

# Validation Report-Combined OQ/PQ

(Reference SOP: \_\_\_\_\_)

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# Validation Report-Combined OQ/PQ

(Reference SOP: \_\_\_\_\_)

## SECTION 1: OPERATIONAL QUALIFICATION REPORT

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### 1. PROCESS DESCRIPTION

Describe your process in details which is subject to validation plan.

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### 2. OBJECTIVE

This Validation Report addresses the requirements of the Validation programme stipulated in the Validation plan and summarises the overall Qualification tests conducted and the results obtained.

The objective of the Operational Qualification is to perform a series of tests to determine that the operation of the equipment/process conforms to the specifications. The results of the Operational Qualification phase of this validation program are stated in part 4.

The objective of the Performance Qualification phase is to ensure continued operation of the process being validated, to meet all in process testing and defined acceptance criteria under routine production operation.

The tests conducted during the Performance Qualification phase of this validation program are outlined in part 7 of this report. Each individual test function listed has the acceptance criteria specified.

The Validation Report gives evidence of the overall Validation activities conducted and the approval of the validated status of the process.

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### 3. 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.

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### 4. TEST FUNCTIONS PERFORMED IN THE OPERATIONAL QUALIFICATION PHASE AND OVERALL RESULTS OBTAINED

	Test Functions	Acceptance Criteria	Results
1.			
2.			
3.			

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### 5. ADDITIONAL VALIDATION REQUIREMENTS

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

<b>Safety Audit</b> Safety, Health and Environmental	<b>Report No :</b>
All critical safety observations are addressed and closed	

<b>Internal Quality Audit</b>	<b>Report No:</b>
All GMP related observations are addressed and closed	Yes / No – Sign & Date

<b>Manufacturing Change Control</b>	
All critical changes effecting process parameter(s) or having a GxP impact are finalised	Yes / No – Sign&Date

<b>Training and Procedures Established</b>	<b>All training requirements stated in the Validation Plan has been fulfilled and approved by the Production Manager</b>
Training conducted	Yes / No – Sign&Date
All SOP's established	Yes / No – Sign&Date

### 6. CONCLUSION FOR OPERATIONAL QUALIFICATION PHASE

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.

*Tabulate and review all data referenced above. Form a conclusion as to the acceptability of the overall program based on the acceptance criteria specified above.*

**Conclusion:**