



**POST RISK ANALYSIS FOR WATER SYSTEM  
(CEPHA BLOCK)**

**RISK ASSESSMENT  
REPORT BY FMECA**

<b>Product/System/Equipment</b>	<b>Water System</b>
<b>Risk Assessment Report No.</b>	
<b>Report Date</b>	



**POST RISK ANALYSIS FOR WATER SYSTEM  
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**DOCUMENT APPROVAL:**

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

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



## **POST RISK ANALYSIS FOR WATER SYSTEM (CEPHA BLOCK)**

### **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 & 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-scalant 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 7500 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 of 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



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Occurrence	Scale	Description
Slight	4	Few failures likely
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
01.	$\geq 76$	Critical	CAPA Required
02.	51 to 75	Major	CAPA Required
03.	26 to 50	Moderate	CAPA Required
04.	Up to 25	Minor	Not applicable



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### 9.0 POST 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	Design Qualification document received is inadequate.	Equipment may not function as desired.	4	No or inadequate clarity (Knowledge) in preparation of URS.	3	1. URS is prepared by experienced personnel with the help of engineering, QA & department Head. 2. Well experienced Personnel from QA, Engineering & User Department verified DQ against URS.	2	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
		cGMP requirement will not meet	7		3		1	21		NA	NA	NA	NA	NA	NA
		Safety measures with respect to operator and environment will not be clear.	4		3		2	24		NA	NA	NA	NA	NA	NA
		Clarity on P & ID diagram will not be clear	3		3		2	18		NA	NA	NA	NA	NA	NA
		Major components list will be missed out.	6		2		2	24		NA	NA	NA	NA	NA	NA





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											Action taken	Severity	occurrence	Detection	New RPN
	Design Qualification document received is inadequate	Requirement of utilities (power and compressed air) will not be clear.	3	No or inadequate clarity (Knowledge) in preparation of URS.	4	Well experienced Personnel from QA, Engineering & user department verified DQ against URS.	2	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
		Functional design specification will not be available.	4		3		2	24		NA	NA	NA	NA	NA	NA
		Generally assembling diagram will not be clear	4		4		1	16		NA	NA	NA	NA	NA	NA
		Instrument list connected with equipment will be missing	4		3		2	24		NA	NA	NA	NA	NA	NA



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2	Design Qualification document is not checked and verified properly.	Document verification related to design verification, cGMP requirement, Instrument & control verification, components verification, utility verification & safety verification will not be appropriate.	4	Inadequate knowledge or inadequate training to all concerned.	3	Well experienced Personnel from QA, Engineering verified DQ against URS.	2	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
3	DQ is not in place	DQ not approved, and machine received may be not as per DQ.	9	Machine not as per URS, DQ not reviewed and approved by the HOD.	1	DQ is in place for the water system.	1	9	Current control measures are adequate	NA	NA	NA	NA	NA	NA



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											Action taken	Severity	occurrence	Detection	New RPN
4	Installation Qualification document is inadequate	Inadequate Installation of equipment	4	Inadequate information in IQ.	3	1. Interpretation of URS along with DQ. 2. SOP is in place for verification of IQ document.	2	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
		Identification of major components will be missing	6		2		2	24		NA	NA	NA	NA	NA	
		No or inadequate clarity on equipment / documents required for completion of IQ.	3		3		2	18		NA	NA	NA	NA	NA	
5	Calibrated Measuring equipment not available at site.	Installation will be improper, system will not perform as intended	6	Inadequate training	4	Ensure Physically for the availability of equipment before execution of IQ.	1	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA



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											Action taken	Severity	occurrence	Detection	New RPN
6	Reference document not available at site during IQ. (FDS, PLC FDS, GA and electrical drawing, installation & Operational manual, Material chart with test certificate & Manual.)	Installation will be improper, Equipment will not perform as intended	6	Inadequate knowledge for verification of reference documents on receipt.	4	Qualification team will ensure Physically for the availability of documents before execution of IQ.	1	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
7	MOC verification not done during IQ ( For contact and non contact parts )	Product may gets contaminated	7	1. MOC Test certificate not provided by vendor. 2. Molybdenum Kit Not available	4	Procedure is in place for verification during IQ.	2	56	Molybdenum kit to be procured	Engineering,					
8	IQ not completed prior to OQ	OQ Cannot be proceed	6	1. Incomplete documentation. 2. Installation not completed	4	SOP is in place to perform OQ after successful completion of IQ	1	24	Controlled measures are in place	NA	NA	NA	NA	NA	NA



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											Action taken	Severity	occurrence	Detection	New RPN
9	Prequalification requirement not checked during OQ.	Accident may happen	10	Inadequate knowledge or safety measures are not followed	2	Activity will performed by trained personnel.	1	20	Controlled measures are in place	NA	NA	NA	NA	NA	NA
	External equipment is not disconnected from the system.	Accident may happen	10	Inadequate knowledge or safety measures are not followed	2	1. Activity will performed by trained personnel. 2. Procedure are in place for verification during OQ	1	20	Controlled measures are in place	NA	NA	NA	NA	NA	NA
10	System operation verification not done. (Noise level).	Equipment will not perform as intended	10	Inadequate knowledge/training for operating the equipment.	2	Procedure are in place for verification during OQ	1	20	Controlled measures are in place	NA	NA	NA	NA	NA	NA
11	Major changes done without any documentation	1. Performances of system will not guarantee. 2. Product quality may get affected	6	Inadequate knowledge/training	3	Change control SOP is in place	1	18	Control measures are in place.	NA	NA	NA	NA	NA	NA



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											Action taken	Severity	occurrence	Detection	New RPN
12	Operational qualification of system not proper	Machine not operated properly if interlocking and other specification of machine not working properly.	9	May causes the machine not run smoothly and not obtained good quality of water.	1	Operational qualification protocol is in place and qualification carried out as per preapproved protocol. The entire interlocking and safety feature has been verified during qualification activity.	1	9	Current control measures are adequate	NA	NA	NA	NA	NA	NA
13	Performance qualification is not conducted	Water should not give consistent result and not get water quality as per specification and URS.	10	All interlocking not working properly water result should not get consistent result.	2	Performance qualification protocol is in place and qualification has to be carried out for a period of 1 year as per preapproved protocol considering Seasonal variation in three phases to check impact on water quality.	2	40	Performance qualification to be carried out	QA, QC, & Engineering					



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											Action taken	Severity	occurrence	Detection	New RPN
14	All components/instrument of water system are not installed / calibrated in sequence and at inappropriate place leading to performance of water System	Water System will not be work as per design specifications	10	All required drawing is not in place. Inadequate knowledge & experience. Instrument not working properly and gives faulty result.	1	Schematic P & ID, GA drawing and identification of components are verified in IQ against user requirement and design specification. Material of construction as per URS verified & found OK. Calibration of instrument has been verified during installation qualification and also schedule prepared as per frequency defined in SOP for recalibration and same has been followed during routine practice. Preventive maintenance SOP is in place	2	20	Current control measures are adequate	NA	NA	NA	NA	NA	NA



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											Action taken	Severity	occurrence	Detection	New RPN
15	Quality of bore well water not meeting the specification.	Final water quality cannot achieved as per specification	9	No check point for the quality of bore well water.	1	Quality of bore well water analysis are carried out as per sampling	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
<b>BOREWELL STAGES</b>															
16	Quality of NaOCl not meeting as per specification	Generated water quality not meeting the specification	9	1. Specification of NaOCl not available. 2. Testing of NaOCl not done. 3. Conc. of prepared Hypochlorite solution not tested by QC.	1	Specification for NaOCL is in place. After QC released NaOCL used for dosing purpose. QC testing is in place after receiving of new consignment.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
17	Chlorine dosing pump not working properly	Microbial growth will not control in the water system and finally affect the water quality	7	If inter locking of Bore well water and dosing pump not done. Chlorine dosing knob not working properly.	1	Interlocking of the bore well water and dosing pump is available and 2 ppm dosing is done.	2	14	Current control measures are adequate	NA	NA	NA	NA	NA	NA





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											Action taken	Severity	occurrence	Detection	New RPN
18	Back washing of MGF not done	Impure water will pass to next stage TSS level will increase	8	Frequency for back washing is not defined in document.	1	Back washing is being done every day morning as per respective SOP. Pressure monitoring before and after is in place.	2	16	Current control measures are adequate	NA	NA	NA	NA	NA	NA
<b>SOFTER PLANT</b>															
19	Quality of resin in the softeners is not proper.	Desire Hardness will not achieved	7	Regeneration not done for softeners.	1	Regeneration is carried out as per respective SOP. Hardness testing done as frequency defined in SOP. Logbook is maintained.	2	14	Current control measures are adequate	NA	NA	NA	NA	NA	NA
20	Hardness testing not done as per frequency	Desire Hardness will not achieved	7	Further stages will be impacted.	1	Procedure for Hardness testing and monitoring available.	2	14	Current control measures are adequate	NA	NA	NA	NA	NA	NA



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											Action taken	Severity	occurrence	Detection	New RPN
21	If level sensor of soft water (Floty level switch & Low level switch) not working properly	Interrupted soft water supply, Tank may be over flow or empty. Water supply not proper to RO Pump.	9	Malfunctioning of level sensor.	1	Interlocking of Feed Water pump and level sensor of storage tank verified during qualification. PM SOP is in place.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
22	Cartridge Filter become clogged	Flow will decrease and TSS increases, Outlet flow will be decrease.	9	If Multi grade Filter back flushing not done timely.	1	Multi grade Filter back flushing is done as per respective SOP. Pressure monitoring before and after is in place.	3	27	Current control measures are adequate	NA	NA	NA	NA	NA	NA

### ULTRA FILTRATION SYSTEM



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											Action taken	Severity	occurrence	Detection	New RPN
23	If Vent Filter not working properly of UF tank.	Air inside the tank cannot be release timely and contamination from outer source	9	Storage tank damaged due to - ve pressure. Microbial contamination generated in the storage tank	1	Every six month vent filter is replaced as per frequency defined in SOP months Sanitization is done twice in month as per respective SOP.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
24	If Ultra filtration ( UF) membrane not work properly	Microbial count will be increases	9	If timely sanitization not done.	1	Sanitization of water system is done twice in month as per respective SOP. Pressure before & after is monitored as	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
25	If UF Storage Tank level sensor not working properly	Interrupted UF feed water supply through pump. Tank may be over flow or empty.	9	If inter locking of RO Feed water pump with UF water storage tank not proper.	1	Inter locking of RO Feed water pump with UF storage tank is available. Preventive Maintenance SOP is in place for verification of sensor.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA



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											Action taken	Severity	occurrence	Detection	New RPN
<b>RO-EDI SYSTEM</b>															
26	Hardness of water increase before RO I & II	RO membrane and EDI get affected	9	If feed water hardness not in limit (NMT 5 ppm) .	1	Existing Procedure for monitoring of hardness before RO Stage I & II is available.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
27	If SMBS dosing not perform	RO membrane and EDI get affected, Chlorine content increases.	9	If level sensor of SMBS dosing not working properly.	2	Level sensor is provided in dosing tank. Dosing set as per SOP and if during running condition chlorine content exceed the limit then ORP sensor indicate and dumping valve open. If continues 300 second chlorine content more than limit then machine trip automatically.	1	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
28	If pH is less than specified limits ( 6.5 to 8.5)	RO membrane and EDI get affected	9	If dosing of caustic not proper.	1	Level sensor is provided in dosing tank. Frequent checking of pH as per respective SOP.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA



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29	Scale formation on RO membrane	Pressure increase in RO membranes & microbial contamination may be increase.	9	If anti scaling dosing pump and tank level switch not interlock properly.	1	Level sensor is provided in dosing tank. There is auto anti scaling dosing system for the control of the scale formation with proper flow rate. Pressure monitoring is in place as per SOP.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
30	Quality of chemical not proper for dosing of ant scaling, pH correction and SMBS dosing	Generated water quality not meeting the specification	9	Specification of SMBS, Caustic & Antiscalant not available. Testing of SMBS, Caustic & Antiscalant not done Conc. of prepared solution not tested by QC.	1	Specification in place. After QC released SMBS, Caustic, Antiscalant agent used for dosing system. QC testing is in place.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
31	The water pH & conductivity not achieve After RO Pass II	EDI conductivity & pH not achieved in desire limits.	10	If pH and conductivity correction dosing pump will not work properly.	1	Dumping valve will open if parameter goes out of limit. Continue drain it till pH & conductivity not achieved with in limit.	2	20	Current control measures are adequate	NA	NA	NA	NA	NA	NA



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32	Conductivity not in limits after RO I & II	Quality of water does not complies to the specification	9	Feed water hardness is not in limit & all dosing not done properly, Sanitization of water not done.	1	Feed water hardness is maintained 5 PPM, Dosing is done properly as per SOP. Sanitization of water is done as per defined frequency.	1	9	Current control measures are adequate	NA	NA	NA	NA	NA	NA
33	Conductivity of water not in limit	Quality of water does not complies to the specification	9	RO Pas II dumping valve not working properly.	1	RO Pass II dumping valve should be work properly , RO Pass II conductivity should not more than 20 µs.	1	9	Current control measures are adequate	NA	NA	NA	NA	NA	NA
34	If EDI water flushing not proper	Water having over limit conductivity goes to the next stage.	9	If RO Pass II dumping valve not work properly. Conductivity meter not calibrated and not properly set.	1	RO Pass II dumping valve should work properly & interlocked. Conductivity meter is calibrated as per schedule and properly set predefined limit as per SOP.	1	9	Current control measures are adequate	NA	NA	NA	NA	NA	NA



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35	Sensors level not working properly	Water of desired specification not produced.	9	Verification not done for level sensor	1	Verification of level sensor done during preventive maintenance.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
<b>DISTRIBUTION SYSTEM</b>															
36	If Sensor level of Purified water Tank not working properly	Interrupted RO feed water supply, Tank may be over flow or empty.	9	If inter locking of pump with Purified water storage tank not working.	1	Inter locking pump with Purified water storage tank is in place. Preventive Maintenance SOP is in place for verification of sensor.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA



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37	If UV Lamp not working	Microbial growth may be increase in the water	9	UV lamp not replaced timely and burning hour not checked.	1	UV lamp is replaced as per frequency defined in SOP monitoring of burning hour is in place.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
38	Circulation of water not proper in loop	Microbial growth increase in the water supply loop and near sampling point.	9	Problem in the circulation pump if conductivity of the water higher. Return velocity not maintained properly. Leakage may be in line	1	Preventive maintenance for distribution system carried out as per frequency defined in SOP. Return velocity maintained NLT 1.2 m/sec or 4100 L/hour & recorded as per frequency in SOP. Zero dead leg sampling point provided at each user point. Distribution loop is completely close with maintained slope of 1:100 so chances of accumulation of water in line are negligible.	1	9	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
39	If Spray ball not working properly	Microbial growth increase in the water if water stagnant in storage tank	10	Any break down in the spray ball / Not working properly	1	Check the working of spray ball routinely through view glass & also checked with camera during Preventive maintenance.	2	20	Current control measures are adequate	NA	NA	NA	NA	NA	NA
40	If temperature of purified Water tank increase surrounding of the tank.	Conductivity may be increase	10	If temperature of jacket tank and surrounding not monitor properly.	1	In return line online conductivity monitoring is in place. Routine monitoring of purified water storage tank is to be performed for temperature	5	50	Current control measures are adequate but additionally monitoring of surrounding temperature for purified water storage tank is to be carried out to control the other parameter.	Engineering					



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## POST RISK ANALYSIS FOR WATER SYSTEM (CEPHA BLOCK)

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
41	If Vent Filer not working properly for distribution tank	Air inside the tank cannot be release timely and contamination from outer source	9	Storage tank damaged due to -ve pressure. Microbial contamination generated in the storage tank	1	Every six month Vent filter is replaced as per frequency defined in respective SOP. Sanitization is performed twice in month as per SOP	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
42	TOC of water may be increases during running of water system	It may result in increase in TOC value and finally affect the quality of water.	10	TOC may be increases during running system may be due to organic impurity. Improper sanitization of system , After sanitization water not drain proper Chlorination of infeed water not proper and it may causes increases in microbial load.	1	Oxidisable substances testing are carried out on daily basis for return sampling point and weekly basis for other sampling point as per respective SOP.	5	50	Current control measures are adequate but additionally online TOC analyzer is required to monitor the TOC with predefined print interval to identify the system is works and may not be increases TOC after chlorination routinely.	Engineering					



## POST RISK ANALYSIS FOR WATER SYSTEM (CEPHA BLOCK)

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
43	Leakage from user points	Water May be contaminated & return velocity may not be maintained. Gasket not proper.	9	Leakage from points due to damage of gasket and loss clamp	1	Preventive maintenance check for gasket and TC is in place. Clamp for leakage & also return velocity monitored on daily basis as per respective SOP.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
44	Sampling Points not defined for analysis and frequency	Water quality at different user points cannot be track for root cause of failure.	9	Unskillful manpower involve in the drafting of the qualification documents	1	Sampling points already defined in the concern qualification documents and SOP for frequency of sampling with ID number.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
45	Preventive Maintenance programme not available of the water system	water system efficiency not cross checked routinely and cause usual breakdown	9	SOP and planner is not available and concern persons are not trained.	1	SOP in place and persons are trained for performing the PM & preparing the PM schedule. Preventive maintenance schedule is in place.	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## POST RISK ANALYSIS FOR WATER SYSTEM (CEPHA BLOCK)

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
46	Failure of water in Microbial load / Chemical	Microbial growth increase in the water and product become failure	9	Microbial / Chemical sampling not done regularly.	1	Sampling and testing schedule is defined for different sampling points in SOP. Return sampling point sampling is carried out on daily basis. Training is given to concern persons. Trending to be quarterly & yearly prepared to check any variation.		18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
47	Operating and maintenance persons are not trained	water system not produce the water of desire quality	10	SOP is not available and concern persons are not trained.	1	Identification and verify the SOP in place and persons are trained.	2	20	Current control measures are adequate	NA	NA	NA	NA	NA	NA



**POST RISK ANALYSIS FOR WATER SYSTEM  
(CEPHA BLOCK)**

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

Action Results					Remarks
Action Taken	Severity	Occurrence	Detection	RPN	



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## POST RISK ANALYSIS FOR WATER SYSTEM (CEPHA BLOCK)

### 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)



**POST RISK ANALYSIS FOR WATER SYSTEM  
(CEPHA BLOCK)**

**11.0 SUMMARY AND CONCLUSION REPORT FOR RISK ASSESSMENT**

**Summary:**

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**Conclusion:**

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**POST RISK ANALYSIS FOR WATER SYSTEM  
(CEPHA BLOCK)**

**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				