FAILURE MODE EFFECT ANALYSIS FOR DRY POWDER INJECTION

S. No.	Description of Activity	Potential Failure Mode	Failure Causes	Failure Impact	Current Control	Reference Doc. No.	Risk with Current control Measure				Proposed Control Measures (if any)	Risk after control measure			Risk Priority Number (RPN)
							Likelihood of Occurrence (1-10) (O)	Likelihood of Detection (1-10) (D)	Severity (1-10) (S)	Risk Priority Number (RPN)		Likelihood of Occurrence (1-10) (O)	Likelihood of Detection (1-10) (D)	Severity (1-10) (S)	
1.	**Dispensing**	Risk of Cross Contamination	Due to dis-balancing of pressure differential.	Material product contaminated.	Magnehelic gauges are provided in the facility. Checking & logging of differential pressure is done twice in a shift for critical areas. At the time of line clearance differential pressure verification is also done by QA.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Person carrying out the dispensing activity is not following proper gowning procedure.	Material & product contaminated.	Gowning procedure is available & pictorials are displayed in all changing room. Before authorize any person to entry in the critical areas training is carried out on entry procedure, gowning procedure & working procedure.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Person carrying out dispensing activity is suffering from infectious disease.	Material & product contaminated.	Person suffering from any infectious disease is not allowed to enter in the premises. Medical checkup of persons working in critical areas is carried out on annual basis.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Due to damaged material container.	Material & product contaminated.	At the time of material receiving check point of container condition is available. At a defined frequency material condition is also verified as per procedure including container physical conditions.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Due to improper cleaning of scoops & utensils used for dispensing.	Material & product contaminated.	Cleaning of all equipments& utensils is done by trained professionals by using validated cleaning procedures.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Due to improper cleaning of area.	Material & product contaminated.	As per procedure & GMP practices cleaning is done before the critical activity & verification of cleaning also done by QA person as per check point of line clearance.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA

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			Cleaning of the area is running simultaneously with dispensing.	Material & product contaminated. .	As per procedure & GMP practices cleaning is done before the critical activity.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Due to improper cleaning of area.		Cleaning of area is done by validated & defined cleaning procedure with the help of validated disinfectant.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			RLAF operation is not done properly.		Operation & cleaning procedure of RLAF is done by defined procedure only by trained staff.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			RLAF is not working properly.		Preventive maintenance of RLAF s done routinely. For checking performance of RLAF viable monitoring is done on daily basis.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			AHU is not working properly.		Preventive maintenance of AHU's is done at defined frequency. For checking performance of AHU viable monitoring is done on weekly basis .Performance of dispensing area AHU is also checked on annual basis by performing air velocity, ,filter integrity, flow pattern, Recovery ,leakage test. Temperature, RH & pressure differential is monitored twice in a day.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Person performing dispensing is not properly trained.		Before dedicating any person for any activity training related to the activity is given & after evaluating training authorization is given by QA Head to start working related to the activity on regular basis.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Use of un-cleaned gowns.		Cleaning of gowns is done on daily basis. At exit change room bin for used garments (washable+ Disposal) is kept to put used garments. Washable garments from used bin are transferred to washing area whereas disposable gowns are disposed by housekeeping professionals.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Pass box used for material transfer from storage area to dispensing area is not working	Material & product contaminated.	Preventive maintenance of pass box is done on quarterly basis.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA

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			properly.												
			Person is not performing sanitization of hands properly.	Material & product contaminated.	Training for entry & exit procedure is given to each individual intended for the area. Training evaluation is also done. Hand sanitization procedure with pictorial is also available in identified change rooms.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Cleaning of area is not done properly.	Material & product contaminated.	Cleaning procedure is available Disinfectant used for cleaning of area are also validated. Persons dedicated for cleaning are also trained.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Improper cleaning of RLAF.	Material & product contaminated.	Cleaning procedure of dispensing booth is available & cleaning of booth is done on daily basis or after every dispensing by trained persons.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Improper cleaning of Pass Box.	Material & product contaminated.	Cleaning procedure of pass box is available & cleaning of pass box is done on daily basis by trained persons.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			RLAF is not working properly.	Material & product contaminated.	RLAF working is checked by viable monitoring on daily basis. After every 06 moth qualification of RLAF is also checked. Preventive maintenance schedule of RLAF is also available. Mehnehalic gauge pressure reading monitoring performs on daily basis.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Use of torned or unclean dispensing containers.	Material & product contaminated.	Before dispensing cleaning & integrity of containers is checked by the store person & QA person also. In case of dispensing in polybags double poly bag is used to dispense material.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Untrained staff.	Wrong quantity dispensing.	Before authorize to any person to carry out dispensing activity training is carried out related to the all activities at	**SOP**	1	4	4	16	NA	NA	NA	NA	NA

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				Dispensing procedure not followed.	the time of dispensing. After training person is evaluated by QA head & after satisfactory observation he/she is authorized to carry out dispensing activity.		1	4	4	16	NA	NA	NA	NA	NA
			Washing area for utensils is not separate.	Chances of material & area contamination will be more.	In the designed facility washing area is kept separately from the processed area.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
		Risk of Mix ups	Wrong material may get dispensed.	Risk to patient & product safety & efficacy.	Only trained person are authorized to carry out dispensing.Men& material movement is kept different. Proper labeling system is followed. At one time only one product dispensing is allowed to avoid mix ups	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Wrong labeling	Risk to product & patient safety.	Proper labeling system is available & followed by trained persons.QA also checks labeling of the material.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Wrong material dispensing	Risk to product & patient safety.	Proper labeling system is available & followed by trained persons.QA also checks labeling of the material.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Quantity of material wrongly taken.	Risk to product & patient safety.	Proper labeling system is available & followed by trained persons.QA also checks labeling of the material.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
		Risk to person Safety.	Due to spillage of material	Loss of material & exposure of material directly with person.	Spill kit, safety devices are available & persons are properly trained for its use.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Due to unavailability of safety devices.	Person Health & life.			1	4	4	16	NA	NA	NA	NA	NA
		Mixing of dispensed material.	Due to presence of various material & product in the same area.	Chances of mixing, contamination & cross contamination.	After dispensing dispensed material for single product is packed in a large polybag & after that polybag is tied up with a cable tie .Proper labeling system is followed & in staging area single batch material is stored on a single	**SOP**	1	4	4	16	NA	NA	NA	NA	NA

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					pellet with proper labeling. At the time of material receiving production person in presence of QA verify the qty. of material against master formula & label pasted on the material. Verification of material qty. is done with the help of calibrated balance & balance calibration is done by production person familiar with the procedure. QA verify the calibration status of balance with the help of label pasted on it										
3.	**Manufacturing of bulk Solution.**	Risk of Product Failure.	Material not added properly.	Chances of contamination cross contamination & product failure will be more.	All activity is performed by trained & educated persons. Process validation procedure is available. Complete manufacturing activity is carried out under the supervision of trained production supervisor. Complete manufacturing activity is verified & monitored by QA. Before starting activity line clearance procedure is followed.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Mixing after addition not done as per validated procedure.				1	4	4	16	NA	NA	NA	NA	NA
			Volume make up is not done correctly.				1	4	4	16	NA	NA	NA	NA	NA
			Cleaning of equipments& utensils not done as per validated cleaning procedure.				1	4	4	16	NA	NA	NA	NA	NA
			SIP of the tank is not done as per validated procedure.				1	4	4	16	NA	NA	NA	NA	NA

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4.	**Batch Manufacturing**	Risk of contamination, cross contamination, improper filtration & sterility failure after filtration	Filter size & material is not as per requirement.	Sterility not gets achieved.	Filtration of bulk solution is performed under Grade A environment surrounded by Grade B in aseptic area. At the time of filter receiving filter is checked against COA to verify the pore size & also to check the bubble point pressure. As per procedure all persons undergo training procedure before authorize to perform activity. Only trained persons are authorized to perform critical operations. To perform sterile activity each person should also undergo personnel qualification procedure so that he must be trained & evaluated against aseptic procedures & behavior in sterile area. Before filtration &equipments is sterilized as per validated procedures & verification of sterilization is done by QA. Before bulk solution filtration filter integrity is checked by checking pre bubble point & after bulk solution filtration by post bubble point. Filter used for bulk solution filtration are single use sterilized membrane filter Filter integrity testing performs before and after filtration. Personnel working in manufacturing area are trained.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Filter integrity not checked.	Filtration not done properly.			1	4	4	16	NA	NA	NA	NA	NA
			Filter get chock up during filtration.				1	4	4	16	NA	NA	NA	NA	NA
			Filtration	Chances of product			1	4	4	16	NA	NA	NA	NA	NA

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			assembly is arranged by untrained person.	loss & contamination will be more.											
			Connections not tighten properly.	Product loss			1	4	4	16	NA	NA	NA	NA	NA
4.	**Washing & Sterilization of Containers.**	Risk of product contamination & patient safety.	Sterilizer is not working properly.	Product may get contaminated & contamination may harm to patient health. Due to product contamination death & adverse reactions may also happens.	Sterilizer working & performance is checked on six month frequency & also preventive maintenance have been performed on every 03 month basis.	**Respective Protocol**	1	4	4	16	NA	NA	NA	NA	NA
			Washing & sterilization is not done by trained operator.	Product may get contaminated & contamination may harm to patient health. Due to product contamination death & adverse reactions may also happens	Only trained & authorized persons are allowed to work in the designated area under the supervision of trained supervisor. QA also monitors that each activity should be performed by trained persons.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Equipment is not qualified.		Before starting activity qualification status of equipments also verified by QA.	**Respective Qualification Protocol**	1	4	4	16	NA	NA	NA	NA	NA
			Sterilization is not as per validated procedure.		Each & every activity shall be performed as per defined process in the batch records. Batch records are approved by QA considering all parameters & after that QA monitors that activity should be performed as per defined procedure.	**Respective BMR**	1	4	4	16	NA	NA	NA	NA	NA

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6.	**Filling & Sealing**	Risk of Contamination, Cross Contamination & Sterility failure.	Operator not familiar with the aseptic area criticality.	Risk for patient & product safety.	After satisfactory evaluation of training related to aseptic area & personnel qualification observations person is permitted to wok in aseptic area. Trained operators are recruited to handle the machine & they also trained for the company equipments. Trained IPQA person remains in the aseptic area during entire process & monitors the operation along with production supervisor.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Filling is done by untrained or unauthorized operator.	Risk for patient & product safety.	After satisfactory evaluation of training related to aseptic area & personnel qualification observations person is permitted to work in aseptic area. Trained operators are recruited to handle the machine & they also trained for the company equipments. Trained IPQA person remains in the aseptic area during entire process & monitors the operation along with production supervisor.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Defect in sealing & bugging.	Risk for patient & product safety.		**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Volume Variation.	Risk for patient & product safety.			1	4	4	16	NA	NA	NA	NA	NA
			Risk for sterility maintenance.	Risk for patient & product safety.	Filling operation is carried out in aseptic area under Grade A environment. Machine parts &equipments are sterilized prior to operation. Hold time for sterilized equipments& accessories are validated. Transfer of sterilized articles & product is carried out under qualified mobile LAF. Sterility of the articles maintained properly. Operators are trained for handling of sterilized articles. All machine connections are done under grade A environment. Media fill also performed for checking sterility confidence in the process.	**Batch Manufacturing Record**	1	4	4	16	NA	NA	NA	NA	NA

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7.	**Visual Inspection**	Inspection not done accurately.	Inspectors are not qualified.	Risk to product safety/ Person Safety	Qualification procedure of visual inspector is available & followed properly.		1	4	4	16	NA	NA	NA	NA	NA
			Light intensity of booth is not proper for visual inspection.		Procedure, frequency for checking of light intensity is available. Light intensity of booth is checked at defined frequency & recorded. In case of deviation from the defined limit replacement also done.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Mixing of good & rejected containers.		Color coding of rejected & good ampoules container is kept different to avoid mix up of rejected & good containers.		1	4	4	16	NA	NA	NA	NA	NA
			Visual inspectors are not re-qualified at the defined frequency.		Medical checkup of visual inspectors are done on semiannual basis.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
			Inspection booth is not qualified		Before giving line clearance QA person checks the qualification of visual inspectors. This check is available in line clearance checks of the QA.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
8.	**Secondary & Tertiary packing of Injectables**	Risk of Mixing Misbranding &mis- labeling.	Wrong labeling	Risk to patient safety product safety & efficacy.	At the time of dispensing of packing material stores labels the material properly this is verified by QA. At the time of material receiving production person also verifies the material. Before starting packing activity QA verifies the absence of any other product material in the packing area & also cleaning of the area. In the beginning of the coding of the packing material production person checks the coding detail which is verified by the QA. During packing activity in process checks is carried out by production & QA persons at the defined frequency.Sample after packing is also send to QC for identification test t avoid any misbranding or mismatching..On the other hand, semi	**BPR**	1	4	4	16	NA	NA	NA	NA	NA

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					finished product in the quarantine is stored with proper labels. At the time of activity start production & QA also verify the details mentioned on labels										
9.	**Transfer & storage of finished goods to finished product store.**	Breakage of glass containers.	Commercial loss & loss of product.	Product safety will be on risk.	Although transfer of finished good from the injection facility to finished product storage area is done manually but this activity is performed by trained persons & under the supervision of trained supervisor.	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
		Degradation of product due to unfavorable environment conditions.	Effect on efficacy & safety of product.	Patient safety will be on risk,	Dedicated storage area for finished product is available in which optimum environment conditions are monitored. Environment conditions of the area are monitored twice in a 8 hrs. shift. Also temp. mapping of the area is preformed on annual basis for 3 days.	**SOP**	4	4	4	64	NA	NA	NA	NA	NA
10.	**Dispatch of finished goods.**	Breakage of glass containers.	Commercial loss & loss of product.	Product safety will be on risk.	Transportation conditions are maintained during transportation. For glass containers 7 ply shippers is used to pack the product. Warning is pasted on shippers" Glass inside Handle with care".	**SOP**	1	4	4	16	NA	NA	NA	NA	NA
		Degradation of product during transportation due to unfavorable environment conditions.	Effect on efficacy & safety of product.	Patient safety will be on risk,			1	4	4	16	NA	NA	NA	NA	NA
11.	**Batch release**	In-complete analytical records and QA release documentation	➢ No SOP for review of analytical records ➢ No SOP for batch release	System failure/ Market Complaint	➢ SOP for review of analytical records ➢ SOP for review batch release	**SOP**	1	4	4	16	NA	NA	NA	NA	NA

FAILURE MODE EFFECT ANALYSIS FOR DRY POWDER INJECTION

Potential Failure Mode: What could go wrong?
Failure Causes: Why would the failure happen?
Failure Effects: What would be the consequences of failure?
Likelihood of Occurrence: 1–10, 10 = Very likely to occur
Likelihood of Detection: 1–10, 10 = Very unlikely to detect
Severity: 1–10, 10 = Most Severe Effect
Rating Scales:

- **Occurrence:**
  1 = Not Likely, 10 = Very Likely
- **Detection:**
  1 = Easy to Detect, 10 = Not easy to Detect
- **Severity**
  1 = Not Severe, 10 = Very Severe

Risk Priority Number (RPN): Likelihood of Occurrence × Likelihood of Detection × Severity

Quality Risk Management Team			Reviewed By Plant Head (Sign & Date)	Approved By Head QA (Sign & Date)
Name	**Department**	**Sign & Date**		

Quality Risk assessment and mitigation summary report

S. No.	Proposed Control measures	Responsible Person	Target Date of Completion

Verification of Action Plan:
All the above agreed actions completed, Not Completed.
(*incase any recommendations not completed, to be tracked through CAPA System)

Remarks (if any)_____

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date