PERFORMANCE QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

Signing of this Performance Qualification Protocol indicates agreement with the Validation Master Plan approach of the equipment. Further if any changes in this protocol are required, protocol will be revised and duly approved.

PREPARED BY:

Organization	Name	Designation	Signature	Date

CHECKED BY:

Organization	Name	Designation	Signature	Date

APPROVED BY:

Organization	Name	Designation	Signature	Date

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1 OBJECTIVE

The objectives of this Performance Qualification (PQ) are as follows:

- To verify that the equipment performs in accordance with the design and user requirements as defined by set acceptance criteria and complies with relevant cGMP requirements.
- To demonstrate that the system will perform reproducibly and consistently within its operating range

Following execution of the protocol a summary report will be written and approved. All results, conclusions, exceptions and variances will be addressed and final disposition of the equipment will be stated. Successful completion of this protocol and approval of the summary report will verify that the Purified Water Generation System meets all the acceptance criteria and is ready for GMP use.

2 SCOPE

This protocol covers all aspects of Performance Qualification for the Purified Water Generation System serving the .....Tablets, Capsules and Liquid Orals Manufacturing Facility. Scope incorporates qualification of all Purified Water Generation components from Feed water inlet, upstream of Sample valve SV1, up to and including Product three way diverter valve V44 in the water treatment stream and oil free filtered Instrument air downstream of V32.
This protocol will define the methods and documentation used to qualify the Purified Water Generation System.

3 RESPONSIBILITIES

..... are ultimately responsible for the qualification of GMP relevant equipment regardless of whether such work is performed by .....staff or contract / consulting staff.
All work is to be performed under .....over site and according to approved procedures.
Engineering Validation Personnel
The following are the responsibilities of Engineering Validation Personnel:

- Writes the protocol using the approved template.
- Ensures that the protocol is in compliance with current policies and procedures.
- Ensures that the content is sufficient, clearly defined technically sound and accurate.
- Ensures compliance with design specifications.
- Submits the draft protocol for review.
- Makes any necessary corrections to the protocol and answers queries from the reviewers
- Submits the corrected protocol for approval.

Validation Personnel
The following are the primary responsibilities of the Validation Personnel:

- Overall CGMP compliance for Qualification
- Review and Pre-Approval of this Protocol
- Issue of controlled copies of the protocol for execution
- Execution of this PQ protocol
- Document Control of this PQ Protocol until such document is completed, approved and after.
- Review and Approval of the executed PQ Protocol
- Training (contract staff) and documentation of training for any procedures required for execution of the PQ.

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4 SYSTEM DESCRIPTION

The Purified water generation system is fed by Chlorinated soft water complying with BIS Standards as filtered through 5.0 µ cartridge filter to control SDI. The quantity of the free chlorine in Feed water shall be kept within 0.02 ppm by SMBS dosing before entering to Purified Water Generation Skid. The Purified Water Generation System shall produce Purified water in compliance with current USP 28, at flow rate of 4 m^3/hour and pressure of < 1.5 bar. Pre conditioning skid consists of heat exchanger, SMBS dosing and NaOH dosing which controls temperature, Conductivity and pH of water respectively. Feed to the purified water system shall be at 7.0 bars from the pre conditioning skid. Pre conditioning skid consists of heat exchanger, SMBS dosing and NaOH dosing which control temperature, chlorine and pH of water respectively. The system comprises of pre-treatment and final treatment section. The pre-treatment section of Generation skid consists of Two Base Exchange Softeners, to reduce total hardness in feed water, and a 5.0 µ cartridge filter to reduce particulate loading on final treatment section. The pre treated feed water is fed to storage to in feed water tank TK1. The pre-treatment section is followed by Reverse Osmosis and Continuous De-Ionization process to generate required grade Purified water. The treated water, which meets the quality requirements specified, enters as Purified Water into the Purified Water storage tank and distributed to manufacturing premises through Distribution skid.
Qualification activities for the PW Generation System incorporate the following system components as listed below in order of process:

- **Two Base Exchange Softeners**: BES-1 and BES-2. The Softener is used to reduce total hardness in feed water
- **5.0 µm cartridge filter FLT 1**: This cartridge filter is used to reduce particulate loading on final treatment section
- **Chlorine Monitor**: Free chlorine will be monitored by chlorine monitor before entrance to the Purified Water generation skid by taking sample at frequency to be determined in Phase 1 & 2 trials and will be a part of operating SOP.
- **Feed water Tank TK1**: Filtered water from the 5.0 µm cartridge filter is stored in this Tank. The Feed water Tank is of 100 Litre capacity and provided with a electric heater. This tank serves as a multipurpose break tank, heating chamber for hot water sanitisation, CIP tank for final treatment section and an expansion tank during hot water sanitisation
- **RO feed pump PU 1**: This pump is variable speed driven and feeds RO unit. This pump's speed is set by PLC to achieve pre-set flow and pressure.
- **RO Unit R01**. This is a two-pass arrangement comprising high pressure Stainless Steel vessels fitted with hot water sanitisable RO elements. The RO feed pump force feeds the feed water to RO unit; the RO unit is designed to have recovery rate of 75%, producing permeate at 4m^3/hour.
- **Degasser DEG A/B**: Degasser enhances the performance of downstream Continuous De-ionization units. Degasser module(s) contain thousands of fine Hydrophobic hollow tubes that will allow only the gases and not the water to pass through. A stream of oil free filtered Instrument air is used to strip out excess levels of Carbon-di-oxide from RO permeate
- **CDI-LX Units CDI-LX A/B**: Process water leaving the RO unit is passed to the CDI System which consists of alternating cation and anion exchange modules. High voltage Direct Current is applied to the electrodes located at either end of the CDI modules; this action will remove ions from the feed water and regenerate ion resins inside the modules continuously. The module produces consistent, predictable water quality which is better than 95% removal with a feed water conductivity of 50 µ S/cm
- **Saturator for regenerating Softeners with brine solution**. A multi port valve located on each

softener controls the regeneration process. Softeners are interlocked so that only one can be regenerated at a time.

- **CIP systems (chemical):** As the chemical cleaning requirements of various parts of final treatment are different, they can be isolated for chemical cleaning in place as three different circuit namely CIP1 (low pressure chemical cleaning of RO unit) and CIP 2 (high pressure cleaning of RO unit) by isolating RO unit from Degasser and CDI; CIP 3 is for CDI-LX Units cleaning. They are all semi-automatic process selected and prompted by PLC**.**
- **Control System**. The PW Generation System is controlled and monitored via a Siemens S7-300 PLC (Programmable Logic Controller) and Human Machine Interface (HMI), with an external PLC Interface to DCS/SCADA using Modbus Protocol and status control system
- **Alarms and Safety Interlocks.** Three different alarm types are incorporated namely warning, non-critical alarm and critical alarms. Emergency stop is hardwired independently from the control system and can thus override control of the PLC.

Hot water sanitization: Final treatment section including the feed water tank is hot water sanitisable up to 85 °C on automatic control set via HMI. It can be either manually initiated or run automatically at a pre-set day and time via time clock.

5 DOCUMENTATION REQUIREMENTS

The PQ File should include:

- This PQ Protocol.
- All laboratory test results or their referenced location.
- Any change control actions that may have occurred during the qualification activities.
- Any variances, exceptions or investigation reports generated during the qualification activities.

6 DATA COLLECTION

All personnel shall have suitable documented training or experience.
All approvals shall be made in *BLUE* ink.
All data entry shall be made in *BLUE* ink.
All corrections to this Protocol, which are not retyped, are to be made in *BLUE* ink. All written corrections to this Protocol or to data entered in this Protocol should be made by using a single line to delete the error. The person who makes the correction shall initial and date it and add comment to explain reason for correction.
After performing the qualification tests, collect all relevant documents and retain for inclusion in the PQ File. If more Data Sheets or Variance Sheets are required, they are to be attached to this Protocol as *Appendices* and to be listed in *Section 13. List of Appendices*.

7 CHANGE CONTROL

Any changes or modifications to the system shall be performed in accordance with the Project Change Control Procedure.
Change Control Forms raised during the execution of this PQ will be filed along with the protocol. An assessment will be made for each change to determine whether or not any re-validation is required.

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8 PRE-QUALIFICATION REQUIREMENTS

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to PQ commencing. Open action items resulting from these tests shall be listed in the Comments section.

8.1 System Pre-requisites

S.No.	Description of Pre-requisite	Completed [Yes / No]	Verified By	Date
1	Verify that the OQ of the Purified Water Generation System has been executed and approved.	Yes / No*		

Note:- * -Circle one, which is appropriate.

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9 TESTS AND CHECKS

9.1 Water system monitoring, sampling and testing

9.1.1 Purpose

The objective of the test is to ensure that the Purified Water Generation system can consistently, over a 28 day period (14 days phase I and 14 days phase II), meet the following at all sample points

- High microbiological standard
- Specifications from the IS – 10500-1991 and Current IP / USP (USP 28) monograph.

9.1.2 Method

The strategy for water system monitoring, sampling and testing as defined below is used to:

1. Establish documented evidence for consistent operation of the treatment stages.
2. Establish a reference for the action and alert limits based on the plant microbial performance at intermediate process stages.
3. Confirm that the overall plant operates to specification over a prolonged period of time when operated and maintained to the SOP's

Monitoring, sampling and testing will take place over a 28day (14 days phase I and 14 days phase II), Sampling for testing will be as per sampling plan described below as sampling Plan (Table-2) covering all the sampling points listed in Test location (Table-1)

Test locations -Table-1

Description	Sample reference	Sampling and Testing	
		Phase I & II	Phase III
Feed water	SW03	Daily	Monthly
Primary Softener outlet	SW04	Daily	Monthly
Feed Tank / TK-1	SW05	Daily	Monthly
Post RO	SW06	Daily	Monthly
CDI Outlet	PW01	Daily	Daily

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Sampling plan – Table-2

Test day	SW03	SW04	SW05	SW06	PW01
1	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
2	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
3	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
4	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
5	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
6	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
7	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
8	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
9	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
10	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
11	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
12	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
13	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
14	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
15	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
16	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
17	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
18	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
19	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
20	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
21	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
22	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
23	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
24	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
25	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
26	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
27	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH
28	M, H, Cl, S, P, D	M, H, P, D	M, H, P, D	M, H, P, D	M, C,TOC, D, P, pH

M	=	Microbial Test	S	=	Silt Density Index
H	=	Hardness	TOC	=	Total Organic Carbon
Cl	=	Free chlorine	C	=	Conductivity (off-line)
D	=	Description	P	=	Pathogens

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Carry out analysis and record result for Microbial, Slit Density Index, visual characteristics, total organic carbon (TOC), and conductivity.

Attach the laboratory worksheets in the appendix and transcribe the results in results section 9.1.5 and 9.1.6 as applicable.

Prior to each day's sampling of the Purified Water, record the conductivity from at CS/TS-1 (Pre RO), CS/TS-2 (Post RO) and CS/TS-3 (Product water) in section 9.1.4 of this protocol.

9.1.3 Acceptance Criteria

Sampling and testing to follow sampling plan in Table –2.

Laboratory worksheets attached in the appendix.

Microbial limit:

All sample points except PW01	Alert level: NMT 200 CFU/ml Action level: NMT 300 CFU/ml
PW01 Sample	Pathogens: *E. coli, Salmonella, S. aureus, P. aeroginosa* should be absent Alert level: NMT 25 CFU/ml Action level: NMT 100 CFU/ml

Chemical limit:

Hardness at SW03/04/05/06	NMT 10 ppm $CaCO_3$ (manufacturer's specifications)
Chlorine at sample point SW03	NLT 0.2 mg/L (manufacturer's specifications)
Conductivity at CS/TS-1	Informative
Conductivity at CS/TS-2	NMT 10 µS/cm
Conductivity at PW01 & CS/TS-3	NMT 1.3 µS/cm at 25°C as per USP 28 <645>
Silt Density Index	NMT 4 (manufacturer's specifications)
Total organic carbon	NMT 500 ppb as per USP 28 <643>
pH at PW01	4.5-7.0
Description at PW01	Clear, colorless, odorless and tasteless liquid.

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9.1.4 Results – Daily On-line monitoring

Test day/ Date	On-line conductivity - µ S/cm			Acceptable (Y/N)	Initial/ Date
	CS/TS-1	CS/TS-2	CS/TS-3		
1/					
2/					
3/					
4/					
5/					
6/					
7/					
8/					
9/					
10/					
11/					
12/					
13/					
14/					
15/					
16/					
17/					
18/					
19/					
20/					
21/					
22/					
23/					
24/					
25/					
26/					
27/					
28/					

Comments:

Reviewed by		Date	

PERFORMANCE QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

9.1.5 Results – Periodic sample and testing

Sample carried out at PW01

Sample day/Date	Description	Objectionable organisms absent? (Y/N)	Off-line Conductivity (µS/cm)	Off-line TOC (ppb)	Microbial (cfu/ml)	Acceptable (Y/N)	Initial/Date
1/							
2/							
3/							
4/							
5/							
6/							
7/							
8/							
9/							
10/							
11/							
12/							
13/							
14/							
15/							
16/							
17/							
18/							
19/							
20/							
21/							
22/							
23/							
24/							
25/							
26/							
27/							
28/							

Comments:

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9.1.6 Results – Daily sampling and testing

TEST DATE:				DAY 1			
Sample point reference	**Microbial (cfu/ml)**	**Objectionable organisms absent? (Y/N)**	**Hardness (PPM)**	**Free Chlorine (PPM)**	**SDI index**	**Acceptable (Y/N)**	**Initial/ Date**
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 2**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 3**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		

Comments:

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9.1.6 Results – Daily sampling and testing (cont'd)

TEST DATE:				DAY 4			
Sample point reference	**Microbial (cfu/ml)**	**Objectionable organisms absent? (Y/N)**	**Hardness (PPM)**	**Free Chlorine (PPM)**	**SDI index**	**Acceptable (Y/N)**	**Initial/ Date**
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 5**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 6**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		

Comments:

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9.1.6 Results – Daily sampling and testing (cont'd)

TEST DATE:				**DAY 7**			
Sample point reference	**Microbial (cfu/ml)**	**Objectionable organisms absent? (Y/N)**	**Hardness (PPM)**	**Free Chlorine (PPM)**	**SDI index**	**Acceptable (Y/N)**	**Initial/ Date**
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 8**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 9**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		

Comments:

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9.1.6 Results – Daily sampling and testing (cont'd)

TEST DATE:				DAY 10			
Sample point reference	**Microbial (cfu/ml)**	**Objectionable organisms absent? (Y/N)**	**Hardness (PPM)**	**Free Chlorine (PPM)**	**SDI index**	**Acceptable (Y/N)**	**Initial/ Date**
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 11**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 12**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		

Comments:

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9.1.6 Results – Daily sampling and testing (cont'd)

TEST DATE:				**DAY 13**			
Sample point reference	**Microbial (cfu/ml)**	**Objectionable organisms absent? (Y/N)**	**Hardness (PPM)**	**Free Chlorine (PPM)**	**SDI index**	**Acceptable (Y/N)**	**Initial/ Date**
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 14**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 15**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		

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9.1.6 Results – Daily sampling and testing (cont'd)

TEST DATE:				**DAY 16**			
Sample point reference	**Microbial (cfu/ml)**	**Objectionable organisms absent? (Y/N)**	**Hardness (PPM)**	**Free Chlorine (PPM)**	**SDI index**	**Acceptable (Y/N)**	**Initial/ Date**
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 17**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 18**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		

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9.1.6 Results – Daily sampling and testing (cont'd)

TEST DATE:				DAY 19			
Sample point reference	**Microbial (cfu/ml)**	**Objectionable organisms absent? (Y/N)**	**Hardness (PPM)**	**Free Chlorine (PPM)**	**SDI index**	**Acceptable (Y/N)**	**Initial/ Date**
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 20**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 21**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		

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9.1.6 Results – Daily sampling and testing (cont'd)

TEST DATE:				**DAY 22**			
Sample point reference	**Microbial (cfu/ml)**	**Objectionable organisms absent? (Y/N)**	**Hardness (PPM)**	**Free Chlorine (PPM)**	**SDI index**	**Acceptable (Y/N)**	**Initial/ Date**
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 23**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 24**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		

Comments:

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9.1.6 Results – Daily sampling and testing (cont'd)

TEST DATE:				**DAY 25**			
Sample point reference	**Microbial (cfu/ml)**	**Objectionable organisms absent? (Y/N)**	**Hardness (PPM)**	**Free Chlorine (PPM)**	**SDI index**	**Acceptable (Y/N)**	**Initial/ Date**
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 26**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		
TEST DATE:				**DAY 27**			
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		

Comments:

Reviewed by		Date	

PERFORMANCE QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

9.1.6 Results – Daily sampling and testing (cont'd)

TEST DATE:			DAY 28				
Sample point reference	**Microbial (cfu/ml)**	**Objectionable organisms absent? (Y/N)**	**Hardness (PPM)**	**Free Chlorine (PPM)**	**SDI index**	**Acceptable (Y/N)**	**Initial/ Date**
SW03							
SW04				N/A	N/A		
SW05				N/A	N/A		
SW06				N/A	N/A		

Comments:

Reviewed by		Date	

PERFORMANCE QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

9.1.7 Results - Record of generation system sanitisation

Date of sanitisation	Time of sanitisation -hrs	Operator Signature	Completed successfully (Yes/No)

Comments:

Reviewed by		Date	

PERFORMANCE QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

10 CHECKLIST OF ALL TESTS AND CHECKS

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Reference No.	Tests or Checks	Executed [Y/N]	Comment
9.1	Water system monitoring, sampling and testing		

11 VARIANCE SHEET

Report any deviations from the acceptance criteria or exceptions from protocol instructions in the Record Sheet as described in SOP–"Handling of Deviations". Record the total number of exceptions / deviations reported during the qualification activities of this Protocol. Record the Deviation Number and Title in the Table below. Include all Deviation Record Sheets in the IQ File.

TOTAL NO. OF VARIANCES = _____

Variance No.	Variance Title	Status

Comments:

Reviewed by		Date	

12 REFERENCES

The Principle Reference is the following

- Master Validation Plan.
- Schedule – M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol 2 – Good Manufacturing Practices and Inspection.

The following references are used to give addition guidance

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, *Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs*, General. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, *Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals*, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, *Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation*, October 1999.
- GAMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.
- Handling of Deviations.
- Change Control Procedure.

PERFORMANCE QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

13 LIST OF APPENDICES

Appendix No.	Document Title

PERFORMANCE QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

14 SUMMARY

PERFORMANCE QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

15 APPROVALS

The following approvals signify that the PQ is complete and acceptable.

EXECUTED BY:

Organization	Name	Designation	Signature	Date

REVIEWED BY:

Organization	Name	Designation	Signature	Date

APPROVED BY:

Organization	Name	Designation	Signature	Date