



Company Information

Send Report To:	Send Invoice To: <input type="checkbox"/> Same as report (Refer to Terms & Conditions attached.)
Attn:	Attn:
Company:	Company:
Address:	Address:
Phone:	Quote Number:
E-mail:	Purchase Order Number:

Service and Sample Handling Instructions

<u>Services</u> (Turn Around Time and Data)	<u>Type of Sample</u>	<u>Storage Conditions</u>	<u>Special Handling</u>	<u>Controlled Substance</u>
<input type="checkbox"/> Standard <input type="checkbox"/> Rush ^{1,2} Date Needed: _____ <input type="checkbox"/> <u>Include Raw Data</u> ¹	<input type="checkbox"/> Raw Material <input type="checkbox"/> Plate/Microbial ID <input type="checkbox"/> Drug Product <input type="checkbox"/> Other _____ <input type="checkbox"/> Stability	<input type="checkbox"/> Room Temperature <input type="checkbox"/> Refrigeration <input type="checkbox"/> -20°C Freezer <input type="checkbox"/> -80°C Freezer <input type="checkbox"/> Other	<input type="checkbox"/> Normal <input type="checkbox"/> Hazardous <input type="checkbox"/> Light Sensitive <input type="checkbox"/> Other	CIRCLE CLASS: I II III IV V REGISTRATION NUMBER: (Required):

Sample and Testing Information

PRODUCT NAME/ DESCRIPTION (All information here is as it will appear on the CoA/Report)		Number Supplied	LOT NUMBER
TEST	METHOD*	CLAIM*	SPECIFICATION*
*Not needed if reference document (i.e. specification or method) that has all of the information entered here Or give previous project number (only if all parameters are identical): _____			
General Comments:			
Completed by:		Date:	
Samples Shipped by (only if need chain of custody):		Date:	
Samples Received by:		Date:	

¹ Various Surcharges May Apply

² Prior notice is required



BOSTON ANALYTICAL, INC.

STABILITY STUDY PROTOCOL FORM

PRODUCT NAME		STRENGTH	
LOT NUMBER		PACKAGE SIZE	

NOTE: please indicate the number of samples to be pulled at each time interval that is listed for each condition.

Storage Conditions	Package Configuration ¹	Intervals (hours, days, months) ²											Extra	Total for Each condition ⁵
25°C/60%RH														
30°C/65%RH														
40°C/75%RH														
5°C														
-20°C														
-80°C														
Photostability ³														
Totals ⁴														

¹ Package Configuration: Type of packaging the sample is sent in. (e.g. blisters, bottles, tubes, etc.) and what position to store in (upright, inverted, unspecified, sideways, etc.)

² Intervals: Enter type of intervals needed for stability. (e.g. Initial, 1M, 2M, 3M, 6M, etc.) Please indicate number of samples to be pulled for appropriate condition(s) at each interval.

³ Photostability: ICH Option 2. Study is performed by exposure to not less than 1.2 Million lux hours and integrated near ultraviolet energy of not less than 200 watt hours/ square meter.

⁴ Totals: Total number of samples needed for each interval, all conditions.

⁵ Total for each condition: Total number of samples to be stored at each condition for the study

Note: If not all tests requested are required for each interval, please specify what tests are required for which intervals (e.g. Assay, Dissolution, Related Compounds, Microbiological testing, etc.)



Standard Terms and Conditions – Boston Analytical, Inc.

GENERAL

All Services to be provided by Boston Analytical, Inc., hereinafter referred to as BA, will be governed by these Terms and Conditions (T&C) as varied by any special T&C agreed to by BA in writing (Special T&C).

SERVICES

In these T&C "Services" means pharmaceutical product testing, environmental monitoring services, extractable & leachable testing or any other services provided by BA. BA will provide the Services using reasonable care and skill, adopting such methods as BA considers appropriate and in accordance with any Special T&C agreed to by BA in writing. The Services will be undertaken in the time period agreed to between BA and the Customer and in the absence of agreement within a reasonable time. BA will not be liable for any delay in providing the Services.

OBLIGATIONS OF THE CUSTOMER

To enable BA to provide the Services, the Customer will ensure that adequate quantities of the samples and materials are provided in a safe condition. Ensure that sufficient information, instructions and documentation is provided; where appropriate provide safe and secure access to the site and access to the Customer's representatives; inform BA in advance of any hazard or danger, actual or potential associated with any samples or testing; immediately inform BA of any change that could affect the provision of the Services or the safety of its personnel.

FEES AND PAYMENT

The Customer will pay the fees agreed between the Customer and BA for the Services. If the parties have not agreed on the fee payable for the Services then the Customer will pay BA's standard fees for the provision of the Services. The fees will be paid within thirty calendar days of the date of Boston Analytical Inc.'s invoice for the Services. Fees will be paid without deduction, set off or counter claim and the Customer cannot retain or defer payment on account of any dispute with BA. If the Customer fails to pay any fees when due, BA may: charge interest at the rate of 1.5% per month calculated on a daily basis for any fees or part of fees outstanding at the due date for payment; commence proceedings for the collection of unpaid fees and the Customer will be liable for all costs incurred by BA (including all legal costs on an attorney – client basis); require that part or all of the fees be paid in advance of providing the Services; cease providing the Services to the Customer without notice. In the event that any unforeseen circumstances or expenses arise in undertaking the Services, BA will endeavor to inform the Customer of any additional costs incurred by BA by means of a change order.

SAMPLES

BA will and may destroy or otherwise dispose of the samples or return the samples to the Customer (at the Customer's cost) 60 days following analysis of the samples. The Customer acknowledges and accepts that: it is solely responsible for the sampling process and warrants that the sample provided to BA is representative of the lot from which the samples were drawn; and BA expresses no opinion and accepts no liability in respect of the Customer's production process or homogeneity of the sample.

TITLE TO PROPERTY AND REPORTS

BA will retain title to any analysis, results, reports or software produced by BA until all fees have been paid by the Customer. The Customer may only reproduce or publish any report by BA in full without alteration. BA name, logo or service marks, or any other means of identification cannot be used in any publication by the Customer unless the Customer has obtained the prior written consent of BA.

LIMITATION OF LIABILITY

The Customer acknowledges that the Services are provided using the then current state of technology and methods developed and generally applied by BA and involve analysis, interpretations, consulting work and conclusions. BA shall use commercially reasonable degree of care in providing the Services. Reports are issued on the basis of information, documents and/or samples provided by, or on behalf of, the Customer and solely for the benefit of the Customer who is responsible for acting as it sees fit on the basis of such reports. Neither BA nor any of its officers, employees, agents or subcontractors shall be liable to the Customer nor any third party for any actions taken or not taken on the basis of such reports nor for any incorrect results arising from unclear, erroneous, incomplete, misleading or false information provided to BA.

BA shall not be liable for any delayed, partial or total non-performance of the Services arising directly or indirectly from any event outside BA's control including failure by the Customer to comply with any of its obligations hereunder. The liability of BA in respect of any claim for loss, damage or expense of any nature and howsoever arising shall in no circumstances exceed the lesser of an amount equal to 3 times the fee paid in respect of the Service which gives rise to such claim or \$15,000.00. BA shall have no liability for any indirect or consequential loss including, without limitation, loss of production, loss of contracts, loss of profits, loss of business or costs incurred from business interruption, loss of opportunity, loss of goodwill or damage to reputation and cost of product recall (including any losses suffered as a result of distribution of the Customer's products subject of the Services prior to the report being released by BA). It shall further have no liability for any loss, damage or expenses arising from the claims of any third party (including, without limitation, product liability claims) that may be incurred by the Customer. In the event of any claim, the Customer must give written notice to BA within 60 days of discovery of the facts alleged to justify such claim and, in any case, BA shall be discharged from all liability for all claims for loss, damage or expense unless proceedings are brought within six calendar months from: the date of performance by BA of the Service which gives rise to the claim; or the date when the Service should have been completed in the event of any alleged nonperformance. Unless BA explicitly agrees in writing, the Services shall be provided exclusively to the Customer and cannot be relied on by a third party. The Customer will indemnify and hold BA harmless against any and all third party claims relating to the provision of the Services to the Customer. The Customer shall be responsible for and indemnifies BA against all costs, damages, liabilities, and injuries that may be caused to or incurred by BA or its personnel or representatives including on the sampling site, during transportation or in the laboratory by the Customer's sample or by sampling site conditions.

FORCE MAJEURE

If BA is prevented from performing or completing the Services for any cause outside BA's control, including, but not limited to, acts of god, war, terrorist activity or industrial action; electricity outage; failure to obtain permits, licenses or registrations; illness, death or resignation of personnel or failure by Customer to comply with any of its obligations the Customer will pay to BA: the amount of all non-refundable expenses incurred by BA; and a proportion of the fee equal to the proportion of the Services actually carried out (provided that if the Services cannot be performed as a result of an act or omission on the part of the Customer, the Customer will pay the full fee and all expenses incurred by BA, and BA will be relieved of all responsibility whatsoever for the partial or total non-performance of the Services).

MISCELLANEOUS

If any one or more provisions of the T&C are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired. Except as expressly provided in these T&C or the Special T&C, the Customer may not assign or transfer any of its rights without BA's prior written consent. The provisions of the Consumer Guarantees Act 1993 shall not apply to the Services provided by BA to the Customer. The parties acknowledge that BA provides the Services to the Customer as an independent contractor and that this agreement does not create any partnership, agency, employment or fiduciary relationship between BA and the Customer. Any failure by BA to require the Customer to perform any of BA obligations under these T&C or Special T&C shall not constitute a waiver of its right to require performance of that or any other obligation. This agreement is exclusively governed by the laws of the State of New Hampshire and the parties submit to the exclusive jurisdiction of the New Hampshire courts. The T&C may be modified in writing from time to time by BA and the order for Services will be governed by the most recent version of these T&C that are in effect at the time BA accepts the order. Unless BA specifically confirms acceptance in writing, BA will not be bound by any T&C set out in the Customer's purchase order or agreement.