Guidance Number 88

Table 1. Suggested Transfer Acceptance Criteria for Assays of Main Components

If the specification is between two limits in the table, the wider criteria of the two should be used. The maximum allowable difference between labs should be set based on method precision, product variability and any historical data available. As always, the criteria suggested in this table should be evaluated against any historical and/or validation data as well as the intended use of the method to ensure that the criteria are appropriate. If the criteria to be used are different than those supplied in Table 1, then appropriate justification should be included in the Transfer Plan. **Reminder:** If commercial lots are used for the transfer, it is recommended to avoid using lots whose most recent results lie near the specification limit.

Product Specification	Maximum Allowable Inter-Laboratory Difference[†] (Absolute)	Within Lab Precision Recommendations
≥99.0%	±0.5%*	RSD ≤ 0.3%
≥98.0%	±1.0%*	RSD ≤ 0.7%
≥97.0%	±1.5%*	RSD ≤ 1.0%
≥95.0%	±2.5%*	RSD ≤ 1.7%
≥90.0%	±3.0%*	RSD ≤ 2.5%

[†] The number of significant figures assigned for the acceptance criteria should be equivalent to the number of significant figures required by the test's specification.

* If the specification or calculations provide results in units other than %LC, the relative differences may be used.

Table 2. Suggested Transfer Acceptance Criteria for Impurities

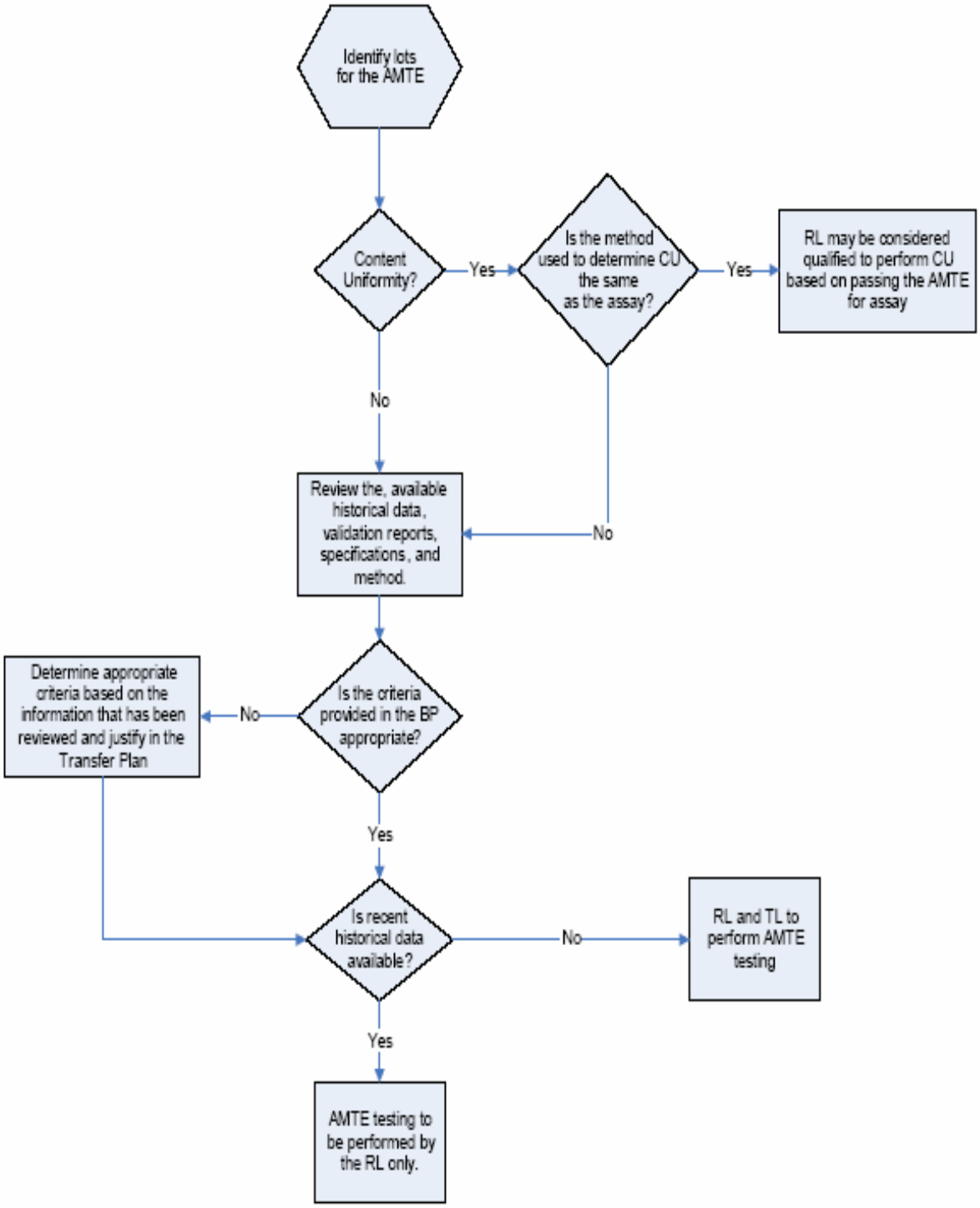
If the specification is between two limits in the table, the wider criteria of the two should be used. The maximum allowable difference between labs should be set based on method precision, product variability and any historical data available. If the criteria to be used are different than those supplied in Table 1, then appropriate justification should be included in the transfer plan. **Reminder:** If commercial lots are used for the transfer, it is recommended to avoid using lots whose most recent results lie near the specification limit..

How to Use This Table: In instances where the amount of an impurity is less than the specification limit, calculate the interlaboratory criteria using the table below. For example, if a lot of material to be used in the transfer has an impurity present at a level of 1.2% and the specification limit is ≤2.0%, then the interlaboratory agreement may be set at ±0.4% (20% of 2.0%). This criterion should be evaluated against any historical and/or validation data available to ensure it is appropriate.

Product Specification	Maximum Allowable Inter-Laboratory Difference[†] (Absolute)	Within Lab Precision Requirements
≤10.0%	± 13% of the expected result	RSD ≤ 5.0%
≤5.0%	± 16% of the expected result	
≤3.0%	± 20% of the expected result	
≤1.0%	± 25% of the expected result	RSD ≤ 10%
≤0.1%	± 40% of the expected result	

[†] The number of significant figures assigned for the acceptance criteria should be equivalent to the number of significant figures required by the test's specification.

APPENDIX I: Assay



APPENDIX II: Impurities