OPERATIONAL QUALIFICATION FOR COMPRESSION MACHINE

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1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved .The protocol cannot be used for execution unless approved by the following authorities.

This Operation Qualification protocol of Double sided rotary tablet m/c 55 stn. has been reviewed and approved by the following Persons

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

OPERATIONAL QUALIFICATION FOR COMPRESSION MACHINE

2.0 OVERVIEW:

2.1 OBJECTIVE:

To perform the Operational Qualification Double sided rotary tablet m/c 55 stn. Compression machine to be used for producing Compressed tablets.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the installed double sided rotary tablet m/c 55 Stn. Compression machine will operate reproducibly and consistently within its full dynamic range of operation according to manufacturer's specifications.

2.3 SCOPE:

The Scope of this protocol is limited to the Operational Qualification of Double sided rotary 55 Stn. m/c in compression area of the manufacturing facility.

2.4 RESPONSIBILITY:

Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The operational checks, calibration, SOP verification, verification of safety features, verification of utility supply shall be carried out by engineering persons and production person.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

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Head – Production/ Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.

2.5 EXECUTION TEAM:

The satisfactory operation of Double sided rotary tablet 55 stn. Compression machine shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Double sided rotary tablet m/c 55 stn. Compression machine is operational and is satisfactorily working.

Execution team is responsible for the execution of Operational of Double sided rotary tablet m/c 55 stn. Compression machine. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The equipment shall be operational as per its specified operating instructions.

3.2 All SOP's for the equipment to be verified and checked.

3.3 Training is important to all the concerned personnel.

3.4 All the functionality of equipment components to be checked for its full range.

The RPM of motor should be in the range of ±5% deviation.

4.0 REVALIDATION CRITERIA:

The Double sided rotary tablet M/C 55 Stn stn. has to be revalidated if

- During relocation of equipment.
- There are any major changes, which affect the performance of equipment.
- During preventive maintenance or break down maintenance if any major components is replaced which affects the performance of equipment?
- As per revalidation date and schedule.

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5.0 OPERATIONAL QUALIFICATION PROCEDURE:

5.1 EQUIPMENT DESCRIPTION:

Equipment Name	:	55 STATION (Double Rotary)
Supplier / Manufacturer	:	……..
Capacity (Tablets / Hr)	:	64800 to 324000 (tabs/Hr) For bi-layer 67500 @ 25 RPM Depend on the product BD
Model	:	……
Serial no.	:	……
Location	:	

Double sided rotary tablet M/C 55 stn Compression machine comprises of following components.

1. Oil drip cup & Tray
2. Powerpack assembly
3. Oil nipples
4. Motor bearing
5. Machine drive wheel
6. Feeder control switches
7. Guards
8. Force feeder discharging assembly
9. Lower guard assembly
10. Upper guard assembly
11. Electrical panel assembly
12. Motor base plate assembly
13. Gear box assembly
14. Electromagnetic clutch assembly
15. Turret unit
16. Lower CAM track assembly

17. Upper CAM track assembly
18. Weight adjusting assembly (LHS/RHS)
19. Punch loading plug assembly
20. Dust extractor assembly
21. Hopper (LHS/RHS)
22. Hopper lid (LHS/RHS)
23. Tablet chute (LHS/RHS)
24. Bearings
25. Oil seals
26. 'O' rings
27. Counter

Double sided rotary tablet M/c 55Stn Compression machine is designed to produce compressed tablets in our in-house specification.

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5.2 INSTRUCTION FOR FILLING THE CHECKLIST

5.2.1 Write the actual observation in observation column

5.2.2 Give the detailed information in the summary and conclusion part of the operational Qualification report.

5.2.3 Whichever column is blank or not used 'NA' shall be used.

5.3 TEST INSTRUMENT DETAILS

This test is intended to describe the equipments/instruments and its complete details to have a tracebility to the national standard which is to be used for the verification of the operation of the compression machine.

S.No.	Name Of Instrument	Inst. ID. Number	Calibration done on	Calibration Due date	Certificate Number

Checked by Date:

Remark: ----------

Reviewed by (Sign/Date)

OPERATIONAL QUALIFICATION FOR COMPRESSION MACHINE

5.4 VERIFICATION OF FUNCTIONAL CHECKS (IN AUTO /MANUAL MODE)

SIMULATION METHODOLOGY	SPECIFIED FUNCTION	OBSERVATION	VERIFIED BY (Sign/Date)
MAIN MOTOR FUNCTIONALITY TEST			
1. Touch/press start button on of machine Controls Screen	The Main motor should start		
2. Open the lower guard and check for the direction of rotation	The direction should be Anti-clockwise as viewed from the pulley end.		
3. Touch/press stop button on the machine Controls Screen	The Main motor should stop		
TURRET JOG TEST (In Manual mode)			
1. Press JOG Touch button for the main motor on the machine Controls screen	The Turret should run at its minimal speed. The Feeders should also run		
2. Release The JOG Touch Button of The Main Motor	The Turret should Stop its rotation along with Feeders		
CLUTCH FUNCTIONALITY TEST (In Auto mode)			
1. PRESS “Start” touch Button on M/C Control screen	The Main motor should start		
2. Press Clutch Engage button of Main Drive	The Turret should start its motion		
3. Press Clutch Disengage touch button of the Main Drive	The turret should Stop its motion		
4. Press the “stop” touch button of the Main Drive	The Main Motor should Stop		
FEEDER- TURRET INTERLOCK TEST (In Auto mode)			

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

OPERATIONAL QUALIFICATION FOR COMPRESSION MACHINE

SIMULATION METHODOLOGY	SPECIFIED FUNCTION	OBSERVATION	VERIFIED BY (Sign/Date)
1. Press the "Start" touch button of the main Drive	The main motor should Start		
2. Press Clutch Engage touch button of the Main Drive	The feeder should start their respective motion. The turret should start its rotation after a defined time interval		
3. Press Clutch Disengage touch button of the Main Drive	The feeder should stop immediately followed by the turret after few Rotation due to inertia		
4. Press "Stop" touch button	The Main Motor should stop its rotation.		
FEEDER JOG FUNCTIONALITY TEST (In manual Mode)			
1. Press the JOG touch button for the Feeder On Machine Control Screen	The feeder should start its motion at the minimal speed		
2. Observe the motion of the Paddles	The Paddles should have inward motion. The Small Paddle should Rotate in Anti- clockwise direction and Big Paddle in clockwise direction		
3. Release the JOG button	The Feeder should stop its motion		
TURRET SPEED TEST			
1. Press "start" touch button of Main Drive on machine Screen	The main motor should start		
2. Press clutch Engage touch button of the Main Drive	The turret should start its motion.		
3. Press the "+" touch button for the Turret RPM	The turret speed should increase.		

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SIMULATION METHODOLOGY	SPECIFIED FUNCTION	OBSERVATION	VERIFIED BY (Sign/Date)
4. Observed the "set RPM" Button	It should indicate the theoretical set RPM, higher than the preceding value		
5. Observe the "Actual RPM" button	It should indicate the Practical RPM.		
6. Press the "-" touch button for the Turret RPM	The turret speed should decrease.		
7. Observe the "Actual RPM" Button	It should indicate the Practical RPM.		
8. Press clutch Disengage touch button on the machine control screen	The turret should stop its Rotation. Turret comes to halt after few rotations due to inertia		
9. Press the Stop touch button for the main drive	The Main motor should Stop its rotation.		
FEEDER SPEED TEST			
1. Press start touch button of the Main motor on the machine controls Screen	The main motor should start		
2. Press the clutch Engage touch button	The Feeder should start their respective motion. The turret should start its rotation after a defined time		
3. Press the "+" touch button for the Feeder control	The Feeder speed should increase.		
4. Observed the "set RPM" Button	It should indicate the theoretical set RPM, more than preceding value.		
5. Observe the "Actual RPM" button	It should indicate the Practical RPM.		

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SIMULATION METHODOLOGY	SPECIFIED FUNCTION	OBSERVATION	VERIFIED BY (Sign/Date)
6. Press the "-" touch button for the Feeder control	The Feeder speed should decrease.		
7. Observe the "set RPM" Button	It should indicate the theoretical set RPM. Lower than the Preceding Value		
8. Observe the "Actual RPM" button	It should indicate the Practical RPM.		
9. Press clutch Disengage touch button of the main drive	The Feeder should stop immediately followed by the Turret after few rotations due to inertia		
10. Press the Stop touch button for the main drive	The Main motor should Stop its rotation.		
TABLET THIKNESS CONTROL FUNCTIONALITY TEST			
1. Rotate the dial for tablet Thickness, situated in the front side of the machine In clockwise direction	The lower pressure Roll Carrier should Move Downwards. This indicates increase in the Tablet thickness.		
2. Rotate the dial for tablet Thickness, situated in the front side of the machine In anti-clockwise direction.	The lower pressure Roll Carrier should Move Upwards. This indicates decrease in the Tablet thickness.		
UPPER PUNCH ENTRY FUNCTIONALITY TEST			

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SIMULATION METHODOLOGY	SPECIFIED FUNCTION	OBSERVATION	VERIFIED BY (Sign/Date)
1. Rotate the dial for Upper Punch Entry, situated in the front side of the machine in clockwise direction	The Rear pressure Roll Carrier should Move Downwards. This indicates increase in the Penetration.		
2. Rotate the dial for Upper Punch Entry, situated in the front side of the machine in anti- clockwise direction	The Rear pressure Roll Carrier should Move Upwards. This indicates decrease in the Penetration.		
DOZER FUNCTIONALITY TEST			
1. Rotate the dial for Dozer, situated at either side of the machine in clockwise direction	The Weight Adjustment Head Should Move Downwards. This indicates increase in the depth of fill.		
2. Rotate the dial for Dozer, situated at either side of the machine in anti-clockwise direction	The Weight Adjustment Head Should Move Upwards. This indicates decrease in the depth of fill.		
COMPACTION FORCE ALTERATION TEST			
1. Press the "+" touch button for Compaction Force (Main Hyd. Sty. Pressure), on M/C control screen	The Hydraulic motor should start and pump up the oil		
2. Observed the Indicator on the MMI	The indicator should show an increased value of compaction force.		
3. Observed the mechanical Pressure Gauge	The needle in the pressure gauge should show a positive deflection indicating.		

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SIMULATION METHODOLOGY	SPECIFIED FUNCTION	OBSERVATION	VERIFIED BY (Sign/Date)
4. Stop activating the "+" touch button.	The compaction force value should not show any increase. It should remain stable at a specified value.		
5. Observe the Mechanical pressure Gauge in the Base Cabinet.	The needle in the pressure gauge should now remain stable at a specified pressure value.		
6. Press the "-" touch button for Compaction Force, on M/C control screen	The compaction force value should gradually decrease.		
7. Observed the Mechanical pressure gauge	The needle in the Pressure Gauge Should show a gradual negative deflection.		
8. Open the pressure Relief valve completely and observed the control panel	The value should be very much near to null value.		
9. Observed the Mechanical pressure gauge in the base cabinet of the machine	The needle in the Pressure Gauge Should indicate a value very much near to null value.		
SAMPLING GATE FUNCTIONALITY TEST			
1. Press sampling touch icon	The sampling gate should get opened		
2. Press again the sampling touch icon	The sampling gate should get closed		
RECIPE MANAGEMENT TEST			
1. Press recipe management touch button, on the Main Menu Screen	The Recipe Management screen should be displayed		

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SIMULATION METHODOLOGY	SPECIFIED FUNCTION	OBSERVATION	VERIFIED BY (Sign/Date)
2. Press the numerical touch button provided for recipe codes.	The Recipe Management screen should be displayed		
3. Click on the respective touch button for entering the data.	A Numeric / Alphanumeric screen should pop up		
4. Enter the resp. data and press “Save ” touch button	The entered data is stored		
5. Press the main Menu touch button.	The Main Menu screen should be displayed.		
BATCH DATA TEST			
1. Press the Recipe Management touch button on Main Menu Screen	The Recipe Management Screen should be displayed		
2. Press the Numerical touch button provided for desired recipe	The Recipe Parameters screen for the defined recipe should be displayed.		
3. Press the “Download” touch button	The set Parameters should be entered in to the batch Data screen		
4. Press main Menu touch button	The main Menu screen should be displayed.		
5. Press batch Data touch button	The Batch data screen should be displayed		
6. Observe for the Recipe Code and Product Name	They should be the same that was selected in the Recipe management screen		
7. Feed the respective figures and Press ENT	The respective data should get stored.		

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SIMULATION METHODOLOGY	SPECIFIED FUNCTION	OBSERVATION	VERIFIED BY (Sign/Date)
8. Press the main Menu touch button.	The main Menu screen should be displayed		
9. Press the machine controls touch button	The Machine Controls screen should be displayed		
10. Press the "Start" touch button for the Main Drive	The Main Motor should be start		
11. Press the "Clutch Engage" touch button	The turret should start its motion		
12. Press the main Menu touch button.	The main Menu screen should be displayed		
13. Press the Batch data touch Button	The Batch data screen should be displayed		
14. Observe for the tablet count	Continuous up gradation of total tablets produced should be visible		
15. Observe for total tablets produced with respect to batch size.	Once the Total tablets produced equal the Batch size, the machine should stop.		
16. Press the batch Reset touch button	The value of total tablets produced should be become zero.		
CHANGE PASSWORD TEST			
1. Press change password touch button , on the Main Menu screen	The change password screen should be displayed		
2. Press dialog box for "ENTER OLD PASSWORD " for Welcome Screen	A Numeric Key keypad should POP-UP		
3. Press CLR and enter any random figures and Press ENT	"Invalid password" Should be displayed		

OPERATIONAL QUALIFICATION FOR COMPRESSION MACHINE

SIMULATION METHODOLOGY	SPECIFIED FUNCTION	OBSERVATION	VERIFIED BY (Sign/Date)
4. Press CLR and enter correct figures	"Old Password" OK should be displayed		
5. Press dialog box for "ENTER NEW PASSWORD " for Welcome Screen	A Numeric Key keypad should POP-UP		
6. FEED New Password and press ENT	"Password Changed " Should be displayed		
7. Press the main Menu touch button	The Main Menu screen should be displayed		

Remark: ----------

Reviewed by (Sign/Date)

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5.5 CHECKING OF VARIOUS INTERLOCKS

Test	Acceptance criteria		Actual Alarm Messages	Verified by Sign/Date
	Alarm Messages	Effect on function		
Password Check				
Press the touch button for any of the level in the security control screen	"Enter password should be displayed	NA		
Enter any random figure other than the actual Password through the numeric keypad.	"Invalid Password" should be displayed.	The system should not accept the Password.		
Enter the correct password through the numeric keypad.	"Password ok" should be displayed.	The Main menu screen should be displayed directly, on acceptance of the correct password.		
Main drive and feeder interlock				
Press the main menu icon on the MMI	NA	Main menu should be displayed		
Put the feeder in manual mode and Press the Start icon of the Main Motor	Main Drive in manual mode, is displayed in the machine status screen	Machine should not start in Auto mode.		
Put the feeder in auto mode and Press the Start icon of the Main Motor	Main Drive in auto mode, is displayed in the machine status screen	The main motor should start		
Press the Stop icon on the MMI	NA	The main motor should stop		
Guards interlock				
Close all guards and put them in interlock mode. Press the start icon of main motor.	NA	Motor should start		

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Open any of the guards.	"Machine Guards Open" is displayed in the machine status screen	Motor should stop		
Close the respective guard and press the start icon again.	Machine guards closed, is displayed in the machine status screen.	Motor should start.		
Press Stop icon on the MMI	NA	The motor should stop		
Repeat the procedure for the all remaining guards.	NA	The Acceptance criteria should be same as that of the previous.		
Emergency Push Button Interlock				
Press the start icon of the main motor	NA	Motor Should start		
Press either of the Emergency Push Button	Emergency Push Button operated	Motor Should stop.		
Release the push button and press the start icon of the motor	Emergency Push Button Released is displayed in the machine status screen.	Motor should start.		
Press the stop icon on the MMI	NA	The Main motor should stop.		
Tablet counting proximity interlock				
Load only the upper punches for tablet Proxy Interlock Verification. (Perform for LH and RH separately.)				
Disturb the setting of the tablet counting proxy Press the start icon of the main motor and Engage the Clutch.	Tablet counting proxy not in position, is displayed in the Machine status screen	Machine will stop & massage will displayed tablet counting proxy not in position		

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Set the tablet counting Proxy. Press the start icon of the main motor and Engage the Clutch.	Tablet counting proxy in position, is displayed in the Machine status screen	Machine should start. Tablet count can be visualized in the Batch Data screen.		
Press disengage icon & finally press Stop icon.	NA	The machine should Stop.		
Batch size interlock				
Feed random figures in the batch data screen. Press the start icon of the main motor and Engage the clutch	Batch size continuous, is displayed in the machine status screen.			
Observed for the completion of targeted value fed in the batch data screen.	Batch size completed, is displayed in the machine screen.	The machine should stop.		
Reset the batch size and press the start icon of the main motor.	NA	The Main Motor should start		
Press the stop icon of the Main Motor.	NA	Motor should Stop.		
Lubrication Oil Level Interlock				
Start the machine in its regular method. Open the lower guard and drain the lubrication oil.	"Lubrication Oil Level Low" should be displayed after an instance, in the machine status screen			
Top up the lubrication oil tank.	"Lubrication oil level Healthy" should be displayed	NA		
Start the machine in its regular Method	NA	The Machine should start.		
Dozer interlock				

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Remove the LH Dozer	LH dozer assembly Not In position should be displayed in the machine status screen.	NA		
Start the machine in its regular Procedure.	LH dozer assembly Not In position should be displayed in the machine status screen	The machine should not start.		
Assemble the LH dozer properly.	LH dozer assembly in position should be displayed	NA		
Start the machine in its regular procedure	NA	The machine should start.		
Press the stop icon of the Main Motor.	NA	Motor should Stop.		
Repeat the procedure for RH Dozer	NA	The Acceptance criteria should be same as that of the previous.		
Press the Clutch Disengage touch icon followed by the stop touch icon of the main drive.	NA	The machine should stop		
Main Set Pressure Interlock (In guard By-pass mode)				
Press the start touch icon of the main Drive followed By the clutch engage.	NA	The Machine Should Start.		
Slightly disturb the Switch near the LH hydraulic cylinder in the base cabinet.	Main set Pressure (LH) overload , should be displayed in the machine Status screen	The machine should not Stop. This is just an Indicative Alarm.		

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Reset the micro – Switch.	Main set Pressure (LH & RH) Healthy Should be Displayed.	NA		
Repeat the same for RH Hydraulic cylinder	NA	The Acceptance criteria should be same as that of the previous.		
Press the Clutch Disengage touch icon followed by the stop touch icon of the main drive	NA	The machine should stop.		
Powder Level interlock				
Press the start touch icon followed by the clutch engage touch Button.	NA	The machine should Start.		
Disturb the setting of the LH Powder Level sensor	LH Powder level low should be displayed	The machine should stop after some time		
Reset the LH powder level sensor	Powder level Healthy, should be displayed	The machine should not start		
Press the start touch button followed by the clutch engage t0uch button	NA	The Machine Should Start.		
Press the Clutch Disengage touch icon followed by the stop touch icon of the main drive	NA	The machine should stop.		
Repeat the same procedure for the RH powder level sensor	NA	Acceptance criteria shall be similar to that of the previous		
Air Pressure Interlock				
Press the start touch button followed by the clutch engage touch button	NA	The machine should start		

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Disconnect the incoming air supply	Air pressure Low, should be displayed	The machine should stop		
Reconnect the incoming air supply	Air pressure Healthy, should be displayed	The machine should not start		
Press the start touch button followed by the clutch engage touch button	NA	The machine should start		
Press the Clutch Disengage touch button followed by the stop touch button	NA	The machine should stop		

Remark: ----------

Reviewed by (Sign/Date)

OPERATIONAL QUALIFICATION FOR COMPRESSION MACHINE

5.6 VERIFICATION OF SAFETY FEATURES:

SAFETY FEATURES DESCRIPTION	FUNCTION	OBSERVATION	VERIFIED BY (SIGN/DATE)
Upper Guards and Lower Guard	Prevents from access to moving parts during motion, having the guards set in interlock mode		
Emergency push button	It is provided to stop the machine in case of emergency		
Machine Main pressure Overload	Alarm Message shall be displayed if the machine is run on overload condition.		
Powder level Sensor	Conveys signal to the PLC, in case the hopper level falls below the sensing area. This is stops the machine after some time.		
Air pressure interlock	The machine shall not start /stops if in motion, should there be no air supply.		

Remark: ----------

Reviewed by (Sign/Date)

5.7 VERIFICATION OF SUPPORTING UTILITIES:

S.No.	UTILITY	OBSERVATION	CHECKED BY (SIGN/DATE)
1.0	Electricity: 3 Phase 415Volts,50 Hz		
2.0	Compressed air NLT 6 Kg/sq.cm		

Remark: ----------

Reviewed by (Sign/Date)

OPERATIONAL QUALIFICATION FOR COMPRESSION MACHINE

5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were verified as important for effective performance of Double side rotary tablet m/c 55 stn. Compression machine operation.

S.No.	SOP TITLE	SOP NUMBER	VERIFIED BY SIGN/DATE

Remark: ----------

Reviewed by (Sign/Date)

OPERATIONAL QUALIFICATION FOR COMPRESSION MACHINE

5.9 VERIFICATION OF CALIBRATED COMPONENT (S)

Verify that the drafted calibration procedures for different identified components in the Double sided rotary tablet m/c 55 stn. Compression machine are adequate and appropriate covering the operating range(s). e.g. Pressure gauge, counter etc (As applicable).

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration valid up to	Certificate number

Checked by Date:

Remark: ----------

Reviewed by (Sign/Date)

5.10 TRAINING RECORD OF PERSONNEL (S):

S.No.	Name of Personnel	Designation	Sign. & Date	Trained By	Remark

Remark: ----------

Reviewed by (Sign/Date)

5.11 LIST OF ANNEXURES:

Annexure No.	Document Title

Remarks (if any)**:** ----------

Done By & Date:

Verified By & Date:

5.12 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S)

Following deficiency was identified and corrective actions taken in consultation with the validation team.

Description of deficiency:
Corrective action(s) taken:

Deviation accepted by
(Sign/Date)

Deviation approved by
(Sign/Date)

6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

All the OQ data sheets and discrepancy report shall be reviewed by validation team to prepare summary report. The summary of OQ shall be used to draw conclusion for approval of Operational qualification report.

6.1 SUMMARY

6.2 CONCLUSION

Prepared By
Sign/Date

Checked By
Sign/Date

6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol. Signature in the block below indicate that all items in this qualification report of Double sided rotary tablet m/c 55 stn have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		