

*LOD - limit of detection

**LOQ - limit of quantitation

If a hydrolysis step is required in the assay, the laboratory includes a control (when available) with each batch to evaluate the effectiveness of hydrolysis.

Evidence of Compliance:

- ✓ QC records at defined frequency

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register*. 2003(Jan 24):5232 [42CFR493.1256(d)(3)(ii)].
- 2) Clinical and Laboratory Standards Institute. *Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline*. 2nd ed. CLSI Document C43-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2010.

CHM.16750 Sample Run Order Phase II

A record of sample run order is maintained for review.

NOTE: The run list must include blanks, standards, controls, and patients included in each run and be stored with the results of each batch run.

CHM.16770 Chromatographic Characteristics/Column Performance Phase II

Chromatographic characteristics and column performance are reviewed and approved for each run before results are released.

NOTE: Checks should record testing variables such as flow rate of carrier gas and amount of sample injected and indications of error, including split peaks, doublets, and tailing.

Evidence of Compliance:

- ✓ Records of review and approval

CHM.16800 Carryover Detection Phase II



The laboratory has a process to detect and evaluate potential carryover.

NOTE: No matter what type of injection is used, the process must address criteria for the evaluation of potential carryover from a preceding elevated (high concentration) sample to the following sample in each analytical batch analysis.

Evidence of Compliance:

- ✓ Records of reassessment of samples with potential carryover

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Preliminary Evaluation of Quantitative Medical Laboratory Measurement Procedures*. 4th ed. CLSI guideline EP10. Clinical and Laboratory Standards Institute, Wayne, PA; 2024.
- 2) Society of Forensic Toxicologists/American Academy of Forensic Sciences. *Forensic Toxicology Laboratory Guidelines*. 2002; 8.2.8:13
- 3) Clinical and Laboratory Standards Institute. *Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline*. 2nd ed. CLSI Document C43-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2010.

CHM.16850 Column Verification Phase II

New columns are verified for performance before use.

Evidence of Compliance:

- ✓ Records of column verification

CHM.16950 Column/Detector Monitoring Phase II



The performance of the column and detector is monitored each day of use.

NOTE: Unextracted standards and extracted calibrators or controls typically containing the target compound(s), may be analyzed each day to monitor critical aspects of column performance. Appropriate criteria for evaluating such parameters as retention time, relative retention time, separation of closely eluting compounds of interest, chromatography quality, and detector response should be established and monitored.

Evidence of Compliance:

- ✓ Records for column and detector monitoring

CHM.17050	Gas Leakage - GC	Phase I
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Gas lines and connections are checked for leaks every time tubing or a connection has been manipulated.

Evidence of Compliance:

- ✓ Records of gas line checks

CHM.17100	Reagent Grade	Phase II
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Reagents, solvents and gases are of appropriate grade.

CHM.17150	Limit of Detection/AMR	Phase II
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The limit of detection (sensitivity) and the AMR for quantitative methods have been determined for each procedure.

Evidence of Compliance:

- ✓ Records of limit of detection and AMR determination

REFERENCES

- 1) Clinical and Laboratory Standards Institute. *Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline*. 2nd ed. CLSI Document C43-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2010.

MASS SPECTROMETRY (MS)

Inspector Instructions:

	<ul style="list-style-type: none"> • Sampling of MS policies and procedures • Sampling of calibration and tuning records • Identification criteria compliance
	<ul style="list-style-type: none"> • How does your laboratory identify possible ion-suppression or enhancement?

CHM.18400	Instrument Calibration	Phase II
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The laboratory calibrates the mass spectrometer and reviews calibration records for acceptability.

REFERENCES