PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR OF DPI

Reference Document No.:	**Risk Assessment No.:**

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Production (DPI)	**Date of Quality Risk Assessment:**

S. No.	**Item / Function**	**Potential Failure Mode**	**Potential Effect of Failure (Effect)**	**Potential Cause/ Mechanism of Failure**	**Current Control**	**Reference**	**Risk with Current control Measure**				**Recommended Actions (if any)**	**Risk after control measure**			**RPN (S*O*D)**
							S	**O**	**D**	**Risk Priority Number (S*O*D)**		**S**	**O**	**D**	
1.	**Sampling**	Probability of use of Un-cleaned garments	Product Failure & mix-up chances	Procedure is not available for Garments cleaning Garments cleaning are performed by untrained personnel. ➢ In-adequate cleaning ➢ Garments Storage Cabinets are not provided for Storage of Garments ➢ Garments cabinet is not Qualified	➢ Cleaning is performed by trained personnel. ➢ Cleaning Procedure is available. ➢ Storage Cabinets are provided for storage of garments. ➢ HEPA filter is provided in garments storage cabinets. ➢ Garments cabinet is previously qualified	SOP Qualification protocol	4	1	4	16	NA	NA	NA	NA	NA
		Probability of mix up of material after Sampling	Contamination and Product failure	➢ Proper Status of Labeling is not done in each container of material. ➢ Material transfer procedure is not available. ➢ Container of Raw material are not segregated ➢ Proper storage condition not followed. ➢ Unskilled/Untrained person performing Sampling. ➢ Material transfer in unsafe manner. ➢ Unclean Tools used for Sampling. ➢ RLAF not clean properly and Pressure Differential not in Limit. ➢ Weighing Balances are not clean.	➢ All containers of materials properly identified by status label. ➢ Staging room is provided for storage of sampled material and kept in Container with proper status label. ➢ SOP is available for Raw material sampling. ➢ Demarcation already done for placing more than one batch in staging area for segregation of batches. ➢ Provision for controlled storage condition is available. ➢ Line clearance procedure followed before start the Sampling	SOP	1	4	4	16	NA	NA	NA	NA	NA
		Personnel Safety during Sampling	Contamination of raw material and Effect on Human Health	➢ Proper gowning procedure is not followed. ➢ Safety devices are not available. ➢ Unskilled/untrained person performing Sampling. ➢ Activity is performed by without supervision of senior person.	➢ Provision of Secondary Change Room before entry in dispensing Area. Gowning procedure are provided and followed. ➢ Safety devices are available i.e. PPE (personnel protective equipments), Gloves, mask, goggles, etc required safety devices are provided. First aid facility is provided in case of any miss happening. ➢ Untrained person is not allowed to work in sampling area. ➢ List of Authorized personnel is displayed in all area. ➢ All activity is performed in presence of senior/experienced chemist.	SOP Safety manual	1	1	4	4	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Sampling	Contamination & Cross Contamination	Product Failure	➢ In adequate cleaning ➢ Area not qualified. ➢ HVAC is not qualified. ➢ Procedure for area cleaning is not available & followed. ➢ Procedure is not available for cleaning schedule of area. ➢ Validated Cleaning Procedure is not available. ➢ Pressure differential of area is not maintained & monitored in regular intervals. ➢ Untrained / Unqualified personnel are allowed in the area. ➢ Cleaning is performed by untrained personnel. ➢ Dedicated area is not provided for Storage of Cleaned sampling tools. ➢ Separate Washing Area is not provided. ➢ Dedicated AHUs is not provided for all the area. ➢ Procedure is not available for AHU cleaning & filter cleaning ➢ Gowning procedure is not available & not followed. ➢ Unidirectional men material movement / Flow are not provided. ➢ Pictorial for gowning procedure are not displayed in respective area. ➢ Procedure is not available for Line clearance of sampling area. ➢ Procedure is not available for cleaning of AHU & equipment filter ➢ Two different products sampled at a time.	➢ Proper cleaning & sanitization procedure are followed. ➢ HVAC & area are previously qualified. ➢ Validation cleaning procedure is available, followed & documented. ➢ Procedure is available & followed for cleaning schedule of area ➢ Pressure differential of the area is maintained, monitored at defined frequency. ➢ Untrained/Unqualified personnel is not allowed in the area. ➢ All activity is performed by trained personnel. ➢ Dedicated area is provided for Storage of Cleaned dispensing tools. ➢ Separate Washing Area is provided. ➢ Dedicated AHUs is provided for all the store area. ➢ Procedure is available for AHU cleaning & filter cleaning ➢ Gowning procedure is available & followed. ➢ Unidirectional Men Material Movement / Flow are provided. ➢ Pictorial for gowning procedure are displayed in respective area. ➢ Procedure is available for Line clearance of sampling area. ➢ Procedure is available for cleaning of AHU & equipment filter ➢ Only single product sampled at a time.	SOP SOP	4	1	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
2.	**Dispensing**	Risk of Cross Contamination	Material & product contaminated.	➢ Due to dis-balancing of pressure differential.	➢ 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**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Person carrying out the dispensing activity is not following proper gowning procedure.	➢ 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**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Person carrying out dispensing activity is suffering from infectious disease.	➢ 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**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Due to damaged material container.	➢ 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**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Due to improper cleaning of scoops & utensils used for dispensing.	➢ Cleaning of all equipments& utensils is done by trained professionals by using validated cleaning procedures.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Due to improper cleaning of area.	➢ 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**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Cleaning of the area is running simultaneously with dispensing.	➢ As per procedure & GMP practices cleaning is done before the critical activity.	**SOP**	4	1	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**	4	1	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**	4	1	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**	4	1	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	**SOP**	4	1	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
					differential is monitored twice in a day.										
	Dispensing	Risk of Cross Contamination	Material & product contaminated.	➢ 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**	4	1	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**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Pass box used for material transfer from storage area to dispensing area is not working properly.	➢ Preventive maintenance of pass box is done on quarterly basis.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Person is not performing sanitization of hands properly.	➢ 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**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Cleaning of area is not done properly.	➢ Cleaning procedure is available Disinfectant used for cleaning of area are also validated. Persons dedicated for cleaning are also trained.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Improper cleaning of RLAF.	➢ Cleaning procedure of dispensing booth is available & cleaning of booth is done on daily basis or after every dispensing by trained persons.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Improper cleaning of Pass Box.	➢ Cleaning procedure of pass box is available & cleaning of pass box is done on daily basis by trained persons.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
				➢ RLAF is not working properly.	➢ 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.	**Qualification Protocol**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Use of torned or unclean dispensing containers.	➢ 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**	4	1	4	16	NA	NA	NA	NA	NA
				➢ Untrained staff. Dispensing procedure not followed.	➢ Before authorize to any person to carry out dispensing activity training is carried out related to the all activities at the time of dispensing. After training person is evaluated by	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
							4	1	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
					QA head & after satisfactory observation he/she is authorized to carry out dispensing activity.										
				➢ Washing area for utensils is not separate.	➢ In the designed facility washing area is kept separately from the processed area.	**Facility Layout**	4	1	4	16	NA	NA	NA	NA	NA
		Risk of Mix ups	Risk to patient & product safety & efficacy.	➢ Wrong material may get dispensed.	➢ 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**	4	1	4	16	NA	NA	NA	NA	NA
			Risk to product & patient safety.	➢ Wrong labeling	➢ Proper labeling system is available & followed by trained persons.QA also checks labeling of the material.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
			Risk to product & patient safety.	➢ Wrong material dispensing	➢ Proper labeling system is available & followed by trained persons.QA also checks labeling of the material.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
			Risk to product & patient safety.	Quantity of material wrongly taken.	➢ Proper labeling system is available & followed by trained persons.QA also checks labeling of the material.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
		Risk to person Safety.	Loss of material & exposure of material directly with person.	➢ Due to spillage of material	➢ Spill kit, safety devices are available & persons are properly trained for its use.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
			Person Health & life.	➢ Due to unavailability of safety devices.			4	1	4	16	NA	NA	NA	NA	NA
		Mixing of dispensed material.	Chances of mixing, contamination & cross contamination.	➢ Due to presence of various material & product in the same area.	➢ 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 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	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
3.	**Washing & Sterilization of Containers.**	Risk of product contamination & patient safety.	Product may get contaminated & contamination may harm to patient health. Due to product contamination	➢ Sterilizer is not working properly.	➢ Sterilizer working & performance is checked on six month frequency & also preventive maintenance has been performed on every 03 month basis.	**Respective Protocol**	4	1	4	16	NA	NA	NA	NA	NA

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			death & adverse reactions may also happens.												
			Product may get contaminated & contamination may harm to patient health. Due to product contamination death & adverse reactions may also happens	➢ Washing & sterilization is not done by trained operator.	➢ 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**	4	1	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**	4	1	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**	4	1	4	16	NA	NA	NA	NA	NA
4.	**Filling & Sealing**	Risk of Contamination, Cross Contamination & Sterility failure.	Risk for patient & product safety.	➢ Operator not familiar with the aseptic area criticality.	➢ 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**	4	1	4	16	NA	NA	NA	NA	NA
	Filling & Sealing	Risk of Contamination, Cross Contamination & Sterility failure.	Risk for patient & product safety.	➢ Filling is done by untrained or unauthorized operator.	➢ 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**	4	1	4	16	NA	NA	NA	NA	NA
			Risk for patient & product safety.	➢ Defect in sealing & bugging.		**SOP**	4	1	4	16	NA	NA	NA	NA	NA
			Risk for patient & product safety.	➢ Weight Variation.			4	1	4	16	NA	NA	NA	NA	NA

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			Risk for patient & product safety.	➢ Risk for sterility maintenance.	➢ 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**	4	1	4	16	NA	NA	NA	NA	NA
5.	**Visual Inspection**	Inspection not done accurately.	Risk to product safety/ Person Safety	➢ Inspectors are not qualified.	➢ Qualification procedure of visual inspector is available & followed properly.	**Qualification Protocol**	4	1	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**	4	1	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.		4	1	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 Medical Report**	4	1	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.	**Line Clearance SOP**	4	1	4	16	NA	NA	NA	NA	NA
6.	**Secondary & Tertiary packing of Injectables**	Risk of Mixing Misbranding &mis- labeling.	Risk to patient safety product safety & efficacy.	➢ Wrong labeling	➢ 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 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	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
7.	**Transfer & storage of**	Breakage of glass	Product safety will be on risk.	➢ Commercial loss & loss of product.	➢ Although transfer of finished goods from the injection facility to finished product storage area is done manually but	**SOP**	4	1	4	16	NA	NA	NA	NA	NA

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	finished goods to finished product store.	containers.			this activity is performed by trained persons & under the supervision of trained supervisor.										
		Degradation of product due to unfavorable environment conditions.	Patient safety will be on risk,	➢ Effect on efficacy & safety of product.	➢ 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
8.	**Dispatch of finished goods.**	Breakage of glass containers.	Product safety will be on risk.	➢ Commercial loss & loss of product.	➢ 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**	4	1	4	16	NA	NA	NA	NA	NA
		Degradation of product during transportation due to unfavorable environment conditions.	Patient safety will be on risk,	➢ Effect on efficacy & safety of product.			4	1	4	16	NA	NA	NA	NA	NA
9.	**Batch release**	In-complete analytical records and QA release documentation	System failure/ Market Complaint	➢No SOP for review of analytical records ➢No SOP for batch release	➢SOP for review of analytical records ➢SOP for review batch release	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
10.	**Quality Control**	Sampling of Raw material not in proper manner	Sample cannot represent the results/quality of Complete Batch.	➢ No SOP for Sampling procedure of Raw Material ➢Unskilled/Untrained person perform the sampling of Raw material ➢Not maintain environmental condition ➢Pressure differential not maintain ➢In addicted procedure of cleaning of sampling tools.	➢Sampling procedure follow at the time of Raw material sampling, ➢Procedure for sampling of Raw material is available. ➢Only Trained person perform the sampling of raw material. ➢Before the start of raw material sampling line clearance procedure follow and all checks points verify at the time of line clearance. ➢Before the environmental condition maintain QA person cannot give the permit to start the sampling.	**SOP**									
		Analysis Results not in Specification Limit	Product safety will be on risk. Patient safety will be on risk,	➢Analyst not qualified ➢Instrument not calibrated ➢Analytical standards not qualified ➢Sampling not in proper	➢Analyst qualification of all analyst are done ➢Calibration of instrument completed as per the scheduled calibration planer. ➢Analytical standards are qualified with respect to Reference standard.	**SOP**									

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							S	**O**	**D**	**Risk Priority Number (S*O*D)**		**S**	**O**	**D**	
				manner ➢Manufacturing procedure not follow as per the pre determine manufacturing procedure/Process	➢Skilled and trained person perform the sampling of material as per the standard sampling procedure ➢Appropriate manufacturing procedure followed, which are specified in the Batch Manufacturing Record.										
		Raw material not testing as per standard test procedure		➢Standard test procedure not followed. ➢Un approved test procedure followed. ➢Standard test procedure of different Raw material can be followed at the time of testing	➢STP of all Raw materials is available. ➢Standard test procedure develops before the indenting of the new upcoming raw material. ➢After the preparation of Standard Test Procedure and Standard Test Specification QC Head Checked this STP & STS and after that QA Head approved for follow the Standard Test Specification and Standard test Procedure. ➢Trained and Skilled Person performs the testing as per Standard Test Specification and Standard Test Procedure.	**SOP**								
		Finished product not testing as per standard test procedure		➢Standard test procedure not followed. ➢Un approved test procedure followed. ➢Standard test procedure of different Product can be followed at the time of testing	➢STP of all Finished Good Product is available. ➢Standard test procedure develops before the indenting of the new upcoming Product. ➢After the preparation of Standard Test Procedure and Standard Test Specification QC Head Checked this STP & STS and after that QA Head approved for follow the Standard Test Specification and Standard test Procedure. ➢Trained and Skilled Person performs the testing as per Standard Test Specification and Standard Test Procedure.	**SOP**								

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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**	**Approved By**
Name	**Department**	**Sign & Date**	**Plant Head (Sign & Date)**	**Head QA (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.

Remarks (if any)_____

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date