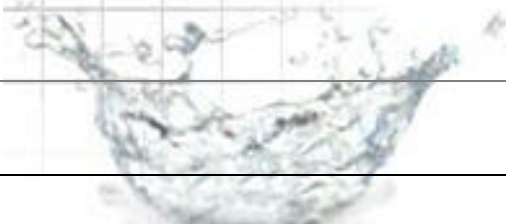
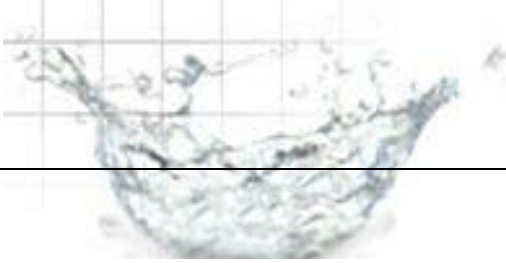


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	<h2>VALIDATION OF PURIFIED WATER SYSTEM</h2>	



A U D I T P r o c e d u r e	DATA Complete	COMMENTS If data incomplete - state missing information
<u>Validation Protocol:</u> Examine Master List of Protocols containing Edition Numbers and Effective dates of the Validation Protocols.	YES <input type="checkbox"/> NO <input type="checkbox"/>	
Review the Master Protocol List to ensure that the Validation Protocol's edition #. was the latest edition at the actual time of the validation run.	<input type="checkbox"/> <input type="checkbox"/>	
<u>Validation Documentation:</u> Check that all pages are adequately filled out and signed and no pages are absent	<input type="checkbox"/> <input type="checkbox"/>	
Verify that all authorization signatures are in place and dated including documentation authorization signatures.	<input type="checkbox"/> <input type="checkbox"/>	
<u>Installation Qualification:</u> Check that all pages are adequately filled out and signed and no pages are absent?.	<input type="checkbox"/> <input type="checkbox"/>	
Is the list of change controls of the equipment from last validation date updated?	<input type="checkbox"/> <input type="checkbox"/>	
<u>Calibration:</u> Examine the list of instruments requiring calibration and check the: <ul style="list-style-type: none"> • Identification numbers (ID #) of instruments. • Instrument Category • State whether instruments are <input type="checkbox"/> Calibrated / <input type="checkbox"/> Not Calibrated. 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	ID _____ Total: <input type="checkbox"/> Calibrated / <input type="checkbox"/> Not Calibrated.

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	<h2>VALIDATION OF PURIFIED WATER SYSTEM</h2>	

A U D I T P r o c e d u r e	DATA Complete	COMMENTS For incomplete data - state omissions
<p><u>System Drawings:</u> Each drawing print has been verified as being correct and is suitably signed and dated?</p>	<p>YES NO</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	
<p><u>Operational Qualification:</u> <u>Safety and Pressure Controls</u> The results recorded comply with the system's written specifications?</p>	<p><input type="checkbox"/> <input type="checkbox"/></p>	
<p><u>pH Control</u> The results recorded comply with the system's written specifications?</p>	<p><input type="checkbox"/> <input type="checkbox"/></p>	
<p><u>Conductivity Control</u> The results recorded comply with the system's written specifications?</p>	<p><input type="checkbox"/> <input type="checkbox"/></p>	
<p><u>Tank (Tanks) Level Control</u> The results recorded comply with the system's written specifications?</p>	<p><input type="checkbox"/> <input type="checkbox"/></p>	
<p><u>Tank Vent Filter ; Temperature Control and Monitor</u> The results recorded comply with the system's written specifications?</p>	<p><input type="checkbox"/> <input type="checkbox"/></p>	

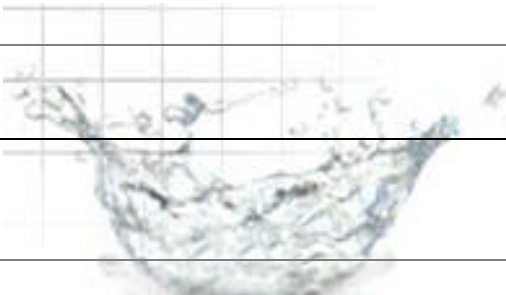
Purified Water - An Ingredient of Solid Dosage Development - Block J.D.; Belle D.; Ford R. Authors may be contacted at research@iagim.org

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<h2 style="margin: 0; color: #808000;">VALIDATION OF PURIFIED WATER SYSTEM</h2>		


A U D I T P r o c e d u r e	DATA Complete	COMMENTS For incomplete data - state omissions
<u>Reverse Osmosis / Purified Water Pump Flow Control</u> Do all the results recorded comply with the system's written specifications?	YES NO <input type="checkbox"/> <input type="checkbox"/>	
<u>PW Loop Flow Monitoring System</u> Do all the results recorded comply with the system's written specifications?	<input type="checkbox"/> <input type="checkbox"/>	
<u>PW Loop Temperature Control and Monitoring</u> Do all the results recorded comply with the system's written specifications?	<input type="checkbox"/> <input type="checkbox"/>	
<u>SOP VERIFICATION</u> - (According to Latest SOP Edition) Check that the appropriate SOPs are in place, dated and signed. Review SOP Index	<input type="checkbox"/> <input type="checkbox"/>	
SOP - Operating Instructions for the Purified Water System SOP - Preventive Maintenance of the Purified Water System	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
SOP - Sanitation of Purified Water System - Monitor Frequency of Sanitation (log) SOP - Daily Purified Water System Checklist	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
SOP - Purified Water System Repairs (Check Reports and Sign-Off) SOP - Maintenance and Replacement of Vent Filter (types) for Purified Water System Check SOPs effective dates against the validation protocol's effective date.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	

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<h2 style="margin: 0; color: #808000;">VALIDATION OF PURIFIED WATER SYSTEM</h2>		

A U D I T P r o c e d u r e	DATA Complete	COMMENTS For incomplete data - state omissions
<p><u>Performance Qualification</u></p> <p><u>Chemical Tests</u></p> <p>Check that all chemical tests are performed as stated in the protocol?</p>	YES NO <input type="checkbox"/> <input type="checkbox"/>	
<p>Are all results and collated data is attached?</p>	<input type="checkbox"/> <input type="checkbox"/>	
<p>Where Out-of-Specification (OOS) Results have occurred, check that appropriate corrective action, as per written SOP / Protocol, has been fully implemented?</p>	<input type="checkbox"/> <input type="checkbox"/>	
<p><u>Microbiological Tests</u></p> <p>Check that all tests are sampled and performed as stated in the protocol?</p> <p>Check that all results and collated data is attached?</p>	<input type="checkbox"/> <input type="checkbox"/>	
<p>Where Out-of-Specification (OOS) Results have occurred, check that appropriate corrective action, as per written protocol, has been fully implemented?</p>	<input type="checkbox"/> <input type="checkbox"/>	
<p><u>Bacterial Endotoxin Tests</u></p> <p>Check that all tests are sampled and performed as stated in the protocol?</p>	<input type="checkbox"/> <input type="checkbox"/>	
<p>Are all results and collated data is attached?</p>	<input type="checkbox"/> <input type="checkbox"/>	
<p>Where Out-of-Specification Results have occurred, check that appropriate corrective action, as per written SOP / Protocol, has been fully implemented.</p>	<input type="checkbox"/> <input type="checkbox"/>	

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	VALIDATION OF PURIFIED WATER SYSTEM	

A U D I T P r o c e d u r e	DATA Complete	COMMENTS For incomplete data - state omissions
Final Report Check that all discrepancies detected are clearly identified in the Final AUDIT Report.	YES NO <input type="checkbox"/> <input type="checkbox"/>	
Have all discrepancies been followed up and signed-off and closed by the QA	<input type="checkbox"/> <input type="checkbox"/>	
All report pages are numbered and contain no "white-out deletions or overwriting"?	<input type="checkbox"/> <input type="checkbox"/>	
Final Report is signed-off with a authorization signature (dated) and printed name.	<input type="checkbox"/> <input type="checkbox"/>	
The Final Report is signed-off by QA and endorsed as "fully complete and closed"	<input type="checkbox"/> <input type="checkbox"/>	

Chemical Testing (P/W ; WFI)



Sampling
Testing
Reporting
Logging Results
Batch Analysis
Review Process

Bacterial Endotoxin Tests (WFI)



Auditing
Out-Of-Spec
Trend Analysis
Review Specs
Resetting Limits
End Report

Microbiological Testing (P/W ; WFI)

