



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR COMPRESSION MACHINE

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1. Objective:-



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- To design, engineer, and supply the 55 Station is 'B' Tooling Tablet Compression Machine manufactured by M/s
- To prove that each operation proceeds as per the design specification and the tolerances prescribed there in the document is the same at utmost transparency.

2. Scope:-

- The scope of this qualification document is limited to the Design Qualification of 'B' tooling with PLC Touch Screen.
- This qualification document is part of a validation activity with PLC Touch Screen Machine.
- Qualification of support utilities is not within the scope of this qualification document.
- The equipment shall be used for compressing the powder into tablets. The equipment shall operate under dust free environment and conditions as per the GMP requirements.



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3. Responsibilities: -

MANUFACTURER: -

1. To provide the complete technical details of the equipment pertaining to its operational functions.
2. To prepare the Design Qualification Protocol incorporating the following parameters:
 - Machine Overview / Description
 - Technical Specifications of bought – out items
 - Material of Construction of different parts
 - Details of the Power Consumption
 - Product surface contact area.
 - Brief process description.
 - Technical write-up of the contents in the MMI touch screen.
 - Safety feature.

To facilitate the client for the Factory acceptance test of the Machine at their works/site.

CLIENT: -

- To Provide the URS for the Equipment.
- To verify the Qualification Protocol.
- To approve the Design Qualification Protocol.
- To Perform the Factory Acceptance Test (FAT).

4. Machine Description:

The 55 station 'B' tooling is a high speed double Rotary Tablet compression machine is controlled through PLC system. It is a versatile machine in the range of tableting Machine can operate in Auto / Manual mode. It is also incorporated with 3 Piece Turret with SS316 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:



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- **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**

❑ **POWDER FEEDING UNIT (LHS & RHS): -**

This comprises of the following –

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

An SS 316 Hopper of capacity 20 Liters 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 tableted & 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 sensing 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. Machine will stop functioning in case there is Low Powder Level Alarm on either side of the 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 –



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Force Feeder: - The force feeder has two counter rotating paddles of SS316, 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 hopper through butterfly valve. When 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 requirement 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 floated 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 powder scraper assembly along with tail over die is mounted on feeder support plate. The springs-loaded scraper scrapes off the excessive material against the turret die table and divert it for re-circulating.

The scrapper of the Gunmetal lies on the RHS of the Feed Frame, which all are. It scrapes out the excess powder after weight adjusting dozer. The discharge powder is recirculated into the next Feed Frame pockets.

❑ **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, 55 station is purely eccentric drive.

N.B.: The rotation of Stations is clockwise.

❑ **Turret** – This is tool holding body is a 3 piece structure having the center die table of SS 316L and the Upper and 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



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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 Center, Pressure Roll and Pressure Roll Pin. The Roll Center 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 Center, Pressure Roll and Pressure Roll Pin. The Roll Center 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): -



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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.

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:

1. Hydraulic Oil Tank –

The Hydraulic oil used for is stored in this reservoir. Generally, the recommended oil is ENKLO – 32 / TELLUS– 37. There is “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.

2. 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.

3. Hydraulic Power Pack Unit –

This unit is responsible for the regulation of the hydraulic pressure. It comprises of the following sub – components:

4. 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

5. 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.

6. 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



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pressure of the Pressure switch, the pressure switch immediately cuts off the power supply of the Hydraulic motor. This stops pumping.

7. Solenoid Valve –

This is direction control valve opening on one side.

8. Pilot Operated Check Valve –

This is plunger-operated valve and plays an important role during release of the hydraulic pressure.

9. 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 kgs./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 is 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 –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



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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 the following:

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



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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.
- ❑ **Tablet takes 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.

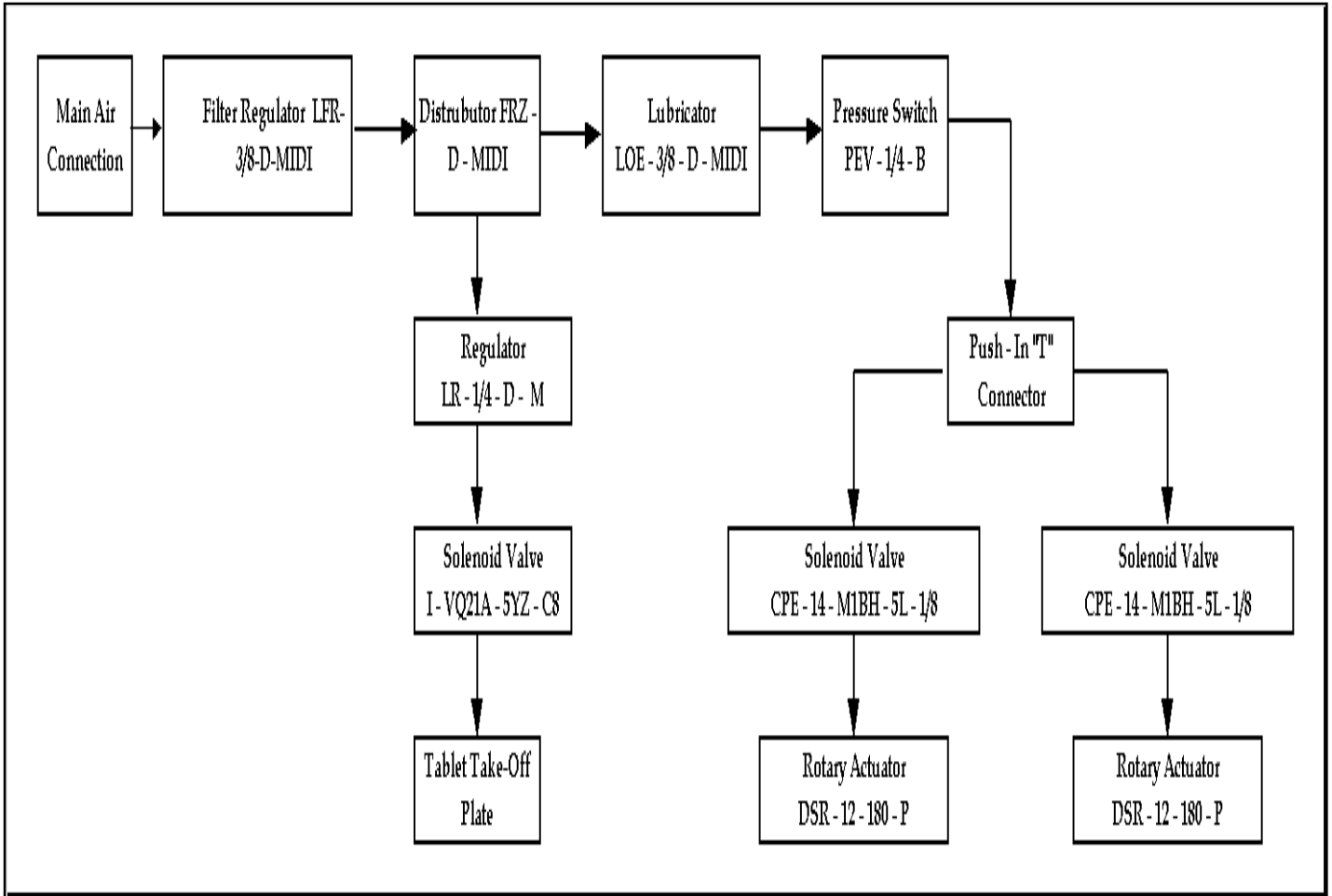
The Auto Rejection system is used for to separate out initial tablets that are not with in required parameters due to various factors when initial starting & stopping of the machine. Nos. of initial compressed tablet rejection can enter the value to separate out the tablets in rejection outlet gate of 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 and Rejections is given through this Take – off plate.



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5. PNEUMATIC FLOW - A BLOCK REPRESENTATION





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6. Technical Specification:-

S.No.	Description	Specifications
1.	Name	CPDIV-55 stn. Double Rotary
2.	Tooling	'B' tooling
3.	Specification	Contact parts - SS316 (Inclusive of the Die pot table) and Non contact parts – SS 304
4.	Turret RPM	Min = 12 / Max = 60
5.	Output (Tablet / Hour.)	Min. = 79200/hr / Max.=396000/hr Depend on the Product BD
N.B.- Point No. 4 and Point No. 5 – Depends upon the product characteristics		
6.	Hopper capacity	20 ± 1 Liters
7.	Upper Punch Penetration (Main)	Min = 3 mm to Max = 6 mm
8.	Upper Punch Penetration (Tamp)	Min = 2 mm Max = 5 mm
9.	Tablet thickness	Min= 2 mm Max=8mm 8 mm Thickness is for Flat Tablet. In case your Tablet is Beveled Edge or Concave, the cup depth for the same will be considered as extra. For example: Flat Tablet Thickness = 8 mm, and Concavity of the Tablet is 1 mm each side, then the total thickness will be 10 mm.
10.	Max. Operating pressure (Main)	65 kN
11.	Max. Tamping Pressure	10 kN
12.	Max. Tablet Dia.	16 mm
13.	Max. Depth Of Fill	17 mm
14.	Approx. Overall dimensions (in mm, with guards open)	1460 x 1610 x 1960H
15.	Type of Feeding	Forced Feeder
16.	Main Drive Motor	10 HP / 7.5 kW, 415V, 50 Hz, 3 Phase, 1455 RPM. Make – C & G
17.	Feeder Drive Motor (02 Nos.)	0.25 HP / 0.18 kW, 1350 RPM, 415V, 50 Hz, 3 Phase., Make – Bharat Bijlee Ltd
18.	Hydraulic Motor (01 No.)	1 HP / 0.75 kW, 1410 RPM, 50 Hz, 3 Phase, Make – C&G
19.	ACVFD for Main Motor	Make – Allen Bradley Specification: 10 HP, 415 V, 3 Ph Model – Powerflex 40
20.	ACVFD for Feeder	Make – Allen Bradley



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S.No.	Description	Specifications
	Motor	Specification: 1 HP, 415 V, 3 Ph Model – Powerflex 4 M
21.	PLC	Make – Omron Model – CP1H-XA40DT1-D
22.	Powder Level Sensor	Make – IFM Electronics Type: KI5023-KIE3015
23.	HMI	Make – Proface Specs: 24 V DC, 6” Colour Model: AGP 3301-S1-D24 24 VDC
24.	Lubrication Pump	Make – MiniHyd Model – PP1
25.	Accumulator	Make -..... Type – Mechanical Spring Loaded.
26.	Electromagnetic Clutch	Make – Golden 20 EBA, 24VDC
27.	MCB – (All in Control Panel)	Make – Schneider
28.	Contactora – Hydraulic Motor	Make – Schneider
29.	Overload Relay for Hydraulic Motor	Make – Schneider
30.	SMPS	Make – Omron Model: S8VK - C06024
31.	Main Isolator Switch	Make – Salzer Model: LB 232 32309 B 33 RDYR
32.	Contactora for Magnetic Clutch	Make – Schneider Specs: 24 A / 240 V AC Model: LC 1D12
33.	Bridge Rectifier	Make – SPE Specs: 5 A / DC Model: MD 5 BU 1016
34.	Control Relay & Sockets	Make – PLA Specs: 24 V AC, 11 Pin, 3 C/O Model: MPC
35.	Control Relay	Make – Phoenix Specs: 24 V DC, 6A
36.	Cooling Fan	Make – Rexonard Specs: 230 V AC, 0.1A
37.	Filter grill for 4” Fan	Make – Jainson
38.	Push Button	Make – Teknic Specs: 24 v AC



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S.No.	Description	Specifications
		Model: 2LHBR 24
39.	Push Button Contact Ele Green	Make – Teknic Specs: 24 v AC, 4 A Model: Teknic (S2)
40.	Push Button Contact Ele Red	Make – Teknic Specs: 24 v AC, 4 A Model: Teknic (S1)
41.	Emergency Push Button Red	Make – Teknic Specs: 24 v AC
42.	Magnetic Micro Switch for guard	Make – B + K Engg Specs: 24 v AC
43.	Delay Timer	Make – BCH Model: BAR
44.	Pilot Lamp Red (for tower)	Make – Teknic Model: 2LHBR 24
45.	Micro Switch	Make – Essen Model: MS – 7
46.	Proxy Switch	Make – Pepperl + Fuchs Model: NBB5 – 18GM50 – E2
47.	PNEUMATIC SYSTEM	
47.1	Filter Regulator for Main Incoming Air Supply	Make – FESTO LFR-D-MINI P1 (max) – 16 bar / P2 (max) – 12 bar Gauge – 0 to 16 bar
47.2	Lubricator for Main Incoming Air Supply	Make – FESTO, LOE-D-MINI, P1 (max) – 16 bar
47.3	Intermediate regulator for Tablet Take off plate	Make – FESTO LR-D-MINI P1 (max) – 16 bar / P2 (max) – 12 bar
47.4	Air Solenoid Valve	Make – FESTO CPE14-M1BH-5L-1/8
47.5	Rotary Actuator for gate operation in the tablet discharge chute	Make – FESTO DSR-12-180-P
47.6	Filter Regulator for Lower Punch Lubrication System	Make – FESTO LFR-D-MINI P1 (max) – 16 bar / P2 (max) – 12 bar Gauge – 0 to 16 bar



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7. Specification of PLC/HMI: -

Description	Specified
PROGRAMMABLE LOGIC CONTROL (PLC)	
Manufacture	OMRON
Description	CP1H-XA40DT1-D
Input Voltage	24 V DC
Output Voltage	24 V DC
HUMAN MACHINE INTERFACE (HMI)	
Manufacture	Proface
Model	PFXGP 4301-TA-DWC 24 VDC



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8. SCREEN DETAILS

SECURITY CONTROL SCREEN

WELCOME SCREEN

MAIN MENU SCREEN

MACHINE CONTROLS SCREEN

TURRET CONTROLS SCREEN

FEEDER CONTROLS SCREEN

COMPACTION FORCE CONTROLS SCREEN

LUBRICATION CONTROLS SCREEN

MACHINE STATUS SCREEN

RECIPE MANAGEMENT SCREEN

RECIPE PARAMETERS SCREEN

BATCH DATA SCREEN

MACHINE TECHNICAL DATA SCREEN

CHANGE PASSWORD SCREEN



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9. Power Consumption:

Motor	Specification
<ul style="list-style-type: none">• Main motor Voltage Hp Amperage	415 V 10 14.5
<ul style="list-style-type: none">• Feeder motor (LHS) Voltage Hp Amperage	415 V 0.25 0.56
<ul style="list-style-type: none">• Feeder motor (RHS) Voltage Hp Amperage	415 V 0.25 0.56
<ul style="list-style-type: none">• Hydraulic Pump motor Voltage Hp Amperage	415 V 1 1.81

Compressed Air Pressure – NLT 6 Kgs. / Sq.cm.

Vacuum Suction – NLT 150 CFM

Power failure:

At the time power failure /power cut off equipment will come to rest & following steps should be follow,

- Operate the emergency switch.**
- Operate the main switch in off position.**
- After the power comes on once again start the machine with login password.**
- After power restart equipment will start from its rest position.**

NOTE: - If machine is shutdown more than 4-5 hours than first of all clean the machine with all punches. Then start the machine as all points mention above.



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10. Material of Construction: -

S.No.	Component	MOC
1.	Turret (Special 3 Piece) <ul style="list-style-type: none">• Upper / Lower piece• Die Table	SGI 600/3 SS 316 L
2.	Press roll - Main (Upper & Lower)	OHNS AISI 01
3.	Force Feeder	Gun Metal
4.	Paddle for Force Feeder	SS 316 L
5.	Hopper	SS 316 L
6.	Butterfly Valve	SS 316 L
7.	Discharge Chute	SS 316 L
8.	Lower Guard	SS 304



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11. Brief Process Description: -

FORCE FEEDING

The formulated powder in the hopper is pulled down using a Force Feeding arrangement consisting of rotary force feeders. The advantage of force feeder is, ensured die filling.

OPERATION

The lower punches, which always remain in the die, hold the powder that is fed into the die, onto it. Further, due to the rotation of the turret, these punches move on the dozer assembly where only required quantity of the powder is held back and the rest is scrapped out. Punches then glide on to the pressure roll. At this stage the upper punch moves down the Upper cam track – Lowering, towards the Main pressure roll after passing under the tamping roll assembly. Both the punches get pressurized under the main pressure rolls. At this instant, due to the heavy compression force, the particles in the formulated powder get bonded to each other and form the tablet. The excessive backpressure generated in this process is absorbed by the hydraulic cylinder, which is suspended onto the lower pressure roll carrier. After the tablet is formed inside the die, it needs to be ejected out. The lower punch moves further on to the ejection cam track and the tablet gets ejected out. At this stage, the upper punch moves onto the Upper cam track – Lifting and glides idly on the upper cam piece. After the tablet is ejected out, the lower punch moves in the lower cam track and comes beneath the feeder and the cycle continues. In one revolution, there is double ejection of tablets.

$$\text{TABLET OUTPUT / REVOLUTION} = \text{No. OF STATIONS} \times 2$$

N.B.: THE TAMPING ROLLS ARE FOR PRE-DENSIFICATION OF THE POWDER AND NOT FOR COMPLETE FORMATION OF THE TABLET.



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12. Safety Features:

S.No.	Alarm Messages	Description	Probable Cause
1.	Turret Motor Overload	The turret motor stops, if the current drawn by the motor is more than 10% of the rated value.	<ul style="list-style-type: none">To check for rasp. output in the PLCTo check the tightness of the timing beltTo check for any one phase failure.
2.	LH Feeder Motor Overload	Motor stops if the current drawn by the motor is more than 10% of the rated value	<ul style="list-style-type: none">Material clogging between the paddles.Gear jamming.
3.	RH Feeder Motor Overload	Motor stops if the current drawn by the motor is more than 10% of the rated value	<ul style="list-style-type: none">Material clogging between the paddles.Gear jamming.
4.	LH Dozzer Assembly Not In Position	Machine shall not start.	The LHS Dozzer has not been assembled properly.
5.	RH Dozzer Assembly Not In Position	Machine shall not start.	The RHS Dozzer has not been assembled properly.
6.	Batch Size Completed	Machine will not start	Batch size being completed and needs resetting.
7.	Emergency Push Button Operated	Machine does not start	Emergency push button being pressed.
8.	Machine Guards Open	Machine will not start and will stop if in motion.	Machine set in interlock mode.
9.	Guards Selected In Bypass Mode	Machines runs but with red-indication in the MMI	Selector icon in by-pass mode. Reset to Interlock mode.
10.	Hydraulic Motor Overload	Motor stops if the current drawn by the motor is more than 10% of the rated value	<ul style="list-style-type: none">Foreign particle in the positive displacement pump.Failure of pressure switch
11.	Lubrication Oil Level Low	Machine will not start. Machine stops, if in motion.	Lubrication Oil reservoir has shortage of oil.
12.	Tablet Counting Proxy Not In Position	Machine will run but with RED indication & message will be displayed tablet counting proxy not in position	Setting being disturbed. Reset as desired.



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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S.No.	Alarm Messages	Description	Probable Cause
13.	Main Set Pressure LH Overload	Machine runs with excessive vibration at lower roll carrier	<ul style="list-style-type: none">• Suspected for hydraulic oil leakage.• Hydraulic pressure not being set before starting the machine. N.B.: Do not run/ start the machine till such time, this problem is resolved and the indication has disappeared.
14.	Main Set Pressure RH Overload	Machine runs with excessive vibration at lower roll carrier	<ul style="list-style-type: none">• Suspected for hydraulic oil leakage.• Hydraulic pressure not being set before starting the machine. N.B.: - Do not run/ start the machine till such time, this problem is resolved and the indication has disappeared.
15.	Main Drive In Manual Mode	The machine shall not start.	The Main Drive is put in the manual mode.
16.	Air Pressure Low.	The machine shall not start.	Incoming Air Pressure Low.
17.	LHS / RHS Powder Level Low.	The machine shall not start.	The Level of powder in LHS / RHS hopper is below the sensing height.
18.	LH/RH Feeder jammed	Machine will stop & message will be displayed LH/RH Feeder jammed	Excess powder get stuck in feeder housing or feeder shaft get jammed
19.	Hydraulic Oil Level Low	Machine will stop & message will be displayed hydraulic Oil level Low	Hydraulic Oil reservoir has shortage of oil.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR COMPRESSION MACHINE

13. Load Calibration Chart:

S.No.	Load (Ton)	Digital Force Indicator reading (kN)	Pressure Gauge Reading (kg / sq. cm)
1.	1	10	7.35
2.	2	20	14.70
3.	3	30	22.05
4.	4	40	29.40
5.	5	50	36.75
6.	6	60	44.10
7.	6.5	65	47.78



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14. Lubrication Details: -

S.No.	Component	Location	Period	Lubricant	
				<i>HP Make</i>	<i>Shell Make</i>
1.	Reservoir for lubrication system	Besides Main drive Gearbox, within lower cabinet.	Fill as required	Enklo – 68	Omala – 220
2.	Main drive gear box	Within lower cabinet	2000 working hours	Enklo – 68	Omala – 220
3.	Gearbox for force feeder drive	Within Lower cabinet	2000 working hours	Enklo – 68	Omala – 220
4.	Oil Drip Trays	Besides Lower Roll Carrier	Fill as required	Enklo – 68	Omala – 220
5.	Oil Nipples for Pre-Pressing Rolls	Near Main Press Roll	One Shot with Oil gun, daily	Enklo – 68	Omala – 220
6.	Grease Nipples for Bearing	Upper and Lower Pressure Roll Centers	One Shot, once in a month	Servogem – 3	Alvania – RA Grease
7.	Motor bearing	Main Drive Motor Force Feeder Drive Motor Hydraulic Pump Motor	Apply manually after about 3000 working hours	Servogem – 3	Alvania RA grease
8.	Power pack system oil reservoir	Within Lower Cabinet	Fill as required	Enklo – 32	Tellus – 37



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15. Product Surface Contact Area:

S.No.	Name of the Part	Product Contact Surface Area in Sq. cm per piece	Total Qty. used in the machine	Total Product Contact Surface Area in Sq. cm
1.	Hopper	4628	2	9256
2.	Flap for Butter Fly Valve	157	2	314
3.	Inlet Connector	409	2	818
4.	Bellow at Inlet connector	294		588
5.	Feeder Sole Plate	700	2	1400
6.	Big Paddle	365	2	730
7.	Small Paddle	275	2	550
8.	Turret (Die Pot Table)	2850	1	2850
9.	Discharging Chute (Inner)	660	2	1320
10.	Discharging Chute (Outer)	770	2	1540
			TOTAL	19366

Total Product Surface Contact Area on 55 station is 19366 Sq. cm.



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16. Test Certificates / Inspection Reports: -

S.No.	Component	Type
1.	Main Drive Motor	Test Certificate
2.	Force Feeder Motor	Test Certificate
3.	Hydraulic Motor	Test Certificate
4.	Spring of Mechanical Accumulator	Test Certificate
5.	Hydraulic Pressure Gauge	Test Certificate
6.	ACVFD for Main Motor	Test Certificate
7.	ACVFD for Feeder Motor	Test Certificate
8.	PLC (Programmable Logic Control)	Test Certificate
9.	HMI	Test Certificate
10.	Electromagnetic Clutch	Test Certificate
11.	Main Drive Gear Box	Inspection Report
12.	Feeder Drive Gear Box	Inspection Report
13.	Adjusting Dials	Inspection Report



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17. MOC Certificates:

S.No.	Component
1.	Turret
2.	Die Table
3.	Press roll - Main (Upper / Lower)
4.	Feeder Platform
5.	Force Feeder
6.	Paddle for Force Feeder
7.	Hopper
8.	Discharge Chute
9.	Lower Guard

18. FAT Procedure:

Factory Acceptance Test Procedure shall be as follows:

- After the completion of erection work of the machine, client or authorized representative, on behalf of the client shall be informed to perform the factory acceptance test (FAT)
- Client or authorized representative, on behalf of the client, shall perform the FAT at the manufacturer site and record all the data in the prescribed FAT document as per the details given below:
 1. Test Criteria
 2. Design verification check list
 3. Deficiency and corrective action report
 4. Pre – installation requirements
 5. Final reports.



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19. Change Control Procedure:

Any modification arising in the design at a later stage, shall be incorporated only after due authentication of Change Control Procedure. The client and the Manufacturer should authenticate the Change control procedure.

20. Reference documents – Annexure:

S.No.	Documents
1.	Technical Specification Sheet
2.	User Requirement Specification
3.	Equipment Brochure
4.	General Arrangement Drawing



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR COMPRESSION MACHINE

22. Abbreviations:

Abbreviated Form	Expanded Form
GMP	Good Manufacturing Practice
URS	User Requirement Specification
FAT	Factory Acceptance Test
SS	Stainless Steel
MPCB	Motor Protection Circuit Breaker
MCB	Miniature Circuit Breaker
PLC	Programmable Logic Controller
AC	Alternating Current
HP	Horse Power
mm	Millimeter
RPM	Revolution Per Minute
kN	Kilo Newton
kW	Kilo Watts
V	Volts
Ph	Phase
Hz	Hertz
Kgs./Sq.cm	Kilograms per square centimeter
ms	Milli seconds
FET	Field Effect Transistor
°C	Degree Centigrade
°F	Degree Fahrenheit
Nm	Newton Meter
in - lb	Inch – Pound
OHNS	Oil Hardened Non – Shrinking
MOC	Material of Construction



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23. Approval Sheet:

Prepared By:

The signature below claims to have compiled the protocol with respect to the User Requirement Specification

Name	Designation	Department	Signature	Date

Reviewed & Approved By:

The below signatory claims to have verified the specifications as laid in the defined qualification protocol and authenticates the protocol to have met with the specifications

Name	Designation	Department	Signature	Date

24. Customers Approval (In accordance to Point no. 22):

Reviewed By:

The Reviewer's signature claims to have verified the specifications as laid in the defined qualification protocol.

Name	Designation	Department	Signature	Date

Approved By: The Approver authenticates the protocol to have met with the specifications as laid in the User Requirement Specification and that the machine is as per the defined protocol.

Name	Designation	Department	Signature	Date