PRE RISK ANALYSIS FOR WATER SYSTEM
(CEPHA BLOCK)

RISK ASSESSMENT

REPORT BY FMECA

Product/System/Equipment	**Water System**
Risk Assessment Report No.	
Report Date	

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DOCUMENT APPROVAL:
This risk analysis study for the preapproval of report by following:

Responsibility	Department	Name	Signature	Date
Prepared by	Quality assurance			
Reviewed by	Production			
	Quality control			
	Engineering			
	Store			
	Quality assurance			
Approved by	Head-QA			

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1.0 Introduction

The Purified water system is intended to provide the water of desire pharma specification for the manufacturing of the oral dosage formulation. Its goal is to provide safe water with respect the acceptable limits. In pharma industry water system use of fulfill the requirement of purified water for manufacturing and cleaning purposes with assurance of the product safety.

2.0 Objective

Objective of this report is to assess the risk associated with the existing Purified water system in the manufacturing facility of Cepha Block, ……. in line with the guidance of the Risk Management manual of …… and ICH Q9

3.0 Scope

The scope of this document is limited to the design, installation, operation and performance of the Purified water system, define its failure mode at different stages of water system with control points, utilities with respect to the operating personnel and belonging instruments and the risk is to be evaluated against the water system installed in the manufactured facility of Cepha Block, ……..

4.0 Risk Assessment Approach

Risk assessment is carried out as per FMECA (Failure mode effects and criticality analysis) method.

5.0 Responsibility

Quality Assurance
Engineering
Production
Quality Control
Store

6.0 Reference Documents

1. ICH Q9-Quality Risk Management

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Background

Bore well is the source of raw water. Bore well water is chlorinated to reduce the microbial load. Chlorinated water is softened and ultra-filtration is done. pH correction and SMBS treatment anti-scalent dosing is done to eliminate chlorine content from soft water. Water is passed through two stage RO membrane filtration and then EDI and. Water is subjected to UV treatment and collected in 5000 ltr. Purified water storage tank. Purified Water is supplied to area in closed loop and return loop is connected to purified water storage tank.

The QRM is prepared for water system at Cepha Block to check the existing system is capable to provide purified water quality with specification.

7.0 RISK RANKING PARAMETERS

7.1 Rating parameters for Severity

Effect	Scale	Description
No effect	1	No effect on output
Very slight	2	Customer not annoyed
Slight	3	Slight
Minor	4	Minor effect on performance
Moderate	5	Moderate effect on performance
Significant	6	Partial failure but operable
Major	7	Product performance severely affected, but some operability and safe
Extreme	8	Very dissatisfied, product inoperable but safe
Serious	9	Potentially hazardous effect, time-dependent failure
Hazardous	10	Hazardous effect, safety related sudden failure

7.2 Rating parameters for Occurrence

Occurrence	Scale	Description
Almost never	1	Failure unlikely; history shows no failures
Remote	2	Rare number of historical failure
Very Slight	3	Very few failures likely
Slight	4	Few failures likely

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Occurrence	Scale	Description
Low	5	Occasional number of failures likely
Medium	6	Medium number of failures likely
Moderately High	7	Moderately high number of failures likely
High	8	High number of failures likely
Very High	9	Very high number of failures likely
Almost certain	10	Failure almost certain

7.3 Rating parameters for Detection control

Detection	Scale	Description
Almost certain	1	Proven detection methods with high reliability
Very High	2	Proven detection methods available
High	3	Detection tools have high chance of detecting methods
Moderately High	4	Almost certain not to detect failure
Medium	5	Detection tools have moderate chance of detecting defect
Low	6	Detection tools have a low chance of detecting failure
Slight	7	Detection tools may not detect failure
Very Slight	8	Detection tools will probably not detect failure
Remote	9	Detection tools most likely will not detect failure
Impossible	10	Failure not detected

Note: Individual contributory factor for each potential failure mode shall be rated. Other scale parameters may also be selected based on the process.

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8.0 ACCEPTANCE CRITERIA FOR RISK ASSESSMENT BY FMECA

Acceptance criteria for FMECA are as follows:

S.No.	RPN Rating	RPN Category	Action Status
1.	≥ 76	Critical	CAPA Required
2.	51 to 75	Major	CAPA Required
3.	26 to 50	Moderate	CAPA Required
4.	Up to 25	Minor	Not applicable

Note: Action plan is also required if any of individual score of Severity, Occurrence, and Detection is high i.e. more than 4 (even if RPN is within acceptance criteria).

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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9.0 PRE RISK ASSESSMENT AS PER FMEA:

Name of facility/Engineering/Equipment/Process/Operation: WATER SYSTEM

S.No.	Potential Failure Mode	Potential effect (s) of failure	Severity (S)	Potential cause/ Mechanism of failure	Occurrence (O)	Current Control	Detection (D)	RPN (S x O x D)	Recommended action	Responsibility and TCD	Action Results				
											Action taken	Severity	Occurrence	Detection	New RPN
1	Required area not sufficient for Water system (storage, Pre treatment and distribution) Installation.	Area will not be suitable for proper functioning of water system (Pre treatment and distribution)	4	No or less clarity for the selection of water System and required area (Pre treatment and distribution)	4	Approved lay out is in place with dimension and required area.	1	16	Current control measures are adequate	NA	NA	NA	NA	NA	NA
2	Source of water is not available.	Water system cannot be functioning.	6	No proper or suitable place is identified for bore well to pump out water from ground.	4	Source of water is identified as bore well water and it is defined in URS. Bore well water will be send for analysis to finalize the design	1	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
3	Required Utility (electricity, compressed air) not available.	Water system Cannot be functioning.	6	No or less clarity for the selection of water system (Pre treatment and distribution)	4	Arrangement is made to supply required power to run the system and defined in URS.	1	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA

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S.No.	Potential Failure Mode	Potential effect (s) of failure	Severity (S)	Potential cause/ Mechanism of failure	Occurrence (O)	Current Control	Detection (D)	RPN (S x O x D)	Recommended action	Responsibility and TCD	Action Results				
											Action taken	Severity	Occurrence	Detection	New RPN
4	Required chemicals for pretreatment not available.	Water system pre-treatment cannot be started	6	No or less clarity for the selection of water System and required chemicals. (Pre treatment and distribution)	4	Vendor is identified for water system and list of chemicals required for pretreatment is Identified.	1	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
5	Wrong system selection in terms of Dimension, design, capacity and output (quantity) and quality of pretreatment water	Desired Quality and Quantity of water cannot be Generated and distributed.	4	No or less clarity for the selection of water system (Pre treatment and distribution) required for entire plant.	4	Approved lay out is in place with dimension and required area. Final quality specification is defined in URS. Selection of vendor will be based on his expertise in water system and reputed on the pharmaceutical field.	1	16	Current control measures are adequate	NA	NA	NA	NA	NA	NA
6	Adequate safety measures are not available	Accident may happen.1) Effect on human safety. 2) Effect on product quality	2	Safety precautions are not properly defined.	2	Requirement of safety measures like generation and distribution Is defined in URS.	2	8	Current control measures are adequate	NA	NA	NA	NA	NA	NA

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S.No.	Potential Failure Mode	Potential effect (s) of failure	Severity (S)	Potential cause/ Mechanism of failure	Occurrence (O)	Current Control	Detection (D)	RPN (S x O x D)	Recommended action	Responsibility and TCD	Action Results				
											Action taken	Severity	Occurrence	Detection	New RPN
7	Required parameter not defined in URS/ URS not proper for system	Systems received are not suitable for proper output of quality with all parameter as per specification. Affect the drug quality.	8	Water quality in URS such as pH, conductivity, TOC and microbiological criteria not defined and not meet quality of water and affect the finish goods product.	2	URS is in place for system with all pre-specified parameter. Specification with test parameters is in place.	1	16	Current control measures are adequate.	NA	NA	NA	NA	NA	NA

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9.1 REVIEW OF RISK ASSESSMENT AS PER FMECA AFTER ACTION TAKEN:

Action Results					Remarks
Action Taken	Severity	Occurrence	Detection	RPN	

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10.0 RISK CONTROL MEASURES

Investigation/ findings: *(an extra sheet can be used if space is insufficient)*

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Corrective Action: *(an extra sheet can be used if space is insufficient)*

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(Sign/Date)

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11.0 SUMMARY AND CONCLUSION REPORT FOR RISK ASSESSMENT

Summary:……..

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Conclusion:

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12.0 FINAL REPORT APPROVAL:

The final report shall be signed after identifying all the risks and critical control parameters. All the reports or documents have been attached to the respective report (if applicable).

Signature in the block below indicates that all the control measures taken are documented and have been reviewed and found to be acceptable.

Department	Name	Designation	Signature	Date
Quality assurance				
Production				
Quality control				
Engineering				
Store				
Head-QA				