RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

Risk Analysis Study Protocol For Warehouse Facility

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

CONTENTS

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

1.0 OBJECTIVE:

To provide the documented evidence that there are sufficient controls to avoid any risk in case of raw materials transferred to warehouse facility.

2.0 SCOPE:

This risk analysis study Protocol is applicable for performing risk analysis study for warehouse facility.

3.0 RESPONSIBILITY:

Department	Responsibility
Quality Assurance	• Shall prepare & review the Risk analysis Protocol. • Execution of the Risk analysis Protocol with Warehouse and Engineering. • Shall prepare summary report. • Risk analysis Protocol shall be approved by the QA prior the execution. • Shall review the executed Protocol to check the compliance and corrective action for any discrepancies found. • Also shall prepare the summary and conclusion of the Risk analysis Study.
Warehouse	• Reviewing of Risk analysis Protocol for correctness, completeness and technical excellence. • To provide support for execution of Risk analysis Study as per Protocol. • Approval of Risk analysis Protocol after execution.
Engineering	• Reviewing of Risk analysis Protocol for correctness, completeness and technical excellence. • To provide support for execution of Risk analysis Study as per Protocol. • Approval of Risk analysis Protocol after execution.

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

4.0 REASON FOR RISK ANALYSIS:

Due to storage constraints of Raw Materials at ……., site management had decided to keep the Raw materials specifically of Oral solids and external preparations in a new. This new storage location need to be evaluated for the risk associated with it & further these risks shall be mitigated accordingly.

5.0 SITE OF STUDY:

New Warehouse facility.

6.0 RISK COMMUNICATION & TRAINING:

- The Risk analysis team shall be authorized by Head-QA or his/her designee.
- Quality Risk Management Team shall be cross functional team comprised of experts from different areas such as QA and Production.
- Training shall be imparted to the team members before execution of Protocol for proper understanding of the procedure.

Quality Risk Management Team:

S.No.	Name	Department
1.		Warehouse
2.		QA
3.		QA

7.0 REFERENCE DOCUMENTS/DRAWINGS:

S.No.	Document Title	Document Number
1.	**Quality Risk Management**	
2.	**Monitoring of Temperature, RH & DP**	
3.	**Layout of Warehouse**	
4.	**Training of Employees**	
5.	**https://gmpsop.com/role-of-the-warehouse-in-pharmaceuticals-manufacturing/#**	
6.	**Warehouse SOP's**	

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

8.0 SYSTEM DESCRIPTION:

The warehouse plays an important role in manufacturing quality products, it is responsible for all incoming goods (including labelling and packaging) and for releasing finished products, there are GMP rules in place to ensure that materials are handled and stored properly, while appropriate documentation is maintained.

There are many materials which are temperature-sensitive, that break down or degrade if exposed to heat or light, thus becoming ineffective. A pharmaceutical warehouse must be expertly managed and run in compliance in order for the company to protect and distribute a quality product.

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

8.3 PROCESS FLOW:

POTENTIAL FAILURE		CONTROLS
• Ruptured Bags & Containers • Unavailability of shed for material receiving	Receiving of Material	• Verified during receiving • Barrier from outside environment
• Improper Verification	Material Verification	• Invoice • Individual material code
• Random arrangement of material	Rack Distribution	• Rack distribution done alphabetically • Off the floor & away from wall
• Temperature not maintained	Material Storage	• Air Conditioning System installed & Temperature Mapping done. • Cold Storage available
• Temperature not maintained during transfer of Temperature sensitive material	Material Distribution	• Transport Validation

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

9.0 RISK IDENTIFICATION, EVALUATION & MITIGATION: At the very basic stage of design, the Risk Assessment is carried out to verify that all features are taken into consideration to avoid the risk of failure of critical GMP and EHS parameter in the equipment. During study, all GMP, EHS and operational parameters will be identified and assessed for the risk, appropriate mitigation will be proposed and verification point will be identified and defined. The Risk Assessment report is produced to provide the documented evidence that design concepts or requirement are complete in considering all GMP, EHS and Operational risks.

S.No.	Risk Identification	Risk Evaluation	Risk Mitigation
1.	**Material Receiving**	In case of absence of shed at receiving bay, the material in rainy season may get exposed to rainy water & get wet. Dust over the surface of containers & bags may contaminate the material.	Risk started from material receiving, material shall be received under shed. During receiving material shall be passed through de-dusting tunnel. All incoming bags & containers shall be verified for their intactness.
2.	**Material Verification**	Lack of trained persons may not be able to verify the related documents.	Incoming materials shall be verified as per the received invoice. Results of the vendor COA shall be within the acceptance criteria.
3.	**Material Arrangement**	Improper material arrangement may create problems during tracing.	Material arrangement shall be traceable & upside. Materials shall be kept at reachable height.
4.	**Material Storage**	Improper material storage may lead to destruction of material bags & containers.	Material storage shall be as per their mentioned requirement. Light sensitive material shall be kept away from light. Moisture sensitive material shall be kept away from moisture. Refrigeration system required for materials which needs 2-8°C storage conditions.
5.	**Material Distribution**	Improper & open material transport system may contaminate or deteriorate the material when directly exposed to environment.	Plant to plant distribution shall be done in containers as per the storage requirement.
6.	**Safety**	Unavailability of Emergency exit may result into panic situation in case of any emergency.	Emergency exit shall be there in case of any emergency.
7.	**Manpower**	Untrained manpower may avoid the basic gmp rules which may result into product failures.	Trained manpower required.
8.	**Qualification**	Weighing, Sampling & Dispensing done with unqualified instruments & equipment. Improper weight. quantity may receive.	Qualification shall be completed prior use.

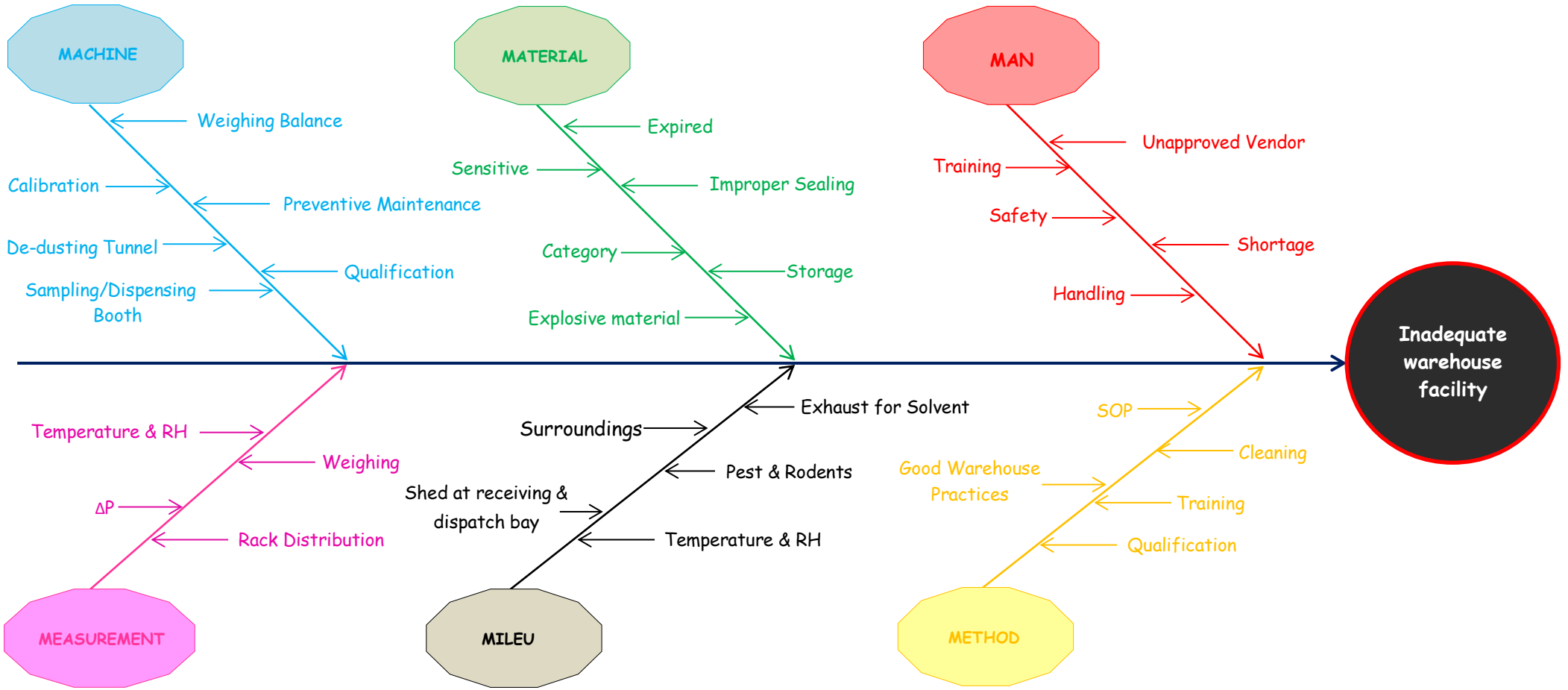
RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

S.No.	Risk Identification	Risk Evaluation	Risk Mitigation
9.	**Documentation**	For the starting of any new facility, Standard operating procedures shall be in place, without any written procedures there will be high risk at every stage.	Related SOP's shall be in place.
10.	**Data Integrity**	Lack of training may lead to data integrity.	Training on GMP, GDP, GWP (Good Warehouse Practices) & Data Integrity shall be given.

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

10.0 RISK ANALYSIS TOOLS, RE-RISK ANALYSIS CRITERIA:

10.1 Cause & Effect Analysis:



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

SUMMARY OF THE 6 M/FISH BONE DIAGRAM/ISHIKAWA DIAGRAM: It is used for the evaluation of inadequate warehouse facility on finished products; following are the areas of concern considered for investigation. Man, Material, Measurement, Method, Milieu & Machine. It has been evaluated that all of the 6 M may contribute in failure of new warehouse facility resulting in failure of product.

MAN: Personnel supervising or performing warehouse activities are not aware of GMP & are untrained which may result into:

- Intermixing of materials.
- Cross contamination.
- Safety related issues.

MATERIAL: Handling & Storage of raw materials plays an important role in Warehouse management. Miss Management may lead to:

- Contaminated material.
- Contamination with microorganisms or other chemicals.
- Degradation from exposure to excessive environmental conditions such as heat, cold, sunlight, moisture, etc.
- Improper labelling.
- Improper sampling and testing, and Use of materials that fails to meet acceptance specifications.
- Material from unapproved vendor.
- Safety related issue may take place during improper handling of explosive material or solvent.
- Improper handling due to unavailability of MSDS.

MILIEU: The facility of the warehouse plays major role in maintaining proper storage conditions, Inadequate surrounding environment may lead to:

- Inadequate filth and pest controls.
- Rough floors, walls, and ceilings.
- Lack of air filtration systems.
- Unavailability of proper shedding at receiving & dispatch bay.
- Improper lighting and ventilation.
- Poorly located vents, ledges, and drains, and inadequate washing, cleaning, toilet, and locker facilities to allow for sanitary operation, cleaning of facilities, equipment, and utensils; and personal cleanliness.
- Exhaust not available for Solvent dispensing area and air is re-circulated.

MACHINE: The equipment & instruments used in warehouse plays important role in day to day activities:

- Inappropriate design, size, material leading to corrosion and accumulation of static material and/or adulteration with lubricants, coolants, dirt, and sanitizing agents.
- Improper cleaning and sanitization.
- Design preventing proper cleaning and maintenance.
- Improper calibration and irregular service, and deliberate use of defective equipment.
- Machine not qualified.
- Inappropriate preventive maintenance.
- Unavailability of De-dusting tunnel.
- Qualification of area & equipment not performed.

METHOD: There are various reasons during warehouse practices which may lead to different failures:

- Inappropriate cleaning in-between batches to minimize the amount of product changeovers.
- Use of an open manufacturing system exposing the product to the immediate room environment.
- Absence of an area line clearance according to approved procedures following each cleaning process and between each batch.

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

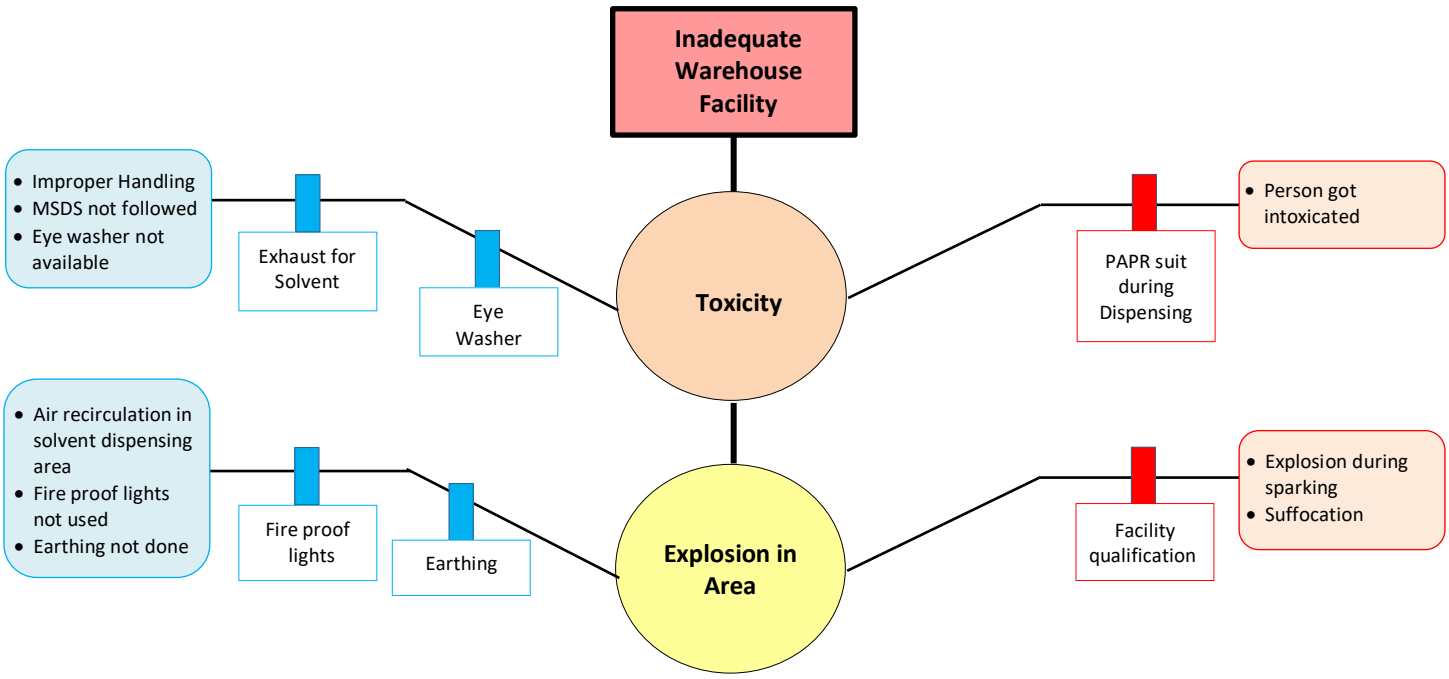
- Lack of cleaning status labelling on all equipment and materials used within the manufacturing facility.
- Improper training and unaware about the Good Warehouse Practices.

MEASUREMENT: There are many factors which shall be regularly monitored & recorded such as:

- Temperature& RH of the area not under control & recording time too exhaustive.
- Rack distribution shall be appropriate & traceable.
- Pressure Differential of RLAF & Area shall be monitored on regular basis to avoid any cross contamination.
- Weighing Balances shall be Calibrated & Verified on daily basis.

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

10.2 Bow Tie analysis:



SUMMARY OF THE BOW TIE ANALYSIS: Bow Tie analysis for inadequate warehouse facility gives an overview of multiple plausible scenarios in a single picture. It provides a simple, visual explanation of a risk that would be much more difficult to explain.

A hazard is being identified as "Inadequate Warehouse Facility", which may results into moment when control is lost over the hazard. There is no damage or negative impact yet, but it is imminent. Threats are considered on the left side and consequences are on the right side. Barriers on the left side interrupt the scenario so that the threats do not occurs while barriers on the right side mitigate the impact.

Following are the barriers need to be focused to control the threats and consequences:

- ✓ Exhaust for Solvent Dispensing.
- ✓ Material shall be handled as per MSDS.
- ✓ PAPR suit for toxic material handling.
- ✓ Fire proof lights shall be used.
- ✓ Earthing for the electrical circuits.

10.3 Failure Mode Effect Analysis:

In the following section a table is produced for the risk analysis using FMEA tool. The significance or instruction for each column is described in the following paragraph.

Column 1:	**Serial number** of Risk Analysis item
Column 2:	**Item/Function:** Identify the process step or component associated with the risk.
Column 3:	**Potential Failure Mode:** Identify the type of risk associated with the process or component.
Column 4:	**Effect of Potential Failure/Cause:** Verify that whether risk have **GMP impact.**
Column 5/6/7/8/9:	**Severity/Occurrence/Detection/Risk level/Risk Acceptance:** Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.
Column 10:	**Risk Mitigation**: Write the risk mitigation strategy as considered in design.
Column 11/12/13/14/15:	**Severity/Occurrence/Detection/Risk level/Risk Acceptance:** Risk Priority Number to be calculated after mitigation by taking Severity, Occurrence & Detection of potential failure into consideration.
Column16:	**Recommended action:** Recommended actions should be given for controlling failure occurrence.

Table 1: Instruction for each column given above

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

Procedure: Material Storage at New Warehouse Facility											**Quality Risk Assessment No.: …….**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/ Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
MAN															
1.	**Logbook Implementation**	• Log books not implemented	• Daily temperature monitoring not done. • Daily Balance Verification not done.	• Excursions not included. • Improper weighing of material. • Critical data not recorded.	• SOP's in place.	• SOP No. "Operation Cleaning Verification Calibration of Electronic Weighing Balances" • SOP No. "Monitoring of Temperature RH & DP"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
2.	**Manpower arrangement**	• Manpower shortage	• Lack of monitoring in critical stages	• Improper line clearance. • Document pendency. • Too much workload.	• Sufficient staff available along with their JD.	• SOP No.: "Preparation of Organogram"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
3.	**Housekeeping arrangement**	• Manpower shortage	• Improper cleaning	• Contamination & Cross Contamination.	• Recruitment done as per requirement	• SOP No.: "Selection and Recruitment of Employee"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
4.	**Training**	• Untrained persons	• GDP, GMP & GWP not followed	• Poor documentation • Process related issues	• Training SOP's in place	• SOP No.: "Training of Employees" • SOP No.: "Good Documentation Practices" • SOP No.: "Daily Verification of Good Manufacturing and Good Documentation"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
5.	**Data Integrity**	• ALCOA not followed	• Back dated data generation • Wrong data generated	• Wrong interpretation	• Training given to every candidate during induction	• SOP No.: "Data Integrity"	**3**	**2**	**1**	**6**	NA	NA	NA	NA	NA
MATERIAL															
6.	**Light Sensitive products labeled with "Protect from Light"**	• Light sensitive material exposed under normal light	• Material degraded & deteriorated.	• Material fails in acceptance criteria	• Separate Sodium lamp available for Light Sensitive materials.	• SOP No.: "Handling and Cleaning of Sodium Vapour Light lamp (Movable)"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
7.	**Material Distribution**	• Storage conditions not maintained during transportation.	• Heat & moisture sensitive material got directly exposed to environmental &		• Containers are properly sealed during transportation.	• SOP No.: "Transfer of Raw Material and Packing Material from one location to another location"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

Procedure: Material Storage at New Warehouse Facility											**Quality Risk Assessment No.: …….**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/ Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
			degraded.												
8.	**Temperature Sensitive**	• Material got exposed to high temperature	• During material distribution to other plant. • Material stored near the side wall which is directly exposed to sun light. • Hot point not concluded during temperature mapping. • Material degraded & deteriorated.	• Material fails in acceptance criteria.	• Temperature Mapping done	• SOP No.: "Handling and Storage of Raw Materials for revision".	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
9.	**RH Sensitive**	• Material got exposed to high moisture	• Material kept touching the walls directly on the floor.	• Material got deteriorated.	• Material kept on pellets & away from walls.	• SOP No.: "Handling and Storage of Raw Materials for revision"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
10.	**Poisonous & Harmful materials**	• Improper Handling of harmful materials • Person got exposed to harmful material.	• MSDS not received. • MSDS not followed.	• Exposure may result into health issues.	• SOP in place for handling of raw material	• SOP No.: "Handling and Storage of Raw Materials for revision"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
11.	**Lock & Key**	• Lock & Key not available	• Psychotropic materials kept with general materials.	• Misuse of material.	• Lock & Key available	• SOP No.: "Handling of Narcotic and Psychotropic Drugs"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
12.	**Sealing**	• Improper Sealing of Containers & Polybags	• Material got exposed to environment.	• Cross Contamination	• Material packed in double polybags. • Sealing of containers properly verified.	• SOP No.: "Receipt of Raw Materials in Warehouse"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
13.	**Narcotic Drugs**	• Not kept in lock & key	• Psychotropic materials kept with general materials.	• Misuse of material.	• Lock & Key available	• SOP No.: "Handling of Narcotic and Psychotropic Drugs"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

Procedure: Material Storage at New Warehouse Facility											**Quality Risk Assessment No.: …….**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/ Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
14.	**Vendor**	• Vendor not qualified	• Material of low quality	• Acceptance criteria not met.	• Only approved vendor materials are used.	• SOP No.: "Creation, Approval & Control of Vendor Through SAP"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
15.	**Rejected & Recalled material**	• Separate area not available	• Material mix ups	• Fail material may be used.	• Separate area available for rejected & recalled materials	• SOP No.: "Handling of Rejected Raw Material Packing Material"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
16.	**Non-Moving material**	• Non usable material kept idle for long time	• Cover excess space.	• Space constraint for other required materials. • Non- moving material got expired and of no use.	• Controlling of non-moving material strategy in place.	• SOP No.: "Handling of Non Moving Raw Materials Packing Materials and Finished Products"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
METHOD															
17.	**SOP Implementation**	• Warehouse practices not followed	• Improper cleaning • Improper line clearance • Improper verification • Data integrity issues may take place. • Cross Contamination. • Environmental failures. • Improper storage of materials.	• Batch failures • Material deterioration • Safety related incidents may take place.	• Warehouse SOP's are in place.	• Warehouse SOP's	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
18.	**Facility Qualification**	• Area viable & non-viable count increases	• Pressure Differential not maintained	• Cross Contamination	• Qualification in place	• Qualification planner	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

Procedure: Material Storage at New Warehouse Facility												**Quality Risk Assessment No.: …….**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/ Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
19.	**Material receiving strategy**	• Material received directly without any MSDS. • Material containers received in damaged condition. • Material received directly in quarantine area without any de-dusting. • Material received without proper verification.	• Special handling not done. • Material Spillage takes place. • Dust accumulated over containers surface. • Expired material received. • Wrong material received.	• Any hazardous incident may take place. • Cross contamination in area. • Material not meets the acceptance criteria.	• Material receiving strategy available. • Handling of Spillage strategy in place.	• SOP No.: "Receipt of Raw Materials in Warehouse". • SOP No.: "Receipt Handling and Storage of Packing Materials" • SOP No.: "Spillage of Material"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
20.	**Rack arrangement**	• Racks touching the side wall • Racks with too much height • Racks not arranged alphabetically.	• Material may absorb moisture • Not reachable. • Difficult to search required material.	• Material deteriorates. • Person or material may fall down resulting into safety related issues. • Takes too much time for further activity.	• Racks are arranged systematically. • Materials are kept in alphabetical order. • Ladder available for materials kept at height.	• SOP No.: "Handling and Storage of Raw Materials"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
21.	**GMP**	• GMP not followed	• Improper cleaning • Improper documentation • Improper practices. • Improper verification • Improper monitoring	• Cross contamination • Data Integrity takes place. • Incidents take place.	• SOP in place. • Training given to all concerned persons.	• SOP No.: "Daily Verification of Good Manufacturing and Good Documentation"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
22.	**QC Approval**	• Sampling not done	• Material release without QC approval.	• Rejected material used for manufacturing.	• Sampling procedure in place.	• SOP No.: "Sampling of Non-Sterile Raw Materials" • SOP No.: "procedure for sampling and testing"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

Procedure: Material Storage at New Warehouse Facility												**Quality Risk Assessment No.: …….**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/ Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
23.	**Calibration & Qualification**	• Unqualified instrument & equipment used for process activities.	• Instrument & Equipment efficiency decreases.	• Wrong results & output results.	• Qualification Planner in place	• SOP No.: "Qualification Planner"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
24.	**FIFO (First In First Out)**	• Secondary & Tertiary packing material not used as per FIFO.	• Artwork may change. • Color may get faded.	• Material to be destroyed, if artwork changes.	• Non-moving materials are tracked routinely through SAP.	• SOP No.: "Dispensing of Raw Materials to Production final". • SOP No.: "Handling of Non Moving Raw Materials Packing Materials and Finished Products"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
25.	**FEFO (First Expired First Out)**	• Raw material & Primary packing material not used as per FEFO.	• Material got expired.	• Shelf life of finished product decreases. • Expired material to be destroyed.	• Non-moving materials are tracked routinely through SAP.	• SOP No.: "Dispensing of Raw Materials to Production final". • SOP No.: "Handling of Non Moving Raw Materials Packing Materials and Finished Products"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
26.	**MSDS**	• MSDS not received.	• Proper handling not done as per specified. • Safety precautions not followed.	• Hazardous impact may take place.	• Material receiving SOP in place • Hazardous materials are kept separately. • PAPR gowning available for handling of toxic drugs.	• SOP "Receipt of Raw Materials in Warehouse". • SOP "Control on Careful Handling, Usage and Spillage of Hazardous Chemicals". • SOP "PAPR Gowning Procedure"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
27.	**Inventory**	• Proper inventory not done.	• Tracking issues takes place.	• Late in further processing activities.	• Strategy in place.	• SOP "Receipt of Raw Materials in Warehouse"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
28.	**Physical Segregation**	• Incoming material not segregated as per their stages.	• Material got mix up.	• Wrong material usage.	• Procedure in place	• SOP "Handling and Storage of Raw Materials"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
29.	**Double Checks**	• Single person can miss the check	• Wrong entry in formats & log books	• Wrong calculations resulting into wrong quantity of material dispensed.	• SOP in place for Good Documentation Practices.	• SOP "Good Documentation Practices"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

Procedure: Material Storage at New Warehouse Facility											**Quality Risk Assessment No.: …….**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/ Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
				• Can lead to Data integrity.											
30.	**Cleaning Programs**	• Dry & Wet cleaning procedure not followed as per requirement.	• Contamination transfer to next material.	• Contamination & Cross Contamination	• Cleaning procedure in place. • Trained housekeeping team.	• SOP "Area room Cleaning in Warehouse"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
31.	**Gowning**	• Gowning procedure not followed.	• Improper gowning. • Secondary gowning not followed for core area.	• Contamination to product. • Area microbial count increases.	• Entry/Exit procedure in place.	• SOP "Entry and Exit Procedure for Workers"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
32.	**Nitrogen Purging**	• Nitrogen purging not done	• Contaminated air not replaced.	• Deterioration of drugs.	• Nitrogen purging procedure in place.	• SOP "Dispensing of Raw Materials to Production"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
33.	**Containers**	• Damaged containers. • Containers without label.	• Material Spillage takes place. • Intermixing of material takes place.	• Contamination & Cross contamination.	• Material verified after receiving. • Container labels verified by QA	• SOP "Receipt of Raw Materials in Warehouse"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
34.	**Sampling & Dispensing procedure**	• GMP not followed during Sampling & Dispensing.	• Improper Gowning. • RLAF not started • Material kept over floor. • Untrained person. • Dirty dispensing and sampling tools used. • Dedicated dispensing & sampling tools not available. • Area not qualified. • RLAF not qualified.	• Contamination takes place.	• Procedure in place.	• SOP No.: "Handling Cleaning of Sampling and Dispensing Tools". • SOP No. "Dispensing of Non-Sterile Raw Material"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

Procedure: Material Storage at New Warehouse Facility											**Quality Risk Assessment No.: …….**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/ Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
35.	**Dispensing & Sampling Tools**	• Improper Sampling & Dispensing	• Dirty Dispensing & Sampling tools • Sampling & Dispensing tools not dedicated	• Contamination & Cross Contamination takes place.	• Cleaning procedure in place • Dedicated ID given to sampling & dispensing tools.	• SOP No. "Handling and Cleaning of Dispensing Tools"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
36.	**Status Labeling**	• Improper Status labels • Status labels not available	• Label got faded. • Forget to put label.	• Difficult to identify material.	• SOP in place.	• SOP "Handling and Storage of Raw Materials"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
MILEU															
37.	**Facility Upgradation**	• Facility not upgraded as per GMP practices.	• Shredding of particles from wall. • Improper coving. • Temperature mapping not done	• Contamination & Cross Contamination. • Product deteriorates.	• Facility qualification done.	• SOP "Facility, Area, LAF, RLAF Qualification"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
38.	**Temperature Mapping (Hot & Cold point)**	• Temperature mapping not done	• Hot point & Cold point not identified	• Material deteriorates in case of EM failure	• Temperature mapping done	• Temperature mapping protocol	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
39.	**Pressure Differential**	• Pressure Differential not Maintained	• Area qualification not done. • Magnehelic Gauge not working.	• Cross Contamination	• Area Qualification done • Calibrated Magnehelic gauges	• Qualification planner. • Calibration Planner	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
40.	**Temperature**	• Temperature not maintained	• AHU not qualified. • Temperature mapping not done.	• Excursion in temperature may deteriorate the material.	• Temperature Mapping done	• Temperature mapping protocol.	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
41.	**Receiving Bay**	• Material not received through de-dusting tunnel.	• De-dusting tunnel not working.	• Dust particles over the container surface may contaminate the area.	• Procedure of material receiving in place. • De-dusting Tunnel qualified.	• SOP "Operation and Cleaning of De-Dusting Conveyor Tunnel".	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
42.	**Safety**	• Toxic material not handled as per instructions.	• Person may come in direct contact with toxic material.	• Acute or chronic health impact on person. • Re-circulated air	• Exhaust given for solvent dispensing. • Hazardous solvents kept	• Occupational Health & Safety Policy • "Safety System"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

Procedure: Material Storage at New Warehouse Facility												**Quality Risk Assessment No.: …….**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/ Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
		• PAPR gowning not done during potent material dispensing. • Exhaust in Solvent area. • Segregation for toxic material. • Lights used in solvent area are not fire proof. • Earthing not done • Eye washer for washing eyes.	• Unavailability of exhaust in solvent dispensing area. • Lock & Key not available. • Sparking in electrical connection. • Eye washer not working	containing solvent may impact the health of concerned person. • Explosion may take place. • Any incident may harm the eyes	in separate area. • Fire proof lights are used • Proper Earthing given. • Eye washer available.	• SOP “Handling of Eye Washer and Safety Shower”									
43.	**Air Distribution**	• Improper air distribution	• Exhaust not available, air is re-circulated.	• Suffocation may take place. • Fire explosion may take place in case of sparking.	• Exhaust system in place. • Earthing done to avoid any sparking.	• Occupational Health & Safety Policy • “Safety System” • SOP “Handling of Eye Washer and Safety Shower”	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
44.	**Pest & Rodent Control**	• Pest control strategy not in place. • Pest & Rodent control strategy not effective.	• Ingress of flies, lizards, birds, rodents inside the premises.	• Ingress of pest inside area may poison the manufactured material.	• Outside agency hired for pest control. • Spraying Insecticides /Pesticides. • Insectocutors used at the entry. • Rodent traps like glue pads available at entry.	• SOP “Pest and Rodents Control” • SOP “Operation and Cleaning of Fly-O-Cide”	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

Procedure: Material Storage at New Warehouse Facility												**Quality Risk Assessment No.: …….**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/ Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
45.	**Microbial Count**	• Microbial count increases	• Contaminated containers. • Dirty gowning. • Bad hygiene practices. • Area qualification not done. • Contaminated water used for manufacturing.	• Product deteriorates & failed in acceptance criteria.	• Containers are cleaned routinely. • Gowning are cleaned routinely. • Training on Good Hygiene Practices given. • Area qualification done. • Continuous monitoring of water done.	• SOP “Cleaning of HDPE Containers” • SOP “Cleaning of Garments” • SOP “Good Hygiene Practices in the Premises”	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
46.	**Off the floors & away from walls**	• Material kept directly on floor & touched with wall.	• Material may gain moisture	• Material deteriorate	• Racks & pallets are available	• SOP “Handling and Storage of Raw Materials”	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
47.	**Barrier from outside environment**	• Contamination through material receiving bay • Drain openings • Air curtains	• Dust may ingress in area in case of de-dusting tunnel failure. • Dirty water may back flush. • Air curtain not working.	• Dust contamination.	• Qualified De-dusting in place at every receiving bay. • Drains are cleaned & sanitize on daily basis. • Air curtain available at every entry.	• SOP “Operation and Cleaning of Air Curtain” • SOP “Cleaning and Sanitization of Drain Traps” • SOP “Operation and Cleaning of De-Dusting Conveyor Tunnel”	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
48.	**Entry/Exit**	• Same entry exit for Staff & workers	• Too much over crowded during entry & exit time.	• Microbial count increases	• Separate area for entry & exit of workers.	• SOP “Entry and Exit Procedure in Non -Sterile Sampling & Dispensing area”	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
49.	**Solvent Storage & Solvent Dispensing area**	• Not separate from general dispensing area • Air circulation in area • Fire proof lighting	• In absence of air exhaust, solvent fumes may create suffocation. • Sparking may take	• Explosion may takes place • Person may get injured.	• Exhaust system available • Fire proof lighting in place.	• Occupational Health & Safety Policy • “Safety System” • SOP “Handling of Eye	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

Procedure: Material Storage at New Warehouse Facility											**Quality Risk Assessment No.: …….**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/ Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
		• Earthing to electrical circuits	place		• Proper earthling in place. • Eye washer available	Washer and Safety Shower"									
MACHINE															
50.	**Data Loggers**	• Data logger not available.	• Quantity is not sufficient. • Data loggers not calibrated.	• Wrong data interpretation during temperature mapping.	• Calibration Planner in place.	• SOP "Calibration Policy"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
51.	**Weighing Balances**	• Weighing Balance not verified • Weighing Balance not Calibrated	• Malfunctioned.	• Wrong data interpretation. • Wrong material quantity weighed.	• Calibration Planner in place. • Preventive maintenance as per schedule.	• SOP "Calibration Policy"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
52.	**Qualification**	• Equipment efficiency decreases	• Preventive maintenance not done timely. • Re-qualification not done.	• Wrong results interpretation. • Cross contamination	• Qualification planner • Calibration planner	• SOP "Qualification Planner" • SOP "Calibration Policy"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
53.	**De-dusting Tunnel**	• Not working	• Dust Contamination	• Cross contamination	• Qualified Tunnel	• SOP "Qualification Planner"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
54.	**Cold Storage**	• Temperature fluctuation	• Required temperature (2-8°C) not achieved.	• Temperature sensitive product deteriorates	• Mapping available • Daily verification for temperature & alarms	• SOP "Operation Cleaning and Sanitization of Cold Chamber"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
55.	**Preventive Maintenance**	• Not Done timely	• Hectic schedule of preventive maintenance • Equipment unavailability.	• Equipment working efficiency decreases.	• Done as per schedule	• SOP "Plant Equipment Preventive Maintenance"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
56.	**SAP**	• Not available	• All inventories & activities done manually resulting into chance of error • Tracking improper	• Chance of error & hectic work.	• SAP system available	• SOP "Handling of SAP System"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

Procedure: Material Storage at New Warehouse Facility											**Quality Risk Assessment No.: …….**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/ Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
MEASUREMENT															
57.	**Temperature**	• Temperature fluctuation	• Data loggers not calibrated	• Wrong data interpretation	• Calibration planner in place.	• SOP "Monitoring of Temperature RH & DP"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
58.	**Rack Distribution**	• Numbering not done	• Material kept randomly • All categories of materials kept together.	• Tracking improper • Intermixing	• Racks arranged in sequence alphabetically.	• SOP "Handling and Storage of Raw Materials"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
59.	**Balance Verification**	• Daily verification not done	• Miss to do so.	• Wrong results interpretation	• Planner available	• SOP "Operation Cleaning Verification Calibration of Electronic Weighing Balances"	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA
60.	**Periodic Inspection**	• Not done periodically	• Daily verification activities to be done periodically (Balance, Temperature, Alarms, Cleaning, Weighment sheet etc.)	• Data integrity may take place.	• Training on data integrity.	• Related SOP's & Log books	**3**	**1**	**1**	**3**	NA	NA	NA	NA	NA

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

FMEA MATRIX

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

The Risk Priority Number (RPN/Overall Risk) changes based upon the risk. The Risk Assessment team shall decide the acceptance criteria. For example the risk priority number is categorized as below:

Severity Ranking:

Severity Effect	Rating
No Effect	1
Moderate Effect	2
Serious Effect	3

Likelihood Occurrence Ranking:

Likelihood Occurrence	Rating
Unlikely	1
Possible	2
Almost Certain (Every time)	3

Detection Ranking:

Severity Effect	Rating
Always Detected	1
Might Detect Failure	2
Lack of detection control	3

Risk Priority Number (RPN)	Risk levels
Up to 6	Low
7-11	Medium
12 to ≤ 27	High

RPN = Severity x Occurrence x Detection

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

11.0 VERIFICATION OF ACTION PLAN:

All the action points as per QRA shall be monitored through CAPA system.

12.0 CONCLUSION:

13.0 RECOMMENDATION:

14.0 DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

Deviations observed from the pre-defined procedures shall be addressed through SOP Titled **"Handling of Deviations".**

15.0 CHANGE CONTROL, IF ANY:

Any changes shall be done through SOP Titled, **"Change Management".**

16.0 ABBREVIATIONS:

FMEA : Failure Mode Effect Analysis

GMP : Good Manufacturing Practices

RPN : Risk Priority Number

RISK ANALYSIS STUDY PROTOCOL FOR WAREHOUSE FACILITY

17.0 PROTOCOL APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
OPERATING MANAGER (WAREHOUSE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			