



PHARMA DEVILS

**INSTLAATION QUALIFICATION PROTOCOL
FOR
SOFT GELATIN ENCAPSULATION MACHINE**

PROTOCOL No.:

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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 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		



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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 Soft Gelatin Encapsulation System and define the installation qualification requirements and acceptance criteria for the Soft Gelatin Encapsulation System (CAP-X-8). Successful completion of these installation qualification requirements will provide assurance that the Soft Gelatin Encapsulation System was installed as required in the manufacturing area.

The Qualification of Soft Gelatin Encapsulation System (CAP-X-8) performed in view of Soft Gelatin Encapsulation area 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:

This Protocol is applicable to installation of Soft Gelatin Encapsulation System (CAP-X-8) in soft Gel Encapsulation area of the manufacturing facility & the subsequent documentation.

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.



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- 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.
- 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 installation 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 installation of Medicament Holding Vessel.

Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

- 3.1 The Soft Gelatin Encapsulation System (CAP-X-8) shall meet the system description given in design qualification.
- 3.2 The Soft Gelatin Encapsulation System (CAP-X-8) shall meet with the acceptance criteria mentioned under the topic “Identification of major components”
- 3.3 All material of constructions of the contact parts to be checked as per the specifications.



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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

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.

The Soft Gelatin Encapsulation Machine (CAP-X-8) Line consists of three Components:

1. Chiller: It consists of following component.

- Compressor: To generate the necessary energy to obtain air conditioning.
- Cold Heat Exchanger: To chill the air by exchanging heat with the refrigerant.
- Condenser Fan: To exhaust the heat from the condenser (air cooled heat exchanger).
- Process Fan: To pass air over the evaporator (air cooled heat exchanger).
- Pressure Transmitters: Safety controls for the refrigeration system.

2. Encapsulation Machine: It consists of following component with their features:

- 8 inch long and 4 inch diameter Capsulators (die rolls).
- Stainless Steel cladding – matte finish.
- Contact Parts: SS 316, Food-grade and D-3 HCHCr (High Carbon, High Chromium) material.
- Spreader box – with adjustable width lip.
- Emergency STOP button.



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- ACVF for step less speed control of die roll rpm.
- Auto-tuning sensors for segment and spreader box temperature control and measurement.
- Pneumatic die roll loading arrangement.
- Food-grade conveyor (bidirectional) to transfer capsules into in-line semi-drier (conveyor length and orientation to be confirmed by client).
- Medicament Hopper with recirculation arrangement.
- Chilled-air cooled ribbon casting drums.
- AUTO adjusting Injection Timing mechanism for injection of medicament into die roll cavities (Gripper).
- Control Panel for machine operations and control wall-mounted or stand-alone with touch screen MMI panel.
- R+D kit comprising 4 inch long and 4 inch diameter die rolls and matching segment and spacers.

3. Tumbler Drier:

- Six baskets arrangement with blower unit.
- Pneumatic conveyor ensures direct feed of capsules into first basket.
- Baskets can be controlled to rotate at desired speed.
- Proprietary PLC ensures optimum drying time in each basket.
- Mobile system can be arranged in-line with the CAPX-8 machine.

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.



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5.3 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	STATEMENT	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY SIGN/DATE
1.	Verify that the "As Built" drawing is complete and represents the design concept.	Visually		
2.	Verify that Purchase order copy is available. (write the P.O. No. in observation)	Visually		
3.	Verify that major components are securely anchored and shock proof.	Visually		
4.	Verify that there is no observable physical damage.	Visually		
5.	Verify that there is sufficient room provided for servicing.	Visually		
6.	Verify that there is no hanging cable.	Visually		
7.	Verify that all electrical connections are done according to the drawings.	Visually		
8.	All access ports are examined and cleared of any debris.	Visually		
9.	Safe electrical connections.	Visually		
10.	Equipment identification nameplate visible.	Visually		
11.	Units installed on foundation are secure in place as per manufacturer's recommendations.	Visually		

Remark: -----

Reviewed by (Sign/Date)



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5.4 IDENTIFICATION OF MAJOR COMPONENTS:

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

Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
Machine Motor	Make:	Rotomotive	Visually on name plate		
	Spec.	2 HP, 3 Phase, 415 V AC	Visually on name plate		
	Qty.:	01 Nos.	Visually / Physically		
	RPM:	1440	Visually on name plate		
	Sr. No.	To be Recorded	Visually on name plate		
	Direction	Clockwise	Visually / Physically		
Machine Conveyor Motor	Make:	Panasonic	Visually / Physically		
	Spec.	25 W, 220 V AC & 3 Phase	Visually / Physically		
	Qty	01 Nos.	Visually / Physically		
	RPM:	1400	Visually on name plate		
	Model No.	M8MX25GAYGA	Visually / Physically		
Mangle Roller Motor	Make:	Panasonic	Visually / Physically		
	Spec.	25 W, 415 V AC & 3 Phase	Visually / Physically		
	Qty	01 Nos.	Visually / Physically		
	Supply:	220 V & 3 phase	Visually / Physically		
	RPM	1450	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		



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Hex Roller /Brush Assembly Motor	Make:	Panasonic	Visually / Physically		
	Spec.	90 W, 220 V AC & 3 Phase	Visually / Physically		
	Qty	01 Nos.	Visually / Physically		
	Model	M9MZ90G4YGA	Visually / Physically		
	RPM	1400	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Segment Temperature Controller	Make	Fuji	Visually / Physically		
	Qty.:	01 Nos.	Visually / Physically		
	Model No	PXR4NCY1-1VM70	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Left Spreader Box Temp. Controller	Make:	Fuji	Visually / Physically		
	Qty.	01 Nos.	Visually / Physically		
	Model No.	PXR4NCY1-1VM70	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Right Spreader Box Temp. Controller	Make	Fuji	Visually / Physically		
	Qty.	01 Nos.	Visually / Physically		
	Model No.:	PXR4NCY1-1VM70	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Drive for Machine Motor (VFD)	Make	Allen Bradley	Visually / Physically		



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	Qty.	01 Nos.	Visually / Physically		
	Model No	Power Flex 4M	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Mangle Roller Speed Control (VFD)	Make	Allen Bradley	Visually / Physically		
	Qty.	01 Nos.	Visually / Physically		
	Model No	Power Flex 4M	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Conveyor Speed Control (VFD)	Make	Allen Bradley	Visually / Physically		
	Qty.	01 Nos.	Visually / Physically		
	Model No	Power Flex 4M	Visually / Physically		
	Sr. No.	to be recorded	Visually / Physically		
Hex Roller Speed Controller (VFD)	Make	Allen Bradley	Visually / Physically		
	Qty.	01 Nos.	Visually / Physically		
	Model No	Power Flex 4M	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Medicine Recirculation Pump Speed Control (VFD)	Make	Allen Bradley	Visually / Physically		
	Qty.	01 Nos.	Visually / Physically		
	Model No	Power Flex 4M	Visually / Physically		



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	Sr. No.	to be recorded	Visually / Physically		
Control Logic (PLC) of Machine	Make	Allen Bradley	Visually / Physically		
	Qty.	01 Nos.	Visually / Physically		
	Model No.	ML 1400	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
HMI for Machine	Make:	Allen Bradley	Visually / Physically		
	Qty.	01 Nos.	Visually / Physically		
	Model No.	PVP 1000	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Medicament Dosing Pipe	Make	Festo	Visually / Physically		
	Qty.	24 Nos.	Visually / Physically		
	Model No.:	PUN-H-6X1	Visually / Physically		
Segment Sensor	Make	Exotherm	Visually / Physically		
	Qty.	02 Nos.	Visually / Physically		
	Model No.	PT 100	Visually / Physically		
Spreader Box Heater	Make:	S.S. SON CONTROLS	Visually / Physically		
	Spec.	750 W	Physically		
	Qty.	04 Nos.	Visually / Physically		
Segment Heater	Make:	S.S. SON CONTROLS	Visually / Physically		



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	Spec.	1KW	Physically		
	Qty.	02 Nos.	Visually / Physically		
Spreader Box Sensor	Make:	Exotherm	Visually / Physically		
	Qty.:	02 Nos.	Visually / Physically		
	Model No.	PT 100	Visually / Physically		
SS Fittings	Qty.	02 Nos.	Visually / Physically		
	MOC	SS 316	From Certificate		
TUMBLER DRIER (Equipment No EQI/SGD/FTD/001)					
Tumbler Drier Basket Motor	Make	Siemens	Visually / Physically		
	Power	2.2 KW	Visually / Physically		
	Supply	3 phase, 415 V ± 10%	Visually / Physically		
	RPM	2880	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Tumbler Drier Blower	Make	Ebm Popst	Visually / Physically		
	Model	G2D160-AF02-01	Visually / Physically		
	Qty:	6 Nos.	Visually / Physically		
	RPM	2300	Visually / Physically		
	Capacity	320 W	Visually / Physically		
	Volt	3 Phase, 400 V	Visually / Physically		
Tumbler Drier Blower VFD	Make	Allen Bradley	Visually / Physically		
	Qty.:	01 Nos.	Visually / Physically		



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PROTOCOL No.:

	Model No.:	Power Flex 4M	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Tumbler Drier Basket VFD	Make	Allen Bradley	Visually / Physically		
	Qty.:	01 Nos.	Visually / Physically		
	Model No.:	Power Flex 4M	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Air heater for Blower	Make	Stego	Visually / Physically		
	Type	CS130	Visually / Physically		
	Power	1200 W	Visually / Physically		
Machine Lubrication System					
Machine Lubrication Motor	Make:	Bonfiglioli	Visually on name plate		
	Spec.	0.18 KW, 3 phase	Visually / Physically		
	Model No.	BN 63 BA B5	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Lubrication Tank	Make:	ARBES	Visually / Physically		
	MOC:	SS 304	From Certificate		
	Capacity	20 liters	Visually / Physically		
Lubrication Tank for Dosing pump	Make:	ARBES	Visually / Physically		
	MOC:	SS 304	From Certificate		
	Capacity	2 liters	Visually / Physically		



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Die Roll Housing Assembly

Die roll Housing Assembly	8 inch long die rolls	(Aluminum Alloy)	Visually / Physically		
	8 inch segment (Virgin lead free brass):Teflon coated		Visually / Physically		
	Mangle Rollers	Serrated and Teflon coated	Visually / Physically		
	Die roll loading system	Pneumatic	Visually / Physically		
	Brush Assembly / Hex roller assembly has an independent drive unit		Visually / Physically		

Ribbon Lubrication System

Miniature Pumps	Miniature pumps for each ribbon roller.		Visually / Physically		
	Tank capacity	5 liters, 2 Nos.	Visually / Physically		
	PLC Timer	For ON/OFF time adjustable	Visually / Physically		

Chiller Indoor Unit (Equipment No: EQ1/SGD/CIU/001)

Motor	Make	Siemens	Visually / Physically		
	RPM	1415	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Motor VFD	Make	Allen Bradley	Visually / Physically		
	Qty.:	01 Nos.	Visually / Physically		
	Model No.:	Power Flex 4M	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		

Pressure Gauges



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Die roll cutting	Make	SMC	Visually / Physically		
	Range	0-10 kg/cm ²	Visually / Physically		
Die roll low	Make	SMC	Visually / Physically		
	Range	0-10 kg/cm ²	Visually / Physically		
GEL flow V Valve	Make	SMC	Visually / Physically		
	Range	0-10 kg/cm ²	Visually / Physically		
FRL	Make	SMC	Visually / Physically		
	Range	0-10 kg/cm ²	Visually / Physically		
Flap opening	Make	SMC	Visually / Physically		
	Range	0-10 kg/cm ²	Visually / Physically		
Die roll loading system	Make	Denvar	Visually / Physically		
	Range	0-10.6 kg/cm ²	Visually / Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:

Name Of Components	Material Of Construction	Method Of Verification	Observation	Verified By Sign/Date
Cladding	SS 316	By Molybdenum Kit/ Test Certificate		
Ribbon Casting Drums	SS 316	By Molybdenum Kit/ Test Certificate		
Ribbon rollers	SS 316	By Molybdenum Kit/ Test Certificate		
Mangle Rollers	SS 316	By Molybdenum Kit/ Test Certificate		
Medicament Hopper	SS 316	By Molybdenum Kit/ Test Certificate		
Tumble dryer Cladding	SS 316/ SS 304	By Molybdenum Kit/ Test Certificate		
Tumble dryer Baskets	SS 316	By Molybdenum Kit/ Test Certificate		
Top connecting plate fittings for medicine hopper	SS 316	By Molybdenum Kit/ Test Certificate		
Top connecting plate	SS 316	By Molybdenum Kit/ Test Certificate		
Pump outlet connection plates.	SS 316	By Molybdenum Kit/ Test Certificate		
Pump side Banks	SS 316	By Molybdenum Kit/ Test Certificate		
Shut- Off assembly (Top plate)	SS 410	Test Certificate		
Segment head	SS 316	By Molybdenum Kit/ Test Certificate		
Idler Rollers	SS 316	By Molybdenum Kit/ Test Certificate		
Tube Below Gelatin Flow Valve	SS 316	By Molybdenum Kit/ Test Certificate		
Tumble Dryer Air Duct	SS 304	By Molybdenum Kit/ Test Certificate		
Tumble Dryer Outlet Tray	SS 316	By Molybdenum Kit/ Test Certificate		



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Medicament Transfer Tubing	Silicon Food Grade	Test Certificate		
Gelatin Transfer Pipe	Food Grade	Test Certificate		
Pump gaskets	Food Grade	Test Certificate		
Dozing Pipes	Food Grade	Test Certificate		
Pump top plate.	Hc.-Hcr	Test Certificate		
Pump slide valve	Hc.-Hcr	Test Certificate		
Pump slide valve side plates	Hc.-Hcr	Test Certificate		
Pump Centre Blocks	Hc.-Hcr	Test Certificate		

Remark: -----

Reviewed by (Sign/Date)



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5.6 IDENTIFICATION 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)



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5.7 IDENTIFICATION OF SAFETY FEATURES:

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

Safety Features Description	Function	Method of verification	Observation	Checked By Sign & Date
Earthing of motor	To avoid the accident due to the leakage of current.	Visually		
Emergency Stop on CAP-X-8 M/C, and Tumbler Drier	For operator safety	Visually		
Thermal Relay in Control panel	For operator and Equipment safety.	Visually		

Remark: -----

Reviewed by (Sign/Date)



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5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were identified as important for effective performance of Soft Gelatin Encapsulation system operation.

S.No.	SOP Title	Verified By Sign/Date

Remark: -----

Reviewed by (Sign/Date)



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5.11 ABBREVIATIONS

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

MOC	:	Material of construction
V	:	Volts
HZ	:	Hertz
Mm	:	Millimeter
Spec.	:	Specification
Qty.	:	Quantity
ltrs.	:	Liters
NA	:	Not applicable
Thk.	:	Thickness
GMP	:	Good manufacturing Practice
Hc.-Hcr	:	High Carbon, High Chromium



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6.0 INSTALLATION QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

**Prepared By
Sign/ Date**

**Checked By
Sign/ Date**



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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		