

procedure that uses a single calibrator at an appropriate concentration is acceptable. Analyses based on a single point calibration must be controlled by appropriate quality control samples. In addition, inclusion of a negative control (reagent blank) is good laboratory practice.

Evidence of Compliance:

- ✓ Records of calibration/calibration verification

FDT.23330	Column Performance	Phase I
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**The performance of the column is monitored on each day of use.**

NOTE: Good laboratory practice dictates the use of a system to monitor the performance of the GC column. Unextracted standards and extracted calibrators or controls typically containing the target compound(s), may be analyzed on each day of use to monitor critical aspects of GC performance. Criteria for evaluating such parameters as retention time, relative retention time, separation of closely eluting compounds of interest, plates, and chromatography quality should be established and monitored. Records must be retained.

Evidence of Compliance:

- ✓ Records for column monitoring

FDT.23380	Extracted Calibrators	Phase II
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**An appropriate extracted calibrator(s) is analyzed with each batch of samples.**

NOTE: At least one extracted calibrator at the commonly accepted cutoff for single-point calibration, or multiple calibrators above and below the commonly accepted cutoff for multipoint calibration, must be analyzed with each run.

Laboratories may use historical calibrations; however, controls must be run with each batch to verify the calibration. In addition, the laboratory must have a record of the validation of the stability of the calibration.

FDT.23430	Daily QC - GC	Phase II
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Appropriate controls are extracted and analyzed with each batch of samples.

NOTE: See General Quality Control section for specific controls required.

Evidence of Compliance:

- ✓ QC records

FDT.23530	Internal Standard	Phase II
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**Internal standards are used as appropriate.**

NOTE: An internal standard is not required for FDA-cleared/approved kits where an internal standard is not used. For a qualitative assay, the use of an internal standard is appropriate if sample preparation includes an extraction step(s), there is low or variable analyte recovery, and/or an accurate sample injection volume is important.

Evidence of Compliance:

- ✓ Records for use of internal standards **OR** written justification for not using an internal standard in assay

FDT.23730	Test Records	Phase II
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There are records of daily evaluation of the performance of GC columns, auto-injectors, detectors, and maintenance such as septum changes, column clipping, flow rates, etc. including corrective action if performance does not meet requirements.

Evidence of Compliance:

- ✓ Records of evaluation of instrument performance **AND**
- ✓ Records of instrument maintenance when performance exceeds defined limits

FDT.23930 Gas Leakage Phase I



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

FDT.24130 GC Records Phase II

Specimen run order, chromatographic peak shape, and retention time for calibrators, controls and unknowns are recorded and maintained for review.

FDT.24230 Analytical Data Phase I

The analytical data are presented to permit scientific review by the analyst of the data for calibrators, controls and unknowns.

FDT.24330 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 for reassessment of samples with potential carryover

FDT.24380 Reinjection/Reanalysis Phase II



The laboratory defines situations when reinjection or reanalysis are indicated.

MASS SPECTROMETRY (MS)

For requirements on inlet system coupled to the mass spectrometer, see the LC and GC sections

Inspector Instructions:

READ

- Sampling of MS policies and procedures
- Identification criteria compliance