

# STABILITY SAMPLE SUBMISSION FORM

Section I – Client Contact Information														
Company Name*							Alcami Contact							
Client Contact Name							PO #							
Client Contact Email														
Report Recipient Email (s)*							Proposal #							
Invoice Recipient Email (s)*								Sample						
Invoice Recipient Address							Destination *		Durham	Morris	sville	St. Louis	Wilmington	
	Section II – Product / Material Information													
Product/Material Name	ng strength)*													
Product Phase*		Special Handling*				Hazardous		lous *						
Controlled Substances		DEA #				NDC#								
TAT Requested*	TAT Requested*		If expedited, state TAT in		n business days			Time S	ime Sensitive Sample*					
Reporting of Results*			Ra		v Data Requested*		Sam		e Disposal					
For micro testing only: Batch Size			Fill Volume		Volume									
	Section III – Lot/Batch Information													
					Lot #*									
					Timepoint(s)									
					Orientation									
Test to be Performed		1ethod for testing	Limit / Specificat	tion	Condition									
	(C	(Compendia, TP, etc)			# of Containers									
					Pull date									
					Sample Storage*						<u> </u>			
					Section IV – Testing Selection (select testing below for each sample)									
COMMENTS														
SIGNATURE								DATE						

# **Stability Sample Submission Instructions**

# Incomplete information may cause testing delays.

- Fill out the form completely, including product name, lot number(s), required test(s) and methods, and the number of samples sent. NOTE- All \* sections are required
- Please submit only one material type to be tested per form. Multiple samples of the same material may be included on a single form.
- All sample containers must be appropriately labeled for the protection of office and laboratory personnel.

#### Section I- Client Contact Information

- Client Contact Name- if this differs from who will be receiving the report or if any questions arise, this will be the contact the Alcami representative will reach out to.
- Report Recipient Email (s)- please include all email addresses that the COA and/or raw data is to be sent.
- Proposal #- Please enter the Proposal Number associated with your sample. The Proposal Number is an 8-character code in ABCD1234 format.

#### Section II- Product/Material Information

- Please fill in product information in this section
- Product Phase- if not known, select "Commercial"
- TAT Requested- Select Standard or Expedited. If Expedited, please confirm with your Project Manager that the timeline can be accommodated and fill in the number of business days in which testing needs to be completed.
- Time Sensitive Sample- This is selected if the sample must go on test in a certain amount of time- for example- water testing, cleaning swabs. Please note in the comments how quickly testing must begin (. Additional charges may apply.
- Reporting of Results- Please select from the following
  - Refer to Specification document provided- please attach the specification you would like us to use. NOTE: Alcami will need this submitted each time the product is submitted for testing to ensure we have the correct version of the specification.
  - See Limit/Spec written below- Specifications may be listed in Section III by each test requested.
  - o Refer to Monograph for Limits- Specification is taken from the compendia the sample is tested by.
  - o Report Results- Just results will be reported. Alcami will not assess conformity against a specification.
- Raw data requested- Please select yes or no, an additional charge will apply for raw data.
- Sample Disposal- Samples will be discarded within 1 month from invoice unless client selects for samples to be returned. If return is required, please provide a shipping label and shipping account number. If not provided, samples will be discarded within 1 month from invoice.
- Batch size- Please fill in for Micro testing only. This is required to determine compliance with the compendia. Fill volume- Please fill in for Micro testing only. This is required to determine compliance with the compendia.

## Section III- Lot/Batch Information

- Test to be performed- please list a brief description of the testing- example- Appearance, Assay, Loss on Drying, TAMC/TYMC,
- Method for testing- please list if this is by a compendium (USP, ACS, EP, etc.) or by an Alcami Procedure (please list TP number if known, this is usually found on your proposal or your PM or BD can help you with this information)
- Limit/Spec- The specification is required to release your material. If you do not want the material assessed against a specification, please note FIO. Copies of specifications can be attached to the SSF or you may reference the compendia (USP, EP, etc.).
- Lot #- please fill in the lot number exactly how it is listed on the container and how it should be listed on the COA
- Timepoint- Please list the time point, 3M, 30 day, 6M, 36M, etc.
- Orientation- Upright, Horizontal, Inverted
- Condition- The stability condition the sample is coming from, example 25C/60RH, -20C, 2-8C, 40C/75RH
- Sample Storage- Please check what temperature you would like the sample stored once it is received at Alcami.

## Section IV- Testing Selection

• Please check which tests are to be performed on each sample submitted.

## Please Use the Following Shipping Addresses for Samples:

mi Corporation	Alcami Corporation	Alcami Corporation
: SCU	Attn: SCU	Attn: Tech Center Sample Receipt
Davis Drive	4260 Forest Park Avenue	2320 Scientific Park Drive
e 300 Morrisville, NC 27560	St. Louis, Missouri 63108	Wilmington, NC 28405
:	SCU Davis Drive	SCUAttn: SCUDavis Drive4260 Forest Park Avenue

#### Please submit Purchase Orders to the Following E-mail Address:

PurchaseOrder@alcaminow.com