QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR BLISTER PACKING MACHINE

Reference Document No.:	Risk Assessment No.: …….

Risk Assessment Document

Blister Packing Machine

Equipment ID: …..

PHARMA DEVILS

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Revision index:

Revision	Date	Reason for Revision

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Prepared By		
Name	**Designation**	**Signature/Date**

Checked By		
Name	**Designation**	**Signature/Date**

Approved By		
Name	**Designation**	**Signature/Date**

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Name (Block Letters)	Function	Signature

Level	Descriptor	Example detail description
1	Minor	• No impact on the product quality or outcome of the equipment. • Features required for easing equipment operation.
2	Moderate	• No direct impact on product quality/ outcome of equipment. however may indirectly affect the product quality. • Minor effect on personnel health • Used in the initial stage of operation, however it may affect the final output but those are not used for final release of output. • Effect on environment such as clean room.
3	Major	• Features having direct impact on product quality/ outcome of equipment like contact parts MOC, Surface finish, Control system, Process air quality etc. • Failure could lead to regulatory non-compliance. • Loss/ damage to equipment or its critical sub-components • Critical instruments not calibrated or not of desired range or accuracy. • Proper supporting documentation not provided. • Major effect on personnel health

Likelihood	Consequences/Impact		
	1 – Minor	2 – Moderate	3 – Major
1 (Unlikely)	Low	Medium	High
2 (Possible)	Low	Medium	High
3 (Likely)	Medium	High	High

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NAME	**DESIGNATION**	**SIGNATURE/DATE**

CHECKED BY		
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APPROVED BY		
NAME	**DESIGNATION**	**SIGNATURE/DATE**

Revision	Date	Reason for revision
00		First Issue

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M	c	M

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Charging										
1.	Tablets charging from container into product hopper	Joint between container and hopper is not leak proof	No	Does not impact quality of the product	EHS	Product exposure to environment	Low	Split valves are used to maintain containment	Acceptable	IQ
2.	Hopper	Emptying of hopper is not detected	Yes	Empty blisters or blisters with missed tablets /capsules may be produced.	Operational	Product loss	Medium	View glass shall be provided for assessing the product level in the hopper	Acceptable	IQ / OQ
3.	Feeding of tablets	Feed rate cannot be controlled	No	Does not impact quality of the product	Operational	Uncontrolled feeding of product will lead to frequent breakdown and loss of productivity.	Medium	Feed rate should be controlled with control of vibration intensity and sensor should be placed to maintain the level of tablets in the distribution plate.	Acceptable	IQ / OQ
Process:										
4.	Inlet Air to containment system	▪ Inlet Air is not filtered.	Yes	It will lead to product contamination	No	NA	High	▪ Air Filter assembly with HEPA filter and differential pressure indicator will be considered at the air inlet in the design. ▪ Provision for PAO port shall be provided.	Acceptable	IQ

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5.	HEPA Filter	HEPA filter got clogged	No	Does not affect the quality of the product	Operational	Isolator canopy may not withstand with extremely high negative air pressure.	High	Differential pressure gauge should be provided for monitoring differential pressure across HEPA filter.	Acceptable	OQ
6.	Exhaust air	Exhaust air contaminate	No	Does not affect the quality of the product	EHS	Product exposure	Low	HEPA filter with wet scrubber shall be provided at exhaust	Acceptable	IQ
7.	Change parts	Provision for change parts is not provided.	No	Does not affect the quality of the product	Operational	Blister packing of tablets of different sizes and in variable blister format is not feasible.	Medium	Machine should be provided with required change parts to pack the tablets or capsules in desired format.	Acceptable	IQ

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8.	Process control	Process parameters such as machine speed, sealing temperature, forming temperature, pressure etc. cannot be monitored and controlled	Yes	Operation cannot be run in control	No	NA	High	M Process parameters will be displayed and control by PLC/HMI	Acceptable	IQ/OQ
9.	In-process control	Blisters with empty pocket are found with the good blisters	Yes	It will produce incorrect blister quantity leading to market complaint	No	NA	High	Provision for Non fill detector or Camera will be considered in the design	Acceptable	IQ / OQ
10.	In-process control	Over-printing is incorrect or illegible.	Yes	Incorrect or illegible printed matter will mislead the patient, lead to market complaint.	No	NA	High	Checking of printed matter and over-printed matter will be done initially and intermittently during entire operation.	Acceptable	OQ
11.	Blister packing	Cold form blister packing cannot be carried out.	No	This is a specific requirement	Operational	Packing of thermo-labile product could not be feasible.	Medium	Provision for cold form packing will be considered in the equipment.	Acceptable	IQ / OQ

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12.	Lubricant System	Lubricant migrates into product	Yes	It will cause contamination	No	NA	High	Lubrication system must be leak proof. Food grade lubricant shall be used	Acceptable	OQ
13.	Foil dispensing station	Absence of foil cannot be assessed	No	Does not affect the quality of the product	Operational	Machine will run without foil leading to breakdown	Low	Foil sensor to be considered in the design.	Acceptable	IQ / OQ
14.	Overprinting	Overprinting / Embossing is not feasible	Yes	Batch identity cannot be overprinted	No	NA	High	Provision for overprinting and embossing unit to be considered in the design	Acceptable	IQ / OQ
15.	Blister cutti g r	Blisters are cut with undesired printed matter	Yes	Product may be produced with incomplete information	No	NA	High	Eye mark detection and correction facility to be considered in design. Finished blisters will be checked intermittently during operation.	Acceptable	IQ / OQ
16.	Blister counting	Blister output cannot be assessed	Yes	Yield cannot be monitored	No	NA	Medium	Blister counter to be considered in the design	Acceptable	IQ / OQ
Discharge										
17.	Blister collation	Blisters cannot be collated	Yes	Unarranged discharge of blister will lead to punctured blister	No	NA	Medium	Blister collator with compatibility to blister format shall be considered.	Acceptable	IQ / OQ

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18.	Reject blister discharge	Rejected blisters are mixed with good blisters	Yes	Blisters with empty pocket may go with good blisters lead to market complaint.	No	NA	Medium	Rejected blister chute should be provided. It will be attached to the rejection box.	Acceptable	IQ / OQ
Cleaning and Material of Construction										
19.	Cleaning	Improper cleaning	Yes	Accumulation of particles leading to Inefficient cleaning process	No	NA	High	▪ Proper cleaning (CIP/ WIP process) method has to be provisioned along with manual cleaning spray nozzles to minimize the contamination risk. ▪ All gaskets provided to avoid leakage should be amenable for easy removal & re-fixing for cleaning. ▪ All bolts, nuts on the exterior part of the equipment shall be provided with cap head or cap nut.	Acceptable	OQ/ SOP

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20.	Cleaning	Difficulty in cleaning	Yes	Parts need to be dissembled for proper cleaning	No	NA	Medium	▪ The design shall ensure adequate clean ability (smooth, crevice free surface, MOC SS316 or better surface). ▪ Parts that cannot be cleaned in mounted position e.g. hopper, feeder etc. to be made suitable to dissemble and clean.	Acceptable	IQ / OQ
21.	Labelling	Labelling of components inappropriate	Yes	Prerequisite for qualification	No	NA	High	▪ Unique identity No. / flow direction must be on components / media, operator panel, etc. (e.g. according to P&ID) ▪ All labelling in English language and according to project standard.	Acceptable	IQ

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22.	s Material of Construction	▪ Surface and construction of the machine is not compatible to product. ▪ Material reacts with cleaning media like PW, IPA etc.	M Yes	It will lead to product contamination due to corrosion	No	NA	High	▪ All product contact metallic surfaces should be of SS 316 or better. ▪ All welds and joints shall be ground finish; metallic surface will have no crevices. ▪ Non Contact surfaces should be SS304 with external surface matt finish.	Acceptable	IQ
23.	Welding	Welding quality not sufficient (Piping)	Yes	GMP requirement; Cleaning problems, surface conditions out of specification in case of bad welding quality.	No	NA	High	▪ Standard welding technique: Orbital welding ▪ Welding verification reports shall be available	Acceptable	IQ
24.	Gaskets, seals and O rings MOC	Gasket MOC not compatible	Yes	▪ Product contamination possible	No	NA	High	▪ MOC should be of food grade (Silicon/PTFE).	Acceptable	IQ

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25.	Surface Finishing	Surface Finishing of Internal & external surface insufficient	Yes	▪ GMP requirement; cleaning problems. ▪ Micro-organisms may accumulate on metallic surfaces	No	NA	High	M ▪ Surface roughness, Ra ≤ 0.5 µm, proven by certificates for internal surface. ▪ Crevice free smooth, rounded corners & smooth surface.	Acceptable	IQ
Maintenance										
26.	Maintenance	Malfunctions due to worn parts	Yes	Basic GMP requirement	No	NA	High	▪ Machine shall be easy to maintain. ▪ Preventive maintenance procedure should be available ▪ The unit must contain necessary protection devices to ensure that the equipment & the article remain in a safe condition.	Acceptable	IQ/SOP
Safety										
27.	Moving & electrical parts	Moving & electrical parts are not covered.	No	NA	EHS	Accident can take place.	Medium	All moving & electrical parts are to be covered properly	Low	IQ

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28.	Gaskets	Joint gaskets are not replaceable	Yes	Worn gasket will contaminate product and affect the integrity	EHS	Result in material leakage	Medium	All the gaskets should be of replaceable type so as to remove the worn out or damaged gaskets.	Acceptable	IQ
29.	Notification of alarms	Failure of utility supply is not indicated	Yes	Process parameters may get disturbed	EHS	High pressure may cause accident	High	Various utilities like compressed air supply, vacuum supply should be interlocked and indicated by alarm.	High	IQ / OQ
30.	Emergency top	Instantaneous stopping of the machine not possible	No	NA	EHS	Emergency stop function is required for equipment, personnel and product protection	High	Emergency stop with alarm to be installed on accessible areas	Acceptable	IQ / OQ
31.	Noise level	More noise is produced by the equipment during the operation	No	NA	EHS	High noise may cause deafness and anxiety	Medium	▪ Equipment should be provided with anti-vibration mountings to reduce vibration and noise. ▪ Noise level shall be below 80 db at a distance of 1 m from the equipment.	Acceptable	IQ/ OQ

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32.	s Door interlock	Door covering the machine can be open during running machine	M No	Does not affect the quality of the product	EHS	Accident may takes place	Medium	Door interlock will be there in place which will stop the machine if door are open	Acceptable	IQ/OQ
33.	Air Handling System	System cannot maintain the negative pressure within the containment system	No	Does not affect the quality of the product	EHS	In case of overpressure chances of leakage into room	High	System to be designed to meet the negative pressure within the containment and display of differential pressure with respect to room and alarm in case of out of limit.	Acceptable	OQ
34.	Containment while sampling	The material may contaminate the personnel working environment.	No	Does not affect the quality of the product	Yes	The product can effect operators health	High	▪ A 'bag out' system should be provided for collection or sampling of tablets. ▪ Glove ports should be provided in the entire system for easy access to all parts.	Acceptable	IQ/ OQ
35.	Containment	Leakage	No	Does not affect the quality of the product	Yes	The product can effect operators health	High	▪ The containment should be leak proof. ▪ Leak test should be conducted.	Acceptable	OQ
Measuring Instruments										

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36.	s Measuring instruments	Measuring instruments not suitable	M Yes	Improper measurements	No	NA	High	▪ Measuring instruments must have a suitable measuring range. M ▪ Operational range of measuring instruments < instrument working range. ▪ They must have appropriate accuracy.	Acceptable	IQ/ OQ
37.	GMP relevant measuring instruments	Measuring instruments cannot be dismounted	Yes	Defective instruments must be dismounted for exchange and calibration	No	NA	High	▪ Mounting of instruments must give the possibility for dismounting and replacement ▪ Constructional solution: easy access for calibration activities shall be given	Acceptable	IQ
38.	Measuring instruments	Instruments not calibrated	Yes	Non calibrated instruments may lead to false machine functions	No	NA	High	▪ Measuring instruments should be calibrated, traceable to national or international standards.	Acceptable	IQ/OQ
Control & Monitoring System										

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39.	s Man-machine Interface	Process / process status not visible for operating personnel	M Yes	Operating personnel must have knowledge on the process status	No	NA	High	Machine shall be fitted with adequate display and clean room suitable key board for operation.	Acceptable	IQ/ OQ
40.	Man-machine Interface	Display language not identified.	Yes	Pre-requisite for the GMP compliant operation	No	NA	High	▪ The language on the display of HMI should be English language only.	Acceptable	OQ
41.	Man-machine Interface	Monitoring/recording and documentation of GMP relevant data not possible	Yes	Basic GMP requirement	No	NA	High	▪ It should be possible to monitor/record GMP relevant data (e.g. recorder with compliance to GAMP 5 / 21 CFR, Part 11 etc.) ▪ Batch records / print outs to be defined. ▪ Printout facility should be available with fade proof prints.	Acceptable	OQ
42.	PLC/ Control system	Control system does not detect failures and generate alarms	Yes	Process optimization and validation is not possible	No	NA	High	Failure of set parameters gets indicated as alarms and machine stops	Acceptable	OQ

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43.	s PLC / Control system	▪ Power failure / emergency stop ▪ Data lost on power failure	M Yes	▪ Process out of specification. ▪ Set parameters will get lost.	No	NA	High	▪ Operator settings unchanged and restored after emergency stop / power failure; ▪ Alarm message; ▪ Machine must not start automatically without operator intervention after incident. ▪ PLC considered with memory back up. ▪ SOP for 'Maintenance and operation of Blister Packing Machine (Alu Alu)'.	Acceptable	OQ/ SOP
44.	PLC / Control system	Status parameters not clear	Yes	Process for the particular product at particular stage can't be regulated easily.	No	NA	High	▪ Status parameters should remain displayed at each process stage. ▪ The flow of the process shall be provided with the help of arrows. ▪ Alarm should also be visualized along with the fault displayed.	Acceptable	OQ
45.	Accessibility to PLC	Parameter settings not identified universally	Yes	Basic GMP requirement	No	NA	High	▪ Parameters settings should be in numeric only.	Acceptable	OQ

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46.	s PLC / Control system	No protection of PLC against manipulation & changes.	M Yes	Basic GMP requirement.	No	NA	High	▪ 3 level password protections should be provided. ➢ Level 1: for operator settable parameters. ➢ Level 2: for editing cycle parameters. ➢ Level 3: for admin/ engineering level setting.	Acceptable	OQ
Documentation:										
47.	User	Faulty operation & maintenance	Yes	SOPs are basic GMP-requirement	No	NA	High	▪ All end-users have to be trained on SOPs ▪ Training of SOPs has to be documented ▪ Training on the job of end users by vendor. ▪ Training on operation, setting parameters, trouble shooting & maintenance related activities.	Acceptable	OQ/ SOP

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48.	s User	Operation SOP does not contain proper information and user may operate system	M Yes	User may make a wrong decision.	No	NA	High	▪ System operation SOP must be reviewed with all aspects and approved. M ▪ Vendor shall provide execution support to the user to complete all stages of the qualification report.	Acceptable	OQ
49.	User	Unauthorized person tries to start/stop the system	Yes	Untrained persons may damage the system or product quality may be affected	No	NA	High	▪ System should not start without password. ▪ Key-switch should be provided for system power up. OR ▪ Physical entry to equipment room is restricted.	Acceptable	IQ/ OQ

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50.	s Vendor	Technical documentation from vendor not adequate	M Yes	Adequate technical documentation is basic GMP requirement	No	NA	High	▪ Vendor documentation (English) shall comprise: -DQ, IQ and OQ -Data sheets -Material certificates -Operating instructions -Maintenance instructions and intervals -Calibration instructions -Software backup -Parts lists(sufficient detailed: part number, supplier, type) ▪ Drawings - P&I-diagrams - Electrical diagrams - (Certificates of initial calibration of sensors); - Filter certificates -As built GA drawings ▪ Running trial certificate. ▪ Certificate of bought out components.	Acceptable	IQ

N

9.0 Summary and Conclusion:

- The risk Assessment is performed to establish the design parameters of the equipment so as to meet the desired performance of the equipment i.e. Blister Packing Machine.
- The critical risks pertaining to GMP and other than GMP were analyzed with justification and mitigation procedures.
- For each recognized GMP-risk and other than GMP risks necessary measures are defined. Organizational measures, like SOPs, are also possible measures for special GMP-risks. The availability of these SOP's will be checked at the time of accomplishment of OQ of the machine.
- To control the risk, various mitigation methods shall be verified through SOP's ,operation & maintenance manuals, and calibration certificates at respective verification points
- Based on Risk Assessment, the URS shall be prepared.

*"It is concluded that the **Risk Assessment** performed for the equipment will mitigate the risk of failures of critical parameters during design, commissioning, installation, operation and performance of the equipment".*