



Company Information

Send Report To:	Send Invoice To: <input type="checkbox"/> Same as report
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/40%RH															
25°C/60%RH															
30°C/65%RH															
40°C/75%RH															
5°C															
25°C															
-10°C to -20°C															
Photostability ³															
Other (specify)															
Totals⁴															

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.)