

Successful transfer of the high and low dosage strengths will qualify the RL to test all of the strengths within the bracketed range, provided that the sample preparations for the different strengths are similar.

When identifying the materials to be used for the transfer, the TL will determine if historical data will be used or if comparative data will be generated specifically for the transfer. Historical data is defined as data generated by a qualified laboratory outside the transfer process. Some sources of historical data are stability, certificate of analysis, and validation data. If commercial lots are used for the transfer, it is recommended to avoid using lots whose most recent results lie near the specification limit. This is not a concern for expired, purposely degraded, or development lots.

Establishing Acceptance Criteria

Tables 1 and 2, in conjunction with the recommendations given herein, provide initial guidance for establishing acceptance criteria. When setting the acceptance criteria for any method transfer, it is recommended that the validation documents, the specification limits, and any available stability data be reviewed. The review of stability data, if available, from the lot to be used in the transfer as well as from other lots is important as it may indicate sources of variability other than the method (e.g. product variability) that must be accounted for when establishing the replicate pattern and acceptance criteria.

At the conclusion of the testing, the TL should review the data to ensure that the results not only meet the criteria set in the transfer plan, but they should also ensure that there is not a significant bias in the data (e.g. the RL passes but their results are consistently higher, or lower, and at the criteria limit). If a bias does present itself, it is strongly recommended that an investigation be conducted to ensure that potential long-term issues are minimized.

Replicate and Criteria Setting When Transferring Assay Methods

1. Replicates

For assay testing of a composite sample of a drug product, assay testing of an API, or unit dose testing of reconstituted lyophiles and liquids, a minimum of 6 individual sample preparations/lot should be analysed. For unit dose testing of POS formulations, solid oral drug products, transdermal patches and inhalations packaged in pre-metered dosage units, an analysis of 10 individual sample preparations/lot is recommended as a minimum.

If the content uniformity method utilizes the same procedure as described in the assay, then a site may be qualified for content uniformity testing by successfully completing the transfer of the assay method. This rationale should be captured in the transfer documentation. If the Content Uniformity test is different from the assay, then 10 samples/lot should be analysed.

2. Inter-and Intra-Laboratory Acceptance Criteria