

Validation Report (Ref.VAL-005)

The tests conducted are outlined in Part 4. of this report. Each individual test function listed has the acceptance criteria specified.

Instrumentation/Calibration

- All critical equipment instrumentation was calibrated as a part of the Installation Qualification. Calibration reports are included as attachments to the Installation Qualification Report.
- All critical test instrumentation was calibrated prior to testing and again when testing is complete. Calibration reports are included as attachments to the Operational Qualification Test Protocol.
- All tests were carried out to a level of accuracy indicated by the acceptance criteria.
- All calibrations were performed as per an approved SOP.

Test Functions performed in the Operational Qualification phase and overall results obtained

| | Test Functions | Acceptance Criteria | Results |
|----|----------------|---------------------|---------|
| 1. | | | |
| 2. | | | |
| 3. | | | |

Additional Validation Requirements

Refer to Validation Plan for the inclusion of the following sections:

| | |
|--|--------------------|
| EHS Audit Safety, Health and Environmental | Report No : |
| All critical EHS observations are addressed and closed | |

| | |
|---|------------------------|
| Internal Quality Audit (Note: For new process lines only) | Report No: |
| All GMP related observations are addressed and closed | Yes / No . Sign & Date |

| | |
|--|--|
| Training and Procedures Established | All training requirements stated in the Validation Plan has been fulfilled and approved by the Production Manager |
| Training conducted | Yes / No . Sign & Date |
| All SOPs established | Yes / No . Sign & Date |

Overall Conclusion

Acceptance criteria for the overall program shall be based on the following:

1. Successful pre-calibration data for all critical test instrumentation
2. Successful completion of all test functions listed in Part 4.
3. Successful post-calibration of all critical test instrumentation.