E-ISSN: 2788-9270
P-ISSN: 2788-9262
Impact Factor (RJIF): 5.37
www.pharmajournal.net
NJPS 2025;5(2): 44-51
Received: 02-08-2025
Accepted: 05-08-2025

Vaishali Rana
Motherhood University, Roorkee, Uttarakhand, India

Shalini Saini
Motherhood University, Roorkee, Uttarakhand, India

Ayushi Tyagi
Motherhood University, Roorkee, Uttarakhand, India

Dheeraj Kumar Vishwakarma
Motherhood University, Roorkee, Uttarakhand, India

Corresponding Author:
Shalini Saini
Motherhood University, Roorkee, Uttarakhand, India

Modern strategies for pharmaceutical water quality management: Types, standards, and validation protocols

Vaishali Rana, Shalini Saini, Ayushi Tyagi and Dheeraj Kumar Vishwakarma

DOI: https://www.doi.org/10.22271/27889262.2025.v5.i2a.139

Abstract
The pharmaceutical industry uses water more than any other material. Water can be a solvent, excipient, processing aid, or cleaning agent. Given that water can affect a product's quality, purity, and most importantly, patient safety, it is vital that pharmaceutical-grade water be water compliant with cGMP and international regulations established by the WHO and various compendia (USP, EP, JP, and JP). This work focuses on assessing the design, installation, operation, and performance validation pertaining to a purified water system in one of the pharmaceutical manufacturing facilities. Primary components like stainless steel 316L storage tanks, sanitary centrifugal pumps, UV disinfection units, spray balls, and some automated monitoring systems were examined for critical variable compliance. To maintain consistent water quality, validation of design qualification (DQ), installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) across Phases I–III as well as the validation of the system were implemented. The system produces water that meets the pharmacopoeia, thereby ensuring compliance with GMP regulations and the continuous operation of the water system in manufacturing activities.

Keywords: Pharmaceutical water systems, Purified Water (PW), Water For Injection (WFI), CGMP Compliance, Who and pharmacopoeial standards, Design Qualification (DQ), Installation Qualification (IQ) etc.

Introduction

Importance of Water in Pharmaceutical Manufacturing

In the pharmaceutical sector, water is the most common raw material and is used as a solvent, excipient, cleaning agent, and processing aid in the formulation of dosage forms, intermediates, and active pharmaceutical ingredients (APIs) [1]. But water is more than an ingredient; it determines the quality, safety, and efficacy of the finished medicinal products [2]. It is required in parenteral preparations, where it must be sterile and apyrogenic, and, in oral formulations, where it must be pure, as this impacts the formulation's stability and shelf life [3]. In addition, water systems clean the instruments and help maintain and control the environment, including humidification [4]. Since every stage of the pharmaceutical production process is in some way interconnected with water, a failure in the water system can halt several processes and, in some cases, stop the entire manufacture of the product [5]. This is why the control of water in the pharmaceutical industry is a basic operational requirement and forms an integral part of Good Manufacturing Practices (GMP) [6].

Regulatory Standards: WHO, cGMP, and Pharmacopoeias

Water use in the pharmaceutical industry is regulated very closely due to its importance in the industry. Organizations such as the World Health Organization (WHO), the U.S. Food and Drug Administration (FDA), and agencies in Europe and Japan require that purified water (PW) and water for injection (WFI) comply with the pharmacopoeia and pass regulations concerning the water and its use's physical attributes (pH, conductivity, total carbon), chemical regulations, microbe regulations, and endotoxins [7]. Current Good Manufacturing Practice (cGMP) requires the water generation, storage, and distribution systems to be validated, and be active in compliance [8]. For example, the United States Pharmacopoeia (USP) recognizes WFI and PW as separate categories of water, with varying uses and quality requirements [9]. This contrast is also found in the European Pharmacopoeia

(EP) and the Japan Pharmacopoeia (JP) [10].These standards build on the system design, validation, and continuous monitoring of the system, to emphasize that water, like APIs, is an active controlled raw material [11].

Challenges in Water Quality Maintenance

Even with oversight, challenges remain with keeping the quality of pharmaceutical water. In the storage and distribution systems, the risks of microbial growth, biofilm, and chemical contamination are more than threats; they are realities [12]. Stagnation and localized over-accumulation of biofilm are the results of dead legs, improper slope gradients, and inadequately periodic cleaning and sanitization of storage units and distribution piping systems [13]. Furthermore, multiple steps of purification, which for instance include reverse osmosis, ultrafiltration, electrodeionization, and UV sterilization, create the scenario of a convoluted monitoring system; this is because monitoring each stage purification for intended outcomes while safeguarding against microbial recontamination is a formidable challenge [14]. Other water treatment units have a more serious and broader impact on water supply than any other piece of equipment because a failure to operate equipment like a tablet press can be bypassed and the equipment replaced relatively easily. This means the water systems are the most critical and the most vulnerable component in the whole pharmaceutical manufacturing process [15].

Purpose of the Study

Well, basically the main aim of the research study is to scrutinize the purifying strategies used in the fabrication of medicines. The study goes in-depth with the technical aspect of the water system including generation, storage, distribution, and validation [16]. Frankly, this is a very important thing. Through the exploration of system components, their technical specifications, and regulatory requirements, the study conveys how water plays a crucial role in achieving globally accepted quality standards [17]. This research study is mainly aimed at assessing the generation, storage, distribution, and validation of purified water systems in pharmaceutical manufacturing. By delving into system components, technical specifications, regulatory requirements, and performance qualification protocols, the study outlines the function of water in ensuring compliance with international quality standards [18]. Moreover, it also links the occurrence of risks with unqualified systems that may become sources of chemical impurities and microbial contamination, thus endangering patient safety and product quality [19]. Consequently, this paper highlights the indelible need for water system qualification programs that are strong enough to include design, installation, operational, and performance validation, so as to guarantee pharmaceutical quality and avoid manufacturing process interruption [20].

2. Objectives

1. To assess water treatment, storage, and distribution systems.
2. To classify types of pharmaceutical water and their applications.
3. To examine purification and disinfection methods for microbial control.
4. To evaluate the role of purified water in manufacturing, cleaning, and laboratory use.
5. To establish validation protocols for consistent water quality and GMP compliance.

3. Validation Steps

A. Design Qualification (DQ): Verifying system design meets requirements

Equipment	Key Specifications / Design Requirement	Make / Model
Storage Tank / Vessel	Top Dish 6 mm, Bottom Dish 8 mm; Jacket Shell & Bottom 5 mm; Cladding 3 mm; Size: 1800 mm Dia × 2000 mm Height; SS 316L contact parts; Internal finish Electro Polish (Ra < 0.3 µm)	TSA Process Equipments Pvt. Ltd.
Purified Water Distribution Pump	Horizontal Centrifugal; Capacity 12.7 m³/h; Discharge Head 6.3 kg/cm²; SS 316L casing, impeller, shaft; Seal TC/TC/EPDM	ALFA LAVAL, Model LKH 40 – 10HP
Spray Ball Assembly	360° Rotation Type; Size 45 mm; Sweep 1.25 m; SS 316L; Shaft assembly for non-immersion	TSA, Mini Spinner
Pressure Gauge	Diaphragm Type; Range 0-10 kg/cm²; SS 316L diaphragm; Case SS 304; Glycerine filled	Waaree
Compound Pressure Gauge	Diaphragm Type; Range -1 to 9 kg/cm²; SS 316L diaphragm; IP65 enclosure; Accuracy ±1% FSD	Waaree
Conductivity Sensor / Analyzer	Sensor Type 403-11-20; Cell constant 0.01–10/cm; Sanitary flanges; Temp range 0–150°C; SS 316 wetted parts	Emerson Rosemount / Bela
Steam Float Trap	Ball Float Type; Body Case Steel ISO 210 FG 260; Design Pressure 16 bar at 120°C	Spirax Marshal, Model FT-10
Temperature Transmitter	PT100, 3-wire; Sheath SS 316, 6 mm × 50 mm; 1.5” TC End Connection	Wika
Ultra Violet (UV) Disinfectant	SS 316L vessel; 2 high-intensity lamps, 30” each; 2537 Å wavelength; Life 9000 hrs; Supply 230 V	APi-70, Alfa Purifiers
Capacitance Type Level Switch	Fully insulated probe; Active length as per tank shell height; Clamp ISO 2852 DN40-51; SS 316L + PTFE	Spink Control, Model SC-CP-S6-PTFE
Flow Transmitter	Vortex type; Sensor SS 316L, Rotor ANC 21; Range 0.37–21 m³/h; Aluminium enclosure IP67	Emerson Rosemount
Manual Diaphragm Valve	Weir Type; Internal finish <0.3 µm; EPDM Grade 325; End connection TC; Sizes 1”-2.5”	Crane Process Flow Technologies
SS Tubes & Fittings	Laser welded, bead removed; ASTM A270 TP 316L; Internal finish <0.3 µm	RATH GIBSON / Alfa Laval / TSA
MicroLogix PLC	Micrologix 1400; 20 DI / 12 DO; 240 VAC Input; DIN Rail Mounting	Allen Bradley

HMI Panel	PV 600 C; 5.7" × 5.7"; DF-1 & RS485 I/O; 18-bit color resolution	Allen Bradley

The pharmaceutical water system comprises SS 316L storage tanks and vessels with electro-polished surfaces (Ra < 0.3 µm), ensuring sanitary conditions. Purified water is circulated via horizontal centrifugal pumps, monitored for flow, conductivity, and temperature using vortex flow transmitters, PT100 sensors, and conductivity analyzers. Cleaning and sterilization are facilitated by 360° spray balls, UV disinfection units, and steam float traps. Process control is achieved through MicroLogix PLC and HMI panels, while manual diaphragm valves and SS tubing/fittings provide hygienic fluid handling. Key design priorities include corrosion resistance, surface finish, sanitary connections, and precise monitoring of critical parameters.

B. Installation Qualification (IQ): Confirming correct installation of components.

Pre-Qualification Checks	Acceptance Criteria
Drawing:	
As build Isometric Drawing	Should be as per Approved Drawing
As build P & ID Drawing	Should be as per approved P & ID Drawing
Certificates:	
MOC Certificates for Tubes & Fittings	Should be available
Hydro Test Certificate	Should be available
Passivation Certificate	Should be available
Sanitization Certificate	Should be available
Slope Verification Report	Should be available
Manuals of major brought out items	Should be available
Orbital Welding Printouts	Should be available
Physical verification:	
Horizontal leveling of the equipment	Ok/Not ok
Positioning of the equipment/ Erection of Loop System.	vertically upright and provided with enough room for upkeep
Any actual physical harm to the walls, floor, or equipment.	No scratches or damage should exist.
Welding	Orbital Welded for All Interconnecting Piping & Argon Welding for Non-Contact Parts.

Prior to commissioning, a comprehensive pre-qualification of the equipment and associated systems is conducted to ensure compliance with design, quality, and safety standards. All as-built drawings, including Isometric and P&ID diagrams, must align with the approved versions. Certificates confirming the material of construction (MOC) for tubes and fittings, hydrostatic testing, passivation, sanitization, slope verification, and manuals of major brought-out items must be available and verifiable. Orbital welding printouts for all interconnecting piping are required to demonstrate adherence to welding standards. Physical verification entails ensuring horizontal leveling of equipment, proper positioning of the system or loop with adequate space for maintenance, and absence of any damage to walls, floors, or equipment surfaces. Welding of interconnecting piping must be performed using orbital welding techniques, while non-contact parts should be joined using argon welding, thereby ensuring structural integrity and compliance with pharmaceutical quality standards.

C. Operational Qualification (OQ): Ensuring operational parameters function within limits.

S. No	Equipment / System	Test / Functional Check	Acceptance Criteria
1	NaOCl Dosing System	Check operation & dosing	System operates as per SOP, dosing accurate
2	Raw Water Pumps (1W + 1SB)	Start/Stop, flow rates, low/high level response	RWP-101/102 starts/stops as per set points; flow meets design
3	Multi Grade Filter	Flow rate test	MGF-101 Feed: 7.5 m^3/hr
4	Softeners (1W + 1SB)	Flow rate & totalized flow	SF-101 Feed: 7.5 m^3/hr; regeneration occurs automatically
5	Soft Water Tank	High/Low/High-High/Low-Low level tests	RWP-101/102 & UFFP-101 operate/trip correctly; alarms displayed
6	UF Feed cum Fast Flush Pump	Start/Stop at low level	UFFP-101 starts as per low-level set point
7	150 Micron Cartridge Filter	Flow and pressure drop test	Pressure within acceptable range; flow uninterrupted
8	Ultra Filtration (UF) System	Trip at high pressure; low/high water levels	UF system trips/starts; alarms & panel indications functional
9	Back Flush Pump	Flow & automatic backflush	Backflush occurs automatically per setpoints
10	UF Water Tank	Level checks: High, Low, High-High, Low-Low	Pumps start/stop correctly; alarms & indication functional
11	Control Panel / SCADA	Key functionality test: Main switch, Emergency, Hooter	Each key functions as per specification; alarm/horn response verified
12	Display / Indication Lamps	Status of power, IPC alarm	Displays indicate correct operational status
13	Pressure Switches PS-101 / PS-102	High pressure trip test	RWP-101/102 and UF system trip with alarms & indications
14	Emergency Stop	System emergency shutdown	System stops immediately; alarms & panel indicators activate; reset functions correctly
15	Sampling Points & Valves	Accessibility & identification	All sampling points clearly identified; valves operate for validation sampling

Tests and Procedures

A. Hydro test

Form no. IR-08 Rev.00

HYDROSTATIC TEST REPORT

Project		Date	01/09/2021
System	purified water distribution		

Type of inspection:	Pressure gauge Make used for hydro test:	Bourdon
☐ Hydro test	Pressure gauge Sr. No.	N182.59-00902
	Calibration Valid Up to -	14-10-2021
	Hydro test Start Time -	5:15 PM
	Hydro test End Time -	6:20 PM

Spool no./Line Size	Test pressure	Hold time	Result (Pass/Fail)	Remarks
1.5"	6.0 kg/cm²	65 Minutes	pass	N.A.

The hydrostatic test was conducted on the 1.5-inch line of the purified water distribution system at a pressure of 6.0 kg/cm² for a duration of 6.5 minutes. The system successfully passed the test without any issues, indicating structural integrity and leak-proof performance. The pressure gauge used was calibrated and traceable, ensuring accurate measurement.

B. Slope verification

Form no.IR-67 Rev-0

Slope verification report

Project		System	purified water distribution
P&I D No.		Isometric drawing No.	
Instrument used / ID No.	N.A.	Calibration of instrument	N.A.
		Date	

Sr. No.	Slope no.	Node to node location From	Node to node location To	Length of pipe Section in mm (Y)	Slope measured in mm (X)	Slope of pipe section X/Y x 100	Remark (Pass/Fail)
1	S-1	N-1	N-2	1550	18	1:1	pass
2	S-2	N-2	N-3	3600	40	1:1	pass
3	S-3	N-3	N-4	5570	62	1:1	pass
4	S-4	N-5	N-6	3050	35	1:1	pass
5	S-5	N-7	N-8	7800	87	1:1	pass
6	S-6	N-9	N-10	1850	22	1:1	pass
7	S-7	N-10	N-11	2650	30	1:1	pass
8	S-8	N-11	N-12	5500	63	1:1	pass
9	S-9	N-12	N-13	1610	18	1:1	pass
10	S-10	N-14	N-15	1550	18	1:1	pass
11	S-11	N-15	N-16	1500	17	1:1	pass
12	S-12	N-16	N-17	3540	40	1:1	pass
13	S-13	N-18	N-19	3540	40	1:1	pass
14	S-14	N-19	N-20	6050	70	1:1	pass
15	S-15	N-20	N-21	8300	95	1:1	pass
16	S-16	N-22	N-23	7300	85	1:1	pass

C. Dead leg checks

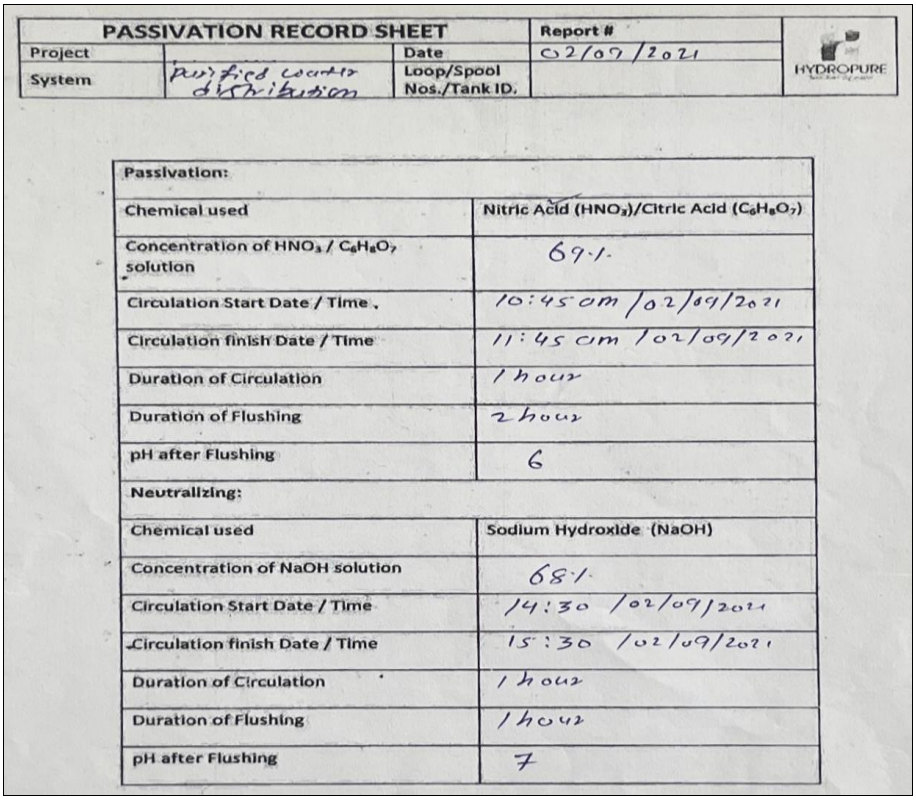
Form no.IR-68 Rev-0

Dead leg verification report

Project		System	purified water distribution
P&I D No.		Isometric drawing No.	
		Date	01/07/2020

Sr. No.	Dead leg no.	Location	Inside Diameter of branch pipe in mm (D)	Length of dead leg Branch pipe in mm (L)	Dead leg ratio (L/D) (≤2)	Remark (Pass/Fail)
1	DV-301	PW tank drain line	34.8	55	1.58	pass
2	PG-302	pw supply line	34.8	50	1.4	pass
3	SP-302	Before UV	9.4	16	1.7	pass
4	SP-301	After UV	9.4	16	1.7	pass
5	PG-303	Return line pw	34.8	50	1.4	pass
6	SP-303	Return line	9.4	16	1.7	pass
7	TT-302	Return line	34.8	50	1.4	pass
8	CT-301	Return line	34.8	30	0.86	

D. Passivation



PASSIVATION RECORD SHEET

Project		Date	02/09/2021
System	Purified water distribution	Loop/Spool Nos./Tank ID.	

HYDROPURE

Passivation:	
Chemical used	Nitric Acid (HNO_3)/Citric Acid ($C_6H_8O_7$)
Concentration of HNO_3 / $C_6H_8O_7$ solution	69.1.
Circulation Start Date / Time	10:45 am / 02/09/2021
Circulation finish Date / Time	11:45 am / 02/09/2021
Duration of Circulation	1 hour
Duration of Flushing	2 hour
pH after Flushing	6
Neutralizing:	
Chemical used	Sodium Hydroxide (NaOH)
Concentration of NaOH solution	68.1.
Circulation Start Date / Time	14:30 / 02/09/2021
Circulation finish Date / Time	15:30 / 02/09/2021
Duration of Circulation	1 hour
Duration of Flushing	1 hour
pH after Flushing	7

4. Technical specifications & critical variables system components Critical Variables To Be Met (Checks On Equipments):

S. No.	Critical Variables	Acceptance Criteria
1.	**PW Storage Tank (T-301))**	
	Quantity	01 No.
	Make	Hydropure Systems Pvt. Ltd.
	Type	Vertical Half Limpeted Tank with cladding
	MOC	SS 316L
	Capacity	5 KL
	Tank Internal Diameter	1750 mm
	Shell Height	2100 mm
	Jacket Diameter	1850 mm
	Jacket Height	1050 mm
	Cladding Diameter	1950 mm
	Cladding Height	1100 mm
	Operating Condition:	
	Insulation	2” Rockwool duly cladded with SS Sheet
	Surface Finish	Internally - < 0.4 Ra, Electro Polished Externally – Matt Finish
	Ladder MOC	SS 304
2.	**Process Loop Pumps (PLP-301/302)**	
	Quantity	02 Nos. (1W+1SB)
	Make	Alfa Laval
	Type	Sanitary Centrifugal Monobloc Pump
	Model No.	LKH 35
	MOC of Housing	SS 316L
	MOC of Back Plate	SS 316L
	MOC of Shaft	SS 316L
	MOC of Impeller & Impeller Screw	SS 316L
	MOC of sealing sleeve	C/SC
	MOC of Product wetted seals	EPDM
	Motor Rating	10 HP, 60 Hz
3.	**High Intensity Ultra Violet Unit (HIUV-301)**	
	Quantity	01 No.
	Make	Ace Hygiene

	Model No.	API-70
	Chamber Material	SS 316L
	No. of UV Lamps	02 No.
	Inlet/Outlet Connection	2" TC End
	UV Intensity Monitor	UVM
	Hour Meter	Provided
	No. of UV Lamps	01 No.

S. No.	Tag No.	Location	Technical Details
Pressure Gauges			
1.	PG-301	In Steam Safety Valve Ass.	0 to 7 kg/cm^2, 100 mm Dial Size, SS internals, Threaded End
2.	PG-302	Supply line of PW loop	0 to 10 kg/cm^2, 100 mm Dial Size, SS internals, Diaphragm Seal End
3.	PG-303	Return line of PW loop	0 to 10 kg/cm^2, 100 mm Dial Size, SS internals, Diaphragm Seal End
4.	CPG-301	On top of T-301	-1 to 9 kg/cm^2, 100 mm Dial Size, SS internals, Diaphragm Seal End
Level Transmitters			
1.	LT-301	On top of T-301	2400 mm ,Capacitance Rope Type, SS 316L, 2" TC End Conn., 4-20 mA Output
Electric Vent Filter			
1.	EVF-301	On top of T-301	10" long ,SS 316L, TC End Connection
2.	Cartridge	In EVF-301	0.2 Micron, 10" long ,PTFE, Code-7 Connection
Spray Balls			
1.	SB-301	In top of T-301	SS 316L, TC End Conn., Model No. – 5MA.319.1Y.AQ, Rotating Type
Steam Trap			
1.	ST-301	Bottom Jacket of T-301	Ball & Float type, SOFT31-O, THD End Conn, 20 NB
Light Sight Glass			
1.	LSG-301	On top of T-301	SS 316L, Flange End Conn., DN100
Temperature Transmitters			
1.	TT-301	In PW Storage Tank (T-301)	200 mm, SS 316L, Pt 100 RTD, ½" BSP Threaded End Conn., 0 to 200 Deg. C
2.	TT-302	In return line of PW loop	50 m, SS 316L, Pt 100 RTD, TC End Conn., 0 to 200 Deg. C
3.	TT-303	For EVF-301	200 mm, SS 316L, Pt 100 RTD, TC End Conn., 0 to 200 Deg. C

S. No.	Tag No.	Location	Technical Details	Make
Conductivity Transmitter				
1.	CT-301	Return line of PW loop	Single Channel, Sanitary type, SS 316, TC End, 4 to 20 mA, 0 to 10 µs/cm	Emerson/E & H
Flow Transmitter				
2.	FT-301	Return line of PW loop	2 to 28 m^3/hr, 2" TC End Conn., 4 to 20 mA O/P, SS 316L, Vortex Type, Suitable for 2" line size	Krohne Marshall/E & H

Checks on Valves:

S. No.	Tag No.	Location	Size	Make	MOC & end connections
Manual Ball Valves					
1.	BV-301	In Steam Safety Valve Ass.	10 mm	Racer Engg	SS 304, THD End Conn.
2.	BV-302	In Steam Trap Assembly	20 mm	Racer Engg	SS 304, THD End Conn.
3.	BV-303	In Steam Trap Assembly	20 mm	Racer Engg	SS 304, THD End Conn.
Diaphragm Valves					
1.	DV-301	T-301 Tank drain	40 mm	Avcon	2 Way valve, SS 316L+ EPDM, TC End Conn.
2.	DV-302	Suction line of PLP-301/302	65 mm	Avcon	2 Way valve, SS 316L+ EPDM, TC End Conn.
3.	DV-303	Discharge line of PLP-301/302	50 mm	Avcon	2 Way valve, SS 316L+ EPDM, TC End Conn.
Sampling Valves					
1.	SP-301	Inlet of HIUV-301	8 mm	Avcon	2 Way valve, SS 316L+ EPDM+PTFE, TC End
2.	SP-302	Outlet of HIUV-301	8 mm	Avcon	2 Way valve, SS 316L+ EPDM+PTFE, TC End
3.	SP-303	Return line of PW loop	8 mm	Avcon	2 Way valve, SS 316L+ EPDM+PTFE, TC End
4.	FDV-301	Return line of PW loop	50 mm	IDMC/ Cipriani / Inoxpa	SS 316L+Viton, TC End Conn.
Back Pressure Regulating Valve					
1.	BPRV-301	Return line of PW loop	50 mm	Leistung	SS 316L+Viton, TC End
Actuated Angle Seat On-Off Valve					
1.	AV-301	Steam inlet line	50 mm	Avcon	SS 316, NC, Flng. End, Pneumatically Act.
Safety valve					
1.	SV-301	In Steam Safety Valve Ass.	½"	Venus Engg.	SS 304, THD End Conn

5. Performance qualification & validation phases

A. Phase -I Validation Study:

The first step in the water system validation process should be started as soon as the distribution and purification systems have been installed and tested. During this phase, water samples will be taken for a period of two to four weeks from every sampling station, which includes all water treatment, storage, and use points. In this period worst case simulation conditions should be arised just before the sample which normally occurs during routine manufacturing

conditions. A tentative frequency of sanitization of not more than two weeks shall be set before the phase I study and confirmed after the phase II study. If there is any failure with respect to bio-burden in between three weeks, the phase I study has to be re-initiated with increase in the frequency of sanitization. At the end of this phase draft SOP for operation, cleaning, sanitization and sampling method of water system shall be confirmed.

B. Phase- II Validation Study

The purpose of this study is to show that, when used in accordance with SOPs, the system will reliably provide water of the appropriate quality. For three weeks, sampling will be conducted from each of the sample locations. In this phase worst case conditions need not be simulated.

Evaluation of Validation Study: The phase I and II validation studies revealed no major deviation from the specifications and all the sampling points were found to be well within the acceptable limit during the entire course of validation.

C. Phase III Validation study:

The purpose of this study is to show that, when used in accordance with SOPs, the system will reliably provide water of the appropriate quality. Every sampling point will be used for the sampling in order to provide aThe purpose of the third validation phase is to show that the water system will reliably generate water with the specified quality attributes when it is operated in compliance with the SOPs for a full year, including any seasonal fluctuations. sample will be conducted throughout this time in accordance with the regular sample plan. which include every site of water purification, at least one point of usage, and at least one storage tank outlet that is completed in a weekly cycle. a duration of three weeks.

6. Summary and Conclusion

Water plays an indispensable role in pharmaceutical manufacturing as a solvent, excipient, cleaning agent, and processing aid, and its quality directly impacts product safety, efficacy, and regulatory compliance. This study reviewed the design, installation, operation, and validation of a purified water system in accordance with WHO, cGMP, and pharmacopoeial standards. The system comprised SS 316L storage tanks, sanitary centrifugal pumps, UV disinfection units, spray balls, and automated monitoring instruments, all verified through design and installation qualifications. Operational tests demonstrated correct functioning of pumps, filters, dosing systems, alarms, and control panels, while performance qualification in three phases confirmed consistent production of water meeting physicochemical and microbiological specifications under routine and worst-case conditions. Together these results show that a well-designed, properly installed, and rigorously validated water system can reliably supply high-quality water for manufacturing, cleaning, and laboratory use, thereby supporting uninterrupted operations, Good Manufacturing Practice (GMP) compliance, and ultimately patient safety.

References

1. Pharma Guideline. Pharmaceutical water: importance and applications. 2012.
2. https://www.pharmaguideline.com/2012/09/pharmaceutical-water.html
3. JMark Systems. The importance of water treatment in pharmaceuticals. https://www.jmarksystems.com/blog/the-importance-of-water-treatment-in-pharmaceuticals
4. European Medicines Agency. Guideline on quality of water for pharmaceutical use. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-quality-water-pharmaceutical-use_en.pdf
5. A3P. Sustainable water management in the pharmaceutical industry. https://www.a3p.org/en/sustainable-water-management-in-the-pharmaceutical-industry
6. WWF International. Diagnosing water risks for the pharmaceutical sector. https://wwfint.awsassets.panda.org/downloads/case_study__diagnosing_water_risks_for_the_pharmaceutical_sector_1.pdf
7. U.S. Food and Drug Administration. Water for pharmaceutical use: inspection technical guide. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-technical-guides/water-pharmaceutical-use
8. Denk Pharma. The importance of water quality in the pharma industry. https://www.denkpharma.com/news/the-importance-of-water-quality-in-the-pharma-industry-quality-made-with-german-expertise
9. Vicol. Water purification system challenges in the pharmaceutical industry. https://www.vicol.co.za/water-purification-system-challenges-in-the-pharmaceutical-industry
10. ScienceDirect. Water efficiency and safe re-use of different grades of water. https://www.sciencedirect.com/science/article/pii/S2212371720300676
11. Xylem. Solving water challenges for the pharmaceutical sector. https://www.xylem.com/en-uk/making-waves/industrial-news/solving-water-for-the-pharmaceutical-sector
12. A3P. Sustainable water management in the pharmaceutical industry. https://www.a3p.org/en/sustainable-water-management-in-the-pharmaceutical-industry
13. Empowering Pumps. Why the future of pharma depends on smarter water management. https://empoweringpumps.com/why-the-future-of-pharma-depends-on-smarter-water-management
14. ResearchGate. A review: application of water in pharmaceuticals. https://www.researchgate.net/publication/289121104_A_review_Application_of_water_in_pharmaceuticals
15. ResearchGate. Water quality for pharmaceutical use: a review. https://www.researchgate.net/publication/260025388_Water_quality_for_Pharmaceutical_use_A_review
16. European Medicines Agency (EMA). Guideline on quality of water for pharmaceutical use. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-quality-water-pharmaceutical-use_en.pdf

17. U.S. Food and Drug Administration (FDA). High purity water system guide (7/93). https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/high-purity-water-system-793
18. Pharma Guideline. Pharmaceutical water: importance and applications. 2012. https://www.pharmaguideline.com/2012/09/pharmaceutical-water.html
19. JMark Systems. The importance of water treatment in pharmaceuticals. https://www.jmarksystems.com/blog/the-importance-of-water-treatment-in-pharmaceuticals
20. A3P. Sustainable water management in the pharmaceutical industry. https://www.a3p.org/en/sustainable-water-management-in-the-pharmaceutical-industry
21. Empowering Pumps. Why the future of pharma depends on smarter water management. https://empoweringpumps.com/why-the-future-of-pharma-depends-on-smarter-water-management