

LC-MSMS Batch Cover Sheet Rev. 7

Sample Table/Result Table file name \_\_\_\_\_

Inst\_1  Inst\_2

Extraction Analyst \_\_\_\_\_ Sample placement checked by \_\_\_\_\_ Data Processing Analyst \_\_\_\_\_

See reverse and reagent logs for reagent, I.S. and calibrator lot #s.

Date Assay F methanol working stock vials opened \_\_\_\_\_

Record Heat Block Temp if used \_\_\_\_\_ Assay B & D: acceptable range 48-52 °C

Assay F: acceptable range 58 to 62 °C

Note sample set-up exceptions here:

Data Review:

Notes:

Observed Rts of all of Highest Calibrator I.S. peaks verified against S.O.P.

1. Peak Shapes acceptable \_\_\_\_\_

2. RRTs and Rts acceptable \_\_\_\_\_

3. Baselines acceptable \_\_\_\_\_

4. S/N of Low Calibrator acceptable \_\_\_\_\_

5. I.S. Peak areas acceptable \_\_\_\_\_

6. Cal Curve R<sup>2</sup> and % dev. acceptable \_\_\_\_\_

7. MRM ratios acceptable when conc. ≥ LLOQ/cutoff \_\_\_\_\_

8. Check for carryover \_\_\_\_\_

9. All blanks used for Neg QC acceptable \_\_\_\_\_

10. Manual integration performed Y N

11. # of re-injected samples \_\_\_\_\_

12. # of repeated samples \_\_\_\_\_

13. Prevent reporting of results to be RPTd \_\_\_\_\_

14. QC acceptable \_\_\_\_\_ Y N

15. QC Results entered \_\_\_\_\_ Y N

16. Assay X I.S. patient average recorded in  
"MSMS IS Tracking and Events" excel file

17. Assay D low calibrator peak area recorded in  
"MSMS IS Tracking and Events" excel file

18. Batch verified in LIS (except for repeats)  
manually  interface

19. If interface used – Interface results reconciled  
with Repeat Log

20. Batch printed:  to file  hard copy

Record Corrective Actions:

Assay	Material	Lot#	Expiration Date	Check or Substitute
<b>A</b>	Internal Standard			
	Calibrator			
	Saturated Na Borate			
	Extraction solvent			
	1% HCl in MeOH			
	Reconstitution solvent			
<b>B</b>	Internal Standard			
	Calibrator			
<b>C</b>	Internal Standard			
	Calibrator			
	$\beta$ -Glucuronidase			
	Na Acetate buffer pH 5			
<b>D</b>	Internal Standard			
	Calibrator			
	$\beta$ -Glucuronidase			
	Na Acetate buffer pH 5			
<b>D</b>	NH4OH at bench ( <b>record open date</b> )			
	Working MeOH Calibrator stocks			
	Internal Standard			
	10 mol/L KOH			
	SPE cartridges			
	NH4OH in hood ( <b>record open date</b> )			
	SPE Wash 1			
	SPE Elution Solvent			
	Reconstitution solvent			
<b>X</b>	I.S. in MeOH/ZnSO4			
	Calibrator			
<b>QC</b>	Adequate volume for next batches	<b>Must be reconst.</b>		<b>48 hrs before use</b>