INSTALLATION QUALIFICATION PROTOCOL CUM REPORT 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 Installation Qualification protocol of Double side rotary tablet compression machine 55 station 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		

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2.0 OVERVIEW :

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Double sided rotary tablet m/c 55 station and define the qualification requirements and acceptance criteria for the Double sided rotary tablet m/c 55 station. Successful completion of these qualification requirements will provide assurance that the Double sided rotary tablet m/c 55 stations was installed as required in the production area.

The objective of the installation qualification is to prove that each activity proceeds as per design specification and the tolerances prescribed there in the document and is the same at utmost transparency.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Double sided rotary tablet m/c 55 station, received matches the Design specification and also to ensure that it is properly and safely installed. Purpose of Double sided rotary tablets m/c 55 station is for compression of different powders to be used in the formulation. The equipment shall operate under dust free environment and conditions as per the cGMP requirements.

2.3 SCOPE:

This Protocol is applicable for installation of Double sided rotary compression m/c 55 station in compression area of the manufacturing facility.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

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 installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons.
- The production operator/supervisor shall carry out the cleaning and operation of machine.

Head – Production/ Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assists 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 installations of the Double sided rotary tablet m/c 55 station shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the 55 station compression m/c is installed satisfactorily. Execution team is responsible for the execution of installation of Double Sided rotary tablet m/c 55 stn. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

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3.0 ACCEPTANCE CRITERIA:

3.1 The Double Sided Rotary Tablet M/C shall meet the system description given in design qualification.

3.2 The Double Sided Rotary Tablet M/C shall meet with the acceptance criteria mentioned under the topic “Identification of major components”

3.3 The Double Sided Rotary Tablet M/C shall be operated by PLC.

3.4 All material of constructions of the contact parts to be checked as per the specifications.

4.0 REQUALIFICATION CRITERIA:

The machine shall be requalified if:

- There are any major changes in system components which affect the performance of the system.
- After major breakdown maintenance is carried out.
- As per revalidation date and schedule.

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5.0 INSTALLATION QUALIFICATION PROCEDURE:

5.1 SYSTEM DESCRIPTION:

1	Equipment Name	:	ACCURA PRESS IV 55 STATION "B" TOOLING.
2	Supplier/Manufacturer	:	Fluidpack.
3	Model	:	PRESS-IV
4	Serial no.	:	
6	Location	:	

Machine Description:

The ACCURA PRESS IV 55 STATION "B" TOOLING is "B" tooling high-speed double rotary tablet compression machine, which is controlled through PLC system. It is a versatile machine in the range of tabletting & it can be operated in auto/ manual mode. This machine is incorporated with 3 Piece Turret with S.S. 316 Die Table, Upper & Lower piece of turret having ELNP coating & Die table having HCP, Auto lubrication system (Intermittent + Continuous), Electromagnetic clutch, Programmable Logic Controller with MMI Touch screen, Powder level sensor, Initial Rejection/ Random sampling Device operating through Pneumatic control, Turret with lower punch key way.

Complete machine can be divided in following sub sections:

- **Powder feeding unit (LHS & RHS)**
- **Powder Transfer unit (LHS & RHS)**
- **Drive unit, Turret and Compression unit**
- **Weight Dozer (LHS & RHS)**
- **Hydraulic Power Pack Assembly**
- **Lubrication Unit (Intermittent + Continuous)**
- **Tablet discharge Unit (LHS & RHS)**
- **Powder Level Sensors (LHS & RHS)**
- **Overload Safety Unit**

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POWDER FEEDING UNIT (LHS & RHS)

This comprises of the following –

- **Hopper with Butterfly valve (LHS & RHS) : -**

An SS 316 Hopper rests on top of the machine, which holds the powder in it and delivers to the feeding assembly through a butterfly valve. The correct setting of material flow is dependent upon the tablet size, type of material being tabletted & the speed of the machine. The flow of the powder should be controlled by the butterfly valve, which is fitted in between the Hopper and the Feeding system. It comprises of a flap, which can be operated using a knob.

- **Powder Level Sensors : -**

Near the sight glass of the hopper a Barrel type Powder level Sensor is fixed on a bracket. The function of the powder level sensor is to stop the machine when powder level goes down below the sensor level in hopper. It senses the Level of the Powder in the hopper and conveying the signal to the PLC thereby facilitating in controlling the operation of the machine. No sooner the level drops below the sensing point, the sensor LED gets OFF and the machine stops based on the desired time interval. The machine will stop functioning in case there is low powder level alarm on either side of machine.

POWDER TRANSFER UNIT

This comprises of the following –

- **Inlet Connector (LHS & RHS):** - It is a SS 316 connector, which links the Hopper and the Force feeder.

- **Force Feeder Assembly (LHS & RHS) :** - It comprises of –

- **Force Feeder: -** The force feeder has two counter rotating paddles of SS 316, driven by reduction gearbox and control by variable frequency AC drive unit. The pressing material enters the feeder in the middle between the two paddles from the hopper through the butterfly valve. With the feeder in the “MANUAL MODE”, the force feeder is operated for initial filling prior to rotating the machine and in “AUTO MODE”; the force feeder will run along with the machine. While machine is in production, always put the feeder in “AUTO MODE”.

- **Tail over die, scrappers at Tail over die and feeder:** - The tail over die is an essential feature of the high-speed tablet press. The function of the tail over die is to keep the filled

die covered until the last moment before the upper punch enters the die. Failure to keep the die covered will result in granules spilling out of the die with subsequent variation of the tablet weight. The tail over die is fitted freely over the turret die table and is pressed against the die table by spring action. Ensure that the bottom surface of the tail over die rests flat and matches with the die table. The spring-loaded scrappers are mounted on feeder support plate. The springs press the scrappers against the turret die table to scrap off the tabletting powder and divert it for re-circulating.

The scrapper scrapes out the excess powder after weight adjusting dozer. The discharge powder is recirculated into the next feed frame pockets.

- **Nozzle Outlet for Suction: -** This comprises of a PVC pipe that is connected to the dust extraction unit. The powder dust coming from the preceding feeder is completely sucked there by avoiding mixing of granules & reduces the dust generation.

DRIVE UNIT, TURRET AND COMPRESSION UNIT

- **Drive unit –** A main motor of 10 HP drives a very high reduction gearbox unit using an electromagnetic clutch and a timing belt. The gearbox unit consists of a Phosphorus bronze (PB2 grade) worm wheel and a Worm shaft of SAE 8620 (with case hardening having 58 – 62 HRC). The worm wheel holds the Pinion. The turret has an internal helical ring, which meshes externally to the pinion. The rotation of the pinion is responsible for turret motion. Thus, CPDIV– 55 station is purely eccentric drive.

N.B.: - The rotation of CPDIV - 55 stations is clockwise.

- **Turret –** This is tool-holding body with a 3-piece Turret structure having the center die table of SS316L & the upper & lower piece of SG iron grade 600/3. The upper piece holds the upper punches, which rests on the upper cam tracks with the cam plate. Similarly, the lower piece holds the lower punches that travel on the lower cam tracks and dozer. The Dies lie in the die cavities provided in the die table with the help of die locking screw assembly. The lower punches are secured using punch holding device comprising of brake plug, anti-turning spring strip and button head screw. There is lower punch scrapper seals

fitted in the lower piece of the turret, which restricts ingress of the powder on to the lower punch shank.

- **Compression Unit** - This comprises of: -
  - **Upper Pressure Roll Assembly (Front & Rear) –** It comprises of a Roll Centre, Pressure Roll and Pressure Roll Pin. The Roll Centre holds the Pressure Roll and is locked using External Circlips. The rotation of the Roll is taken care by 02 Nos. cylindrical roller bearings.
  - **Lower Pressure Roll Assembly (Front & Rear) -** It comprises of a Roll Centre, Pressure Roll and Pressure Roll Pin. The Roll Centre holds the Pressure Roll and is locked using External Circlips. The rotation of the Roll is taken care by 02 Nos. cylindrical roller bearings.
  - **Upper Tamping Pressure Roll Assembly (Front and Rear) –** It comprises of Tamping roll, Needle Roll Bearing NKI – 25/30 and lower tamping roll pin.
  - **Lower Tamping Pressure Roll Assembly (Front and Rear) –** It comprises of Upper tamping roll, Needle Roll Bearing NKI – 25/30 and roll pin.
  - **Upper Punch Penetration Assembly (Front & Rear)** – This is the assembly, which is responsible for the entry height of the upper punch in the die. Whenever the wheel of upper punch penetration is rotated, the entire upper pressure assembly with the carrier along with the lower pressure assembly is moved up and down. Always care needs to be taken to set the upper punch penetration initially and only then the thickness.
  - **Tablet Thickness Assembly (Front & Rear) –** This is the assembly, which is responsible in deciding the tablet thickness. The upward and downward movement of the lower pressure carrier assembly varies the thickness.

WEIGHT DOZER (LHS AND RHS): -

This assembly is responsible for adjusting the weight of the tablet by varying the depth of fill. The depth of fill is adjusted by the upward and downward movement of the weight adjusting head through a dozer adjusting screw with the help of dial. The Weight Dozer is easily detachable by removal of two knobs.

4.5 HYDRAULIC POWER PACK ASSEMBLY:

This system controls the safety overload mechanism, which governs the maximum pressure level, at which particular tablets are being made. The oil reservoir for this system is located in front LH

corner within lower cabinet. Removing the lower side guard (LH) can access it. The oil level in the reservoir should be checked regularly through the oil level indicator. It comprises of:

- **Hydraulic Oil Tank –** The Hydraulic oil used for is stored in this reservoir. Generally, the recommended oil is ENKLO – 32 / TELLUS– 37. There is a "L" type oil level indicator provided on the tank to indicate the current oil level. A drain plug is provided so as to drain the oil in the tank to facilitate the cleaning of the tank.

- **Pumping Unit –** It comprises of a foot mounted A.C. Electric motor of 1 HP coupled to a hydraulic pump of 1.2 Liters capacity. The hydraulic pump pumps up the oil from the reservoir.

- **Hydraulic Power Pack Unit–** This unit is responsible for the regulation of the hydraulic pressure. It comprises of the following sub – components:

- **Non-return Valve –** The pumped oil passes through the Non Return valve before passing through the Pressure Release Valve. The Non Return Valve is a uni – directional valve and shall not permit the oil to trace back the line.

- **Pressure Release valve –** It is a plunger-operated valve, which permits the oil to pass through only under defined pressure. It is the initial safety device to prevent from over pressurizing. In case the pressure exceeds beyond the set limit, the oil is by – passed back into the hydraulic oil tank.

- **Pressure Switch –** This is the second and utmost important safety device in the Power Pack unit. The setting of the switch is done at for a pressure slightly below the maximum operating pressure, to be on the safer side. In case of failure of the Pressure Release Valve, the pressure starts building up tremendously. Once it crosses the set pressure of the Pressure switch, the pressure switch immediately cuts off the power supply of the Hydraulic motor. This stops pumping.

- **Solenoid Valve –** This is direction control valve opening on one side.

- **Pilot Operated Check Valve –** This is plunger-operated valve and plays an important role during release of the hydraulic pressure.

- **Flow Control Valve –** It controls / throttles the flow during release of the hydraulic pressure. Gradual release of the hydraulic pressure is taken care by this valve.

Pressure Sensing and Indication Unit –

It comprises of the following:

❖ **Electronic Pressure Sensor (Effector – 500) –** It senses the pressure in the line and transmits the signal to the PLC, which in turn shall display the value in the MMI.

❖ **Mechanical Pressure Gauge –** It is also for the indication of the line pressure. The range of this gauge is 0 – 100 kg /sq.cm

❖ **Mechanical Accumulator –** It is a spring-loaded shock-absorbing unit. The accumulated pressure is neutralized in this accumulator by the compression action of the spring.

❖ **Hydraulic Cylinders –** They are suspended onto the lower pressure carriers. They are filled with Hydraulic Oil, which acts as the force absorbing fluid. A cup seal within the hydraulic cylinder plays an effective role in prevention of any oil leakage during running of the machine.

LUBRICATION UNIT: -

There are two types of lubrication: Continuous Lubrication & Intermittent Lubrication

❖ **Continuous Lubrication –**

This unit comprises of the following:

Continuous Lubrication Oil Tank – The oil used for lubrication of various parts of the machine is stored in this reservoir. Generally, the recommended oil is ENKLO – 68 / OMALA – 220. A float switch is inserted in the tank from the top end. The switch will indicate the oil level in the tank. An oil filter helps in supply of filtered oil so that no choking of tubes takes place. Filtered oil gives smooth functioning of the respective component. Any foreign particle in the oil creates friction that could be responsible for wear and tear. Towards the base of tank, there is a drain plug, through which the oil in the tank can be drained out for

facilitating cleaning of the tank. A sight glass helps in visual judgment of the oil level in the tank.

Oil Pump – This is a gear pump that pumps the oil from the lubrication oil tank to the distribution manifold. The oil pump shall operate only when the turret is put ON. It is coupled to a flexible shaft using a rubber coupling. The pump has an oil seal on its top end that prevents oil leakage from the pump.

Oil Manifold – This is a distribution sub – component that receives the oil from the lubrication oil tank through the oil pump. The oil is distributed to three different locations from the manifold…viz.… Center Pillar, Pinion and Manifold for Intermittent Lubrication.

Drain Pipe – The oil that lubricates the center pillar and pinion falls back to the tabletop from where it drips back into the lubrication tank through the drainpipe.

Pressure Gauge – This component indicates the continuous lubrication pressure.

- **Intermittent Lubrication –** This unit comprises of:
  - **Solenoid Valve –** This valve permits / prevents the oil to the intermittent lubrication manifold.
  - **Intermittent Lubrication Manifold –** The oil that passes through the solenoid valve, enters the Intermittent Lubrication Manifold from where it gets distributed to the following points:
    - Fork (Front) pin at Rear lower carrier
    - Fork (Rear) pin at Rear lower carrier
    - Fork (Rear) pin at Front lower carrier
    - Fork (Front) pin at Front lower carrier
    - Pivot pin at rear lower carrier
    - Pivot pin at front lower carrier

TABLET DISCHARGE UNIT:

- **Ejection Cam (LHS & RHS): -** The lower punch glides on the ejection cam and ejects the tablet. The height of the ejection cam needs to be set in such a way that the tip of the lower punch is slightly above the die so as to avoid tablet-chipping problem.

- **Tablets take off plate assembly (LHS & RHS): -** As soon as the tablet is ejected out it strikes the tablet take off plate assembly, which directs the tablet to the discharge chute.

Care should be taken so that the tip of the lower punch does not strike the tablet scrapper assembly.

- **Tablet discharge chute (LHS & RHS): -** It is made of SS 316 with acrylic cover. Tablets slide out through this chute to the container. The discharge chute is divided into three channels, viz…. Normal production, sampling port, rejection port.

AUTO REJECTION/ RANDOM SAMPLING: -

This system is operating through the pneumatic circuit, which consists of discharge chute with two outlets, rotary actuator with flap, pneumatic accessories.

The auto rejection system is used to separate out initial tablets that are not with in the required parameters due to various factors when initial starting & stopping of the machine. Nos. of initial compressed tablet rejection can enter the value to separate out the tablets in rejection outlet gate of discharge chute, so that no distorted parametric tablets are mixed with good tablets.

The random sampling is used when sample tablets are required for IPQA inspection purpose during running production batch. Sample tablet can be taken out through rejection outlet gate of discharge chute till sampling touch button is pressed. The air blow for the sampling & rejections is given through this take- off plate.

5.2 INSTRUCTION FOR FILLING THE CHECKLIST

5.2.1 In case of identification of major component actual observation should be written in specified location.

5.2.2 In case of the compliance of the test actual observation should be written in specified location.

5.2.3 For identification of utilities actual observation should be written in specified location.

5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.

5.2.5 Actual observation of the component should be written in specified location.

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

5.3 INSTALLATION CHECKLIST

S.No.	Statement	Method of verification	Actual Observation	Verified by (sign/date)
01.	Verify the purchase order copy and PO no. Shall be written in observation column	Physically		
02.	Verify that the "As Built" drawing is complete and represents the design concept.	Physically		
03.	Verify that major components are securely anchored and shock proof.	Physically		
04.	Verify that there is no observable physical damage.	Physically		
05.	Verify that there is sufficient room provided for servicing.	Physically		
06.	Verify that all piping and electrical connections are done according to the drawings.	Physically		
07.	All access ports are examined and cleared of	Physically		

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S.No.	Statement	Method of verification	Actual Observation	Verified by (sign/date)
01.	Verify the purchase order copy and PO no. Shall be written in observation column	Physically		
	any debris.			
08.	Safe electrical connections.	Physically		
09.	Wiring diagram affixed to inside section of control panel.	Physically		
10.	Equipment identification nameplate visible.	Physically		
11.	Units installed on foundation are secure in place as per manufacturer's recommendations.	Physically		

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

Reviewed by (Sign/Date)

5.4 IDENTIFICATION OF MAJOR COMPONENTS:

Describe each critical component and check them and fill the inspection checklist.

System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Equipment Description	Name	ACCURA PRESS IV 55 STATION "B" TOOLING	Visually from name plate		
	Make	Fluidpack	Visually from name plate.		
	Model	Press -IV	Visually from name plate		
	Sr. No.	062	Visually from name plate		
	Turret speed	12 to 60 RPM for single layer. 12 to 24 for double layer.	Visually from name plate/ Technical specification.		
	Tooling	"B'' Tooling	Visually		
	Overall Dimension (With guards open)	2570 mm (H) x2800mm (L) x2330 mm(W)	Physically		
	Powder feeding system	Force feeder	Visually		
	Upper punch penetration (Main)	Min= 3 mm Max= 6 mm	Physically/Technical Certificate		
	Upper punch penetration (Tamp)	Min= 2 mm Max= 5 mm	Physically/ Technical Certificate		

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System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Tablet thickness	Min= 2 mm Max= 8 mm 8 mm thickness is for flat tablet. In case of beveled edge or concave tablet, the cup depth for the same will be considered as extra.	Physically/ Technical Certificate		
	Max. operating pressure	10 KN	Physically/ Technical Certificate		
	Max. tamping pressure	10kN	Physically/ Technical Certificate		
	Max. tablet dia.	16 mm	Physically/ Technical Certificate		
	Max. depth of fill	17.4 mm	Physically/ Technical Certificate		
	Type of feeding	Force feeder	Visually/ Physically		
Hopper	Location	On the roof top of machine	Physically		
Hopper Lid	Location	On the top end of the hopper	Physically		
Force Feeder Assembly	Location	On the feeder platform in the working zone	Physically		
Upper Pressure Roll Assembly	Location	On the top rear side of the machine, held on the roll carriers	Physically		

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System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Upper Tamping Roll Assembly	Location	On the top right side of the machine, with the working zone	Physically		
Lower Pressure Roll Assembly	Location	On the bottom rear side of the machine, held on the roll carriers	Physically		
Lower Tamping Roll Assembly	Location	On the bottom right side of the machine	Physically		
Main Motor	Location	Base cabinet	Physically		
	Make	MEGA ROTO TECH	Visually/ Physically		
	Type	Foot mounted			
	Sr. No.	2015060784	Visually/ Physically		
	RPM	1440	Visually/ Physically		
	Voltage	415V±10V	Visually/ Physically		
	Phase	3 Phase	Visually/ Physically		
	Sr. No.	To be recorded	Visually/ Physically		
	Barring No.	To be recorded	Visually/ Physically		
Hydraulic Motor	Location	Base cabinet	Physically		
	Make	Crompton Greaves	Visually/ Physically		
	Power	1 HP / 0.75 kW,	Visually/ Physically		
	Phase	3 Phase, 50Hz	Visually/ Physically		
	RPM	1410	Visually/ Physically		

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System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Sr.No.	To be recorded	Visually/ Physically		
	Barring No.	To be recorded	Visually/ Physically		
	Qty.	01 No.	Visually/ Physically		
ACVFD for main motor	Make	Allen Bradley	Visually/ Physically		
	Model	To be recorded	Visually		
	Power	10HP	Visually/ Physically		
	Phase	3 phase, 415 V	Visually/ Physically		
	Sr.No	To be recorded	Visually/ Physically		
Feeder Motor	Location	Within the bottom cabinet	Physically		
	Make	Bharat Bijlee Ltd.	Visually/ Physically		
	Power	0.25 HP / 0.19 kW	Visually/ Physically		
	Voltage	3 Phase, 415 V	Visually/ Physically		
	Frequency	50Hz±5%	Visually/ Physically		
	RPM	1330	Visually/ Physically		
	S.No.	LH: U-1300863 RH: U-1300862	Visually/ Physically		
	Barring No.	To be recorded	Visually/ Physically		
	Qty	02 Nos.	Visually/ Physically		
ACVFD for feeder motor	Make	Allen Bradley	Visually/ Physically		
	Model	To be recorded	Visually/ Physically		
	Power	0.5 HP, 415V, 3Ph	Visually/ Physically		
	Sr. No	To be recorded	Visually/ Physically		

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System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Power pack motor	Make	Mega Roto Tech.	Physically		
	Sr. No	2015040122	Physically		
	Type	Foot Mounted.	Physically		
	RPM	1390	Physically		
	Amperage	1.9	Physically		
	Frequency	50Hz	Physically		
Main Drive Gear Box	Make		Technical Certificate		
	Type	Worm & Worm Wheel	Technical Certificate		
	Reduction Stage	Single	Technical Certificate		
	Center Distance	4.975”	Technical Certificate		
	Input H.P.	10	Technical Certificate		
	Input R.P.M. (Max.)	1500	Technical Certificate		
	Output torque nm	350	Technical Certificate		
Gear box for feeder drive(LH)	Type	Worm geared, oil immersed	Visually/ Technical certificate.		
	Sr. No.	To be recorded	Visually		
Gear box for feeder drive(LH)	Type	Worm geared, oil immersed	Visually/ Technical certificate.		
	Sr. No.	To be recorded	Visually		
PLC	Make	Allen Bradely	Visually/ Physically		
	Model	Micrologix 1400	Visually/ Physically		
	Sr.No	To be recorded	Visually/ Physically		
HMI	Model	HMIGX 3501	Visually		
	Make	Schneider	Visually		
	Sr. No.	To be recorded	Visually		
Lubrication Pump	Location	Base cabinet below the main drive gear box	Physically		

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System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Make	Mini Hyd	Visually/ Physically		
	Model	PP1	Visually/ Physically		
Accumulator	Location	Base cabinet	Physically		
	Make	……	Visually/ Physically		
	Type	Mechanical spring loaded	Visually/ Physically		
Electromagnetic Clutch.	Location	Within the base cabinet, on RHS of machine behind the hand wheel	Physically		
	Make	Golden	Visually		
	Model	To be recorded	Physically		
Weight Adjustment Dial	Location	On the either side of the machine	Physically		
Tablet Thickness Control Dial	Location	On the front side of the machine	Physically		
Tamping Thickness Control Dial	Location	On the front side of the machine	Physically		
Upper Punch Penetration Control Dial	Location	On the front side of the machine	Physically		
Hydraulic Power Pack Assembly	Location	Base cabinet	Physically		
Hydraulic Cylinder	Location	Base cabinet	Physically		
MCB (All in control panel)	Make	Schneider	Visually/ Physically		
Contactor – Hydraulic Motor	Make	Schneider	Visually/ Physically		
Overload relay for hydraulic motor	Make	Schneider	Visually/ Physically		
SMPS	Make	Omron	Visually/ Physically		

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System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Model	S8VK-C06024	Visually/ Physically		
Contactor for magnetic clutch	Make	Schneider	Visually/ Physically		
	Model	LC1D12	Visually/ Physically		
	Specs.	24 A/ 240 V AC	Visually/ Physically		
Main isolator switch	Make	Salzer	Visually/ Physically		
	Model	LB23232309 B33RDYR	Visually/ Physically		
Bridge Rectifier	Make	SPE	Visually/ Physically		
	Model	MD5BU1016	Visually/ Physically		
	Specs.	5A/DC	Visually/ Physically		
Control Relay & Sockets	Make	PLA	Visually/ Physically		
	Model	3 C/O MPC	Visually/ Physically		
	Specs.	24 VAC, 11 pin	Visually/ Physically		
	Qty.	To be recorded	Visually/ Physically		
Control Relay	Make	Phoenix	Visually/ Physically		
	Specs.	24 VDC, 6A	Visually/ Physically		
Cooling Fan	Make	Rexonard	Visually/ Physically		
	Specs.	230 VAC, 0.1 A	Visually/ Physically		
Filter grill for 4” Fan	Make	Jainson	Visually/ Physically		
Push Button	Make	Teknic	Visually/ Physically		
	Model	2LHBR24	Visually/ Physically		
	Spec.	24 VAC	Visually/ Physically		

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System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Push Button Contact Ele Green	Make	Teknic	Visually/ Physically		
	Model	Teknic (S1)	Visually/ Physically		
	Spec.	24 VAC, 4A	Visually/ Physically		
Push Button Contact Ele Red	Make	Teknic	Visually/ Physically		
	Model	Teknic (S2)	Visually/ Physically		
	Spec.	24 VAC, 4A	Visually/ Physically		
Emergency Push Button Red	Make	Teknic	Visually/ Physically		
	Spec.	24 VAC	Visually/ Physically		
Magnetic Micro Switch for guard	Make	B + K Engg	Visually/ Physically		
	Spec.	24 VAC	Visually/ Physically		
Delay Timer	Make	BCH	Visually/ Physically		
	Model	BAR	Visually/ Physically		
Pilot Lamp Red (for tower)	Make	Teknic	Visually/ Physically		
	Model	2LHBR24	Visually/ Physically		
Micro Switch	Make	Essen	Visually/ Physically		
	Model	MBC1P1	Visually/ Physically		
Proxy Switch	Location	On the upper cam disc assembly	Physically		
	Make	Pepperel + Fuchs	Visually/ Physically		
	Model	NBB5-18GM50-E2	Visually/ Physically		
Filter Regulator for Main Incoming Air Supply	Make	FESTO	Visually/ Physically		
	Model	LFR-D-MINI	Visually/ Physically		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COMPRESSION MACHINE

System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Spec.	P1 (max)- 16 bar/ P2 (max)-12 bar	Visually/ Physically		
	Gauge	0 to 16 bar	Visually/ Physically		
Lubricator for Main Incoming Air Supply	Make	FESTO	Visually/ Physically		
	Model	LOE-D-MINI	Visually/ Physically		
	Spec.	P1 (max)- 16 bar	Visually/ Physically		
Air Solenoid Valve	Make	FESTO	Visually/ Physically		
	Model	CPE14-M1BH-5L-1/8	Visually/ Physically		
Rotary Actuator for gate operation in the tablet discharge chute	Make	FESTO	Visually/ Physically		
	Model	DSR-12-180-P	Visually/ Physically		
Control Transformer	Make	Narmada	Visually/ Physically		
Hydraulic Pressure Sensor	Location	On the hydraulic line in the base cabinet	Physically		
	Make	IFM	Visually/ Physically		
	Model	PA3022	Visually/ Physically		
Powder Level Sensor	Make	IFM Electronics	Visually/ Physically		
	Type	KI5023-KIE3015-FPKG/NI	Visually/ Physically		

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

Reviewed by (Sign/Date)

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COMPRESSION MACHINE

5.5 Verification of Material of Construction:

S.No.	Component	MOC	Method of verification	Actual Observation	Checked By Sign / Date
1.	Turret (Special 3 piece) • Upper and lower piece • Die table	SGI 500/07 with nickel plating on turret SS316L	Molybdenum kit/ Technical Certificate		
2.	Pressure Roll- Main (Upper & Lower)	OHNS AISI 01	Molybdenum kit/ Technical Certificate		
3.	Force Feeder	Gun Metal	Technical		
4.	Feeder housing	HE-30	Certificate		
5.	Paddle for Force Feeder	SS 316 L	Molybdenum kit/ Technical Certificate		
6.	Discharge chute	SS 316 L	Molybdenum kit/ Technical Certificate		
7.	Hopper	SS 316 L	Molybdenum kit/ Technical Certificate		
8.	Lower guard	SS 304	Molybdenum kit/ Technical Certificate		
9.	Butterfly valve	SS 316 L	Molybdenum kit/ Technical Certificate		

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

Reviewed by (Sign/Date)

5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

UTILITY	OBSERVATION	CHECKED BY (SIGN/DATE)
Electricity: 3 Phase, 415Volts,50 Hz	Physically with clamp meter	
Compressed air NLT 6 Kg/cm^2	Visually from pressure gauge.	

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

Reviewed by (Sign/Date)

5.7 IDENTIFICATION OF SAFETY FEATURES:

Identify and record the safety features (if any) and their function in following tables:

Safety Features Description	Location/Identification	Method of Verification	Observation	Identified By Sign/Date
Guard: Machine should stop when guard is opened	Limit switch for upper acrylic guards.	Visually		
Emergency Switch: To stop the machine immediately.	Should be provide in operating panel.	Visually		
MCB: to trip the machine when overloaded.	Should be present in control panel.	Visually		

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

Reviewed by (Sign/Date)

5.8 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were identified as important for effective performance of Compression Machine.

S.No.	SOP TITLE	IDENTIFIED BY	DATE

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

Reviewed by (Sign/Date)

5.9 IDENTIFICATION OF COMPONENT (S) TO BE CALIBRATED

Identified that the drafted calibration procedures for different identified components in Compression Machine are adequate and appropriate covering the operating range(s). e.g. Pressure gauge, counter etc (As applicable)

Name of Components	Range	Make	ID	Location	Identified By Sign/Date

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

Reviewed by (Sign/Date)

5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	Drawing And Document Detail	Verified By Sign/Date

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

Reviewed by (Sign/Date)

5.11 ABBREVIATIONS:

Following Abbreviations are used in the installation qualification protocol of Double Side Rotary Tablet Compression M/C 55 Station:

MOC: Material of construction

RPM: Revolution per minute

GMP: Good Manufacturing practices

HP: Horse Power

kW: Kilowatt

OHNS: Oil Hardened Non – Shrinking

GM: Gun Metal

Hz: Hertz

V: Volts

Ph: Phase

PLC: Programmable Logic Controller

MMI: Man Machine Interface

SS: Stainless Steel

AC: Alternating Current

KN: Kilo Newton

MCB: Miniature Circuit Breaker

m/c: Machine

Stn.: Station

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)

5.13 Annexure (S)

Annexure No.	Details Of Annexure

Remarks (if any)**:**

_____

_____

Done By & Date: **Verified By & Date:**

6.0 INSTALLATION QUALIFICATION FINAL 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. All amendments and discrepancies are documented, approved and attached to this protocol. If applicable signature in the block below indicates 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. After the successful installation qualification of the Double Sided rotary tablet m/c 55 station the equipment can be taken for operational qualification.

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