# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## FAILURE MODE EFFECT ANALYSIS FOR PURIFIED WATER GENERATION & DISTRIBUTION SYSTEM

| S.No. | Item/ Function | Potential Failure Mode (Failure Mode ) | Potential Effect of Failure (Effect) | Potential Cause/ Mechanism of Failure | Current Control | Reference | S | O | D | Risk Priority Number (S*O*D) | Recommend-ended Actions (if any) | Post Risk | | | |
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| | | | | | | | | | | | | S | O | D | RPN S*O *D |
| **Purified water Generation system:** | | | | | | | | | | | | | | | |
| 1 | **Bore well water** | ➢ Increased microbial and particle contamination of the in-feed raw water. | ➢ Can cause to contaminate the final product. | ➢ The system shall be inefficient to remove the increased microbial and particulate contamination. | ➢ The raw water from the bore well has been transferred to a closed underground storage tank.<br>➢ The transfer piping has been provided with the facility for automatically adding NAOCL Solution in line to raw water. | IQ & Qualification document | 4 | 2 | 1 | 8 Low category & Risk Accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 2 | **Bore well water** | ➢ Insufficient quantity of raw water | ➢ The quantity of raw water shall not have any impact on the product quality.<br>➢ The process may stop due to lack of raw water. | ➢ Bore well not working properly.<br>➢ SOP for bore well operation not handle properly. | ➢ 02 nos. of bore well are there in plant for full fill the required quantity of raw water. | IQ & Qualification document | 1 | 2 | 1 | 2 Low category & Risk Accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 3 | **Bore well water** | ➢ Tank wall & floor is not leak proof. | ➢ Water may be contaminated by sewage water or contaminated by heavy minerals. | ➢ Unexpected intrusion of micro organism. | ➢ Tank should have suitable construction of RCC and tank must be checked on regular basis for any crack. | IQ & Qualification document | 4 | 1 | 1 | 4 Low category & Risk Accepted | Adequate procedure no recommendation required | NA | NA | NA | NA |

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| **4** | **Raw water** | ➢ Water stagnant in underground tank. | ➢ The water stagnant will raise the microbial content in the water. | ➢ Not a proper cleaning of underground raw water tank.<br>➢ No training provided to persons. | ➢ An online sodium hypochlorite dosing in water is considered with sampling points.<br>➢ During validation sanitization process and frequency has been established.<br>➢ SOP has been written, confirmed and implemented. | IQ & Qualification document | 4 | 1 | 1 | 4 Low category & Risk Accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| **5** | **Raw water tank** | ➢ Cleaning of underground storage tank is done on regularly. | ➢ After a long period of time the microbial and particulate contamination may be increased and the system may be inefficient to remove the increased microbial and particulate contamination. | ➢ No proper entry for cleaning in regular interval.<br>➢ No training provided to persons. | ➢ The tank has been provided with man entry for cleaning in regular interval.<br>➢ The SOP for cleaning has been prepared and the frequency of the cleaning established. | Qualification document | 3 | 1 | 1 | 3 Low category & Risk Accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| **6** | **Chlorine level** | ➢ Low chemical level in dosing tank. | ➢ Low level of chemical will not disinfect as per the requirement. | ➢ No proper quantity of chemical is in dosing tank.<br>➢ No level sensors are there for provide a low level of chlorine. | ➢ Level sensor has been provided in case of low level of chlorine in dosing tank. | IQ & Qualification document | 3 | 2 | 1 | 6 Low category & Risk Accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

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| 7 | **Chlorination of raw water** | ➢ Chlorination of raw water failure | ➢ Raw water Chemically & microbial contamination increases | ➢ Chlorine dosing system not working properly<br>➢ Chlorine dosing tank not cleaned<br>➢ SOP of chlorination of raw water not followed | ➢ Calibrated dosing pump is in used for chlorine dosing for checking its working efficiency.<br>➢ Chlorination of raw water is done as per its SOP.<br>➢ Training provided. | IQ & Qualification document | 4 | 2 | 1 | 8 Low category & Risk Accepted. | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 8 | **Cleaning of chlorinated raw water tank** | ➢ Chlorinated raw water tank Not Cleaned. | ➢ Chlorinated raw water tank chance to increased level of contamination. | ➢ Cleaning of raw water tank not done<br>➢ Personnel involved in operation lack of adequate knowledge<br>➢ SOP of cleaning of raw water tank not followed. | ➢ Cleaning of chlorinated water tank done on monthly basis.<br>➢ All involve persons are trained. | As per SOP | 4 | 1 | 1 | 4 Low category & Risk Accepted. | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 9 | **Multi grade filter** | ➢ Choking of the filters | ➢ Choking of the filters shall have no impact on the product quality.<br>➢ Choked filters can reduce the quantity of filtration. | ➢ Frequent removal of the filters.<br>➢ Suspended solid particles from Borewell can cause the choking of filters.<br>➢ Not proper washing of filter. | ➢ Multi grade filter has dismountable type for easy removal and installation.<br>➢ Installing of Pressure Gauge at the inlet of MGF and across the filter to detect the chock.<br>➢ Sampling Point has been provided at inlet and outlet.<br>➢ Backwash with high flow rate. | Qualification document | 3 | 2 | 1 | 6 Low category & Risk Accepted. | Adequate procedure no recommendation required. | NA | NA | NA | NA |

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| 10 | **Multi grade filter** | ➢ Microbial growth in filters. | ➢ It can be increase the level of microbes in raw water. | ➢ During non operation of the system the water hold up will be stagnant and Possibility for microbial growth. | ➢ Whole installation has been designed as complete drainable type to avoid such hold up and pressure Gauges are also installed.<br>➢ As the water is chlorinated the possibility of microbial growth is considerable less. | IQ & Qualification document | 4 | 1 | 1 | 4 Low category & Risk Accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 12 | **MGF Back Wash & rinse** | ➢ Multi-grade filter back wash & rinse Failure. | ➢ Suspended solids & dirt increases in raw water. | ➢ Back wash & rinse of multi-grade filter not done.<br>➢ Working personnel inadequate of knowledge.<br>➢ Back wash &rinse of multi-grade filter sop not followed. | ➢ Back wash & rinse of multi-grade filter done on daily basis as 24 hours once in time and the time duration is on automatic mode.<br>➢ Cleaning (back wash) is done as per sop by trained persons. | Qualification document | 3 | 3 | 1 | 9 Low category & Risk Accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 13 | **Softener Charging &rinsing** | ➢ Softener charging failure. | ➢ Hardness of raw water increased | ➢ Charging of softener & rinsing not done.<br>➢ Personnel doing softener charging inadequate knowledge.<br>➢ SOP for softener charging & rinsing not followed. | ➢ Charging of softener & rinsing done automatically after every 1440 min. as per the sop and done by trained person. | As per SOP | 3 | 2 | 1 | 6 Low category & Risk Accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

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| 14 | **Soft water storage tank cleaning & Sanitization** | ➢ Cleaning & sanitization of soft water storage tank not done | ➢ Chemical &microbial contamination level in soft water increased. | ➢ Cleaning & sanitization of soft water storage tank not done<br>➢ Working personnel lack of adequate knowledge<br>➢ Soft water storage tank cleaning& sanitization sop not followed. | ➢ Cleaning & sanitization of soft water storage tank done on monthly basis as per the sop and done by trained person. | Qualification document | 4 | 1 | 1 | 4 Low category & Risk Accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 15 | **UF cartridge filter (0.03µ ) pressurized** | ➢ UF cartridge filter choked or pressurized. | ➢ Required quantity of ultra filtered not available for normal operation of UF system.<br>➢ Suspended solid increased affected UF water quality.<br>➢ Leakage of UF system.<br>➢ Microbial contamination increases in UF water. | ➢ Replacement of cartridge filter not done.<br>➢ Working personnel lack of adequate knowledge.<br>➢ Monthly sanitization sop not followed.<br>➢ Daily basis cartridge filter pressure not checked Replacement of cartridge filter not done.<br>➢ Cartridge filter replacement sop not followed. | ➢ Replacement of cartridge filter done.<br>➢ Training provided.<br>➢ Monthly sanitization sop are followed.<br>➢ Daily basis cartridge filter pressure checked. | Qualification document | 4 | 3 | 1 | 12 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 16 | **UF system backwash & back flushing** | ➢ UF system backwash & back flushing failure | ➢ Back wash & flushing of UF system not done automatically by system. | ➢ Back wash & flushing of UF system automatically not done at interval of every 60 minutes during system in operation continuously.<br>➢ Working personnel lack of adequate knowledge | ➢ UF Back wash & flushing automatically done at interval of every 600 minutes during system in operation continuously.<br>➢ Training provided. | As per sop. | 3 | 3 | 1 | 9 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

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| 17 | **UF storage tank cleaning & sanitization** | ➢ Cleaning & sanitization of UF water storage tank not done. | ➢ Chemical & microbial contamination level in UF water storage increased. | ➢ Cleaning & sanitization of UF water storage tank not done<br>➢ Working personnel lack of adequate knowledge<br>➢ UF water storage tank cleaning & sanitization sop not followed. | ➢ Cleaning & sanitization of soft water storage tank done on monthly basis as per sop by the trained persons. | As per sop. | 3 | 1 | 1 | 6 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 18 | **SMBS Dosing system & storage tank cleaning** | ➢ Sodium meta bisulphate dosing system failure | ➢ Chlorine not removed from RO water.<br>➢ Excess Chlorine get damaged RO membrane | ➢ Sodium meta bi sulphite dosing pump not working<br>➢ SMBS dosing supply Interrupted.<br>➢ SMBS dosing pump not calibrated<br>➢ Working personnel lack of adequate knowledge.<br>➢ Cleaning of SMBS dosing not followed as per sop.<br>➢ Dosing of SMBS not followed as per sop | ➢ Sodium meta bi sulphite dosing pump working<br>➢ SMBS dosing supply daily basis checked & updated dosing system status.<br>➢ Training provided.<br>➢ Cleaning of SMBS dosing tank after consumption of solution on daily basis before freshly prepared dosing solution in dosing tank follow as per sop.<br>➢ Dosing of SMBS followed as per sop.<br>➢ ORP sensor provided after dosing. | As per SOP. | 3 | 3 | 2 | 18 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

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| **19** | **SMBS dosing** | ➢ Chlorine content high. | ➢ The chlorine content in water shall lead to oxidation of the RO membrane and hence shall affect the final water quality. | ➢ SMBS dosing supply Interrupted.<br>➢ SMBS dosing pump not calibrated<br>➢ ORP Sensor not provided or working. | ➢ The dosing unit has been provided for sodium meta-bi-sulfite (SMBS) addition to the water.<br>➢ The ORP sensor has been provided for monitoring the chlorine content of water with auto dump valve. | As per SOP & Qualification document | 3 | 2 | 1 | 6 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| **20** | **Anti Scalent dosing system &Cleaning** | ➢ Anti Scalent dosing system failure | ➢ Scaling of water increased in tube & RO water pipe line.<br>➢ Scaling causes microbial load increased frequently RO membrane get damaged with flow decline | ➢ Anti Scalent dosing pump not working<br>➢ Anti Scalent dosing supply Interrupted.<br>➢ Anti Scalent dosing pump not calibrated<br>➢ Working personnel lack of adequate knowledge.<br>➢ Cleaning of Anti Scalent dosing not followed as per sop.<br>➢ Dosing of Anti Scalent not followed as per sop | ➢ Anti Scalent dosing pump working.<br>➢ Anti Scalent dosing supply, Daily basis checked & updated dosing system status.<br>➢ Anti Scalent dosing pump calibrated as per schedule.<br>➢ Training provided.<br>➢ Cleaning of Anti Scalent dosing tank after consumption of solution on daily basis before freshly prepared dosing solution in dosing tank follow as per sop. | As per sop. | 3 | 1 | 1 | 3 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

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| 21 | **AUTO pH dosing system & cleaning** | ➢ Auto pH Dosing system failure | ➢ pH not maintained in RO water<br>➢ Excessive production of $CO_2$ in closed pipe line system. | ➢ Sodium hydroxide dosing pump not working.<br>➢ Sodium hydroxide dosing supply interrupted.<br>➢ Sodium hydroxide dosing pump not calibrated.<br>➢ Working personnel lack of adequate knowledge.<br>➢ Cleaning of Sodium hydroxide dosing not followed as per sop.<br>➢ Dosing of Sodium hydroxide not followed as per sop. | ➢ Sodium hydroxide dosing pump working.<br>➢ Sodium hydroxide dosing supply, Daily basis checked. &updated dosing system status.<br>➢ Sodium hydroxide dosing pump calibrated as per schedule.<br>➢ Training provided.<br>➢ Cleaning of Sodium hydroxide dosing tank after consumption of solution on daily basis before freshly prepared dosing solution in dosing tank follow as per Sop. | As per SOP & Qualification document | 4 | 3 | 1 | 12 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 22 | ➢ **5µ cartridge filter choked or pressurized** | ➢ 5µ cartridge filter choked or pressurized | ➢ Required quantity of water not available for normal operation of RO Pump.<br>➢ Suspended solid increased affected RO Feed water quality.<br>➢ Leakage of cartridge housing system<br>➢ Microbial contamination increases in RO water. | ➢ Replacement of cartridge filter not done<br>➢ Working personnel lack of adequate knowledge<br>➢ Monthly sanitization sop not followed<br>➢ Daily basis cartridge filter pressure not checked Replacement of cartridge filter not done<br>➢ Cartridge filter replacement sop not followed | ➢ Training provided.<br>➢ daily basis cartridge filter pressure monitoring in recorded<br>➢ Cartridge filter replacement sop followed. | As per SOP & Qualification document | 4 | 2 | 2 | 16 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

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| 23 | **RO high pressure pump low pressure** | ➢ ROHP Failure | ➢ Low pressure of water causing failure to start of ROHP pump. | ➢ ROHP interlocking system not working<br>➢ Working personnel lack of adequate knowledge.<br>➢ preventive maintenance not done as per schedule | ➢ ROHP interlocking system working<br>➢ working personnel provide training<br>➢ preventive maintenance done as per schedule | As per SOP & Qualification document | 3 | 3 | 1 | 9 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 24 | **RO membrane I & II pressurized /Chocked** | ➢ RO membrane Pressurized RO water flow very low output of water | ➢ Very low flow final out put volume of RO water decreases of purified water.<br>➢ RO water generation.<br>➢ Leakage of RO membrane system. | ➢ Required quantity of RO water not available.<br>➢ Pressure gauge not calibrated.<br>➢ Sanitization of RO membrane not done as per schedule.<br>➢ Microbial contamination increases in RO water.<br>➢ Interlocking system not working.<br>➢ Preventive maintenance not done as per schedule.<br>➢ Working personnel lack of adequate knowledge. | ➢ Replacement of RO membrane.<br>➢ Pressure gauge calibration done as per schedule.<br>➢ Result of microbial with in limit as per trending.<br>➢ Interlocking system Properly Working. | As per SOP & Qualification document | 3 | 3 | 2 | 18 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 25 | **Industrial RO Unit (RO-I & II)** | ➢ No provision for Sampling after RO | ➢ RO unit is required to generate process water, required for purified water Generation system. Water quality shall not be checked. | ➢ No sampling points provided for sampling after RO I & II.<br>➢ No Training provided to person.<br>➢ Sop for sampling is not followed. | ➢ Industrial RO unit has been provided where water is separated from dissolved salts in solution by filtering through a semi permeable membrane.<br>➢ Sampling point after RO has been provided. | As per SOP & Qualification document | 4 | 1 | 1 | 4 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

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| 26 | **Conductivity of RO System More than specified limit** | ➢ RO conductivity high | ➢ RO water conductivity increased finally chances to purified water conductivity raises manufacturing product may be degraded or detonated. | ➢ Conductivity sensor with monitor malfunctioning.<br>➢ Microbial load increased<br>➢ Sanitization of RO membrane not done as per schedule.<br>➢ Microbial contamination increases in RO water.<br>➢ Interlocking system failure<br>➢ Working personnel lack of adequate knowledge.<br>➢ Preventive maintenance not done as per schedule | ➢ On line conductivity monitored inbuilt in RO system<br>➢ Conductivity sensor Interlocking with HMI, dumping valve open do not feed RO water for EDI still within 5 minutes conductivity in range either RO plant tripped<br>➢ Calibrated conductivity monitor with sensor used for RO System.<br>➢ Sanitization of RO membrane done as per schedule.<br>➢ Microbial contamination increases in RO water.<br>➢ Interlocking system working properly.<br>➢ Preventive maintenance done as per schedule. | As per sop & IQ | 4 | 3 | 1 | 12 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 27 | **Industrial RO Unit (RO-I & II)** | ➢ Water quality fails at out let of RO+EDI unit. | ➢ Water quality didn't meet the specified conductivity. | ➢ RO conductivity high<br>➢ Working personnel lack of adequate knowledge.<br>➢ Preventive maintenance not done as per schedule | ➢ The water has been dumped and recalculated to soft water tank. | As per SOP & Qualification document | 3 | 3 | 1 | 9 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

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| 28 | **EDI feed pressure low** | ➢ EDI flow low | ➢ Very low flow final out put volume reduced of purified water.<br>➢ EDI Tripped within 5 minutes not maintained whole plant tripped.<br>➢ EDI drainage of concentrated more than specified amount. | ➢ EDI chocked or pressurized<br>➢ Pressure gauge not calibrated<br>➢ Sanitization of EDI membrane not done as per schedule.<br>➢ Microbial contamination increases in RO water.<br>➢ Pressure switch with Interlocking system not working.<br>➢ Preventive maintenance not done as per schedule.<br>➢ Working personnel lack of adequate knowledge. | ➢ Pressure gauge calibration done as per schedule.<br>➢ Result of microbial with in limit as per trending.<br>➢ Interlocking system Properly Working. | As per SOP & Qualification document | 3 | 3 | 1 | 9 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 29 | **EDI** | ➢ Various process parameters like pH, conductivity, flow rate, TOC are not monitored.<br>➢ Sampling not done after EDI. | ➢ Critical GMP process parameter water quality shall not be checked | ➢ Sampling point after EDI not provided.<br>➢ EDI didn't have provision to monitor the check parameters. | ➢ The unit has been provided with the Provision for monitoring, indicating and controlling the pH, conductivity and flow rate of water.<br>➢ Sampling point after EDI has been provided.<br>➢ Sampling done as per schedule. | As per SOP & Qualification document | 4 | 3 | 1 | 12 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

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| 30 | **EDI conductivity more than Specified limit** | ➢ EDI conductivity high | ➢ Pharmaceutical Product degraded or Detiorated. | ➢ EDI Conductivity sensor with monitor malfunctioning.<br>➢ Microbial load increased<br>➢ Sanitization of EDI not done as per schedule.<br>➢ EDI conductivity interlocking system failure.<br>➢ Working personnel lack of adequate knowledge.<br>➢ Preventive maintenance not done as per schedule. | ➢ EDI conductivity sensor with monitor calibrated working properly daily basis operation checked.<br>➢ EDI conductivity Interlocking system working properly with auto dumping valve facility controlled by HMI.<br>➢ Working personnel lack of adequate knowledge.<br>➢ Preventive maintenance Done as per schedule<br>➢ Training provided | As per SOP & Qualification document | 4 | 2 | 1 | 8 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 31 | **Purified water Storage Tank** | ➢ No storage of purified water before use. | ➢ The water quality shall not be affected if not stored.<br>➢ It is difficult for providing several user points from the single point of generation. | ➢ Un-availability of purified water storage tank. | ➢ The generated purified water has been stored in a storage tank (purified water storage tank). | As per SOP & Qualification document | 3 | 1 | 1 | 3 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 32 | **Purified water Storage Tank** | ➢ Low water level in the storage tank. | ➢ The water level shall not affect the water quality.<br>➢ No water in the tank, the Pump will run dry. It may lead to damage the pump and affect the process. | ➢ Manual observation of the water level is difficult. | ➢ The storage tank has been provided with level sensor for water low & high level. | As per SOP & Qualification document | 3 | 1 | 1 | 3 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

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| | | | | | | | | | | | | S | O | D | RPN S*O*D |
| 33 | **Purified water storage tank & loop sanitization** | ➢ Purified water storage & Distribution system sanitization failure | ➢ Microbial ,chemical contamination increases<br>➢ Germs increases in purified water<br>➢ Pharmaceutical product may be degraded or decay earliest before expiry | ➢ Plant steam required pressure not maintained regularly during system sanitization<br>➢ Sanitization temperature & time duration not maintained.<br>➢ Sanitization process interrupted as utility failure<br>➢ Temperature sensor mal functioning<br>➢ Sanitization properly not done as schedule de frequency<br>➢ Storage & distribution system required temperature not achieved during time for sanitization.<br>➢ Conductivity may be increased<br>➢ Working personnel lack of adequate knowledge.<br>➢ Purified water storage & distribution system leakage.<br>➢ Preventive maintenance not done as per schedule. | ➢ As required plant Steam pressure are available for sanitization<br>➢ Sanitization temperature & time duration maintained as required for sanitization<br>➢ Time of sanitization process no any long time utility failure<br>➢ Temperature sensor calibrated as per schedule.<br>➢ Sanitization done properly as per mentioned schedule as frequency monthly<br>➢ Storage & distribution system Sanitization temperature maintained.<br>➢ On line Conductivity sensor in return loop calibrated as per schedule<br>➢ No any leakage found in system | As per SOP & Qualification document | 5 | 2 | 1 | 10 Medium category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 34 | **Purified water storage tank vent filter integrity** | ➢ Vent filter integrity failure | ➢ Microbial contamination<br>➢ Tank over pressurized | ➢ Filter integrity testing not done as per schedule.<br>➢ Handling of vent filter not properly<br>➢ Vent filter choked<br>➢ Working personnel lack of adequate knowledge. | ➢ Additional integrity tested filter available<br>➢ Handling of vent filter properly wrapped in Alu- foil.<br>➢ Training provided<br>➢ Before installed at tank integrity has been tested/checked. | As per SOP & Qualification document | 4 | 2 | 1 | 8 Medium category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

# FAILURE MODE EFFECT ANALYSIS FOR PURIFIED WATER GENERATION & DISTRIBUTION SYSTEM

| S.No. | Item/ Function | Potential Failure Mode (Failure Mode ) | Potential Effect of Failure (Effect) | Potential Cause/ Mechanism of Failure | Current Control | Reference | S | O | D | Risk Priority Number (S*O*D) | Recommend-ended Actions (if any) | Post Risk | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN S*O*D |
| 35 | **Purified water Return loop conductivity more** | ➢ Return loop conductivity More | ➢ Chemical Contamination<br>➢ Pharmaceutical product may be degraded or decay earliest before expiry | ➢ Malfunctioning of Conductivity sensor.<br>➢ Microbial load may be increased.<br>➢ Sanitization of purified return loop not done as per schedule.<br>➢ Return loop auto dumping valve not working as per Interlocking system.<br>➢ Working personnel lack of adequate knowledge.<br>➢ Preventive maintenance not done as per schedule. | ➢ Conductivity sensor of purified water return loop line are Calibrated as per schedule.<br>➢ Sanitization of purified water loop done as per schedule monthly.<br>➢ Return loop conductivity raises auto dumping valve effectively working as open still after 300 sec. finally entire system tripped.<br>➢ Training provided | As per SOP & Qualification document | 5 | 2 | 1 | 10 Medium category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 36 | **Purified water return loop flow OR loop velocities** | ➢ Purified water return loop flow OR velocities Loop failure/not maintained. | ➢ Microbial load may be increases.<br>➢ May be Chances of Loop proliferation<br>➢ Turbulent flow failure in loop<br>➢ Product may be degraded before shelf life | ➢ Loop Purified Pump water flow not full fill as per requirement.<br>➢ Pipe size more than Pipe nominal size as per DQ Not maintained. | ➢ Product handling SOP to be followed. | As per SOP & Qualification document | 3 | 2 | 1 | 6 Medium category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 37 | **Purified water supply loop line UV lamp failure/low intensity** | ➢ Purified water supply loop line UV lamp failure/low intensity | ➢ Microbial ,chemical contamination increases<br>➢ Germs increases in purified water<br>➢ Pharmaceutical product may be degraded or decay earliest before expiry | ➢ UV monitor & sensor malfunctioning<br>➢ UV meter not calibrated<br>➢ Preventive maintenance not done as per schedule.<br>➢ Burning hour completion<br>➢ Alarming system not work system interlocking.<br>➢ Working personnel lack of adequate knowledge. | ➢ UV sensor/monitor system calibrated used.<br>➢ 12000 hour completion/either low intensities.<br>➢ Alarming system work as lamp failure & low intensity.<br>➢ All related Working personnel, Training provided. | As per SOP & Qualification document | 4 | 2 | 1 | 8 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

# FAILURE MODE EFFECT ANALYSIS FOR PURIFIED WATER GENERATION & DISTRIBUTION SYSTEM

| S.No. | Item/ Function | Potential Failure Mode (Failure Mode ) | Potential Effect of Failure (Effect) | Potential Cause/ Mechanism of Failure | Current Control | Reference | S | O | D | Risk Priority Number (S*O*D) | Recommend-ended Actions (if any) | Post Risk | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN S*O *D |
| 38 | **Purified water distribution** | ➢ Water stagnancy in the distribution line to different user Points.<br>➢ No sampling point provided. | ➢ Water contamination may increase due to the bio-load in the distribution line to different user points. | ➢ Sampling point is not provided in loop and user points.<br>➢ Removal of stagnant water each time before use shall be very difficult. | ➢ The water distribution has been in a loop system. The water has in continuous flow in the loop.<br>➢ All pipelines have drainable slope of > 1:100.<br>➢ The dead leg in the loop has been more than 1.5d. (d- diameter of the extended part) Sampling points has been provided at return loop and all user points. | As per SOP & Qualification document | 4 | 1 | 1 | 4 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |
| 39 | **Purified water distribution** | ➢ Bio-film formation in the pipe. | ➢ It can cause a contamination to the product. | ➢ Flow rate in the loop is low & Low flow rate tends to Bio-film formation in the pipe. | ➢ Specified flow rate has been maintained in the loop at supply and return line.<br>➢ Flow switch has been considered on the return line with VFD connection to the distribution pump. | As per SOP & Qualification document | 5 | 2 | 1 | 10 Low category and Risk accepted | Adequate procedure no recommendation required. | NA | NA | NA | NA |

**Where: S=Severity; O=Occurrence Probability; D=Detection**

**Remarks (if any):-**

# FAILURE MODE EFFECT ANALYSIS FOR PURIFIED WATER GENERATION & DISTRIBUTION SYSTEM

| Quality Risk Management Team | | | Reviewed By<br>Head Operations<br>Sign & Date | Approved By<br>Head QA<br>Sign & Date |
|---|---|---|---|---|
| **Name** | **Department** | **Sign & Date** | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

## QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

| **Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation: Purified water generation & distribution system** | | Date: | |
|---|---|---|---|
| **S. No.** | **Recommended Action** | **Responsible Person** | **Target Date of Completion** |
| 1. | | | |
| 2. | | | |

**Verification of Action Plan:**
All the above agreed actions completed, Not Completed.
(*incase any recommendations not completed, to be tracked through CAPA System)

**Remarks (if any):** NA

**Verified By**
**QA**
**Sign & Date**

**Approved By**
**Head QA**
**Sign & Date**