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Review Article on Risk Assessment

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Abstract: Risk assessment is the combined effort of: Identifying and analyzing potential (future) events that may negatively impact individuals, assets and / or the environment (i.e. risk analysis); and Making judgments "on the tolerability of the risk on the basis of a risk analysis " while considering influencing factors (i.e. risk evaluation) Making it simpler, risk assessment determines the possible mishaps, their likelihood and consequences and the tolerances for such events.

Keyword: Risk, evaluation, identification, control.

Primary principles of quality risk management are:

The evaluation of the risk to quality shall be based on scientific knowledge and ultimately link to the protection of the Patient.

The level of effort, formality and documentation of the quality risk management process shall be commensurate with level of risk.

Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the drug product across the product lifecycle.

The emphasis on each component of the framework might differ from case to case but a robust process will incorporate consideration of all the elements at a level of details that is commensurate with the specific risk.

Following are some of the definitions of some words which are commonly used during performing any risk assessment:

Detectability: The ability to discover or determine the existence, presence or fact of a hazard.

Harm: Damage to health, including the damage that can occur from loss of product quality or availability.

Hazards: The potential source of harm.

Risk: The combination of the probability of occurrence of harm and the severity of that harm.

Risk assessment: A systematic process of organizing information to support a risk decision to make within a risk management process. It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.

Risk initiation: Identifying the risk using suitable technique such as brain storming process.

Risk management: The systematic application of quality management policies, procedure and practices to tasks of assessing, controlling, communicating and reviewing risks.

Risk Acceptance: The decision to accept risk.

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Quality: The degree to which a set of inherent properties of a product, system or process fulfils requirements.

Quality risk management: A systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product life style.

Quality System: The sum of all aspects of a system that implement quality policy and ensure that quality objectives are met.

Risk Analysis: The estimation of the risk associated with the identified hazards.

Risk Control: Actions implementing risk management decisions.

Risk Mitigation: Systematic reduction in the extent of exposure to a risk and /or the likelihood of its occurrence. Also termed as risk reduction.

Risk reduction: Actions taken to lessen the probability of occurrence of harm and severity of that harm.

Risk evaluation: The comparison of the estimated risk to given risk to given criteria using a quantitative or qualitative scale to determine the significance of the risk.

Risk identification: the systematic use of information to identify potential sources of harm (hazards) referring to the risk question or problem description.

Risk communication: The sharing of information about risk management between the decision maker and other applicable department.

Risk summary / conclusion: It is summary report of observations / mitigation which has high risk with appropriate actions proposed target date and responsible person to reduce the identified risk.

Risk review report: Review or monitoring of output/results of the risk management process considering (if appropriate) new knowledge and experience about the risk.

Severity: A measure of the possible consequences of a hazard.

High risk: The equipment or system or process that will have focused and immediate impact of product quality. (Some of examples: water system, non fill detector system on a packing line, air handling unit system for areas where product / materials are exposed during operation etc.).

Medium risk: The equipment or system or process expected to have incidental or secondary impact on product quality. (Some examples: boiler steam, raw water system, over coding machine.)

Low risk: The Non impact shall have no direct or indirect impact on product quality. (Some examples: effluent treatment plan incinerator & shrink wrapping machine etc.).

For clearly defining risk, Three Fundamental Questions are often helpful:

What might go wrong?

What is the likelihood (Probability) it will go wrong?

What are the Consequences (Severity)?

Risk assessment shall be carried out for:

Quality management system:

Facilities, equipment and utilities: New facility, equipment, instrument, utility or major modification in facility, equipment, instrument & utility, transfer of location.

Production system:

For each manufacturing process.

In-process sampling and testing.

Risk assessment can be categorized as planned and unplanned risk assessment:

A Planned Risk Assessment is one that is conducted in advance of conducting an activity, either before any activity is conducted or before further activity is conducted. This would often allow quality to be built in to activities and risk reduced (quality by design).

Example: Design of facilities for manufacture of products or design of a label printing room.

An unplanned risk assessment is one that is conducted to assess the impact of a situation that has already occurred.

Example: Impact of a deviation from normal ways of working.

Risk analysis is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harms.

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Team shall analyze the risk linking the likelihood of occurrence, detection and severity of harm using qualitative descriptor, such as **"High"**, **"Medium"** and **"Low**

Relative Risk	Description
High	The operation / practice / equipment / condition / system / documents / materials etc. that may have direct impact on product quality / safety. Failure of the system which may result in an inappropriate decision or action related to product quality / safety. There is no other system to check or verify the product quality / safety.
Medium	The system can have an indirect impact on product quality / safety. Failure of the system which may result in an inappropriate decision or action related to supporting process or system that have direct impact on product quality / safety.
Low	The system does not have an impact on product quality. Failure of the system may result into changes in practices, procedure, SOP modification etc. with no risk to product quality / safety.

Risk shall be analyzed by setting occurrence level based on actual occurrence history of particular problem / failure by referring documents like deviations, change control, market complaint, impact of OOS result, review of reports of previous of previous inspection and follow-up actions, review of report of any samples by competent authorities, risk record, environmental monitoring records, sterility testing pressure differentials and interventions that could potentially impact batch quality and sterility.

Risk Identification:

Risk may be identified by anyone working in his/her respective workplace with the systematic use of information.

Identify the risk related to product, process, procedure, equipment, instrument, starting material, facility, environment controls, or others.

If any change in the process, equipment and facility through change control or deviation can also trigger the initiation of the risk assessment to identify, evaluate and assess the various risk involved in the activity.

A brain storming session shall be arranged of concerned personnel to discuss the risk assessment pertaining to the identified area.

Risk identification addresses the "what might go wrong?" question, including identifying the possible consequences.

Risk identification shall be done after elaborate team discussions based on prior knowledge, historical data, theoretical and literature references.

Quality Risk Management Methodology:

Quality risk management supports a scientific and practical approach to decision making. it provides documented, transparent and reproducible methods to accomplish steps of quality risk management process based on current knowledge about assessing the probability, severity and sometimes detectability of the risk.

Traditionally, risks to quality have been assessed and managed in a variety of informal ways (empirical and / or internal procedures) based on, for example, compilation of observations, trend and other information. Such approaches continue to provide useful information that might support topics such as handling of complaints, quality defects, deviations and allocation of resources.

Additionally, the pharmaceutical industry and regulators can access and manage risk using recognized risk management tools and / or internal procedure (e.g. standard operating procedures). Below is a non-exhaustive list of some of these tools.

Failure mode effect analysis (FMEA)

Hazard analysis and critical control points (HACCP)

Basic risk management facilitation methods (flowcharts, check sheet etc.).

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Hazard operability analysis (HAZOP)
Fault tree analysis (FTA)
Preliminary hazard analysis (PHA)
Risk ranking and filtering

The most commonly tools used for risk assessment is Failure Mode Effects Analysis (FMEA):

FMEA provides for an evaluation of potential failure modes for processes and the likely effect on outcomes and / or product performance.
Once failure modes are established, risk reduction can be used to eliminate, reduce or control the potential failures.
FMEA relies on product and process understanding. FMEA methodically breaks down the analysis of complex processes into manageable steps.
FMEA is a powerful tool for summarizing the important Modes of Failure, Factors causing these failures and the likely effects of these failures.
FMEA can be used to prioritize risks and monitor the effectiveness of risk control activities.
FMEA can be applied to Equipment and Facilities, and might be used to analyze a manufacturing operation and its effect on product or process. It identifies elements / operations within the system that render it vulnerable.
The output / result of FMEA can be used as a basis for design or further analysis or to guide resource deployment.

Following steps to be followed to carry out risk assessment by using FMEA Tool.
List the elements of the system.
List potential failure modes
Describe the effect of the Failure
Determine failure severity (S), occurrence (O) and detectability (D)
Determine cause (s) of the Failure
Determine risk level on the basis of S, O, and D
Check whether the risk is accepted or not
Take action to reduce the highest risk.

Qualitative risk component ranking shall be done on the basis of below mentioned details:
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
Risk Level shall be determined on the basis of Severity, Occurrence and Detection Risk.
Risk Level shall be checked whether accepted or not. If accepted, actions shall be recommended to control the risk, where required.
If risk is not accepted, new engineering (e.g. new design) or administrative controls (e.g. new system / procedures) or process changes with validation through change control shall be recommended to reduce the risk to the acceptable level.
Analyze the each risk for its severity, probability and chances of detection. The methodology used to analyze the risks for these parameters shall be allocation of scores to the risk as follows:
Severity of impact:
Identify the severity of impact of the risk on the quality of the product/service. And effect on patients and categorize the severity of impact of risk as below:

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Level	Patient Effect	Process Effect
10	Patient getting effected Fatally	Irreparable damage to batch/product
		Product Quality Attributes are affected.
		possible regulatory deficiency / customer query
7	Patient is not affected fatally but deemed efficacy is not achieved. But the effect is Not noticeable.	Reprocessing is possible but without affecting the quality attributes
4	Patient is not affected fatally but deemed efficacy is not achieved. But the effect is noticeable and manageable.	Manufacturing related deviations not affecting the quality of the product.
1	No impact on Patient.	No impact on Process & Quality

Probability:

Identify the Probability of risk based on the occurrence, frequency and categorize the probability as below.

Level	Patient Effect	Process Effect
10	[Certainty] Availability of prior Knowledge / information Reference [KIR] that the phenomenon shall occur	Irreparable damage to batch/product
		Product quality attributes are affected.
		possible regulatory deficiency / customer query
7	[Uncertain] No KIR available with possibility of surprise/stray results.[risk]	Fairly certain of the chances
4	[Uncertain] No KIR available, but needs to be studied.	Remote possibility of Chance
1	Availability of prior [KIR] that the phenomenon shall not occur	Almost uncertain no probability to happen

Chances of detection:

Identify the chances if detection based on the process control and analytical control as follows:

Level	Process Control	Analytical Control
10	In-process Checks / Parameters / Systems/ Procedural controls are not available.	No Analytical Technique/Procedure is available.
7	In-Process parameters / Procedural controls to be established.	Qualitative detection technique. Inadequate controls exist to detect the failure.
4	In-process Parameters / Procedural controls to be standardized.	Quantitative Detection technique. Controls exist but are not robust enough.
1	In-process Test / Checks / Parameters / Systems are available.	Multiple analytical tests support Detection/Measurement of required attributes. Test procedures & lab controls are adequate to detect the failure.

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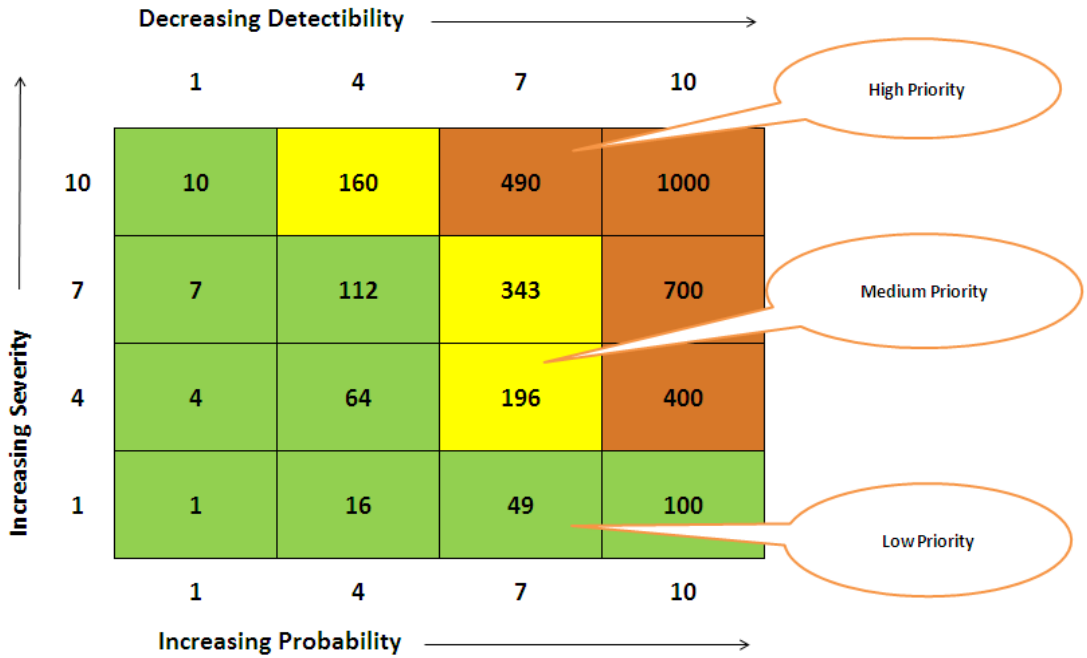
Calculation of the risk level:

Calculate the total score for the particular risk by multiplying the scores of Severity, Probability and chances of detection of risk as follows:



Risk Level	Obtained Score
Low Priority	1 to 125
Medium Priority	126 to 343
High Priority	344 to 1000

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Example of Risk assessment:

1. Title of the Risk Assessment: General Procedures of Quality Department

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			
							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)	Risk Priority Number (RPN)
1.	**Sampling**	Probability of Wrong Sampling	➢ Sampling procedure is not available & followed. ➢ Sampling activity is performed by untrained personnel. ➢ Sampling plan is not available & followed. ➢ Status labeling is not followed. ➢ Material is not stored in proper manner. ➢ Sampling Booth not properly cleaned and maintained.	Result variation may occur due to wrong sampling which may leads to Product Failure.	➢ Sampling procedure is available & followed. ➢ Sampling activity is performed by trained personnel. ➢ Sampling plan is available & followed. ➢ Status labeling is followed. ➢ Material is stored in proper manner. ➢ Procedure for the sample booth cleaning and maintenance is available.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	N A
2.	**Sample Management**	Probability of mishandling of sampled container	➢ Procedure for sample management is not available & followed. ➢ Dedicated storage area is not available. ➢ Personnel are not trained for handling of samples. ➢ Lock & key arrangement is not provided for storage of the samples. ➢ Procedure for control sample management	Spillage may occur while sampling which may leads to wrong reporting of results	➢ Procedure for sample management is available & followed. ➢ Dedicated storage area is available for storage of sample. ➢ Personnel are trained for handling of samples. ➢ SS Almirah with Lock & key arrangement is provided for storage of the samples. ➢ Procedure for control		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	N A

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			not available. ➢ Procedure for destruction of leftover sample not available.		sample management available. ➢ Procedure for destruction of leftover sample available.										
3.	**Calibration**	Probability of use of un-calibrated instruments	➢ Calibration planner (internal & external) is not available & followed. ➢ Procedures for calibration of instruments are not available & followed. ➢ Calibration activity is performed by untrained personnel. ➢ Instruments are not working properly. ➢ Standard used in calibration not available.	Result variation which lead to Product Failure.	➢ Calibration planner (internal & external) for all instruments is available & followed. ➢ Procedures for calibration of instruments are available & followed. ➢ Calibration activity is performed by trained personnel. ➢ Instruments are working properly. ➢ Standard used in calibration are available and carried as per respective SOP.		**4**	**1**	**7**	**28**	**NA**	**NA**	**NA**	**NA**	NA
4.	**Sample Analysis**	Probability of false result reporting	➢ Approved Specification & Method of analysis are not available & followed. ➢ Testing is performed on un-calibrated instruments. ➢ Analyst is not qualified for the performing the analysis.	Product failure & market complaint	➢ Approved Specification & Method of analysis are available for all products & material & followed. ➢ All instruments are calibrated as per schedule. ➢ All Analysts are qualified & all testing		**4**	**1**	**7**	**28**	**NA**	**NA**	**NA**	**NA**	NA

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			➢ Analysis is performed by untrained & unqualified personnel. ➢ Instruments are not working properly. ➢ Analysis activity is not monitored by senior person. ➢ Data calculation & results are not checked by a second person. ➢ Procedure for checking the results & calculation is not available & followed. ➢ Anti-vibrating table for Analytical Balance is not available.		are performing by the qualified analyst. ➢ Instruments are working properly. ➢ Analysis activity is monitored by senior person. ➢ Data calculation & results are checked by a second person. ➢ Procedure for checking the results & calculation is available. ➢ Anti-vibrating table for Analytical Balance available.										
5.	**Chemical & Reagent Handling**	Safety Risk	➢ Procedure for handling of Chemical & reagents are not available & followed. ➢ Material safety data sheet are not available. ➢ Dedicated areas are not provided for the storage of different type of reagents & chemicals. ➢ Personnel are not trained for handling of Chemical & reagents.	Health & Hazard Problem	➢ Procedure for handling of Chemical & reagents are available & followed. ➢ Material safety data sheet are available for all chemicals. ➢ Dedicated areas are provided for the storage of different type of reagents & chemicals. ➢ Personnel are trained for handling of Chemical & reagents.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA

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6.	**Contamination & Cross Contamination**	False result reporting	➢ Storage of samples in improper manner. ➢ Area, LAF & other utility of Microbiology Area are not qualified. ➢ Procedure for handling of Microbiological waste & discarding procedure is not available & followed. ➢ Procedure for Media Handling is not available. ➢ Gowning Procedure is not available & followed. ➢ Activity is performed by untrained personnel.	Wrong result reporting & market complaint	➢ All received samples are stored in proper manner. ➢ Area, LAF & other utility of Microbiology Area are qualified. ➢ Procedure for handling of Microbiological waste & discarding procedure is available & followed. ➢ Procedure for Media Handling is available & followed. ➢ Gowning Procedure is available & followed. ➢ All activity is performed by a trained dedicated personnel.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA
7.	**Analyst Qualification**	Wrong Result Reporting	➢ Procedure for Analysts qualification is not available & followed. ➢ Analysts are not qualified. ➢ Refresher Trainings are not provided to concern personnel.	False result reporting & market complaint	➢ Procedure for Analysts Qualification is available & followed. ➢ All Analysts are qualified for their work. ➢ Refresher Trainings are provided to concern personnel.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA
8.	**Safety Risk**	Safety Risk	➢ Eye washer & shower are not available. ➢ All MSDS are not available. ➢ Fuming Hood is not	Health & Hazard Problem	➢ Eye washer and safety shower is available. ➢ All MSDS are available. ➢ Fuming Hood is		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA

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			provided. ➢ Proper storage area for storage of solvents & other reagent is not provided ➢ Personal Protective equipment not provided to analyst.		provided for de-fuming activity. ➢ Proper storage area for storage of solvents & other reagent is provided. ➢ Personal Protective equipment is provided to analyst.										
9.	**Reference & Working Standard Management**	Error in Results.	➢ Procedure for handling of Working & Reference Standards is not available & followed. ➢ Storage area is not provided. ➢ Monitoring records are not available. ➢ Handling is done by untrained personnel.	Wrong result reporting & Market Complaint	➢ Procedure for handling of Working & Reference Standards is available & followed. ➢ Dedicated Storage area is provided for storage of Working & reference standard. ➢ Monitoring records, Logs are available. ➢ Handling is done by dedicated trained personnel.		**4**	**1**	**7**	**28**	**NA**	**NA**	**NA**	**NA**	NA
10.	**Media Management**	Error in Results.	➢ Procedure is not available & followed. ➢ Required details are not mentioned on individual container. ➢ Media handling is done by untrained personnel. ➢ Dedicated area is not provided for storage of media. ➢ Media is not procured	Wrong result reporting & Market Complaint	➢ Procedure for handling of media is available & followed. ➢ Required details are mentioned on individual container. ➢ Media handling is done by trained dedicated personnel. ➢ Dedicated area is provided for storage of		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	NA

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			from approved source.		media. ➢ All Media is procured from approved source.										
11.	**Documentation & Data Control**	Probability of mishandling of documents & data integrity issue	➢ Procedure is not available & followed. ➢ Documents & Data Controlling is not performed by QA personnel. ➢ Activity is performed by untrained personnel. ➢ Issuance & control of raw data sheets is not performed by QA.	Wrong Result Reporting	➢ Procedure for documentation & data control is available & followed. ➢ Documents & Data Controlling is performed by QA personnel. ➢ Activity is performed by trained personnel. ➢ Issuance & control of raw data sheets is performed by QA. All worksheets are issued by QA Personnel after recording the details in respective Log.		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	NA
12.	**Pharmacopoeia & Guideline Update**	Probability of documents & system not update as per new requirement.	➢ Procedures are not available. ➢ Training is not provided to all concern personnel.	Product not complies as per requirement	➢ Procedure for "Pharmacopoeia Amendments and Guidelines Updates" is available & followed. ➢ Activity is performed by trained QC & QA personnel.		**4**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	NA
13.	**Result Reporting & Checking of results**	Probability of False result reporting	➢ Procedure for checking of Data & Results is not available & followed. ➢ Activity is performed	Wrong results	➢ Procedure for checking of Data & Results is available & followed. ➢ Activity is performed by trained personnel.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA

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			by untrained personnel. ➢ Data & results are not checked by a second person.		➢ Data & results are checked by a second person.										
14.	**Preparation of COA**	Probability of False result reporting	➢ Procedure for checking of Data & approval is not available & followed. ➢ Activity is performed by untrained personnel. ➢ Data & results are not checked by a second person.	Wrong results	➢ Procedure for Data review & approval is available & followed. ➢ Activity is performed by trained personnel. ➢ Data & Results are checked by a second person.		**4**	**1**	**7**	**28**	**NA**	**NA**	**NA**	**NA**	NA
15.	**Destruction of Samples & Media**	Probability of Mix up of leftover product samples with current samples	➢ Procedure is not available & followed for destruction of left over samples. ➢ Activity is not performed by trained personnel.	False results	Procedure is available & followed for destruction of left over samples.		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	NA
16.	**Management of HPLC Column**	Probability of False result reporting	➢ Procedure for Handling & Storage of HPLC Column is not available & followed. ➢ Activity is not performed by trained personnel. ➢ Storage cabinet with lock & key arrangement is not provided.	False results	➢ Procedure for Handling & Storage of HPLC Column is available & followed. ➢ Activity is performed by trained personnel. ➢ Storage cabinet for HPLC Column with lock & key arrangement is provided.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA
17.	**Qualification of Outside testing**	Probability of false	➢ Procedure for Qualification of	Product failure & market compliant	➢ Procedure for Qualification of		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**N**	N

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	laboratory & Testing from outside lab	result reporting & status of analysis is not clear	Outside testing lab is not available & followed. ➢ Qualification activity is not performed. ➢ Written agreement copy is not available. ➢ Procedure for outside testing is not available. ➢ Activity is performed by untrained personnel.		Outside testing lab is available & followed. ➢ Qualification activity is performed. ➢ Written agreement copy is available. ➢ Procedure for outside testing is available. ➢ Activity is performed by trained personnel.									**A**	A
18.	**Stability Study**	Product failure and Market complaint.	Stability study Protocol and Procedure not available.	Failure to comply ICH guidelines and in case of investigation of Market Complaint.	Stability study procedure and protocols are available in laboratory.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA
19.	**LIMS**	Delay in Analysis and release of the products.	➢ Insufficient of personnel for activity. ➢ Personnel not trained properly to operate LIMS.	Product release delay.	There are sufficient personal for the activity and are personnel are well trained to perform the activity.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA

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

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2. Title of the Risk Assessment: High Performance Liquid Chromatography

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			
							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)	Risk Priority Number (RPN)
1.	**Quaternary Pump**	1. Lost Prime 2. System Pressure Fluctuation 3. Lack of Consistent Flow rate	Presence of Air Bubbles due to improper flushing of channels or mobile phase ports and non-performance of Priming of the system.	1. Shift in Retention Time of Principle Peak 2. Sequence stop due to Lost Prime. 3. Area Variation in replicate Injections of standard and Test. 4. Missing of Principle peak due to improper elution.	Procedure of Dry Prime and Wet prime is defined with its procedure and how to operate from Display of HPLC.	.	**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA
2.	**Injector**	Improper dispensed quantity of standard and test solution	Presence of Air bubbles and non-performance of Purge Injector	1. % RSD failure 2. Area variation in replicate Injections of standard and Test. 3. Contamination in current running sample due to previous run sample.	Purge Injector for 6.50 minutes with same instrument method is incorporated in sample set sequence.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA

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							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)	Risk Priority Number (RPN)
3.	**Detector**	Improper Level of energy of Lamp.	Running of HPLC Lamp for long time or either not switching off lamp when not in use.	Due to Low energy level improper detection of principle peak as well as impurity peaks with very low concentration area	Shut down method after completion of sequence is in procedure. Reviewer verifies the sequence and methodology of shutting down lamp before running the sequence.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA
4.	**Auto Sampler**	Improper functioning of carousels.	1. Opening of Carousels door while selecting vial for injection or injecting of standard or sample solution. 2. Positions of Carousels interchanged. 3. Carousels are placed in disbalanced position	1. Sequence stop due to malfunctioning of Carousels. 2. Due to interchanged position of carousels the selection of vials according to sample set shall get changed which lead into wrong results of Product.	Training session is conducted in regarding to aware HPLC users about the Auto sampler and its working.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	**NA**
5.	**Integration**	1. Peak Tailing 2. Peak Fronting 3. Split Peaks	1. Column void 2. Interfering peak 3. Wrong mobile – phase pH 4. Sample reacting with	1. Improper peak shape 2. Shift in Retention Time of Main	1. Replace inlet frit or Replace column 2. Column washing to be done proper. 3. Change Mobile phase		**4**	**1**	**7**	**28**	**NA**	**NA**	**NA**	**NA**	**NA**

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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			
							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)	Risk Priority Number (RPN)
		4. Distortion of Larger peaks 5. Distortion of Early Peaks 6. Extra Peaks 7. Baseline drift 8. Baseline noise 9. Broad Peaks 10. Loss of Resolution 11. Wrong Processing 12. Insufficient information of injection runs.	active sites. 5. Low Temperature 6. Wrong sample solvent 7. Contamination on analytical column inlet. 8. Other components in sample 9. Ghost peaks 10. Column Temperature Fluctuation 11. Non homogenous mobile phase 12. Contamination in detector cell 13. Change in flow rate 14. Slow column equilibration 15. Leakage 16. Wrong integration and wrong selection of path. 17. Specific Report layout not selected.	analyte peak 3. Improper Detection of Principle Peak. 4. Improper Results.	4. Adjust pH 5. Column and sample temperature is defined for every product. 6. Usage of particular solvents id defined for every products. 7. If analytical column is obstructed, flush. 8. Filtration of Mobile Phase after preparation. 9. After running of sequence not to open the column door. 10. Usage of HPLC grade Solvents, high purity salts, Degassing of mobile phase and use of sonicator to mix the solutions. 11. Flushing of the detector cell with methanol or other strong solvent. 12. Incorporation of flow rate in Instrument methods as per test procedure of products. 13. Run 10-20 column volumes of new										

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							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)	Risk Priority Number (RPN)
					mobile phase before analysis. 14. Before running the sequence it is in practice to check the leakage in column and system. 15. Integration and Processing done by trained personnel. 16. Specific report layout presents for each test and run.										
6.	**Sequence**	Wrong Sequence run.	1. Sequence name given wrong. 2. Alteration in sequence done without any comment. 3. Sequence prepared wrong.	1. Information about sample not justified. 2. Informative justification of alteration misses. 3. Error in results.	1. Naming pattern of sequence mention in SOP. 2. Justification of alteration in sequence mention in SOP. 3. After preparing sample set by analyst. Same sequence is verified by Reviewer.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA

3. Dissolution

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			
							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)	Risk Priority Number (RPN)

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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			
							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)	Risk Priority Number (RPN)
1.	**Sampling Practice**	Wrong Results	➢ Wrong sampling point chooses for sampling. ➢ Wrong sampling Time chooses for sampling.	Error in sample preparation which leads to the wrong elution of principle peak area which leads to wrong results and product failure.	➢ All samples must be withdrawn ½ way between top of paddle/basket and media, no closer than 1cm from vessel wall. It is recommend not sampling within 1cm of spindle ➢ Must sample (and filter) within 2% of the time point. Paddles/baskets must still be stirring while sampling		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA
2.	**Filtration**	Wrong Results	Wrong filter chooses for filtration of sample and standard.	Area Variation and Product failure.	Use of particular filter is mention in each product / material test procedure.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA
3.	**Contamination**	Wrong Results	Previous product Syringe, Cannula and filter used for sampling.	Elution of extra peaks, Area variation and Product Failure	Fresh filters are used for each analysis. Syringes and Cannula are used after proper cleaning.	-	**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	NA
4.	**Vibration**	Wrong Results	Vibration near to dissolution will allow the sample to disintegrate easily.	Error in results.	All dissolution surfaces are vibration free.		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	NA
5.	**Poor Techniques**	Wrong Results	Performance of wrong dissolution and Product Failure	Product Failure	All the persons involving in performance of dissolution test are well trained and experience.		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	NA
6.	**Wrong volume**	Wrong Results	➢ Use of Uncalibrated	Product Failure	➢ All measuring		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	NA

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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			
							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)	Risk Priority Number (RPN)
	used		measuring cylinders ➢ Untrained personnel's.		cylinder used are of A grade. ➢ All personnel are well trained for the activity.										

4. FTIR

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			
							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)	Risk Priority Number (RPN)
1.	**FTIR Assembly**	Wrong Result	Wrong choice of FTIR assembly for analyzing sample (solid & liquid).	Error in detection of principle peak which leads to wrong results and product failure.	Before start of analysis FTIR assembly to check properly as per the required sample to analyze.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	**NA**
2.	**Analysis using FT-IR spectrometer.**	Electrical hazards.	Electric Shock	Possible electric shock if spectrometer is not properly grounded. Electrocution may occur upon contact with exposed wires.	Ensure that the spectrometer is properly grounded and all the cables are properly insulated. Check that the area around is clean and dry before operating the spectrometer.		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	**NA**
3.	**Preparation of the liquid film sample for IR measurement.**	Health Hazard	➢ Broken glassware (glass dropper) ➢ Chemical hazards (2-ethylaniline, 3-methylbenzonitrile, 4- bromoanisole,	➢ Injury sustained from contact with broken glassware. ➢ Damage to	➢ Handle the glassware with care during assembly. Visually inspect glassware before use. ➢ Wear proper PPE (lab		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	**NA**

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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			
							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)	Risk Priority Number (RPN)
			tert -butylamine, isobutylamine, chloroform). ➢ Flammable liquids (tert - butylamine, isobutylamine)	health if swallowed, inhaled, or exposed to skin and eyes. 2-ethylaniline is toxic by skin contact and if inhaled, and may cause organ damage through repeated exposure. tert - butylamine is harmful if swallowed, toxic if inhaled, and causes severe skin burns and eye damage. Isobutylamine is toxic if swallowed and causes severe skin burns and eye damage. Chloroform is harmful if swallowed, toxic if	coat, goggles, gloves). Prepare the samples inside a well ventilated fume hood. ➢ Keep away from heat/sparks/open flames/hot surfaces.										

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							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)	Risk Priority Number (RPN)
				inhaled, causes skin irritation and severe eye irritation, and may cause drowsiness or dizziness. Chloroform has carcinogenic effects. ➢ Fire.											
4.	**Procedure**	Wrong Results	➢ Procedure not available. ➢ Data (Spectrum) Storage not proper. ➢ Analysis performed by untrained personnel. ➢ Exposure of sample to unwanted conditions.	➢ Product/Material Failure. ➢ Misplacement of Data.	➢ Test procedure for Products/Materials is available. ➢ Proper storage of Data available. ➢ All personnel are well trained for performance of activity. ➢ During analysis all activities are performed in conditions as mention in test procedure to prevent any possible error.		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	**NA**

5. TOC Analyzer

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							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)	Risk Priority Number (RPN)
1.	**Power Cable**	Electrical hazards.	Electric Shock	Possible electric shock if wires are not properly grounded. Electrocution may occur upon contact with exposed wires.	Ensure that the analyzer wires are properly grounded and all the cables are properly insulated. Check that the area around is clean and dry before operating the analyzer.		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	**NA**
2.	**Carrier Gas**	Instrument Error	Improper flow of carrier gas to analyzer.	Running sample got stopped which leads to delay in release of TOC sample used in production or manufacturing of batches.	Before start of analysis carrier gas pressure is checked.		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	**NA**
3.	**Connecting Accessories**	Instrument Error	Accessories are not arranged or placed as required.	Leakage and pressure drop may observe.	Before start of analysis all connecting accessories to be placed as per specific SOP.		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	**NA**
4.	**Sample Preparation in Calibration**	Wrong results	Error in weight taken which leads to error in sample preparation.	Calibration of analyzer may get failure.	Sample preparation for calibration of analyzer is described in specified SOP.		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	**NA**

6. UV

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			
							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)	Risk Priority Number (RPN)
1.	**Detector**	Improper Level	Running of UV Lamp for	Due to Low energy	Shut down of UV Lamp		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	**NA**

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							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)	Risk Priority Number (RPN)
		of energy of Lamp.	long time or either not switching off lamp when not in use.	level improper detection of principle peak as well as improper base line.	after analysis for better working and review of the same by section in-charge for UV lamp.										
2.	**Sample Analysis**	Wrong Results and Market Complaints.	Wrong choice of solvents as blank.	Error in detection of principle peak which leads to wrong results and product failure.	Choice of Blank as per the solvent used in preparation of standard and sample solution.		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	**NA**
3.	**Cuvette**	Wrong Results.	➢ Improper handling of cuvette during analysis. ➢ Error in cleaning of cuvette. ➢ Improper placement of cuvette.	Error in detection of principle peak which leads to wrong results and product failure.	➢ During analysis UV cuvettes are hold in such a manner that the opaque sides are held between two fingers. ➢ Before keeping the cuvettes inside the holder clean with tissue paper from all sides. ➢ While inserting the cuvettes inside the holder avoid excessive force. ➢ Ensure the transparent sides of the cuvettes are in the optical path.		**4**	**1**	**4**	**16**	**NA**	**NA**	**NA**	**NA**	**NA**
4.	**Sample Holder Compartment**	Wrong Results	Sample compartment wrongly closed after placing of sample.	Error in detection of principle peak which leads to	Sample holder compartment to be closed properly before start of		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	**NA**

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							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)	Risk Priority Number (RPN)
				wrong results and product failure.	UV analysis.										
5.	**Miscellaneous**	Wrong Results	➢ Selection of wrong wavelength ➢ Wrong Path selection for data. ➢ Improper Baseline.	➢ Error in detection of principle peak. ➢ Misplace of Data save in software ➢ Improper reading.	➢ Wavelength on which analysis is to perform is particular mention in Test procedure of Assay and Dissolution. ➢ Month wise folders are there to prevent intermixing of data. ➢ Before run of the standard and sample solution Blank scan and absorbance is locked or Auto zero operation is performed.		**1**	**1**	**4**	**4**	**NA**	**NA**	**NA**	**NA**	**NA**

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