The purpose of the validation/verification protocol is to document the validation/verification of the specific test method chosen for the testing and release of a particular product or material.

5.1.3. Validation/Verification Summary Reports
Summary reports are generated at the completion of a validation/verification study. The summary memo may provide the justification for the use of a particular test method for the release testing of a product or material.

5.2. Required Content and Format for Development Protocols
The following sections are required, additional sections may be added based on technology specific requirements.

5.2.1. Header
Contains: company name, template type, page number, protocol title and protocol version number, document code. The version number reflects the version of the document being generated with the template, not the version of the template.

5.2.2. Footer None

5.2.3. Approval page

5.2.4. Table of contents
Listing, at minimum, the title and page number of all sections.

5.2.5. Revision History
The protocol may need to be revised at some point during the performance of the validation. This section allows the tracking of all approved and in-process versions of a protocol.

5.2.6. Definitions, Acronyms and Abbreviations Section
The definitions of all terms, acronyms, and abbreviations required to properly interpret the protocol requirements must be provided in this section.

5.2.7. Objective Section
States the purpose of the validation study. Identify the product(s) or material(s) that is to be the subject of the protocol. Identify whether it is a validation or revalidation.

5.2.8. Scope Section
Summarise the principles and boundaries of the validation or verification studies.

5.2.9. Protocol Deviations Section
Documents and details any deviations identified during the execution of an approved protocol. All Deviations are reported in the final summary report. See Section 5.9 of this procedure for more information on Deviations.

5.3. Required Content and Format for Validation/Verification Protocols
All requirements listed in Section 5.2 above must also be met for the validation protocol. In addition the following sections are required.

This section also verifies that each person involved in the validation studies has been trained on all procedures listed in the Prerequisites Section.

5.3.6. References Section
Lists any references used for the validation studies. This may include, but is not limited to, reference to compendia for the establishment of acceptance criteria.

5.4. Required Content and Format for Summary Reports
All requirements listed in Section 5.2 above must also be met for the validation summary report. In addition, the following sections are required.

5.4.1. Data Transcription Checker
All data transcribed into a final report must be checked against the primary data for completeness and accuracy. The person responsible for this check signs and dates the final report prior to routing for approval. The data transcription checker can be anyone other than the person responsible for data transcription.

5.4.2. Deviations Provide a list of all deviations, a brief description of the deviation, and the corrective action (if required) associated with each.

5.4.3. Discussion/Results

5.4.3.1. Validation Conclusion - Provide a clearly stated conclusion that confirms the successful or unsuccessful completion of the validation.

5.4.3.2. Pre-requisites Verification – List all pre-requisites listed in the protocol and whether they were met. This can be done in table format.

5.4.3.3. Results – Provide a list of all tests performed, whether they passed the predetermined acceptance criteria and whether they were performed without deviation.

5.4.4. Additional Content
Additional sections may be used in validation templates based on technology specific requirements. Additional sections may also be added at the time of protocol generation. These additional sections should be noted in the SCOPE section of the protocol. Examples of addition sections may include, but are not limited to.

5.4.4.1. Supporting Documentation Section
Lists any supporting documentation used during the validation studies. All supporting documents are attached to the executed protocol.

5.4.4.2. Appendices Section Contain any tables used to record information referred to in the main text of the protocol (ex. a list of calibrated equipment used for validation studies).

5.4.4.3. Attachment Section Contains any supporting documentation referred to in the main text of the protocol (ex. A calibration status report for all equipment used for

additional pages must be initialled and dated by the laboratory analyst executing the protocol as well as laboratory management.

5.7.6. Reports all deviations to originator and/or laboratory management within 2 business days of discovery.

5.7.7. Completes all requirements of the protocol. Upon completion provides the protocol to an appropriate Record checker.

Record Checker

5.7.8. Second checks all data for accuracy and completeness.

5.7.9. Returns executed protocol to analyst for corrections if necessary. Does not approve any incomplete data.

5.8. Deviations

The following guidelines can be used to aid in determining whether a deviation report is needed. These guidelines apply only to deviations related to validation protocols. Deviations associated with the execution of development protocols are handled at the discretion of laboratory management.

5.8.1. A deviation report is not required if:

5.8.1.1. The entire protocol must be re-executed following a failure requiring additional method development.

The protocol, containing the revised test method, is reissued with an increased version number. If a new protocol template is needed, a validation termination report is issued describing the protocol failure. This incident should be addressed in the final summary report.

5.8.1.2. A new protocol is needed because the original protocol was physically destroyed. The protocol should be reissued with an increased version number. If data was generated in the destroyed protocol and can be salvaged, it is transcribed into the new protocol after approval. The transcription must be record checked for accuracy. If data was generated but cannot be salvaged, the studies must be repeated. This incident should be addressed in the final summary report.

5.8.1.3. A validation study is terminated for reasons outside the control of the laboratory (ex. validation is cancelled by requestor). A validation termination report is issued to close out the protocol.

5.8.1.4. A typographical or editorial error is noted after approval but prior to execution of the protocol. An assessment is to be made as to whether the protocol can be corrected with a lineout or if a new version of the protocol needs to be issued. The originator of the protocol, with the assistance of laboratory management, will decide whether a new protocol is to be issued.

5.9.2.5. Other – a deviation that cannot be classified by the above categories. A full explanation of this is required. This may include (but is not limited to) assay variability, suspected laboratory contamination, etc.

5.9.2.6. "Root cause analysis" - describes why the deviation occurred. The explanation should support the type of deviation selected.

5.9.2.7. "Impact" - describes the impact of the deviation on existing validation plans, protocols, requirements, specifications, product quality, completed tests, and/or other manufacturing concerns.

5.9.2.8. "Corrective action" - outlines all corrective actions and a rationale for the said corrective actions. If the corrective action requires retesting or additional testing, attach the appropriate test section from the qualification protocol with any required modifications.

5.9.3. Signs and dates the report as the originator.

5.9.4. Brings the deviation report to laboratory management for approval.

Laboratory management/designee

5.9.5. Reviews the disposition of the deviation prior to execution of any proposed corrective actions, additional testing, or modified testing and determine if the specified activities are appropriate and if additional review by QA is required.

5.9.6. For deviations where a change or a modification to the protocol is required

5.9.6.1. If the change does not impact previously completed tests, document the change in the deviation report.

5.9.6.2. If the change impacts previously completed tests, the deviation report must address all previously completed sections that have been impacted by the change.

5.9.6.3. If, based on the impact of the deviation, it is determined that re-execution of the entire protocol is required (as determined by Microbiology Support Management): Revise the protocol (increment version number) and route for approval prior to execution.

5.9.6.4. Approves the deviation report.

5.9.6.5. Returns the approved deviation report to the laboratory analyst.

Laboratory Analyst

5.9.7. After approval of the corrective actions, completes all outstanding work necessary to resolve the deviation.

5.9.7.1. Completes any necessary corrective action approved by Microbiology Support Management.

7.0 REFERENCES

None

8.0 SUMMARY OF CHANGES

Version #	Revision History
MICLAB-135	New

