RISK ANALYSIS STUDY PROTOCOL FOR EXTENDING & DISCONTINUATION OF SAMPLING FREQUENCY OF SAMPLING & USER POINTS OF PURIFIED WATER

RISK ANALYSIS STUDY PROTOCOL FOR EXTENDING & DISCONTINUATION OF SAMPLING FREQUENCY OF SAMPLING & USER POINTS OF PURIFIED WATER

DATE OF RISK ANALYSIS	
SUPERSEDE PROTOCOL No.	**NIL**

RISK ANALYSIS STUDY PROTOCOL FOR EXTENDING & DISCONTINUATION OF SAMPLING FREQUENCY OF SAMPLING & USER POINTS OF PURIFIED WATER

PROTOCOL CONTENTS

RISK ANALYSIS STUDY PROTOCOL FOR EXTENDING & DISCONTINUATION OF SAMPLING FREQUENCY OF SAMPLING & USER POINTS OF PURIFIED WATER

1.0 PROTOCOL APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

RISK ANALYSIS STUDY PROTOCOL FOR EXTENDING & DISCONTINUATION OF SAMPLING FREQUENCY OF SAMPLING & USER POINTS OF PURIFIED WATER

2.0 OBJECTIVE:

- To provide documented evidence that there is no risk in extending& discontinuation of sampling frequency of sampling & User points of Purified Water.

3.0 SCOPE:

- This risk analysis study Protocol is applicable for performing risk analysis study for extending frequency of Sampling points & User points of Purified Water.

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4.0 RESPONSIBILITY:

Department	Responsibility
Quality Assurance	• Shall prepare & Review the Risk analysis Protocol. • Execution of the Risk analysis Protocol with Production and Quality Control. • Shall compile the data & Prepare Summary Report • Risk analysis Protocol shall be approved by the QA prior the execution. • Shall review the executed Protocol to check the compliance and corrective action for any discrepancies found. Also shall prepare the summary and conclusion of the Risk analysis Study.
Quality Control	• Reviewing of Risk analysis Protocol for Correctness, Completeness and Technical Excellence. • Post approval of Risk analysis Protocol after Execution.
Production	• Reviewing of Risk analysis Protocol for Correctness, Completeness and Technical Excellence. • To provide support for execution of Risk analysis Study as per Protocol. • Post approval of Risk analysis Protocol after execution.

5.0 REASON FOR RISK ANALYSIS:

To evaluate the risk in extending & discontinuation of sampling frequency of Sampling & user points of Purified Water.

6.0 SITE OF STUDY:

Manufacturing area (Granulation/Compression/Coating and Packing) floor, Q-block (Ointment Section & Liquid Section) & I Block manufacturing area.

7.0 RISK COMMUNICATION & TRAINING:

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

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8.0 RISK IDENTIFICATION & EVALUATION:

- There are 02 Purified Water Generation & Distribution System.
- Detail given below:

System	**Purified Water Generation & Distribution System 01**		**Purified Water Generation & Distribution System 02**	
Capacity	**3 KL**		**5 KL**	
Loop	Loop 01	QC & I-Block	Loop 04	Ointment Section, FFS, Ampoule, MCDP & Store
	Loop 02	Granulation &Softgel Section	Loop 05	F-Block
	Loop 03	Coating & Packing	Loop 06	Coating, Granulation & Three Piece Line
Sampling Points	13 Nos.		13 Nos.	
User Points	76 Nos.		49 Nos.	

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9.0 RISK MITIGATION:

- Sampling planner to be revised.
- Daily monitoring to be redefined.

10.0 RISK ANALYSIS, RE-RISK ANALYSISCRITERIA:

10.1 Failure Mode Effect Analysis:

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

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

Table 1: Instruction for each column given above

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FACILITY: EXTENDING &DISCONTINUATION OF SAMPLING FREQUENCY OF SAMPLING & USER POINTS FOR ANALYSIS (FOR PURIFIED WATER)

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
1.	**Sampling points frequency extension & Discontinuation in Generation System**	Microbial contamination may occur	Microbial count may increase	• Bio-burden failure	• Monthly sanitization • Vent filter integrity • Qualification done for 03 phases. • UV installed in Generation.	• "Sanitization of Purified water Generation & Distribution system"(SOP . • Filter integrity testing • Water System Validation. • Performance Qualification report.	4	3	1	12	NA	NA	NA	NA	NA
		Bio-burden in water increases	Pathogen enhancement	• MLT failure	• Monthly sanitization • Vent filter integrity. • Qualification done for 03 phases.	• "Sanitization of Purified water Generation & Distribution system" (SOP. • Filter integrity testing. • Water System Validation. • Performance Qualification report.	4	3	1	12	NA	NA	NA	NA	NA
		Chemical impurities enhances in products	Unwanted impurity increases	• Contamination	• Conductivity meter installed. • Qualification done for 03 phases.	• Operational Qualification report. • Performance Qualification report.	5	2	3	30	Trend of online Conductivity to be monitored regularly	5	2	1	10
		Description failure	Unwanted impurity increases	• Contamination	• Chemical & Microbial analysis done for Generation Supply & Return loop on daily basis • Qualification done for 03 phases.	• Water Trend. • Performance Qualification report.	5	2	3	30	Trend of online Conductivity to be monitored regularly	5	2	1	10
		Conductivity failure	Increase in ions due to impurity.	• Oxidation-Reduction reaction takes place	• Alarm system in SCADA. • Auto dumping valve. • Qualification done for 03 phases.	• Operational Qualification report. • Performance Qualification report.	5	3	1	15	NA	NA	NA	NA	NA

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S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
		TOC failure	Bio-burden results into increase in carbon	•Carbon value increases in batch	• Chemical & Microbial analysis done for Generation Supply & Return loop on daily basis. • Qualification done for 03 phases.	• Water Trend. • Performance Qualification report.	3	3	1	9	NA	NA	NA	NA	NA
		Acidity/Alkalinity failure	Imbalance in pH	Batch failure	• Chemical & Microbial analysis done for Generation Supply & Return loop on daily basis • Qualification done for 03 phases.	• Water Trend. • Performance Qualification report.	3	1	1	3	NA	NA	NA	NA	NA
2.	**Sampling points frequency extension & Discontinuation in Distribution System**	Microbial Contamination may occur in Production batches	Degradation of products	•Batches may fail in bio-burden	• Monthly sanitization • Vent filter integrity • Qualification done for 03 phases.	• "Sanitization of Purified water Generation & Distribution system" SOP. • Filter integrity testing. • Water System Validation. • Performance Qualification report.	4	3	1	12	NA	NA	NA	NA	NA
		Bio-burden in water increases	Pathogen enhancement	• Bio-burden failure	• Monthly sanitization • Vent filter integrity. • Qualification done for 03 phases.	• "Sanitization of Purified water Generation & Distribution system" SOP • Filter integrity testing. • Water System Validation. Performance Qualification report.	4	3	1	12	NA	NA	NA	NA	NA
		Chemical impurities enhances in products	New Impurity development	Contamination	• Conductivity meter installed. • Qualification done for 03 phases.	• Operational Qualification report. • Performance Qualification report.	5	2	3	30	Trend of online Conductivity to be monitored regularly	5	2	1	10

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S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
		Description failure	Unwanted impurity increases	•Resulting into failure of product description	•Chemical & Microbial analysis done for Generation Supply & Return loop on daily basis •Qualification done for 03 phases.	• Water Trend. • Performance Qualification report.	5	2	3	30	Trend of online Conductivity to be monitored regularly	5	2	1	10
		Conductivity failure	Increase in ions due to impurity.	• Oxidation-Reduction reaction takes place	•Alarm system in SCADA. • Auto dumping valve •Qualification done for 03 phases.	•Operational Qualification report. • Performance Qualification report.	5	3	1	15	NA	NA	NA	NA	NA
		TOC failure	Bio-burden results into increase in carbon	•Carbon value increases in batch	•Chemical & Microbial analysis done for Generation Supply & Return loop on daily basis •Qualification done for 03 phases.	• Water Trend. • Performance Qualification report.	3	3	1	9	NA	NA	NA	NA	NA
		Acidity/Alkalinity failure	Imbalance in pH	•Change in finished product property	•Chemical & Microbial analysis done for Generation Supply & Return loop on daily basis •Qualification done for 03 phases.	• Water Trend. •Performance Qualification report.	3	1	1	3	NA	NA	NA	NA	NA
3.	**Operational parameters at Generation System**	Online Conductivity Meter failure	Increase in ions due to impurity.	•Oxidation-Reduction reaction takes place resulting into product degradation	•Alarm in SCADA. •Auto dumping starts •Off line conductivity verification of supply & return line on daily basis. •Qualification done for 03 phases.	•Operational Qualification report. • Performance Qualification report.	5	3	1	15	NA	NA	NA	NA	NA
		Auto pH adjustment with ORP failure	pH may imbalance	•Change in finished product property resulting into product degradation	•Alarm in SCADA •Plant will shut down as pH is out of limit. •Qualification done for 03 phases.	•Operational Qualification report. •Performance Qualification report.	5	3	1	15	NA	NA	NA	NA	NA
		UV lamp failure	Microbial count increases	•MLT failure	•Alarm in SCADA •Auto dumping •Qualification done for 03 phases.	•Operational Qualification report. •Performance Qualification report.	5	3	1	15	NA	NA	NA	NA	NA

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S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
4.	**Operational parameters at Distribution System**	Online Conductivity Meter failure	Increase in ions due to impurity.	• Oxidation-Reduction reaction takes place resulting into product degradation	• Alarm in SCADA. • Auto dumping starts • Off line conductivity verification of supply & return line on daily basis. • Qualification done for 03 phases.	• Operational Qualification report. • Performance Qualification report.	5	3	1	15	NA	NA	NA	NA	NA
		UV lamp failure	Microbial count increases	• MLT failure	• Alarm in SCADA • Auto dumping. • Qualification done for 03 phases.	• Operational Qualification report. • Performance Qualification report.	5	3	1	15	NA	NA	NA	NA	NA

Table 2: The above table shows Potential failure mode, effect of potential failure along with Risk Probable Number, Risk Mitigation & Recommended Actions.

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

Risk Priority Number (RPN)	Risk levels
Upto 25	**Low**
26-50	**Medium**
51 to ≤ 125	**High**

RPN = Severity x Occurrence x Detection

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11.0 CONCLUSION:

Risk analysis data shall be written on Risk Analysis Study Report for extending the Sampling points & user points of Purified Water, clearly stating the achievement or non-compliance of the acceptance criteria, effect of the deviations made during the Risk analysis and in case of failure, investigation carried out and their findings.

12.0 RECOMMENDATION:

Recommendation shall be written on the Risk Analysis Study Report for extending the Sampling points & user points of Purified Water, clearly stating that there is no impact/adverse impact on the product quality & personnel can be/can`t be merged under recommended environmental conditions.

13.0 REFERENCES:

SOP **"Quality Risk Management".**

14.0 DOCUMENTS TO BE ATTACHED:

- Training Record.
- Reference SOP.

15.0 DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

Deviations from pre-defined procedures & specification during extending the frequency of analysis of Purified water shall be investigated in accordance with CQA SOP **"Handling of Deviations"**, **SOP** and shall be documented in the Risk analysis report.

16.0 CHANGE CONTROL, IF ANY:

Change control during extending the frequency of Purified water analysis shall be authorized in accordance with CQA SOP **"Change Control"** and shall be documented in the Risk analysis report.

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17.0 ABBREVIATIONS:

FMEA : Failure Mode Effect Analysis
GMP : Good Manufacturing Practices
RPN : Risk Priority Number

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18.0 Annexure:

Annexure I

Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
Purified Water Generation System	Before Ultra Violet		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/ validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. All parameters has been verified online in SCADA during generation of Purified Water.
Purified Water Generation System	After Ultra Violet		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. All parameters have been verified online in SCADA during generation of Purified Water.
Purified Water Generation System	Before Conductivity		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. All parameters have been verified online in SCADA during generation of Purified Water.
QC Laboratory	Hot Zone Area		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is to be used for Chemical testing only; hence increase in the bio-load had no impact on product quality.
QC Laboratory	Washing Area		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
					all 03 qualification/ validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is to be used for Chemical testing only; hence increase in the bio-load had no impact on product quality.
QC Laboratory	Dissolution Area		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/ validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is to be used for Chemical testing only; hence increase in the bio-load had no impact on product quality.
QC Laboratory	Dissolution Area		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/ validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is to be used for Chemical testing only; hence increase in the bio-load had no impact on product quality.
QC Laboratory	Dissolution Washing Area		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/ validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is to be used for Chemical testing only; hence increase in the bio-load had no impact on product quality.
QC Laboratory	Dissolution Washing Area		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/ validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is to be used for Chemical testing only; hence increase in the bio-load

RISK ANALYSIS STUDY PROTOCOL FOR EXTENDING & DISCONTINUATION OF SAMPLING FREQUENCY OF SAMPLING & USER POINTS OF PURIFIED WATER

Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
					had no impact on product quality.
Micro Laboratory	Autoclave		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Purified water of this point is used for generation of steam for Autoclave purpose. Hence had no critical value in terms of bio-burden.
I block DPI	Garment Room		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is to be used for washing purpose only; hence increase in the bio-load had no impact on product quality. Prior to use all the garments are autoclaved & sterilized by UV also.
I block DPI	Janitor Room		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is to be used for area cleaning only (D Grade), increase in the bio-load had no impact on product quality as area is cleaned by disinfectant (Lysol/Virosil/ Dettol).
I block DPI	Janitor Room		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is to be used for area cleaning only (D Grade), increase in the bio-load had no impact on product quality as area is cleaned by disinfectant (Lysol/Virosil/ Dettol).

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
I block DPI	Unit Preparation Room		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is used in Autoclave for bung sterilization, garment sterilization & accessories sterilization only, As Bung Processor runs at 121.4°C for 30 minutes remaining water got sterilized, hence no impact on product quality.
I block DPI	Utensil Room		**Weekly**	**Monthly**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is used for machine accessories cleaning, these cleaned utensils are then sterilized for further use. As water comes in direct contact of accessories hence can be tested monthly.
I block DPI	Vial Washing Area		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is used for vial washing, these washed vials are then transferred to depyrogenation tunnel for sterilization, hence no need for analysis.
I Block 2nd Floor	PSG (Pure Steam Generator)		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is used in generation of Pure Steam used for Bung Processor, CIP, SIP & Terminal Sterilizer. All these process works itself on

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
					Sterilizing principle, hence no impact on product quality. So point can be discontinued.
I Block 2nd Floor	MCDP(Multi-column Distillation Plant)		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is used in generation of wfi used for Manufacturing. MCDP works itself on Sterilizing principle & produce pyrogen free wfi hence no impact on product quality. So point can be discontinued.
Q.C Laboratory	Hot Zone Area		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is used for washing of glasswares only, hence no impact on product quality.
Q.C Laboratory	Chemical Section Room		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is used for washing of glasswares only, hence no impact on product quality.
Q.C Laboratory	Dissolution Room		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is used for washing of glasswares only, hence no impact on product quality.
Q.C Laboratory	Glass Ware Washing Room		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
					consistent & within trend. Water is used for washing of glasswares only, hence no impact on product quality.
Q.C Laboratory	Chemical Section Room		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is used for washing of glasswares only, hence no impact on product quality.
Q.C Laboratory	Dissolution Room		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is used for washing of glasswares only, hence no impact on product quality.
Q.C Laboratory	HPLC Sample Preparation Room		**Weekly**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. Water is used for washing of glasswares only, hence no impact on product quality.
	Before Ultra Violet		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. All parameters have been verified online in SCADA during generation of Purified Water.
	After Ultra Violet		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. All parameters have been verified online in SCADA during generation of Purified Water.

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
	Return Loop (Before Conductivity)		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. All parameters have been verified online in SCADA during generation of Purified Water.
General Block	Gr-01 Equipment Washing		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no chance of microbial growth in the distribution line, while there is a chance of cross contamination in user points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
	Gr-01 Paste Preparation Room		**Monthly**	**Once in a month**	Sampling point is critical as the water is directly used in formulation hence after certain period an evaluation should be done.
	Gr-02 Equipment Washing		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no chance of microbial growth in the distribution line, while there is a chance of cross contamination in user points but during qualification the tip & surrounding of

RISK ANALYSIS STUDY PROTOCOL FOR EXTENDING & DISCONTINUATION OF SAMPLING FREQUENCY OF SAMPLING & USER POINTS OF PURIFIED WATER

Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
					the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
	Gr-02 Paste Preparation Room		**Monthly**	**Once in a month**	Sampling point is critical as the water is directly used in formulation hence after certain period an evaluation should be done.
General Block	Gr-03 Equipment Washing		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no chance of microbial growth in the distribution line, while there is a chance of cross contamination in user points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
	Gr-03 Paste Preparation Room		**Monthly**	**Once in a month**	Sampling point is critical as the water is directly used in formulation hence after certain period an evaluation should be done.
	Gr-05 Equipment Washing		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no chance of microbial growth in the distribution line, while there is a chance of cross contamination in user

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
					points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
	Gr-05 Paste Preparation Room		**Monthly**	**Once in a month**	Sampling point is critical as the water is directly used in formulation hence after certain period an evaluation should be done.
General Block	Gr-06 Equipment Washing		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no chance of microbial growth in the distribution line, while there is a chance of cross contamination in user points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
	Gr-06 Paste Preparation Room		**Monthly**	**Once in a month**	Sampling point is critical as the water is directly used in formulation hence after certain period an evaluation should be done.
	Gr-07 Equipment Washing		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no chance of microbial growth in the distribution line,

RISK ANALYSIS STUDY PROTOCOL FOR EXTENDING & DISCONTINUATION OF SAMPLING FREQUENCY OF SAMPLING & USER POINTS OF PURIFIED WATER

Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
					while there is a chance of cross contamination in user points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
	Gr-07 Paste Preparation Room		**Monthly**	**Once in a month**	Sampling point is critical as the water is directly used in formulation hence after certain period an evaluation should be done.
General Block	Gr-08 Equipment Washing		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no chance of microbial growth in the distribution line, while there is a chance of cross contamination in user points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
General Block	Gr-08 Paste Preparation Room		**Monthly**	**Once in a month**	Sampling point is critical as the water is directly used in formulation hence after certain period an evaluation should be done.
	Gr-09 Equipment Washing		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
					chance of microbial growth in the distribution line, while there is a chance of cross contamination in user points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
	Gr-09 Paste Preparation Room		**Monthly**	**Once in a month**	Sampling point is critical as the water is directly used in formulation hence after certain period an evaluation should be done.
	Gr-10 Equipment Washing		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no chance of microbial growth in the distribution line, while there is a chance of cross contamination in user points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
General Block	Gr-10 Paste Preparation Room		**Monthly**	**Once in a month**	Sampling point is critical as the water is directly used in formulation hence after certain period an evaluation should be done.
	Washing Area		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
					has been observed during qualification, so there is no chance of microbial growth in the distribution line, while there is a chance of cross contamination in user points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
	Filter Washing Area		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Washing Area		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no chance of microbial growth in the distribution line, while there is a chance of cross contamination in user points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
General Block	Medicament Area		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Gelatin		**Monthly**	**Once in a**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
				month	has been observed in all 03 phases. All phases results are consistent & within trend.
	Washing Area (Ground)		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no chance of microbial growth in the distribution line, while there is a chance of cross contamination in user points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
General Block	Washing Area		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no chance of microbial growth in the distribution line, while there is a chance of cross contamination in user points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
	Before Ultra Violet		**Monthly**	**Once in a**	Sampling point is not critical as the sampling is done for

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
Purified Water Generation System				**month**	all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. All parameters have been verified online in SCADA during generation of Purified Water.
	After Ultra Violet		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. All parameters have been verified online in SCADA during generation of Purified Water.
	Before Conductivity		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. All parameters have been verified online in SCADA during generation of Purified Water.
General Block	Coating Area-01		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Coating Area-02		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Solution Preparation Room		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
General Block	Coating Area-03		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
					been observed in all 03 phases. All phases results are consistent & within trend.
	Washing Area		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. As the water system is continuous and has a flow of 4.2 m^3/hr & no dead leg has been observed during qualification, so there is no chance of microbial growth in the distribution line, while there is a chance of cross contamination in user points but during qualification the tip & surrounding of the point is sanitized by 70% IPA and it has no impact on washing as the washing is done in D Class environment, hence there is no chance of contamination during distribution. So the mentioned user point can be discontinued.
	Coating Area-04		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Solution Preparation Room		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Coating Area-05		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Coating Area-06		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
General Block	Coating Area-07		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Coating Area-08		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Coating Area-09		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Coating Area-10		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Coating Area-11		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Coating Area-12		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Coating Area-13		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Coating Area-16		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
General Block	Coating Area-15		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Coating Area-14		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Washing Area		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	IPQA Room (Adjacent to Rubber Stereo Room)		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Filter Washing Area		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Washing Area		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	IPQA Area		**Monthly**	**Once in a month**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Before Ultra Violet		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. All parameters have been

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
					verified online in SCADA during generation of Purified Water.
General Block	After Ultra Violet		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend. All parameters have been verified online in SCADA during generation of Purified Water.
	Garment Wash Room		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	CIP/SIP Room		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Unit Preparation & Sterilization Room		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Equipment Washing Sterilization		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Ampoule Washing & Sterilization		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Leak Test & Terminal Sterilization		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
General Block	FFS line		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Equipment Washing		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	MCDP Line		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	PSG Line		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	USER POINT (SPARE)		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Washing room		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Janitor Room		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Washing Room		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
	IPQA room		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Janitor Room		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	IPQA room		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Washing room		**After every 15 days**	**Discontinued**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
WFI (I Block)	In return loop line before conductivity		**After every 15 days**	**Six months**	Sampling point is not critical as the sampling is done for supply & return loop for all 03 qualification/ validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Disinfectant preparation Room (DPI)		**After every 15 days**	**Six months**	Sampling point is not critical as the sampling is done for preparation of disinfectant and all 03 qualification/ validation phases have been completed. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Equipment Washing room (DPI)		**After every 15 days**	**Six months**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. Water is used for washing purpose only. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
	Unit Preparation room (DPI)		**After every 15 days**	**Six months**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. Water is used for Autoclave purpose. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Vial Washing & Sterilizing room (DPI)		**After every 15 days**	**Six months**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. Water is used for vial washing, finally washed vials were sterilized. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Garment Washing room (TP)		**After every 15 days**	**Six months**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	CIP/SIP (TP)		**After every 15 days**	**Six months**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Manufacturing 2 (TP)		**After every 15 days**	**Six months**	Sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Filtration 1(TP)		**After every 15 days**	**Six months**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Filtration 2 (TP)		**After every 15 days**	**Six months**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.

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Location	Sampling point details	Sampling point & user point	Existing sampling frequency	Proposed Frequency of Sampling	Justification
	Equipment Wash (TP)		**After every 15 days**	**Six months**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.
	Disinfectant room (TP)		**After every 15 days**	**Six months**	Sampling point is not critical as the sampling is done for all 03 qualification/validation phases. No deviation has been observed in all 03 phases. All phases results are consistent & within trend.