FAILURE MODE EFFECTS AND CRITICALITY ANALYSIS

Department: Quality Assurance/Engineering **Date:**

Equipment/Process/Product: Encapsulation Machine with Tumble Dryer (*Equipment ID*)

FMECA No.: Number of Risk Assessment

S.No.	Potential Failure mode	Potential Effect (Process/ end users) or consequences	S	Contributory Factor or Cause	O	Current Control Measures	D	RPN (SxOxD)	Corrective Action	S	O	D	Reviewed RPN
1.0	Failure of Cooling Motor	Ribbon formation will not properly.	**8**	Increase temperature of castic drum. Cooling motor electronically damaged.	**2**	If any temperature variation on castic drum alarm will be ring. Cooling unit is the part of Preventive Maintenance checklist and being maintained as per SOP No. NNN.	**2**	**32**	Air supply from the cooling air for cooling drum should be the part of Operation SOP and check it before manufacturing of Capsules.	**8**	**2**	**1**	**16**
2.0	Failure of gravity feed pipes	Improper flow gelatin mass, Thinness of gelatin ribbon will disturb, Formation of air bubble in gelatin, Defects in capsule shape.	**8**	Improper cleaning of gravity feed pipes, leakage of gravity feed pipes, temperature increase in gravity feed pipes.	**1**	Cleaning of gravity feed pipes has been done as per SOP No. NNN under the Title- "Cleaning Procedure for Encapsulation Machine, Tumble Dryer, Transfer Pumps, Silicon Pipes and Gravity feed Pipes", Visual Examination of gravity feed pipes is there. Silicon hose for gelatin transfer spare part has been maintained.	**1**	**8**	Not Applicable	-	-	-	-
3.0	Failure of die roll or improper alignment of die rolls.	Leakage of capsule, shape and dimension defects can occur. Cutting of capsule	**8**	Improper handling, maintenance and storage condition, Operator training issues. Improper pressure on die roll, Turning pressure regulator is not functioning.	**1**	Zero point settings of die rolls with wedge and timing of filling pump has been set prior to operation as per SOP No. NNN. for pressure setting of the die rolls has been set by turning pressure regulator switch. Preventive maintenance of the all regulators and valves has been maintained as per SOP No.	**1**	**8**	Not Applicable	-	-	-	-

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4.0	Failure of Medicine injection pump.	Injection pump will not fill accurate quantity through the leads and wedge and into the gelatins ribbons between the two die rolls. Weight variation of capsules.	**8**	Puncturing and damage of O gasket. Plungers damaged.	**1**	O rings gaskets spare part has been maintained as per Spare Part list of Encapsulation machine., During in process average weight of capsule has been checked as per product respective BMR. Fill weight variation can be controlled within ±0.05ml.(design accuracy is there)	**1**	**8**	Not Applicable	-	-	-	-
5.0	Spreader Box Failure	Control over the gelatin flow will not maintain. Formation of ribbon will not proper. Thickness of gelatin ribbon can change.	**8**	Temperature sensor failure, sensor not installed, calibration of sensor is not there, Heater malfunction.	**1**	Spreader Box heater and sensor are the part of spare parts list. Preventive maintenance is in place and being performed as per SOP No. NNN. Alarm message is there.	**1**	**8**	Not Applicable	-	-	-	-
6.0	Failure of automatic oil supply system or improper oil supply.	Gelatin ribbon will not easily separate from wedge, gelatin ribbon can expand.	**7**	Improper Oil Supply, Top up of oil. Inside or outside oil roller, Lubrication oil pump failure. Die roll speed can change.	**2**	The speed of the oil pump on the model NNN is automatically changed to supply the same amount of oil as the die roll speed is changed (Automatic Control is there), Same grade oil is in place. Alarm system is there if any oil level can change.	**3**	**42**	Before starting of machine the The quantity of oil in the oil tank for gelatin ribbon and filling pump shall be check and should be the part of Operation SOP.	**7**	**2**	**1**	**14**

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7.0	Filling material transfer pump or motor	Off balance of soft capsule's weigh. Improper filling can occur, weight variation	**7**	Magnetic stirrer is not working, Functioning and leakage of silicon house	**1**	All motors have been checked during preventive maintenance for their proper functioning, overloaded tripping or any abnormal noise as per SOP No. NNN. Magnetic switch is there to control filling material in hopper. Silicon house cleaning and physical inspection has been done as per SOP. Filling material transfer pump woks on automation.	**1**	**7**	Not Applicable	-	-	-	-
8.0	Capsule formation is not proper	Quality of capsule can affect. Leakage can occur.	**8**	Gelatin ribbons formation is not proper m not lubricated, wedge orificies alignment is not proper. Wedge heater and sensor failure. Electrical failure, Pneumatic Pressure failure. Wedge orifices can damage, air pressure failure.	**1**	Heating temperature adjustment provision is there and to check the temperature of wedge temperature sensor is there.	1	**8**	Not Applicable	-	-	-	-
9.0	Improper wedge temperature	Encapsulation does not perfectly sealing.	**8**	Desired temperature is not achieved, heater failure.	**3**	The wedge heater is automatically controlled by a sensitive controller and sensor. Temperature of the wedge heater is different depending on the characteristics of the filling material or respective product. Before manufacturing of capsule wedge heater and sensor	**1**	**24**	NA	-	-	-	-

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						has been checked as per SOP No. NNN.							
10.0	Bursting and bending of soft capsules.	Deformed capsule can manufacture, Quality can affect.	**8**	Wedge Teflon coating is not proper, Die roll 'o' point damage, Status of surface of die roll is not good.	**3**	Further in downstream process physical inspection of process capsule is there to check any leaked capsules or any deformed capsules. All critical components have been control as per SOP No. NNN, Title-"Control of die roll and segments".	**1**	**24**	NA	-	-	-	-
11.0	Cooling drum temperature fluctuation.	Encapsulation does not perfectly sealing.	**7**	Temperature controller is not working. Coolant concentration is improper inside the cooling drum. Chilled water circulation from left to right drum is not functioned.	**3**	Calibration of temperature controller is in place. Temperature of chilled water is 8-12^{0}C and required cooling drum temperature is not more than 18^{0}C.	**1**	**21**	NA	-	-	-	-
12.0	Extreme usage of die rolls.	Sealing failure of capsules.	**7**	Storage, cleanliness of die roll, is not proper.	**2**	Product respective die roll is in place and physically inspect. Control of die segment has been done as per SOP No. NNN.	**1**	**21**	NA	-	-	-	-
13.	Tumble drier motor and gear failure	Capsule drying process will not completed, leakage is there, after encapsulation remains oil can contaminate or spillage the other capsules. Further	**8**	Air blower of Tumble Dryer is not working, Filter is choked or rupture, supplied air volume is not regulated to optimize the drying depending upon the product being dried.	**3**	Two sensors per tumble dryer is in place, Preventive maintenance of all gears and motor is in place and being performed as per PM SOP. Rotation per minute and drying percentage is control PLC and	**2**	**48**	Preventive Maintenance SOP shall be revised to check the status of all critical components.	**8**	**2**	**1**	**16**

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		downstream process will disturb. Effect on Hardness, Polishing of capsules sustained, capsule shape damaged.		Abnormal sound in motor, electrical connection tightness is not there, wear and tear of gear box; nut and bolt tightness is not there. Rotation of Tumble Dryer.		sensor. Desired air pressure is not achieved alarm is in place.							
14.	Capsule transfer air blower is not working.	Capsule from the conveyor to inlet of the tumble drying machine will not transfer.	**7**	Air Blower is not working, desired CFM of the air is not getting.	**3**	Prior to operation machine has been checked for correct functions and further process has been started as per product manufacturing technical directions and operating procedure of Encapsulation Machine.	**1**	**21**	NA	-	-	-	-
15.	Inadequate drying in Tumble.	Quality Can affect, further drying period can long, Moisture content failure.	**8**	Tumble air blower failure, Pre-filter is failure.	**3**	Sensor of Tumble dryer is working or not to be the part of PM checklist. For air blower	**2**	**48**	PM checklist shall be revised.	**8**	**2**	**1**	**16**

Scale of Severity, Occurrence, Detection.
1.0 Severity:

Effect	Scale	Description of 'System Impact'
No nearby	1	No effect on output
Very Slight	2	Stakholder /customer not annoyed
Slight	3	Slight
Minor	4	Minor effect on performance
Moderate	5	Moderate Effect on performance
Significant	6	Partial Failure but operable
Major	7	Product performance severely affected, but some operability and safe
Extreme	8	Very dissatisfied, product Inoperable but safe.
Serious	9	Potentially hazardous effect, time –dependent failure
Hazardous	10	Hazardous Effect, Safety related sudden failure

2.0 Occurrence:

Occurrence	Scale	Description
Almost Never	1	Failure Unlikely :history shows no failures
Remote	2	Rare number of historical failure
Very slight	3	Very few failures likely
Slight	4	Few Failures likely
Low	5	Occasional number of failures likely
Medium	6	Medium number of failures likely
Moderately High	7	Moderately high number of failures likely
High	8	High number of failures likely
Very high	9	Very high number of failures likely.
Almost certain	10	Failure almost certain

3.0 Detection:

Probability of detection	**Scale**	**Description of "Detection"**
Almost certain	1	Proven detection methods with high reliability
Very high	2	Proven detection methods available
High	3	Detection tools have high chance of detecting methods.
Moderately high	4	Almost certain not to detect failures
Medium	5	Detection tools have moderate chance of detecting defect.
Low	6	Detection tools have a low chance of detecting failure
Slight	7	Detection tools may not detect failure
Very slight	8	Detection tools will probably not detect failure
Remote	9	Detection tools most likely will not detect failure
Impossible	10	Failure not detected

4.0 RPN Rating:

Sr.No.	RPN Rating	RPN Category	Action Status	Criteria
01	≥76	Critical	CAPA is required	Functions directly or indirectly affect product quality, identity, purity, strength or efficacy and safety. Failure of system or function would result in customer harm. Usually, the main function of the system. Direct or likely regulatory impact. Requires several layers of risk mitigation, designed into the system, in process checks, release testing or in standard operating procedures.Operator safety would be in jeopardy if failure occurred. Customer complaints likely if function fails.
02	51 to 75	Major	CAPA is required	Failure of function causes system to fail or leads to significant production downtime. Failure of function results in product hold, significant amount of lost units, added inspection, etc. Failure of function has a potential to have a regulatory impact. The failure has a potential to cause customer harm. Operator safety would be a major concern, if failure occurred. Potential customer complaints if the function fails.
03	26 to 50	Moderate	CAPA is required	Failure in extreme circumstances could cause customer harm or adds cosmetic value only to product or system If failed would result in occasional lost units. Unlikely possibility of regulatory impact. Operator safety would be of minor concern or no concern, if failure occurred, downtime would be negligible when failure occurs. Customer complaints would be unlikely. Risk is ALARA(as low as readily achievable) or ALARP(as low as readily practicable)
04	Up to 25	Minor	Not Applicable	Negligible Risk, risk is acceptable.