

Evidence of Compliance:

- ✓ Records of calibration/control materials

FDT.17230 Quality of Calibration Standards**Phase II**

The quality of drug calibration standards is recorded.

NOTE: The laboratory may use manufacturer's certification data for the purity of the drug calibration standards, but must still independently record the quantitative accuracy of any calibrator solutions created from the calibration standard. If manufacturer's certification of purity is not available, then the laboratory must validate the purity by determining if any significant extraneous compounds are present, using the appropriate analytical methods. Minimum requirements would be the analysis of a pure drug standard solution using GC/MS (or the same method used for drug confirmation analysis) to demonstrate that no interfering compounds are present.

Evidence of Compliance:

- ✓ Records of calibration materials

FDT.17330 Calibrator Preparation**Phase II**

If the laboratory prepares calibrators and controls in-house, different sources or lot numbers of drug calibration standards are used (when possible) for the creation of calibrators and controls, or these materials are prepared separately, at minimum.

FDT.17363 Control Matrix**Phase II**

Control material is matrix-matched or validated against the matrix by the laboratory.

NOTE:

1. *Urine: Urine based matrix*
2. *Oral-Fluid: Buffer/preservative solution from the collection device or purified saliva as appropriate*
3. *Hair: Negative hair digest or extract*
4. *Blood: Whole blood, plasma, or serum based matrix, as appropriate*
5. *Other materials may be used if validated by the laboratory and shown to be equivalent to the above*

Evidence of Compliance:

- ✓ Records of validation when differing matrices are used

FDT.17396 Calibrator Matrix**Phase II**

Calibration material is matrix-matched or validated against the matrix by the laboratory.

NOTE:

1. *Urine: Urine based matrix*
2. *Oral-Fluid: Buffer/preservative solution from the collection device or purified saliva as appropriate*
3. *Hair: Negative hair digest or extract*
4. *Blood: Aqueous calibrators when appropriate*
5. *Other materials may be used if validated by the laboratory and shown to be equivalent to the above*

Evidence of Compliance:

- ✓ Records of validation when differing matrices are used