

T2 Typical validation parameters and acceptance criteria

PARAMETER	ACCEPTANCE CRITERIA
Sensitivity	Background signal < 20% lower limit of measuring interval (LLMI)
Matrix Effects	≤15% coefficient of variation (CV)
Carryover	≤ 25% LLMI
LLMI	Trueness < 15% bias; imprecision < 20%; signal to noise ratio > 10
Linearity of calibration	9 to 11 points should be analyzed
Dilution	Recovery/trueness ≤ 15% bias; imprecision ≤ 20%
Impression	≤ 15% CV except LLMI ≤ 20% CV
Blank	< 20% LLMI
Retention Time (RT)	A tolerance of ± 2.5% RT of the analyte to that of internal standard
Recovery	Consistent