QUALITY RISK ASSESSMENT FOR TABLET COMPRESSION MACHINE

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR TABLET COMPRESSION MACHINE

PREPARED BY		
NAME	**DESIGNATION**	**SIGNATURE /DATE**

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

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

Name (block letters)	Function	Signature

FAILURE MODE EFFECT ANALYSIS FOR TABLET COMPRESSION MACHINE

Level	Descriptor	Example detail description
1	Unlikely	May occur at some time
2	Possible	Might occur at some time
3	Likely	Will probably occur in most circumstances

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

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								Mitigation Method	Residual risk level	Verification
Charging										
1.	Granule cha ging from container into granule hop er.	Joint between container and hopper is not leak proof	Yes	Material leakage, Area contamination	EHS	Product exposure to the environment	High	The container is directly docked to hopper of compression machine and the product is passed through containment split valve	Acceptable	IQ
2.	Hopper	Emptying of container is not detected	Yes	It may lead to weight variation	Operational requirement	No indication to change the IBC	High	Sight glass to be considered in the design	Acceptable	IQ
3.	Granule charging	Granules clogged in the hopper	Yes	It may lead to weight variation	No	NA	High	Design of the hopper to be ensured to enhance flow of granules	Acceptable	IQ
4.	Powder level sensor	Emptying of hopper is not detected	Yes	Leads to weight variation	No	NA	High	Powder level sensor to be provided which will generate alarm and interlocked	Acceptable	IQ / OQ
Process:										
5.	Powder Feeding Unit	Uneven feeding of powder	Yes	Uneven feeding of powder will cause weight variation	No	NA	High	Force feeding assembly with speed control to be considered in the design	Acceptable	IQ / OQ
6.	Main Body	Turret RPM can not be controlled	Yes	It may affect quality of the tablet	No	NA	High	VFD based operation to be considered	Acceptable	IQ/OQ

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7.	Compression process	Process parameters, compression force, thickness, weight, output could not be monitored or controlled	Yes	Product quality will be inconsistent.	No	NA	High	PLC based operation with provision of Compaction Force Controller system (CFC).	Acceptable	IQ/OQ
8.	Ejection ca	Broken tablets are produced	Yes	Deviation from specification	No	NA	High	Ejection cam should be designed so that tablets do not get damaged. Ejection monitoring force will be evaluated.	Acceptable	OQ
9.	De-duster	Excess powder is smeared over the tablets.	Yes	Tablets will not be palatable and may create problem in further processing viz. coating and packaging	No	NA	High	▪ Efficient de-dusting devices shall be installed at the discharge line of machine. ▪ Alarm provision on stoppage of de-duster.	Acceptable	IQ / OQ
10.	Metal detector	Contamination of tablet with metal particles	Yes	Product will get contaminated	No	NA	High	▪ Online metal detector should be considered at the discharge with rejection system. ▪ The metal detector should have ports for adding or removing test pieces.	Acceptable	IQ / OQ

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11.	Feed rate cannot be maintained	Powder cannot be removed efficiently from tablets	Yes	Tablets will not be palatable	EHS	Product exposure	High	Vibration speed / feed rate should be adjustable	Acceptable	OQ
12.	De-duster	Powder accumulates in the de-dusting equipment	Yes	Powder could not be removed efficiently resulting powder smeared tablets	EHS	Product exposure	High	Connection with de-dust extraction system should be considered in the design	Acceptable	IQ
13.	Metal detector	Sensitivity of metal detection system cannot be tuned	Yes	Tablets with metal particle may get passed resulting product contamination	Productivity	High sensitivity of the unit may reject good tablets	High	Provision for adjustment of powder level or sensitivity should be considered	Acceptable	OQ
14.	Rejection system	Tablets with metal impurities cannot be rejected	Yes	Tablets with metal particles may get passed resulting product contamination	No	NA	High	Synchronization of the system should be checked for rejection of objects with ferrous, non-ferrous and stainless steel metal pieces and without metal.	Acceptable	OQ

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15.	Lubrication system	Powder get contaminated by lubricant from feeder driving system	Yes	Product will get contaminated	No	NA	High	Auto lubrication system to be provided considering the strategic points to ensure no product contamination. Lubricants used must be food grade.	Acceptable	IQ / OQ
16.	Tablet counting	Tablet output cannot be assessed on screen	Yes	Essential requirement for yield assessment	No	NA	Medium	Online tablet counting should be displayed on the PLC display	Acceptable	OQ
17.	In-process sampling	In-process assessment cannot be performed	Yes	Online sampling is required during setting the machine and In-process control	No	NA	Medium	Sampling point to be placed along with exit chute	Acceptable	IQ
18.	Collection o Tablets	Machine stop while collecting compressed tablet	No	NA	Operational	Yield less. Process takes long time	Medium	A ‘Y’ piece arrangement with two collection ports should be provided at the discharge to collect tablets in flexible bags without stopping the machine.	Acceptable	IQ

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19.	Air control and Filtration system for isolator	The contained enclosure doesn't have any air control and filtration system.	Yes	The process should be carried out under clean room environment.	EHS	Health risk to personnel in case of isolator failure	High	▪ The system should have its own supply and exhaust system with HEPA filters at both supply and exhaust. ▪ A minimum of 20 air changes should be designed for the system ▪ The isolator should meet the particulate matter count as per ISO 8 (at rest). ▪ The filter choke alarm should be provided. ▪ Filter should be	Acceptable	IQ/ OQ/ SOP
20.	Filters	Damage of filters by particles	Yes	Contamination possibility high	No	NA	High	▪ Regular check up of HEPA filters. ▪ Routine filter integrity test. ▪ Differential pressure indicator and transmitter should be provided to monitor pressure across HEPA filters.	Acceptable	SOP

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21.	Tablet press isolator chamber	Differential pressure across chamber and atmosphere could not be monitored	No	Does not have any impact on product quality	EHS	Health risk to personnel in case of isolator failure	High	▪ Differential pressure indicator and transmitter should be provided to monitor and control the differential pressure. ▪ Alarm for containment breached with interlocking should be provided in case of isolator failure.	Acceptable	IQ/ OQ
22.	n Exhaust Filter of main isolator chamber	Differential pressure across chamber and exhaust filter of main chamber and atmosphere could not be monitored	No	Does not have any impact on product quality	EHS	Health risk to personnel in case of isolator failure	High	▪ Differential pressure indicator and transmitter should be provided to monitor and control the differential pressure. ▪ Alarm for containment breached with interlocking should be provided in case of isolator failure.	Acceptable	IQ/ OQ
23.	ɛ ı Blower Motor trips/ Blower speed could not be maintained	The required velocity for maintaining the isolator conditions could not be maintained.	No	Does not have any impact on product quality	EHS	Minimum velocity is required to be maintained to meet isolator conditions.	High	▪ VFD should be provided to maintain and control the speed of the blower. ▪ Alarm to be provided in case of blower motor trip	Acceptable	IQ/ OQ

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24.	Labeling	Labeling of components inappropriate	Yes	Prerequisite for qualification	No	NA	High	▪ Equipment, Valves and instrumentation shall be uniquely identified in accordance with a standard numbering and location system. All valves and instruments are to be physically labeled with their identification numbers. ▪ All labeling in English language and according to project standard.	Acceptable	IQ
Control & Monitoring System										
25.	Man-machine Interface	Process / process status not visible for operating personnel	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
26.	Man-machine Interface	Display language not identified.	Yes	Pre-requisite for the GMP compliant operation	No	NA	High	▪ The language on the display of MMI should be English language only.	Acceptable	OQ

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27.	Man-machine Interface	Recorder failure	Yes	Basis GMP requirement (incomplete / no documentation)	No	NA	High	▪ Data backup for process data must be foreseen (electronic recording, 21 CFR part 11 compliant). ▪ Diagnostic function test to be a part of qualification activity.	Acceptable	IQ & OQ
28.	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
29.	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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30.	PLC / Control system	Power failure / emergency stop	Yes	Process out of specification	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 ▪ SOP for 'Maintenance and operation of Tablet compression machine'.	Acceptable	OQ
31.	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

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32.	PLC / Control system	Malfunction	Yes	Correct function basic requirement for GMP-compliant operation	No	NA	High	▪ Supplier analysis (quality management system for software and control system hardware development) ▪ Input/ Output test implementation in qualification activities ▪ The system must contain all necessary protection devices to ensure that the equipment and article remain in safe condition.	Acceptable	OQ
33.	Accessibility to PLC	Parameter settings not identified universally	Yes	Basic GMP requirement	No	NA	High	▪ Parameters settings should be in numeric only.	Acceptable	OQ
34.	PLC / Control system y	Time measurement works incorrect	Yes	Process insufficient	No	NA	High	▪ PLC Clock verification ▪ SOP “calibration and maintenance” ▪ Time synchronisation of system	Acceptable	OQ

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35.	PLC / Control system	No protection of PLC against manipulation & changes.	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
Discharge:										
36.	Tablet discharge	Tablets get clogged during exit	Yes	Tablets may be damaged	No	NA	High	Easy clearance of tablets should be considered during discharge	Acceptable	OQ
37.	Tablet discharge	Discharge is not possible in closed exposure	No	NA	EHS	Product exposure	Low	Personnel shall wear PPE during operation	Acceptable	PQ
Cleaning and Material of Construction :										

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38.	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
39.	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

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40.	Material of Construction	▪ Surface and construction of the machine is not compatible to product. ▪ Material reacts with cleaning media like PW, IPA etc.	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
41.	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
42.	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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43.	Surface Finishing	Surface Finishing of Internal & external surface insufficient	Yes	▪ GMP requirement; cleaning problems. ▪ Micro-organisms may accumulate on metallic surfaces	No	NA	High	▪ Surface roughness, Ra ≤ 0.5 µm, proven by certificates for internal surface. ▪ Crevice free smooth, rounded corners & smooth surface.	Acceptable	IQ
Maintenance										
44.	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/SO P
45.	Tool parts	Long time is required to change tool parts	No	NA	Operational	Operational time will be lossed in changing tool parts	Low	▪ Tool parts should be changed within 30 minutes.	Acceptable	OQ
Safety:										

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46.	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
47.	Gaskets	Gaskets are not compatible with material handled in equipment	Yes	Product contamination	No	NA	High	Gaskets to be made of approved food grade elastomer	Acceptable	IQ / OQ
48.	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
49.	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
50.	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

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51.	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
52.	Door interlock	Door covering the machine can be open during running machine	No	NA	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

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53.	Containment	The material transfer from IBC to hopper is not contained.	No	NA	Yes	The product can effect operators health	High	▪ The material transfer from IBC to hopper shall be carried out through split valves so that product does not leak in the personnel-working environment. ▪ A negative pressure should be provided in the containment chamber and failure should be alarmed and interlocked. ▪ Glove ports should be provided in the entire system for easy access to all parts.	Acceptable	IQ/ OQ
54.	Containment while sampling or rejection	The material may contaminate the personnel working environment.	No	NA	Yes	The product can effect operators health	High	▪ A 'bag out' system should be provided for collection or sampling of tablets and for collection of rejects tablets. ▪ A negative pressure should be provided in the containment chamber and failure should be alarmed and interlocked.	Acceptable	IQ/ OQ

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55.	Containment	Leakage	No	NA	Yes	The product can effect operators health	High	▪ The containment should be leak proof. ▪ Leak test should be conducted.	Acceptable	OQ
Measuring Instruments:										
56.	Measuring instruments	Measuring instruments not suitable	Yes	Improper measurements	No	NA	High	▪ Measuring instruments must have a suitable measuring range. ▪ Operational range of measuring instruments < instrument working range. ▪ They must have appropriate accuracy.	Acceptable	IQ/ OQ
57.	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
58.	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

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Documentation:										
59.	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
60.	User	Operation SOP does not contain proper information and user may operate system	Yes	User may make a wrong decision.	No	NA	High	▪ System operation SOP must be reviewed with all aspects and approved. ▪ Vendor shall provide execution support to the user to complete all stages of the qualification report.	Acceptable	OQ

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61.	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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62.	Vendor	Technical documentation from vendor not adequate	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

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. Tablet Compression 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 SOPs will be checked at the time of accomplishment of OQ of the machine.
- To control the risk, various mitigation methods shall be verified through SOPs ,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".*

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Acronym	Definition
cGMP	Current Good Manufacturing Practice
db	Decibel
EU-GMP	European –Good Manufacturing Practice
GA	General Arrangement
MMI	Man Machine Interface
IQ	Installation Qualification
OQ	Operational Qualification
DQ	Design Qualification
MOC	Material Of Construction
EHS	Environment Health Safety
IBC	In process Batch Container
O & M	Operation and Maintenance Manual
PLC	Programmable Logic Controller
RPM	Revolution per minute
SOP	Standard Operating Procedures
SS	Stainless steel
URS	User Requirement Specification
VFD	Variable Frequency Drive
HEPA	High Efficiency Particulate Air Filter
PPE	Personnel Protective Equipment
PW	Purified Water
IPA	Iso Propyl Alcohol
PTFE	Poly tetra fluoro Ehtylene

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