accompanying Report. Data Packs may also contain supporting records such as documentation detailing OOS Investigations and NCW's.
Design Qualification (DQ)	The documented verification that the proposed design of the facilities, systems and Analytical Equipment is suitable for the intended purpose.
Deviation	A departure, either intentional (Planned) or unintentional (Unplanned), from an agreed Method, procedure or protocol. A type of NCW.
FDA	Food and Drug Administration (USA).
GCP	Good Clinical Practice, as laid down in Regulation EU No. 536/2014..
GLP	The principles of Good Laboratory Practice in accordance with The Good Laboratory Practice Regulations 1999 (Statutory Instrument 1999 No. 3106) which are based on the Good Laboratory Practice Principles set out in Section II of Annex I to the European Parliament and Council Directive 2004/10/EC.
GMO	Genetically modified organism.
GMP	The principles of Good Manufacturing Practice as laid down in EU Commission Directive 2003/94/EC and also 21 CFR Parts 210 and 211 in respect of medicinal products for human use and investigational medicinal products for human use.
Health & Safety (H&S)	Those aspects of the Health & Safety at Work Act 1974, the Management of Health & Safety at Work Regulations 1999, and all other associated legislation which remains effective and relevant, as they relate to Butterworth.
ICH Guidelines	Guidelines of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.
Installation Qualification (IQ)	The documented verification that new or modified systems and Analytical Equipment have been installed correctly and safely in accordance with the requirements and specifications.
Material	A general term used to denote Reagents, Raw Materials, process aids, intermediates, API's, finished products, packaging and labelling materials.
Method	A detailed description of the process to be followed to perform an Analysis of Samples. These may be in the form of in-house developed methods prefixed with the letters BLM, methods supplied by clients or those published by internationally recognised bodies such as the BP, EP, USP, JP, BSi and AOAC.
Method Validation	The documented process demonstrating that a method is fit for its intended purpose i.e: it operates within established parameters and can perform effectively and reproducibly to test a material to predetermined specifications and quality attributes.
MHRA	Medicines and Healthcare products Regulatory Agency.
Month	A calendar month.
MSDQ	Material Safety Data Questionnaire.

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MSDS	Material Safety Data Sheet.
Non-Conforming Result	Where a result does not fit a trend or the value expected by the Client, but is not OOS.
Non-Conforming Work (NCW)	Work not carried out to the specified or agreed method, procedure, policy, agreement or plan/protocol.
Out of Specification (OOS)	Any Result that falls outside the defined specification or acceptance criteria for the material tested. This term refers to results for the chemical testing of raw materials, API's, in-process materials and finished drug products related to manufacture of registered drugs in order to meet current GMP requirements only.
Out of Trend Result	A type of Non-Conforming Result.
Operational Qualification (OQ)	The documented verification that the facilities, systems and Analytical Equipment, as installed or modified, perform as intended throughout the anticipated operating ranges.
Party	Either one of the Client or Butterworth.
Planned Deviations	A change that has been considered and approved by the relevant party before implementation.
Performance Qualification (PQ)	The documented verification that the facilities, systems and Analytical Instruments/Equipment, as connected together, can perform effectively and be replicated, based on the approved process method.
Purchase Order	A document, uniquely identified, used to approve, track and process purchased products/services.
Quality Assurance (QA)	QA describes the overall measures that Butterworth uses to ensure the quality of its operations.
Quality Control (QC)	The operational techniques and activities that are used to fulfil requirements for quality.
Qualified Person (QP)	A person defined in Article 48 of Directive 2001/83/EC or Article 52 of Directive 2001/82/EC.
Quality Management System (QMS)	Butterworth's system of documented policies, programmes, procedures and instructions to assure the quality of the Services provided. The QMS incorporates the requirements of the GLP, GCP and GMP regulations along with those for ISO17025.
Quotation	has the meaning given in Butterworth's Terms and Conditions.
Raw Data	Original records and documentation, which are the result of the original observations and activities relating to the test result. This may be in the format of hand written notes and calculations, instrument print-outs or in the form of electronic records.
Raw Material	A general term used to denote, reagents and excipients intended for use in the production of finished products, intermediates or API's.
Reagent	Any Material used during analysis other than a Sample or a Reference Material/Standard.
Reference Material/Standard	Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the Calibration of equipment, the assessment of a Method's performance, or for assigning values to Materials.
Regulatory Authority/Regulator	A government agency or other entity, that exercises a legal right to control the use or sale of products within its jurisdiction, and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.
Regulatory Status	Registration status with a Regulator or the holding of any licence or authorisation from a Regulator.

Report	An authorised document containing results and outcomes relating to the Service(s) provided. Reports may be in the form of a Certificate of Analysis, a validation report or otherwise.
Record Retention	The controlled and secure storage of records. Their maintenance and storage ensures their recovery in a readable format throughout the Retention Period. Only documents supporting GLP compliant work need to be specifically controlled as Archived as these fall directly under the control of an appointed Archivist as defined by the UK GLP Regulations.
Retention Period	A period of time for which records and materials are to be retained. Unless specified and agreed, items may be retained beyond the defined retention period where there are benefits to do so.
Risk Assessment	The assessment of the level of risk associated with a practice or procedure. Hazards may be present but if sufficiently controlled they may present little or low risk.
Sample(s)	has the meaning given in Butterworth's Terms and Conditions.
SDS	Safety Data Sheet.
Service(s)	has the meaning given in Butterworth's Terms and Conditions.
Site	As defined in Appendix D for both Parties.
SOPs	Written and approved Standard Operating Procedures which describe how to perform certain activities.
Tests	Shall mean the Method used by Butterworth to perform an Analysis on Sample(s).
Third Party	Any person other than the Parties to this Agreement.
Traceability	Property of the result of a measurement or the value of a Reference Material/Standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.
Unplanned Deviation	A change or event that is not planned or anticipated and where no prior approval has been provided by the relevant party.
UKAS Accreditation	Accreditation by United Kingdom Accreditation Service (UKAS) to BS EN ISO/IEC 17025.
Validation	A documented programme that provides a high degree of assurance that a specific process, Method or system will consistently produce a result meeting predetermined acceptance criteria.
Validation protocol	A written plan stating how validation will be conducted and defining acceptance criteria.

APPENDIX C

KEY CONTACTS

All duly authorised or appointed representatives should be listed below:

Butterworth Details:

Managing Director	David Hawkins	david.hawkins@butterworth-labs.co.uk
Technical Director	David Riches	david.riches@butterworth-labs.co.uk
Associate Director - Business Operations	John Welch	john.welch@butterworth-labs.co.uk
Head of Projects	Rebecca Dodds	Rebecca.dodds@butterworth-labs.co.uk
Head of Quality Assurance	Stuart Davey	stuart.davey@butterworth-labs.co.uk

Service Agreement. Reference No:

Analytical Operations Manager	Craig McConville	Craig.mcconville@butterworth-labs.co.uk

Client Details:

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APPENDIX D

SITE DETAILS

Butterworth Laboratories Ltd Sites	
Main Site and Laboratory Facilities: 54 – 56 Waldegrave Road Teddington Middlesex TW11 8NY	Archive Facility: Unit 10 Castle Business Mews Hampton Middlesex TW11 2BX
Administration Facility: First Floor No 14 Castle Mews Hampton Middlesex TW12 2NP	

Client Division Details

		(Client)	

Service Agreement. Reference No:

APPENDIX E SCOPE OF WORK APPROVED

Butterworth have been approved by the Client to carry out the following types of testing:

- Chemical Analysis of Raw Materials and API's to Pharmacopoeia Monograph methods.
- Chemical Analysis of Raw Materials and API's to the Client's supplied Methods.
- Chemical Analysis of Raw Materials and API's to the Contract Acceptor's Documented and Validated in-house methods.

APPENDIX F LICENCE DETAILS

Where Butterworth is named on the Client's Marketing Authorisations details should be listed below: