

**Summary Sheet for Sample Testing Results**

Name of Company: \_\_\_\_\_

Model of LC tendered: \_\_\_\_\_

**Section A: Carryover studies (Sample A)**

Composition of washing solvent used: \_\_\_\_\_

Condition of final external needle wash used: \_\_\_\_\_

Tick the boxes if peaks are present in blanks at the specified wavelengths. If peaks are present, indicate the retention time, area under the peak and possible identity of the peak/s (e.g. Caffeine).

If no other peaks are observed, indicate by a 'X'.

**Day 1**

| Name of Data File | Peak(s) present at 215 nm | Peak(s) present at 240nm | If yes, indicate the retention time, area under the peak and possible identity of the peak. |
|-------------------|---------------------------|--------------------------|---------------------------------------------------------------------------------------------|
| Blank 1           |                           |                          |                                                                                             |
| Blank 2           |                           |                          |                                                                                             |
| Blank 3           |                           |                          |                                                                                             |

**Day 2**

| Name of Data File | Peak(s) present at 215 nm | Peak(s) present at 240nm | If yes, indicate the retention time, area under the peak and possible identity of the peak. |
|-------------------|---------------------------|--------------------------|---------------------------------------------------------------------------------------------|
| Blank 1           |                           |                          |                                                                                             |
| Blank 2           |                           |                          |                                                                                             |
| Blank 3           |                           |                          |                                                                                             |

**Day 3**

| <b>Name of Data File</b> | <b>Peak(s) present at 215nm</b> | <b>Peak(s) present at 240nm</b> | <b>If yes, indicate the retention time, area under the peak and possible identity of the peak.</b> |
|--------------------------|---------------------------------|---------------------------------|----------------------------------------------------------------------------------------------------|
| Blank 1                  |                                 |                                 |                                                                                                    |
| Blank 2                  |                                 |                                 |                                                                                                    |
| Blank 3                  |                                 |                                 |                                                                                                    |

**Section B: Accuracy and Repeatability studies (Sample B)****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 215nm and 240 nm in table below
- (v) Indicate if peak homogeneity pass with a 'P' and fail with a 'F' in the table below

|                                | BCA<br>215nm | BCB<br>215nm | BCA<br>240nm | BCB<br>240nm |
|--------------------------------|--------------|--------------|--------------|--------------|
| Set 1 Found (mg/ml)            |              |              |              |              |
| Set 2 Found (mg/ml)            |              |              |              |              |
| Peak homogeneity of POI (P/F)  |              |              |              |              |
| Peak homogeneity of ISTD (P/F) |              |              |              |              |

- (vi) Tick the boxes if peaks are present in blanks at the specified wavelengths. 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 at 215nm | Peak(s) present at 240nm | If yes, indicate the retention time, area under the peak and possible identity of the peak. |
|-------------------|--------------------------|--------------------------|---------------------------------------------------------------------------------------------|
| Blank 1           |                          |                          |                                                                                             |
| Blank 2           |                          |                          |                                                                                             |
| Blank 3           |                          |                          |                                                                                             |
| Blank 4           |                          |                          |                                                                                             |
| BCA-2             |                          |                          |                                                                                             |
| BCB-2             |                          |                          |                                                                                             |

- (i) With the results obtained from the 3 injections of **Samples B1-4**, use EXCEL to provide the following information below for **Samples B1-4** in mg/ml (at 215 nm).
- (ii) For peak homogeneity of Sample B: Indicate if one of the injections has peak homogeneity fail of either POI or ISTD with a 'F' in the table below.

| Sample | Injection No. | Observed Conc (mg/ml) | Mean (3 s.f) | SD | RSD | Peak homogeneity of POI (F) | Peak homogeneity of ISTD (F) |
|--------|---------------|-----------------------|--------------|----|-----|-----------------------------|------------------------------|
| B1     | 1             |                       |              |    |     |                             |                              |
|        | 2             |                       |              |    |     |                             |                              |
|        | 3             |                       |              |    |     |                             |                              |
| B2     | 1             |                       |              |    |     |                             |                              |
|        | 2             |                       |              |    |     |                             |                              |
|        | 3             |                       |              |    |     |                             |                              |
| B3     | 1             |                       |              |    |     |                             |                              |
|        | 2             |                       |              |    |     |                             |                              |
|        | 3             |                       |              |    |     |                             |                              |
| B4     | 1             |                       |              |    |     |                             |                              |
|        | 2             |                       |              |    |     |                             |                              |
|        | 3             |                       |              |    |     |                             |                              |

- (iii) Indicate the specific parameters for the peak homogeneity calculation:

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

Noise Range: \_\_\_\_\_

Correction factor: \_\_\_\_\_

Others: \_\_\_\_\_

**Section C: Evaluation of Peak Homogeneity and Library Matching Capability (Sample C)****Indicate the following information:****Peak homogeneity:**

Conditions of the alternative method used, if applicable:

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

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Any post processing done for peak homogeneity: Y/N

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

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Indicate the specific parameters for the peak homogeneity calculation:

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

Noise Range: \_\_\_\_\_

Correction factor: \_\_\_\_\_

Others: \_\_\_\_\_

**UV library matching:**

Tenderer's criteria for a positive UV library match:

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Any post processing for library matching: Y/N

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

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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 |                                                  |        |        |        |