



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## Risk Management for Enterprise Resource Planning System Implementation

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
1.0	- Contamination with foreign particles.	- Product failure - Product contamination	5	- Improper cleaning of blister machine and its change parts	1	- Cleaning procedure mentioned in SOP for product to product changeover and batch to batch changeover. - Line clearance prior to operation given by Quality assurance for product change over. - Line clearance recorded in line clearance checklist / BPR. - Pictorial album refers for line clearance to check hard to clean area. - Activity carried out under supervision of Production staff. - Training given to all concern.	1	5	- Current control measures are adequate - Risk is acceptable
2.0	- Failure in Product feeding / Cavity filling	- Quality failure.	5	- Feeder failure - Excessive tablet dropping. - Flood feeder - No precise control.	1	- Assemble the machine as per SOP. - Adjust the photo level sensor setting for tablets / capsule feeding. - Tablet feeding unit with photo-Level control and vibrator positive feeling of blisters with minimum deposition of dust on the sealing surface. - Camera system controls installed on blister machine to control blister cavity product feeding.	1	5	- Current control measures are adequate - Risk is acceptable

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3.0	- Improper blister cavity formation.	- Quality failure - Failure in leak testing.	5	- Forming temperature uncontrolled. - Compressed air pressure is not regulated. - Quality of forming materials (PVC).	1	- The temperature of the blister performing rollers is controlled by Temperature controller and can be regulated for optimum results during machine operation. - Record the forming temp in BPR as per in-process frequency. - Used calibrated instrument for temperature monitoring. - Compressed air regulator is calibrated. - Packing materials are approved by the QC after testing (as per STP).	1	5	- Current control measures are adequate - Risk is acceptable
4.0	- Failure of camera filling control	- Product filling failure - Market complaint	5	- Non filling detector is not working - PLC validation not done. - Challenge test procedure not available. - In-process activity not defined.	1	- Camera setting procedure defined in SOP. - Performance qualification has been done for Camera filling control system as protocol. - PLC validation has been done for non-filling camera control system. - Camera challenge test procedure defined in BPR for empty cavity, broken tablets, multiple tablets, foreign color, different size and shape, black spot.	1	5	- Current control measures are adequate - Risk is acceptable

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						<ul style="list-style-type: none"> <li>- Challenge test has been performed by Production and IPQA as per define frequency (initial, end &amp; any breakdown) and recorded in BPR.</li> <li>- In-process activity defined in BPR and performed by production and IPQA and recorded in BPR.</li> <li>- Training has been imparted to all concern.</li> </ul>			
5.0	- Failure in leak testing.	- Product and quality failure.	5	<ul style="list-style-type: none"> <li>- Sealing temperature uncontrolled.</li> <li>- Sealing pressure is not regulated.</li> <li>- Quality of leading materials (PVC).</li> </ul>	1	<ul style="list-style-type: none"> <li>- The temperature of the sealing rollers is controlled by Temperature controller and can be regulated for optimum results during machine operation.</li> <li>- Record the sealing temp in BPR as per in-process frequency by production &amp; IPQA person.</li> <li>- Sealing temperature range controlled by sealing station sensor. If temperature is out of range then machine automatically stop and restart when value attend.</li> <li>- Used calibrated instrument for temperature monitoring.</li> <li>- Packing materials are approved by the QC before use.</li> </ul>	1	5	<ul style="list-style-type: none"> <li>- Current control measures are adequate</li> <li>- Risk is acceptable</li> </ul>

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6.0	- Failure in blister feeding in carton	- Quality failure - Market complaint	4	- Feeder failure - Machine qualification not done - User interface PLC is not validated. - Operation procedures not define. - Operator is not trained.	1	- Product feeding sensor installed to control for number of blister per carton. - Empty carton is automatically rejected and controlled by feeding sensor and checkweigher. - Auto-cartonater machine is qualified for blister feeding and its control as per protocol. - PLC validation has been done as per protocol. - Operating procedure for auto-cartonator has defined in SOP. - Challenge test for auto-cartonator has been defined in BPR and performed by production and IPQA as per frequency (Initial, end and any breakdown) for missing leaflet, less blister, additional blister and recorded in BPR. - Training has been imparted to all concern.	1	4	- Current control measures are adequate - Risk is acceptable
7.0	- Failure in leaflet insertion	- Quality failure and market complaint	4	- Feeder failure - Machine qualification not done - User interface	1	- Correct leaflet folding is controlled by sensor. - Wrong folded / empty carton/leaflet missing carton automatically rejected at the end	1	4	- Current control measures are adequate - Risk is acceptable

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				<ul style="list-style-type: none"> <li>PLC is not validated.</li> <li>- Operation procedures not define.</li> <li>- Challenge test system is not in place.</li> <li>- Operator is not trained.</li> </ul>		<ul style="list-style-type: none"> <li>of machine.</li> <li>- Auto-cartonater machine is qualified for leaflet feeding and its control as per protocol.</li> <li>- PLC validation has been done as per protocol.</li> <li>- Challenge test for autocartonator has been defined in BPR and performed by production and IPQA as per frequency (Initial, end and any breakdown) for missing leaflet, less blister, additional blister and recorded in BPR.</li> <li>- Operating procedure for autocartonator has defined in SOP.</li> <li>- Training has been imparted to all concern</li> </ul>			
8.0	- Failure of Pharma Code reader	Quality failure	4	<ul style="list-style-type: none"> <li>- Machine setting procedure not in place</li> <li>- Head sensor performance is not done.</li> <li>- Machine qualification not done</li> <li>- User interface</li> </ul>	1	<ul style="list-style-type: none"> <li>- Autocatnator machine is operated as per SOP.</li> <li>- Pharma code reader is qualified as per protocol.</li> <li>- Autocartonater machine is qualified as per protocol.</li> <li>- PLC validation has been done as per protocol.</li> <li>- Challenge test for pharmacode reader has been defined in BPR</li> </ul>	1	4	<ul style="list-style-type: none"> <li>- Current control measures are adequate</li> <li>- Risk is acceptable</li> </ul>

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				<ul style="list-style-type: none"> <li>PLC is not validated.</li> <li>- Challenge test system is not in place.</li> <li>- Operator is not trained.</li> </ul>		<ul style="list-style-type: none"> <li>and performed by production and IPQA as per frequency (Initial, end and any breakdown) for extra bar, fewer bar, thin &amp; thick position interchange and recorded in BPR.</li> <li>- Training has been imparted to all concern</li> </ul>			
9.0	- Failure of check weigher	- Quality failure due to underweight / overweight carton (missing tablets/ capsules/blister/leaflet)	5	<ul style="list-style-type: none"> <li>- Operating procedure not defined.</li> <li>- Checkweigher is not qualified.</li> <li>- Challenge test procedure is not defined.</li> </ul>	1	<ul style="list-style-type: none"> <li>- Operating procedure for checkweigher has defined in SOP.</li> <li>- Checkweigher is qualified as per protocol.</li> <li>- Challenge test for Checkweigher has been defined in BPR and performed by production and IPQA as per frequency (Initial, end and any breakdown) for carton without leaflet, with additional leaflet, less blister and additional blister and recorded in BPR.</li> <li>- Training has been imparted to all concern</li> </ul>	1	5	<ul style="list-style-type: none"> <li>- Current control measures are adequate</li> <li>- Risk is acceptable</li> </ul>
Overall RPN								42	

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**Conclusion-** On the basis of overall risk rating calculation (RPN) and evaluation of risk assessment it has been concluded that the operation of blister machine is comes in moderate category and RPN is within acceptance limit. As per above risk assessment there is no impact on product quality and operation of blister machine will be controlled by routine monitoring of control measures.