

Operational Qualification Report

(Ref.VAL-005)

Process Description

(Describe the process which is due to Operational Qualification)

Objective

The objective of the Operations Qualification is to perform a series of tests to determine that the operation of the equipment/process conforms to the specifications.

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