

Summary Sheet for Sample Testing Results

Name of Company: _____

Model of LC tendered: _____

Section A: Accuracy and Repeatability studies (Sample Set A)**Indicate the following information:**

- (i) Incorporation of an external needle wash in the method (Circle appropriately):
Y/N
- (ii) Pump pressure reading (in bars): _____
- (iii) Response factor of POI: _____
- (iv) Indicate the observed concentration of Controls at 215 nm in table below
- (v) Indicate if peak purity pass with a 'P' and fail with a 'F' in the table below

	ACA	ACB
Set 1 Found (mg/ml)		
Set 2 Found (mg/ml)		
Peak purity of POI (P/F)		
Peak purity of ISTD (P/F)		

- (vi) Tick the boxes if peaks are present in blanks. If peaks are present, indicate the retention time, area under the peak and possible identity of the peak/s (e.g.Caffeine). For Control A and B, tick the boxes only if peaks other than POI and ISTD are seen. If no other peaks are observed, indicate by a 'X'.

Name of Data File	Peak(s) present	If yes, indicate the retention time, area under the peak and possible identity of the peak.
Blank 1		
Blank 2		
Blank 3		
Blank 4		
Blank 5		
ACA-2		
ACB-2		

- (i) With the results obtained from the 3 injections of **Samples A1-4**, use EXCEL to provide the following information below for **Samples A1-4** in mg/ml (at 215 nm).
- (ii) For peak purity of Sample A: Indicate if any injection has peak purity fail for either POI or ISTD with a 'F' in the table below.

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Annex E

Sample	Injection No.	Observed Conc (mg/ml)	Mean (3 s.f)	SD	RSD	Peak purity of POI (F)	Peak purity of ISTD (F)
A1	1						
	2						
	3						
A2	1						
	2						
	3						
A3	1						
	2						
	3						
A4	1						
	2						
	3						

(iii) Indicate the specific parameters for the peak purity calculation:

Any other factors which are crucial to obtaining acceptable peak purity should be indicated under 'Others'

Noise Range : _____
 Correction factor : _____
 Others : _____

Section B: Evaluation of Library Matching Function (Sample Set B)

Indicate the following information:

Peak purity:

Conditions of the alternative method used, if applicable:

Tenderer's criteria for a peak to be spectrally homogenous:

Any post processing done for peak purity: Y/N

Type of post processing carried out for peak purity (if applicable):

Indicate the specific parameters for the peak purity calculation:

Any other factors which are crucial to obtaining acceptable peak purity should be indicated under 'Others'

Noise Range : _____

Correction factor : _____

Others : _____

UV library matching:

Tenderer's criteria for a positive UV library match:

Any post processing for library matching: Y/N

Type of post processing carried out for library matching (if applicable):

Match the peaks in each sample solution to the libraries as specified in each table:

*Note: Peak 1 is the earliest eluting peak

T1	Quality Match Factor (or whichever term is used)		
	L-GEN (Indicate Identity)	L-POI1	L-POI2
Peak 1			
Peak 2			

T2	Quality Match Factor (or whichever term is used)		
	L-GEN (Indicate Identity)	L-POI1	L-POI2
Peak 1			
Peak 2			

T3	Quality Match Factor (or whichever term is used)			
	L-GEN (Indicate Identity)	L-POI3	L-POI4	L-POI5
Peak 1				
Peak 2				
Peak 3				

T4	Quality Match Factor (or whichever term is used)			
	L-GEN (Indicate Identity)	L-POI3	L-POI4	L-POI5
Peak 1				
Peak 2				
Peak 3				