



STANDARD OPERATING PROCEDURE

Department: Production (Soft gel)	SOP No.:
Title: Operation and Cleaning of Encapsulation Machine	Effective Date:
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1.0 OBJECTIVE :
To lay down the procedure for Operation and Cleaning of Encapsulation Machine.

2.0 SCOPE :
This procedure is applicable for the Operation and Cleaning of Encapsulation Machine in Encapsulation area.

3.0 RESPONSIBILITY:
Technician/Officer/Executive/Manager-Production.
Head of Department: To ensure execution & compliance.
Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 OPERATING PROCEDURE OF PLC SCREEN OF ENCAPSULATION MACHINE.

- 4.1.1 Switch "ON" the electric supply of the control panel.
- 4.1.2 Switch "ON" the electric supply of the HMI. The main screen is displayed as the start-up screen.
- 4.1.3 Displayed of the HMI shows all setting parameters.
- 4.1.4 Ensure the display screen shows segment Temp., spreader box temp.(left and right), segment position (up and down), brush assemblyhex roller, conveyor belt (forward and reverse), pinch valve (ON/OFF), die-rolls loading and Fluidizer Tumbler Dryer.
- 4.1.5 Check the proper working of all lubrication systems of the machine.
- 4.1.6 Check the proper working of pinch valve of gelatin mass transfer pipe.
- 4.1.7 Check the proper working of the segment heater and spreader box heater (Left and Right).
- 4.1.8 Check the proper working of segment lift (UP and DOWN).
- 4.1.9 Check the operation of the brush assemblies/ hex-roller, mangle roller.
- 4.1.10 Check the forward and reverse movement of the conveyor belt.



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4.1.11 Check the forward and reverse direction of the Fluidizer Tumbler Dryer (Auto and manual mode).

4.1.12 Check the chilled air supply for the cooling drum.

4.1.13 Check the capsules counter of the machine and cutting pressure of the die rolls (High and Low Pressure).

4.2 Operation

4.2.1 Ensure the cleanliness of Encapsulation Machine, Fluidizer Tumbler Dryer and Degreasing Pan and area.

4.2.2 Ensure the environmental conditions are within the limit as per given in the BMR. Ensure that all the doors are closed and no chance of cross- contamination.

4.2.3 Ensure that the BMR is available and all the entry is completed properly till this stage.

4.2.4 Ensure that all containers are properly closed and kept on the pallet with status label.

4.2.5 Ensure that compressed air, chilled air supply unit and other utilities are required is working properly as per requirement.

4.2.6 Ensure that the Light Liquid paraffin is available in Encapsulation Machine and lubrication oil system of gelatin ribbon roller, slider, housing pump are working properly.

4.2.7 Connect the one end of the gelatin feeding pipe to the Gelatin Holding Tank and another end with pinch valve of spreader box of the Encapsulation Machine.

4.2.8 Connect one end of the medicament feeding pipe to the Medicament Holding Tank and another end to the medicament hopper of the Encapsulation Machine.

4.2.9 Ensure that "CLEANED" label affixed on the Encapsulation Machine, Fluidizer Tumbler Dryer and Degreasing Pan.

4.2.10 Update the "AREA STATUS BOARD" with duly filled and signature of production officer.

4.2.11 Take the line clearance from QA personnel.

4.2.12 Remove "CLEANED" label from the Encapsulation Machine, Fluidizer Tumbler Dryer, Degreasing Pan and affix the "STATUS LABEL" with duly filled and



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signature of production officer.

- 4.2.13 Enter the start time of the Encapsulation Machine in equipment usage log book as per SOP.
- 4.2.14 Switch “ON” the electric supply of the gelatin feeding pipe and set the heating temperature as per BMR specification.
- 4.2.15 Switch “ON” the main electric supply of the Encapsulation Machine and set the heating temperature limit of the spreader box.
- 4.2.16 Set the temperature limit of the cooling drum as per limit mentioned in BMR.
- 4.2.17 Open the valve of the Gelatin Holding Tank and pinch valve.
- 4.2.18 Fill the spreader box with gelatin mass and adjust the height of spreader box plate to form the gelatin ribbon.
- 4.2.19 Start the lubrication oil pump of gelatin ribbon.
- 4.2.20 Start the Encapsulation Machine by touching the start icon on the PLC.
- 4.2.21 The gelatin mass spread on the cooling drum and form a gelatin ribbon which passes to the net collection container through the lubrication roller, supporting roller, die roll, hex roller, and mangle roller.
- 4.2.22 Set the ribbon thickness with the help of calibrated ribbon thickness dial gauge as per mentioned in BMR.
- 4.2.23 Down the segment to proper position between the die rolls on the gelatin ribbon and start the segment heating temperature as per BMR.
- 4.2.24 Open the compressed air valve and release the die cutting pressure. The cutting pressure should be 3-5 kg/cm².
- 4.2.25 Check the sealing, shape of the empty capsules and proper cutting of the die rolls.
- 4.2.26 If found “OK” fill the batch vehicle in the hopper and open the shut off valve of the segment for filling of the oil into capsules.
- 4.2.27 Check the sealing, shape and filled weight of the oil filled dummy capsules. set the fill weight of the capsules by adjusting the knob.
- 4.2.28 Start the conveyor belt to the reverse direction to transfer slugs and rejected capsules into rejection box.



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- 4.2.29 After capsule fill weight setting, drain the filled vehicle from the medicament hopper by opening of return pipe.
- 4.2.30 Open the medicament discharge valve of the Medicament Holding Tank and feeding pipe to fill the medicament in hopper up to the level.
- 4.2.31 Start the Fluidizer Tumbler Dryer in auto or manual mode as per requirement.
- 4.2.32 Open the shut off valve of the segment to start the filling of medicament into capsules.
- 4.2.33 Check the capsule sealing, shape and standard filled weight of each cavity as per BMR specification.
- 4.2.34 After setting of all parameters of capsule start the conveyor belt to forward direction to transfer the capsules in Fluidizer Tumbler Dryer.
- 4.2.35 Collect the capsules into SS container from discharge point of the Fluidizer Fluidizer Tumbler Dryer.
- 4.2.36 Put the capsules into Degreasing Pan for capsules polishing.
- 4.2.37 All the In-process parameters should be checked by both QA and production officer and record in the respective BMR.
- 4.2.38 After batch completion enter the operation complete time in equipment usage log book as per SOP.
- 4.2.39 Close the valve of gelatin and Medicament Holding Tank.
- 4.2.40 Switch "OFF" the chilled air supply from the cooling duct.
- 4.2.41 Switch "OFF" the spreader box and gelatin transfer pipe heating temperature.
- 4.2.42 Switch "OFF" the Lubricating oil pump.
- 4.2.43 Release the cutting pressure of the die rolls.
- 4.2.44 Put the segment on "UP" position and switch "OFF" the heating temperature.
- 4.2.45 Switch "OFF" the stripper and mangle roller.
- 4.2.46 Switch "OFF" the Encapsulation Machine and main electric supply from the panel.
- 4.2.47 Remove "STATUS LABEL" and affix the "TO BE CLEANED" label on the Encapsulation Machine with duly filled and signature of production officer.
- 4.2.48 Update the "AREA STATUS BOARD" with duly filled and signature of production



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officer.

4.3 Precaution

- 4.3.1 Ensure that the working conditions of Stripe and mangle roller is in normal condition.
- 4.3.2 Ensure the zero point setting of die rolls.
- 4.3.3 Ensure that the external surface of die rolls and segment is in good condition.
- 4.3.4 Ensure that the coating of wedge and edge of wedge is not removed from the outer surface.
- 4.3.5 Do not apply cutting pressure on die rolls without in feed of gelatin ribbon in the die
- 4.3.6 Do not down the segment on the die rolls without in feed of gelatin ribbon in the die rolls.

gelatin ribbon

4.4 Cleaning procedure

4.4.1 Cleaning procedure Type A

Change over from one batch to next batch of the same product and same potency and of similar product with ascending potency.

- 4.4.1.1 Remove “TO BE CLEANED” label and affix “UNDER CLEANING” label to the machine with date and signature of the production officer as per SOP.
- 4.4.1.2 Enter the cleaning start time in equipment usage log book as per SOP.
- 4.4.1.3 Flush the medicament filling pump with vehicle (vehicle is the oil in which the medicament has been prepared).
- 4.4.1.4 Switch “OFF” the main power supply of the Encapsulation Machine.
- 4.4.1.5 Clean the Encapsulation Machine with dry lint free cloth followed by 70% v/v IPA.
- 4.4.1.6 Transfer the spreader box, pinch valve gelatin and medicament transfer pipe to the washing area with SS trolley.
- 4.4.1.7 Left the spreader box for cooling, and after cooling remove the adhered gelatin waste.
Clean the gelatin and medicament feeding pipe with hot water then wash with purified water.



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4.4.1.8 Dry the clean equipment with compressed air. Then clean with dry lint free cloth followed by 70% v/v IPA.

4.4.1.9 Clean the area as per SOP.

4.4.1.10 Replace the “UNDER CLEANING” status label with “CLEANED” status label with date and signature of the Production Officer.

4.4.1.11 Record the cleaning complete time in equipment usage log book as per SOP.

4.4.2 Cleaning procedure Type B

This is a cleaning procedure for Change over of product with different actives/color/descending potency or after maintenance of contact parts.

4.4.2.1 Replace the “UNDER CLEANING” status label with “CLEANED” status label with date and signature of the Production Officer.

4.4.2.2 Enter the cleaning start time in equipment usage log book as per SOP.

4.4.2.3 Gelatin feeding Pipe:

4.4.2.3.1 Transfer the gelatin feeding pipe to the first floor washing area and pass the hot water through the gelatin feeding pipe till adhered gelatin mass is to be removed completely.

4.4.2.3.2 Clean the inside and outside of the feeding pipe with 1.0% Teepol solution and rinse with the sufficient purified water to remove trace of Teepol.

4.4.2.3.3 Finally wash the inside and outside with purified water.

4.4.2.3.4 Dry the gelatin feeding pipe with compressed air and mop with 70% IPA solution.

4.4.2.4 Die Rolls:

4.4.2.4.1 Check that pneumatic valve is released and die rolls are not under pressure.

4.4.2.4.2 Ensure that the main valve is in the “OFF” position (located inside the pneumatic control panel).

4.4.2.4.3 Turn the idler rollers (located above the die rolls) clockwise to guide the die rolls away from each other.

4.4.2.4.4 Loose the centre front knobs of the yoke by turning them anti-clockwise which hold the die rolls in position.

4.4.2.4.5 Loose the remaining two rear side (outer side) yoke clamping knobs to release the



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yoke from the die rolls assembly body.

4.4.2.4.6 Bring the yoke forward (away from the machine) and turn it on the left hand side of the machine. the die roll shaft free from the yoke and pin adapter in the front.

4.4.2.4.7 Slowly release the left hand side die roll from the three locating pins at the back and slide it out of the shaft. repeat the same operation for the right hand side die rolls.

4.4.2.4.8 Keep the die rolls on the spare parts trolley and take it to washing area.

4.4.2.4.9 clean the die rolls with purified water then soak into warm purified water. Then clean with 1.0 % v/v Teepol Solution for 10 minutes to remove oil and medicament residue.

4.4.2.4.10 After proper cleaning rinse with purified water to remove traces of Teepol solution.

4.4.2.4.11 Dry the die rolls by compressed air and dry lint free cloth.

4.4.2.5 Injection Wedge and Segment:

4.4.2.5.1 Remove the segment heater rod and sensor from the segment wedge. loose the L & Key bolt from the shut off valve to separate segment edge and gasket with distribution plate.

4.4.2.5.2 Separate the shut off valve assembly from the main wedge assembly.

4.4.2.5.3 Unscrew the 6 brass screws provided on the flat surface of the wedge and slide the plate out. all dismantled part transfer to the washing area.

4.4.2.5.4 Clean the segment & distribution plate with purified water. Then clean with 1.0 % v/v Teepol Solution.

4.4.2.5.5 Rinse the segment with purified water to clean the traces of Teepol Solution. and flush the water into holes of segment edge, distribution plate and shut off valve.

4.4.2.5.6 Dry the Injection Wedge, Segment and all holes by Compressed air.

4.4.2.5.7 Clean the segment and distribution plate with dry lint free cloth and wet by paraffin oil and store it in the designated box and record the details in change parts.

4.4.2.6 Spreader Box:

4.4.2.6.1 Remove the pinch valve from the spreader box of both sides.

4.4.2.6.2 Remove the heater and sensor from the spreader box.

4.4.2.6.3 Carefully remove the spring clips, Teflon protective piece and gate of the spreader



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box.

4.4.2.6.4 Put down the spreader box on the trolley from Encapsulation Machine and left for cooling.

4.4.2.6.5 After cooling remove the gelatin waste and transfer to washing area.

4.4.2.6.6 Clean the spreader box and pinch valve with purified water.

4.4.2.6.7 Then clean with 1.0 % v/v Teepol Solution and purified water.

4.4.2.6.8 Rinse it with purified water to clean the traces of Teepol solution.

4.4.2.6.9 Dry the spreader box with compressed air and dry lint free cloth.

4.4.2.7 Conveyor belt:

4.4.2.7.1 Loose the screw from the machine body and remove the conveyor assembly from the machine and put down on the pallet.

4.4.2.7.2 Remove the side plate and unscrew the tension of the nylon belt and remove the nylon conveyor belt.

4.4.2.7.3 Remove the drive chain from the chain spoke and keep it separately.

4.4.2.7.4 Remove the gear, support parts of the belt and kept on the trolley and transfer into washing area.

4.4.2.7.5 Clean the all parts with hot water. Then wash with 1.0 % v/v Teepol solution.

4.4.2.7.6 Finally wash the conveyor and its parts with sufficient purified water to properly cleaning of traces of Teepol solution.

4.4.2.7.7 Dry the conveyor nylon belt and other parts with compressed air followed by dry lint free cloth.

4.4.2.7.8 Wipe the conveyor belt and body with 70 % v/v IPA solution.

4.4.2.8 Pump assembly and Hopper:

4.4.2.8.1 Remove the top tube assembly plate along with the pipes and bottom lead plate.

4.4.2.8.2 Remove the slide valve lubrication pump assembly which is fit on back plate end.

4.4.2.8.3 Unscrew the 4 Allen screw which hold to the pump assembly with main housing block.

4.4.2.8.4 Loose the plungers from the cradle by loosen the end bolts of each plunger.

4.4.2.8.5 Unscrew all Allen screw from each side of the pump and remove them completely to



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release the side blocks from the main centre block.

4.4.2.8.6 Remove the spacer and U-cup seal from the two blocks without damaging the inner surfaces / edges. Remove the flat washer from main block.

4.4.2.8.7 Clean the all dismantle parts by 1.0 %v/v Teepol solution.

4.4.2.8.8 Finally wash the all dismantle parts with purified water. and flush the hopper with purified water to clean adhered medicament, oil and scrubbing with nylon scrubber using 1.0 % v/v Teepol solution.

4.4.2.8.9 Dry the all dismantle parts with compressed air.

4.4.2.8.10 Wipe the all dismantle parts using a dry lint free cloth.

4.4.2.9 Pump Housing and Dosing Pipes:

4.4.2.9.1 Drain the oil and collect it into SS container.

4.4.2.9.2 Lift the housing from the main body of the machine and transfer to washing area by SS trolley.

4.4.2.9.3 Clean the Pump Housing along with the cradle assembly with 1.0 %v/v Teepol Solution using soft nylon brush and then wash with purified water.

4.4.2.9.4 Dry the Pump Housing along with the cradle assembly with compressed air and dry with lint free cloth.

4.4.2.9.5 Wipe the Pump Housing cradle assembly with 70 % v/v IPA solution with dry lint free cloth.

4.4.2.9.6 Remove the top dosing tubes assembly plate along with pipes and bottom lead plate. Place it on SS tray and transfer to washing area.

4.4.2.9.7 Flush the dosing pipes one by one with purified water for proper cleaning of oils and medicament traces. Then dipped into 1.0 % v/v Teepol solution in a SS container.

4.4.2.9.8 Flush with purified water of all dosing pipes and dosing plate holes.

4.4.2.9.9 Dry the all dosing pipes with compressed air and dry lint free cloth.

4.4.2.10 Shut off Valve:

4.4.2.10.1 Remove the 6 Allen screw to release the top, bottom and side plate of the shut off valve and remove sliding valve.

4.4.2.10.2 All dismantle parts transfer to washing area and flush with purified water and 1.0 %



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v/v Teepol solution with nylon scrubber.

4.4.2.10.3 Dry the shut off valve with compressed air and dry lint free cloth.

4.4.2.11 Cleaning of Machine Body :

4.4.2.11.1 Clean the outer body of Encapsulation Machine and outer part of Fluidizer Tumbler Drier with dry lint free cloth soaked with 70% v/v IPA solution.

4.4.2.11.2 Clean the filter of internal lubrication with compressed air and dry lint free cloth.

4.4.2.11.3 Change the internal lubrication oil, if the oil is dis-colored (turned blackish).

4.4.2.11.4 Clean the panels and lubricating pumps by wiping with dry lint free cloth.

4.4.2.12 Assembling of the Pump, Injection Wedge and Die Rolls :

4.4.2.12.1 Assembling of the Pump :

4.4.2.12.1.1 Keep the main block of the pump one side up on the table and wet with LLP lubrication oil.

4.4.2.12.1.2 Place flat Teflon washer provided on the pump main block, then place side end block over it.

4.4.2.12.1.3 Fasten all the Allen screws after matching with the main centre block of the pump.

4.4.2.12.1.4 Place the U-cup seals with flat Teflon spacer washer provided on side end block.

4.4.2.12.1.5 Repeat the same operation on the other side of the pump.

4.4.2.12.1.6 Place the pump horizontally, take one plunger shaft apply thin layer of lubrication oil and insert the gland into the shaft with the head towards the outside and threaded part towards the inside.

4.4.2.12.1.7 Tighten the gland slowly but not fully tight, repeat the operation for all the remaining plungers in a similar way.

4.4.2.12.1.8 Check for the free movement of the cam around the screw and pump assembly.

4.4.2.12.1.9 Replace the worn out Teflon flat washer, u cup seal washer if needed.

4.4.2.12.1.10 Put the two rectangular side strips on pump by matching their numbers with the pump main block.

4.4.2.12.1.11 Put the slide valve in the slot between two strips and the roller pin of the slide valve in the groove of the cam assembly on the block. Put the distribution plate on the top



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of this by matching the numbers with pump main block.

4.4.2.12.1.12 Put the all Allen screws in position and tighten them in such a way that slide valve movement is free.

4.4.2.12.2 Setting of the Pump in Pump Assembly :

4.4.2.12.2.1 Check the housing pump for cleanness.

4.4.2.12.2.2 Check the free movement of cradle by rotating the timing shaft using a spanner in clockwise direction if the movement is not free dismantles the cradle assembly set again.

4.4.2.12.2.3 Adjust the pump stroke by turning the timing shaft in clockwise direction

4.4.2.12.2.4 Lock the position of timing shaft in square drive location of change gear assembly plate.

4.4.2.12.2.5 Place the pump assembly on the top of the brass strips of cradle. Place all 4 Allen screw in the screws slot and tighten them alternately.

4.4.2.12.2.6 Pull the plunger slightly out and fasten them to this cradle by placing them in the groove and tighten the bolts with the washer from the side.

4.4.2.12.2.7 Place lead plates (tube assembly plates) on the top of the distribution plate.

4.4.2.12.2.8 Keep the gasket on the top of the lead pipe and set the hopper on the top of the gasket. Put all the 6 nuts in and tighten them.

4.4.2.12.2.9 Fix the lubricating pump assembly at the back of the housing pump and matching the drive with the cam and connect the tubing in front.

4.4.2.12.3 Setting of the Die Rolls:

4.4.2.12.3.1 Insert the left die rolls (marked "L") on the left hand shaft pin located on the adapters.

4.4.2.12.3.2 Insert the right hand side die roll (marked "R") on the right hand shaft pin located on adapters.

4.4.2.12.3.3 The yoke, which was moved to a vertical position after dismantling of die rolls. It brought back to its original position and slid into it location, turn the two centre knobs and two outside knobs on the yoke and tighten them.

4.4.2.12.3.4 Check the front and back adapters have been tightened to the adapters leaving no gap



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in between adapters face and resting face of die roll.

4.4.2.12.4 Setting of the Injection Wedge :

4.4.2.12.4.1 Place the distribution plate over the flat surface of the wedge. Checks that the outlets in the distribution plate coincide with the wedge.

4.4.2.12.4.2 Place the gasket on the distribution plate and on them places the shut off valve. Place another gasket on the shut off valve and match the dosing holes.

4.4.2.12.4.3 Assemble this complete unit to the lower lead plate and tighten the nuts.

4.4.2.12.4.4 Insert the segment heating & sensor in the segment wedge.

4.4.2.12.5 Setting of the Conveyor Belt:

4.4.2.12.5.1 Set the roller and the gears in the conveyor body.

4.4.2.12.5.2 Set the conveyor belt on the rollers and adjust the tension between the rollers and belt.

4.4.2.12.5.3 Set the side plate with the conveyor.

4.4.2.12.5.4 Connect the conveyor belt with the inlet of Encapsulation Machine and connect the electrical connection.

5.0 ANNEXURE (S):

Nil

6.0 REFERENCE (S):

SOP-Procedure of filling of equipment log book.

SOP-Preparation, approval, distribution control, revision and destruction of standard operating procedure.

7.0 ABBREVIATION (S)/DEFINITION (S):

BMR : Batch Manufacturing Record

SOP : Standard Operating Procedure

LLP : Light Liquid Paraffin

LP : Liquid Paraffin



PHARMA DEVILS

PRODUCTION DEPARTMENT

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CFM : Cubic Feet per minute

IPA : Iso Propyl Alcohol

v/v : Volume/Volume

ML : Milliliter

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S)FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---