PHARMA DEVILS	OPERATIONAL QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 Soft Gelatin Encapsulation System (CAP-X-8) 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		

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Soft Gelatin Encapsulation System (CAP-X-8) and define the qualification requirements and acceptance criteria for the machine and to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document, are the same at utmost transparency.

The Qualification of Soft Gelatin Encapsulation System (CAP-X-8) performed in view of Line II of Soft gel packing hall of manufacturing facility.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Soft Gelatin Encapsulation System (CAP-X-8) received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

The Scope of this protocol is limited to the operational Qualification of Soft Gelatin Encapsulation System (CAP-X-8) in Line II of Soft gel packing hall of manufacturing facility.

Once the operational qualification of Soft Gelatin Encapsulation System (CAP-X-8) has been completed successfully, the equipment shall be preceded for the performance qualification procedure.

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 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.

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 the Soft Gelatin Encapsulation System (CAP-X-8) shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Soft Gelatin Encapsulation System (CAP-X-8) is installed satisfactorily.

Execution team is responsible for the execution of operation of Soft Gelatin Encapsulation System (CAP-X-8). 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 shall be verified and checked.

3.3 All the functionality of equipment components to be checked.

3.4 All the safety features of the equipment shall be verified and utilities shall be available near the equipment.

3.5 The validity of the calibration of tests instruments shall be checked and all the required calibration of the components of the equipment shall be performed.

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

4.0 REVALIDATION CRITERIA:

The machine has to be revalidated if

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

5.0 INSTALLATION QUALIFICATION PROCEDURE:

5.1 SYSTEM DESCRIPTION:

1.	Equipment Name	:	Soft Gelatin Encapsulation Machine
2.	Supplier/Manufacturer	:	ARBES TOOL PVT. LTD.
3.	Model	:	ARBES - CAP - X - 8
4.	Serial no.	:	484
5.	Overall Dimensions	:	1590 mm X 1070 mm X 2055 mm
6.	Location	:	Soft Gelatin Manufacturing Area.

General Description:

The Automatic Rotary Die Soft Gelatin Encapsulation Machine is designed to perform the process of Encapsulation with different fill weights in different shape and sizes of capsules.

The production capacity of the machine is 13800 to 36000 capsules per hour @ 3.0 rpm. The capsules are manufactured by passing the gelatin film of uniform thickness over two rotating die rolls of cylindrical form with cavities on periphery. A metering pump forces premeasured injection of fill material through a heated feeder segment placed between two gelatin films into matching die roll cavities. The filled capsules are formed between the two die rolls. Through pressure and heat sealing, the two halves of ribbon get effectively fused. Freshly formed soft gelatin capsules discharged from the machine and pass along a transfer conveyor into Tumbler Drier. On completion of the tumbling, the capsules are placed on trays which are then stacked and transferred into the capsule Drying Room for further drying.

The Soft Gel Encapsulation Machine (CAP-X-8) consists of following sub assemblies:

1. **Gelatin Ribbon Formation:**

   The molten gelatin mass (at 60°± 5°C) is fed to the spreader boxes and is discharged onto the ribbon casting drums to form a gelatin ribbon. The thickness of the gelatin ribbon can be adjusted by controlling the opening of spreader box gates. The level of the gelatin in the spreader box can be controlled via electronic sensor + pneumatically operated valve system.

   These ribbons then pass through oil lubrication roller assembly where they get lubricated with oil (with the ability to have different inner and outer lubricants on the ribbon), and then pass over the die rolls, where medicine is injected through segment holes and capsules are formed.

2. **Medicine Metering:**

   A positive displacement medicine pump delivers the medicine to the die pockets through injection dozing pipes and wedge (segment). Uniformity of fill weight of capsules is a critical operational parameter in this system. Fill volume can be controlled by turning the stroke-adjusting knob.

3. **Capsule Formation and Sealing:**

   The ribbon casting drums rotate at a pre-set speed relative to the die rolls, to ensure proper encapsulation process. The die rolls are fitted on the die roll housing. The gear drive system in the die roll housing supplies the rotary power for the dies as well as the drive power for the medicine pump. The heaters provided in the segment provide the sealing heat for the capsule seam. The heaters can operate up to 90° C and temperature setting will depend on the formulation of the medicament and the gelatin. The shut-off valve acts like an injection **ON/OFF** switch for medicament injection into the die pockets. The Alternate Frequency Drive will allow the operator to control the rpm of the die rolls, and hence encapsulation speeds.

   Transfer of Capsules to Tumbler Drier: The capsules formed are taken on a belt conveyor and transferred to the Tumbler Drier for further processing. The belt is made up of food-grade material.

4. Preliminary Drying of Capsules:

The newly-formed capsules are soft in nature and have uncured seals, which get strengthened by the rotational motion of the Tumbler Drier baskets and the chilled air blown on the capsules. The baskets rotate at an adjustable speed. The time that the capsules are rotated in the baskets helps in ensuring a strong seal as well as a firm shape. Cold air from the room is blown (at high cfm) onto the rotating capsules. The newly formed capsules which enter the tumbler drier have an oily exterior due to the encapsulation process. Blowing this chilled room air onto the rotating capsules removes (to a very great extent) the peripheral oil on the capsules. When the capsules are discharged out of the tumbler drier, a qualitative decrease in the oiliness of the capsules is seen as well as capsules have better shape and firmness.

5. PLC for Encapsulation system:

ARBES Encapsulation system offers the user a great deal of flexibility. The VFDs provided for all motors, the Pneumatic systems, and the temperature controllers, the timers are controlled by the PLC.

This system allows the operator to set the total drying time for capsules, using proprietary programming logic which controls the time of holding of capsules in each basket.

6. Pneumatic Systems provided:

The encapsulation machine is provided with:

1) Pneumatic die roll loading system.
2) Segment lifting system.
3) Electro-pneumatic lubrication systems of the
   (a) Medicine pump slide valve and

   (b) cam+ brush assembly.

4) Clamping (Gripper) unit to fine-tune the injection timing.
5) Gelatin flow control valves (pinch valves).

There is one pressure regulator, which receives the line pressure (air line provided through a dedicated compressor). This line pressure is then directed to the following pneumatic sub-systems:

1) **Pneumatic die roll loading system :**

For the die roll loading system, the two cylinders on the left side of the yoke constitute the pressure loaders. By operating the loading controls on the PLC, the die rolls are pressured (pressed against each other). When the cylinders are de-energised, the die rolls can be manually pushed apart. (Never energise the die roll loading system if no die rolls are loaded on the shafts or if no gelatin ribbon is present between the die rolls). Additionally, the die rolls can be pressed against each other at two different pressures the lower pressure to allow an imprint of the cavity on the ribbons and the higher pressure for capsule slug cutting.

2) **Segment Lifting System:**

The segment lifting system is pneumatically controlled through the PLC. In the event of an emergency, the system is designed to automatically lift the segment.

3) **Electro-pneumatic lubrication system of the medicine pump slide valve and cam+ brush assembly :**

The lubrication system consists of metering cartridges controlled by the PLC timer. It is similar to a plunger type injection system having independent metering injectors for each assembly. The amount of oil at each lubrication point is controlled by using the single-shot 'METERING CARTRIDGES'. Fill the oil tank with Food-Grade Paraffin Oil / MCT (medium chain triglyceride).

Minimum working pressure is 3 kg/cm^2. The PLC timer for ON/OFF time is adjusted to control the number of strokes of lubrication oil per minute. The number of strokes/minute can be adjusted from 4 strokes/min to 15 strokes/min using the timer arrangement. Each plunger will inject 0.2 cc /stroke.

4) **Clamping unit to allow fine-tuning of the injection system:**

The medicine pump is fitted in its place by taking care that the mark on the cam gear is matched with the mark on the driving gear fitted to the crank shaft. The Clamping unit is used to fine-tune the injection of the medicine into the respective pocket of the die-roll. By energising the clamping unit, the injection is accelerated (injected earlier) into the pocket.

5) Gelatin flow control valves (pinch valves):

The pinch valves are used to supply gelatin mass to the respective spreader boxes. They are operated using compressed air. The solenoid valves and the level sensors control the opening and closing of the valves.

5.2 INSTRUCTION FOR FILLING THE CHECKLIST

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

5.2.2 For identification of the components of the equipment and utilities actual observation should be written in specified location.

5.2.3 Give the detailed information in the summary and conclusion part of the Operational Qualification report.

5.2.4 Whichever column is blank or not used ‘NA’ shall be used.

5.3 Verification of Calibrated component:

This test is intended to describe the equipments/instruments and its complete details to have traceability to the national standard, which is to be used for the verification of the operation of the Soft Gelatin Encapsulation system.

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

Done By & Date:

Remarks:

Verified By & Date:

5.4 Test instrument Details:

Review the calibration status for the test instrument to be utilized in operational qualification testing and record the calibration due dates in the table below. All equipment / instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilized.

S.No.	Test Instrument	ID	Calibration done Date	Calibration Due Date	Calibration Certificate No.

Checked By/Date:

Remarks:

Verified By/Date:

5.5 VERIFICATION OF FUCTIONAL CHECKS:

OBJECTIVE: To check the working efficiency of the ARBES CAP-X-8 Machine sub-assemblies:

METHOD:

TEST RUN: During the test run following checks to be performed and also check the efficiency of the machine:-

1) First check manually the movement of the belt of Main Drive Motor connected to pulley fitted to the horizontal shaft of machine gear box assembly.

2) If the machine is free, fit the change parts and operate the CAP-X-8 machine without gelatin load at the standard speed of 3.0 rpm to check the following :

- **a.** Check the internal lubrication of machine.
- **b.** Note any vibrations or jerking movement of Ribbon Casting Drums.
- **c.** Check the direction of rotation of die rolls.
- **d.** Check the working of HMI screen by operating buttons provided on the screen.
- **e.** Check the working of Hex roller assembly, mangle rollers (ribbon pulling rollers) Main conveyor, Medicine transfer pump, ribbon roller lubrication pumps.
- **f.** Switch ON the spreader box heaters and set temperature at 55°C.
- **g.** Switch ON the segment heater and set temperature at 35°C.
- **h.** Check any leakages from medicament injection tubes assembly.
- **i.** Check the functioning of each spreader box gates by turning the locking knobs of gates in clockwise and then in anti-clockwise direction.
- **j.** Check the working of electro pneumatic systems provided; i.e. segment lifting system, Die roll loading /unloading system, ribbon lubrication system, gripper unit, and pinch valves.
- **k.** Check working of Die-Roll Alignment system provided.
- **l.** Change the RPM of the die rolls.

3) If all the above tests are satisfactory then connect the gelatin mass tank valve to the gelatin feed pipes of both pinch valves. Fill the machine hopper with Light Liquid Paraffin.
Run the machine at 3 RPM as per the SOP to encapsulate the oil and check:

a. Left Hand Side Ribbon Thickness.

b. Right Hand Side Ribbon Thickness.

c. Check Capsule from each row for proper shape, proper sealing and fill weight.

d. Check cutting of capsules from gelatin ribbon.

e. Check removal of capsules from die-pockets by brushes and from gelatin ribbon net by Hex Rollers.

f. Check pulling of gelatin ribbon by Mangle Rollers.

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Name of System Component	Acceptance Criteria	Method of Verification	Observation	Verified By Sign/Date
Soft Gel Encapsulation Machine (CAP-X-8)				
Belt of main motor	The movement of the belt should be free	Visually		
Internal lubrication	Internal lubrication of the machine shall be satisfactory when seen through the site glass provided in the die roll housing	Visually		
Machine Drum movement	The running should be smooth and without vibration	Visually		
Rotation of Die Rolls	Left and right die rolls should be rotate in clockwise and anti-clockwise directions respectively when viewed from the front side.	Visually		
Operation of HMI	The soft keys provided on the HMI screen should be operative.	By Challenging		
Mangle roller Assembly	The hex roller assembly, mangle rollers (ribbon pulling rollers), main conveyor, Gelatin feeding, and ribbon roller lubrication pumps should be working when switched ON.	By Challenging		
Hex roller assembly	Working satisfactory.	By Challenging		

PHARMA DEVILS	OPERATIONAL QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

Name of System Component	Acceptance Criteria	Method of Verification	Observation	Verified By Sign/Date
Main conveyor	Working satisfactory; speed can be adjusted	By Challenging		
Ribbon roller lubrication pumps	Should be supply sufficient oil to the rollers.	Visually		
Spreader box Temperature controller	Spreader box temperature should be maintained at 55° ± 5°C	By Challenging		
Segment Temperature control	Segment temperature should be maintained as per Product Specification	By Challenging		
Injection tube assembly	There shall be no leakage from medicament injection tubes assembly.	Visually		
Spreader Box Gates	The gates of the spreader box shall be raised when the knobs will turn clockwise direction and the gates shall be lower when knobs will turned in anticlockwise direction.	By Challenging		
Segment lifting assembly	The electro pneumatic systems provided i.e. segment lifting, die roll loading / unloading,	By Challenging		
Die roll loading system		By Challenging		

PHARMA DEVILS	OPERATIONAL QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

Name of System Component	Acceptance Criteria	Method of Verification	Observation	Verified By Sign/Date
Slide valve lubrication system	slide valve and cam, brush assembly lubrication, gripper unit, pinch valves are working.	Visually		
Cam assembly lubrication system		Visually		
Gripper unit		Visually		
Pinch valves		Visually		
Die roll RPM setting	The die roll RPM shall be adjustable between 2 and 5 RPM.	Challenging		
LH Side Ribbon Thickness	Manually can be adjustable	Challenging		
RH Side Ribbon Thickness	Manually can be adjustable	Challenging		
Fill Weights	Capsules from each row has proper shape, proper sealing and Fill Weight is = _____ ± 5% (for die of 6 minim sizes) and ±2% (for sizes less than 6 minim)	Challenging		
Cutting of Gelatin ribbon to form capsules	Cutting of capsules from gelatin ribbon should be satisfactory	Visually		
Brush & Hex rollers working	Capsules should be removed from die rolls & from Gelatin ribbon net	Visually		

Name of System Component	Acceptance Criteria	Method of Verification	Observation	Verified By Sign/Date
Pulling of ribbon by Mangle Rollers	Mangle Rollers shall pull gelatin ribbon effectively	Visually		
TUMBLE DRYER				
Tumbler Drier Basket	RPM of the baskets can be set as desired.	Challenging		
Tumbler Drier Blowers	Can be switched ON/ OFF & RPM can be set as desired from the HMI control panel	Challenging		
Tumbler Drier Basket Flaps	Open as per requirement in AUTO mode and when activated in MANUAL mode	Challenging		
Working of HMI	The buttons provided on HMI screen should be operative	Challenging		

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

Reviewed by (Sign/Date)

5.6 VERIFICATION OF KEY FUCTIONAL OF MAJOR COMPONENT OF THE SYSTEM:

Following component of the system have been verified for key functionality:

Name of System Component	Acceptance Criteria	Method of Verification	Observation	Verified By Sign/Date
Soft Gel Encapsulation Machine (CAP-X-8)				
Main Switch **ON**	**Machine should start**	By twisting the main switch towards ON position		
Main Switch **OFF**	**Machine should stop**	By twisting the main switch towards **OFF** position		

PLC:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
Visually	**Welcome screen should come on start of the machine**		

Data Log:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching Data Log icon.	**Machine data log should appear on the screen**		
By touching BACK icon.	**Go back to the main menu by touching the BACK icon**		

Machine ON/OFF:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching icon	**Machine should** START/ STOP **by touching the icon. Following POP UP shall appear on the screen.** **MACHINE CONTROL** STATUS START STOP OFF INCHING HOLDING FOR JOGGING		

RPM setting:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching icon & entering the value.	RPM of die roll should be set by touching the icon and entering the value.		

Die Roll: LOAD/ UNLOAD

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By Touching The Icon Displayed On The Screen.	**Die Roll Should Be Load/ Unload When Touch The Icon Displayed on the Screen. Following Pop Up Shall Appear on the Screen.** **Die roll Loading** CLOSE UNLOAD LOADING @ LOW PRESSURE LOADING @ CUTTING PRESSURE STATUS UNLOADED		

Spreader Roller Left

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen.	**Should be** ON/ OFF **by touching the icon displayed on the screen. Following POP UP shall appear on the screen.** **LEFT SPREADER BOX HEATER** CLOSE STATUS ON OFF OFF PV XX SV XX C STATUS		

Spreader Roller Right:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen.	**Should be** ON/ OFF **by touching the icon displayed on the screen. Following POP UP shall appear on the screen.** RIGHT SPREADER BOX HEATER CLOSE STATUS ON OFF OFF PV XX.X SV XX.X C STATUS		

Segment Heater: ON/ OFF

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen.	**Should be** ON/ OFF **by touching the icon displayed on the screen. Following POP UP shall appear on the screen.** SoGMENT HEATER CLOSE STATUS ON OFF OFF PV SV °C STATUS XX.X XX.X		
	SEGMENT LIFTING CLOSE UP STOP DOWN UP STATUS		

Spreader box Valve: Left Hand Side

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen.	**Should be** ON/ OFF **by touching the icon displayed on the screen.**		

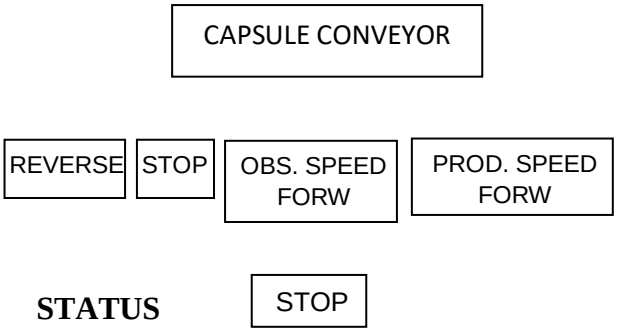
Spreader box Valve: Right Hand Side

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen.	**Should be** ON/ OFF **by touching the icon displayed on the screen.**		

Hex Roller:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen.	**Should be** START/ STOP **by touching the icon displayed on the screen. Following POP UP shall appear on the screen.** **HEX ROLLER / BRUSH ASSY** CLOSE FORWARD KICK OUT STOP **STATUS** STOP		

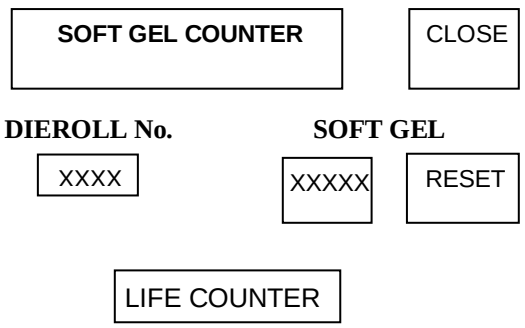
Conveyor:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen.	**Should be** START/ STOP **or** REVERSE **by touching the icon displayed on the screen. Following POP UP shall appear on the screen.** 		

Stretching Factor:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen and entering the value in the box by numeric key pad appeared on the screen(In the setting option)	**Should be set the value by entering in the box appeared by numeric key pad appeared on touching the icon.**		

Counter:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen.	**Capsule counter shall be display on pushing the icon "Counter" on the screen. Following POP UP shall appear on the screen.** 		

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
Switching **OFF** from the main supply and restart the machine.	**Capsule counter shall be resuming the number in case of power failure.**		

Valve:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen.	**Following POP UP shall appear on the screen:** VALVE CONTROL MED SLIDE VALVE OFF INNER RIBBON LUBRIC VALVE OFF OUTER RIBBON LUBRIC VALVE OFF LEFT SPREADER BOX VALVE OFF RIGHT SPREADER BOX VALVE OFF MAIN SETTING		

Alarms:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen.	**Following POP UP shall appear on the screen.** **ALARM TIME TIME ACKNOWLEDGE MESSAGE** MAIN ACK DRIVE △ ▽		

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Settings:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen.	MFG AT: ..... EQ. ID NO CAP X8-484 SHIFT XX USER NAME arbes DIEROLL RPM xx CAP GROSS WT. xx DIEROLL NO XX STRACH xx IED PUMP FREQ xx NO.OF CAVITIES xx CHILL MOTOR FREQ. xx DIROLL SIZE xx SEGMENT NO. xx BATCH NO. xxx DIEROLL SHAPE OVAL Timer setting TIMER ON TIMER OFF MEP SIDE VALVE LUBRIC TIMER INNER RIBBON LUBRIC TIMER OUTER RIBBON LUBRIC TIMER MAIN CAP COU OEM LOGIN IO STATUS HOOTER OFF		

Gripper:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By touching the icon displayed on the screen.	Following POP UP shall appear on the screen. GRIPPER CLOSE ADVANCE IN DEG XXX.XX ACTIVATE **or** INCH GRIPPER INCH GRIPPER STATUS OFF		

Tumbler Drier:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
Touch the icon TUMBLER DRIER	**ARBES TOOL** **SOFTGEL SYSTEM** CONTINUE CYCLE RESET CYCLE MAIN		
Touch the icon CONTINUE CYCLE	MOTOR SPEED XXX HZ BLOWER SET SPEED XX Hz DUCT HEATER TEM. SV XXX Deg. C° OEM SCREEN AUTO NEXT		
Touch the icon NEXT	FLAP TIME XX SEC. (15-17) TOTAL CYCLE TIME XX XX Hrs. Min CYCLE TIME RANGE Min: 00 Hrs : 15 mins, max. : 02 Hr: 32 Min		

	BACK SCREEN AUTO OEM		
Touch the icon **OEM**	AUTO MODE SELECTED AUTO MANUAL GO TO AUTO SCREEN		

Tumbler Drier Blower:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
Switch **ON/OFF** the blower of the drier by touching the icon displayed on the screen.	Blower can be switched **ON/OFF** from the screen.		

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
Touch the icon TUMBLER DRIER On Main Screen then Touch RESET CYCLE icon and Touch the icon MANUAL	In **AUTO** mode the flap should be open after drying time. In **MANUAL** mode the flap should open when touch the button. BASKET 1 FLAP CLOSE BASKET 2 FLAP CLOSE BASKET 3 FLAP CLOSE BASKET 3 FLAP CLOSE BASKET 5 FLAP CLOSE BASKET 6 FLAP CLOSE BASKET 7 FLAP CLOSE BASKET 8 FLAP CLOSE AUTO/MANUA SET MACHINE		

Emergency Stop:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By pushing the **RED** button.	In case of any emergency machine shall be stop immediately by pushing the **RED** button provided on the right hand side of the screen.		

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

Reviewed by (Sign/Date)

5.7 VERIFICATION OF SAFETY FEATURES:

Verify & record the safety/interlocking features and their function in following tables:

Safety Features Description	Function	Method of Verification	Observation	Verified By Sign & Date
Emergency Switch Operation on HMI Panel.	Machine should be stop, die rolls shall get unloaded, segment shall be move up, Indicator shall be glow and alarm shall be appear on HMI screen.	By challenging		
Emergency Switch Operation on Tumble Dryer	Tumbler Drier shall be stop, Indicator shall be glow and alarm shall appear on HMI screen.	By challenging		
Put **OFF** the **MCB** Switch provided in control panel.	In case of leakage of current, switch shall be trip and machine should be stop immediately.	By challenging		

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

Reviewed by (Sign/Date)

5.8 VERIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method Of Verification	Observation	Checked By Sign & Date
1.	**Electricity:** 415 V, 3 Phase, 50 Hz, with Neutral and Earth.	Physically with clamp meter		
2.	Compressed Air (6 kg/cm^2)	Physically		

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

Reviewed by (Sign/Date)

5.9	VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)
The following Standard Operating Procedures were identified as important for effective performance of Soft Gelatin Encapsulation system.	

S.No.	SOP Title	SOP Number	Verified By (Sign/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

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

Reviewed by (Sign/Date)

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

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:

Corrective action(s) taken:

Deviation accepted by
(Sign/Date)

Deviation Approved by
(Sign/Date)

5.13 ABBREVIATIONS

Following Abbreviations are used in the installation qualification protocol of Soft Gelatin Encapsulation system.

MOC : Material of Construction

PLC : Programmable Logic Controller

RPM : Rotations per Minute

ELCB : Earth Leakage Circuit Breaker

HMI : Human Machine Interface

VFD : Variable Frequency drive

SOP : Standard Operating Procedure

6.0 OPERATIONAL 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 Soft Gelatin Encapsulation system 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 Soft Gelatin Encapsulation system, 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		