

verified by periodic multipoint calibration verification and AMR verification protocols, a calibration 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.22230 Column Performance

Phase II



The performance of the column is monitored on each day of use.

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

Evidence of Compliance:

- ✓ Records for column monitoring

FDT.22280 Extracted Calibrators

Phase II



An appropriate extracted calibrator(s) is analyzed with each batch of samples.

NOTE: At least one extracted calibrator at the commonly accepted cut-off for single-point calibration, or multiple calibrators above and below the commonly accepted cut-off 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.22330 Daily QC - LC

Phase II

Appropriate controls are extracted and analyzed with each batch of specimens.

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

Evidence of Compliance:

- ✓ QC records

FDT.22430 Internal Standard

Phase II



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.22830 LC Records

Phase II