



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR BI BLENDER

**FAILURE MODE EFFECT ANALYSIS
FOR
BIN BLENDER**



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S. No	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
1.	Blender	Powder leakage during blending.	Yes	Product loss, area contamination.	EHS	Health hazard to person in contact of product.	High	All the covers and valves must be designed in leak proof closing.	Acceptable	IQ
2.	Sampling	Sampling is not possible from the blender.	Yes	Sampling is required for validation study and routine assessment sample.	No	NA	High	Provision for sampling in sampling isolator should be provided to assist sampling.	Acceptable	IQ/OQ
3.	Machine operation	Operator and staff are not trained.	Yes	Untrained operators may not operate equipment properly.	Operational/EHS	Chances of accidents	High	Proper training to be imparted to operator and staff.	Acceptable	OQ
Discharge:										
4.	Discharge arrangement	The bin can't be easily detached from the blender after the completion of cycle and proceed for the compression cycle.	No	Does not affect the quality of the product	Operational	Productivity may get decreased due to loss of material during transfer.	Medium	Bin could be easily detached from the blender after the completion of cycle and processed for the compression process	Acceptable	OQ
Cleaning and Material of Construction:										



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5.	Surface Finish	Internal Surface material is not cleanable	Yes	Cross contamination	No	NA	High	Smooth surface without crevices mirror finish for internal surface and grounded welding finish will be considered in the design. Sealing with silicon will be furnished over the pedestal joints.	Acceptable	IQ
6.	MOC	Product non-contact metallic surface cannot be cleaned	Yes	Contamination	Operational	Corrosion may take place	High	All metallic product non-contact surfaces should be constructed of 304 grade stainless steel with external surface matt finish.	Acceptable	IQ
7.	Cleaning	Inadequate space for cleaning	Yes	Chance of contamination due to improper cleaning	No	NA	High	Lid/ Manhole of suitable size should be provided on the bin to increase access for cleaning.	Acceptable	IQ
8.	MOC	Product contact surface material is not compatible with products and to clean	Yes	Uncleanable surfaces lead to product contamination	No	NA	High	All metallic product contact surfaces should be constructed of SS 316 or better grade with internal mirror finish and external surface matt finish.	Acceptable	IQ
Safety										
9.	Gaskets	Joint gaskets are not replaceable	Yes	Cross-contamination	EHS	Containment failure in case of eroded gaskets	Medium	All gaskets shall be replaceable	Acceptable	IQ
10.	Gaskets	Gaskets are not compatible with material handled in equipment	Yes	Contamination	EHS	Containment failure in case of eroded gaskets	High	All gaskets must be inert in nature to product and should be of food grade quality.	Acceptable	IQ
11.	Noise level	More noise is produced by the equipment during the operation	No	Does not have any impact on quality of the product	EHS	High noise may cause deafness and anxiety	Medium	Noise level shall be below 80 db at a distance of 1 m from the equipment.	Acceptable	OQ



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12.	Emergency stop	Emergency stop not provided	No	Does not have any impact on quality of the product	EHS	Emergency stop function is required for equipment, personnel and product protection	High	Emergency stop to be installed on accessible areas	Acceptable	IQ
13.	Electricity	Power recovery is not warned	No	Does not have any impact on quality of the product	EHS	Staff protection	Medium	Equipment starts with human intervention only	Acceptable	OQ
14.	Closure of the all rotating & electrical part	Appropriate closure of the rotating & electrical part is not provided.	No	Does not have any impact on quality of the product	EHS	It may lead to accident	High	Appropriate closure of all the rotating & electrical parts.	Acceptable	IQ
Measuring Instruments:										
15.	Measuring Instruments	Measuring instruments are not in defined range	Yes	Instruments are not suitable for use.	No	NA	High	Measuring ranges shall be defined	Acceptable	IQ / OQ
16.	Measuring Instruments	Measuring instruments could not be calibrated	Yes	Instruments are not suitable for calibration.	No	NA	High	Must be calibrated and suitable for re-calibration	Acceptable	IQ / OQ
Documentation:										
17.	Documentation	Critical surfaces are not tested for material of construction and test reports are not provided	Yes	Lack of documented evidence leads to question on the quality of MOC	No	NA	High	MOC description and certification of critical parts to be provided	Acceptable	IQ
18.	Documentation	Instruments are not provided with calibration certificate	Yes	Calibration cannot be assured due to lack of documented evidence	No	NA	High	Critical instrumentation shall be supported with calibration certificates.	Acceptable	IQ



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19.	Documentation	Equipment is not provided with design and functional specification	Yes	Design qualification is not possible	No	NA	High	Design and functional specification should be supplied as per URS	Acceptable	IQ
20.	Documentation	Equipment is not provided with Operation & maintenance manual	Yes	Correct operation is not ensured and Qualification requirement	No	NA	High	O & M manual should be supplied per URS	Acceptable	IQ
21.	Standard Operating procedure	Standard operating procedures are not available.	Yes	Procedures critical operations cannot be carried out successfully resulting process failure.	Operational	Productivity will get decrease to unavailability of procedure.	High	SOPs for Operation, Cleaning and maintenance shall be prepared in line with operational and maintenance manual and finalized.	Acceptable	IQ