

System Name	MobiVue PMMS	Document Number	BCI_2023-24_Ajanta-MobiVue PMMS –Installation Qualification Protocol Cum Report (WMS)
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Installation Qualification cum Report For MobiVue PMMS (WMS) System

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Revision History

Revision Number	Date	Prepared By	Reviewed By	Comment
00	31-Aug.-2023	Leena Patil	Sailendra Das	Installation Qualification Protocol Cum Report

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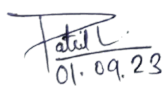
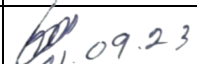
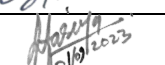
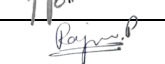
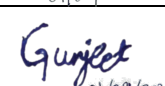
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1 PROTOCOL APPROVAL

M/S Bar Code India Ltd.:-

--	Name	Department	Designation	Sign & Date
Prepared By	Leena Patil	Software	Technical Document Writer	 01.09.23
Reviewed By	Sailendra Das	Software	Business Analyst	 01.09.23
Reviewed By	Hemant Gariya	Software	Development Lead	 01/09/2023
Reviewed By	Rajeevkumar P	Software	Quality Tester	 01/09/23
Approved By	Gunjeet Singh	Software	Software Quality Lead	 01/09/2023

Ajanta Pharma Ltd :-

--	Name	Department	Designation	Sign & Date
Reviewed By				
Reviewed By				
Reviewed By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				

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2 OBJECTIVE

The objective of this protocol cum report is:

1. To define the Installation Qualification (IQ) requirements for the MobiVue PMMS (WMS) System.
2. To ensure that the MobiVue PMMS (WMS) System is in accordance with the requirements and conforms to the purchase specifications.
3. The MobiVue PMMS (WMS) System is installed correctly and in accordance with installation plan and as per the manufacturer's installation instructions.
4. To establish documented evidence that the installation qualification of MobiVue PMMS (WMS) System is carried out as per the specified requirements.

3 SCOPE

The scope of this protocol cum report includes installation qualification procedure of the MobiVue PMMS (WMS part) System at Ajanta Pharma Guwahati Ltd.

4 QUALIFICATION TEAM

Responsible staff from:

1. IT
2. Maintenance
3. Warehouse
4. Production
5. QC
6. Quality Assurance
7. BCI team (Vendor)

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5 RESPONSIBILITIES

Responsibilities	Details
Vendor	<ul style="list-style-type: none"> To provide installation qualification document & execute the installation qualification.
Information Technology	<ul style="list-style-type: none"> Shall be witness the activity & provide technical support during installation
Maintenance	<ul style="list-style-type: none"> To provide support during installation To check the installation activity as per protocol cum report.
Warehouse, Production and QC	<ul style="list-style-type: none"> Checking of protocol cum report. To verify the installation activity as per protocol cum report. To provide area for installation and make related arrangements.
QA	<ul style="list-style-type: none"> Review and Approval of Protocol Cum Report

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6 SYSTEM DESCRIPTION

MobiVue PMMS (Pharmaceutical Manufacturing Management System) is developed and implemented for Ajanta Pharma Limited, Guwahati to automate system at Warehouse the solution will facilitate user to manage the storage of inventory at warehouse and also helps in efficient allocation of Material for Sampling and Dispensing. Barcode Labels will be generated for all the received Material pack i.e. Containers or Bags against the Gate Entry Number. The materials will be tracked through this barcode in process i.e. picking, pre-staging, staging, dispensing, put-away during movement the materials will be validated against the system input data process order , Inspection lot Number. The application also provides identification for Equipment, Dispensing Booths, Weighing Balance, In-process machines, Pallets, and process/dispensing rooms. This application has been using the English (US) language for interface.

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7 EXECUTION INSTRUCTIONS

Instructions for execution of the qualification activity:

1. Read the contents of the document thoroughly before proceeding for execution of the activity (In case of doubts / contradictions / contact the approvers of the document for clarifications). All the details are to be verified jointly by the validation team members with assistance of supplier's representative as applicable.
2. All the columns in the following pages are to be filled by the vendor. If a particular detail is not applicable, indicate the same by putting NA in the column.
3. Follow the specific instructions as mentioned in the particular test for verifying the parameters & recording the observations.
4. Check for the availability of following documents as Pre-requisite to initiate the qualification activity – User requirement specifications (URS), Design Qualification (DQ) or FDS (Functional Designing Specification).
5. Check the installation verification of the system as per checklist and record the details.
6. Identify the major components of the system and records the details.
7. Verify the specification of major components and record the same.
8. Deviation Handling: During execution, if any deviation is observed.
9. A summary report of the qualification activities conducted shall be prepared. Report shall be checked by IT, Maintenance, Warehouse, Production, QC, QA and approved by Head QA.
10. Upon successful completion of installation qualification activity, operation qualification shall be initiated.

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8 ACCEPTANCE CRITERIA

System and its accessories should be as per the purchase order and free from any physical damage.

The installation of system shall be checked in accordance with this protocol and it should be found satisfactory.

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9 PREREQUISITE TO INITIATE THE INSTALLATION QUALIFICATION

Sr. No.	Document	Status (Available / Unavailable)	Checked By Sign /Date
1.	User Requirement Specifications (URS)		
2.	Functional Designing Specification (FDS)		

9.1 INSTALLATION VERIFICATION OF TEST DETAILS

Sr. No.	Test Case	Test Procedure	Acceptance Criteria
1.	Verification of installed hardware, operating system and software (if any) of server required for installation of Mobivue PMMS UAT/Quality environment	<ul style="list-style-type: none"> Verify hardware Compare the information with recommended hardware and software infrastructure document provided by software vendor. 	<ul style="list-style-type: none"> Unique identification number (Asset No.) for server shall be available. Server hardware & software configuration should comply with recommended hardware and software infrastructure document.
2.	Verification of Installed Antivirus Software on Application and Database Server	Verify the availability of antivirus software and its updates.	Licensed antivirus software should be installed and updated virus definitions should available for

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Sr. No.	Test Case	Test Procedure	Acceptance Criteria
			database and application server.
3.	Verification of browser applicability at quality environment	Verify the availability of browser	Browser should be available.
4.	Verification of Power Utilities at Server Room	<ul style="list-style-type: none"> Identify the power equipment. Note down specification from manufacturers tag plate. Switch off mains and verify that system transfers the load on battery backup. Verify the battery voltage after 10 min. 	<ul style="list-style-type: none"> UPS system with battery back-up should be installed for the power stability. Battery backup time must be minimum 30 minutes for safe shutdown or switchover to alternate power source in case of power failure. System load should be less the 80% of total UPS system capacity (or as per manufacturer's specifications).

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Sr. No.	Test Case	Test Procedure	Acceptance Criteria
5.	Verification of Environmental Condition and physical security for the installed infrastructure (server room)	<ul style="list-style-type: none"> • Verify the server room environment condition record and check with technical specification. • In case of non-availability of temperature and relative humidity record, measure the same during the execution and record measured value in the test table. • Verify server room physical security (i.e. biometric access or lock and key). 	<ul style="list-style-type: none"> • The system environment conditions shall be within the specified limit as per specification of server manufacturer. • The server room should access to authorized persons only.
6.	Verification of Security Policies of Server.	<ul style="list-style-type: none"> • Login in Mobivue PMMS server with 'Administrator' level user. • Verify security settings from 'Default domain security settings'. • Verify account policy, password policy and different local policies. 	<ul style="list-style-type: none"> • Actual observations noted in respective tables should match with expected results (APL policy) for all required parameters for Server's.

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Sr. No.	Test Case	Test Procedure	Acceptance Criteria
7.	Verification of installed hardware and operating system and antivirus of client required to operate Mobivue PMMS UAT/Quality environment.	<ul style="list-style-type: none"> • Select client stations as samples for Mobivue PMMS user client. • Verify hardware and software information and compare the information with recommended hardware and software infrastructure document provided by software vendor. • Verify the availability of Antivirus Software and its updates. 	<ul style="list-style-type: none"> • Unique identification number (Asset No.) for client station shall be available. • Client hardware & software configuration should comply with recommended hardware and software infrastructure document. • Licenses of all installed software shall be available. • Licensed Antivirus software should be installed and updated virus definitions should available for client.

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Sr. No.	Test Case	Test Procedure	Acceptance Criteria
8.	Verification of Security Policies of Client (user desktop).	<ul style="list-style-type: none"> • Login in client with 'Administrator' level user. • Verify security settings from 'Default domain security settings'. • Verify account policy, password policy and different local policies. 	<ul style="list-style-type: none"> • Actual observations noted in respective tables should match with expected results (APL policy) for all required parameters for client.
9.	Verification of Network Connectivity	<ul style="list-style-type: none"> • Verify network connectivity of test client system with Ping to Mobivue PMMS UAT/Quality and Production server and record results. 	<ul style="list-style-type: none"> • The client should get PING response from server without any error message like "Request timed Out" and/or "Destination Host Unreachable" or vice versa.
10.	Verification of Network component	<ul style="list-style-type: none"> • Verify details of network component 	<ul style="list-style-type: none"> • Should be meet with acceptance criteria
11.	Verification hardware of MobiVUE PMMS System	<ul style="list-style-type: none"> • Verify hardware configuration details of MobiVUE PMMS System 	<ul style="list-style-type: none"> • Should be meet with acceptance criteria

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10 INSTALLATION VERIFICATION

Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
A. General Verification					
1	No Physical damage to the system after locating on the final site of installation.	There should not be any physically damage			
2	All components are installed.	All component should be installed			
3	All electrical connections have been done	All connection should be done			
4	All utilities are connected properly	All utilities should be connected properly			
5	Verify Development Browser	Development server http://172.16.200.28:4200/Dev			
6	Verify UAT/Quality Browser	UAT/Quality server http://172.16.200.28:4300/Qty			

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11 HARDWARE AND SOFTWARE DETAILS

Sr. No	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
A. Verification of Application Server Hardware Configuration for UAT/Quality environment					
1	Asset no.	*			
2	Server Make	*			
3	Host Name	*			
4	Serial Number	*			
5	Gateway	*			
6	IP Address	*			
7	Domain Name System	*			
8	Make	*			
9	Model	*			
10	Processors	3.40GHz, 3.41GHz			
11	Central Processing Unit (CPU)	Intel® Xenon® E-2224 CPU			
12	Random Access Memory (RAM)	8 GB or higher			

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Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
13	Hard Disk Capacity	Minimum 50GB			
B. Verification of Application Server Software Configuration for UAT/Quality environment					
1	Server operating system	Windows Server 2016 Standard			
2	System type	32-bit or 64-bit			
3	OS Version	*			
4	Additional software (if any)	*			
5	License	Should be available			

Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
C. Verification of Data base Server Hardware Configuration for UAT/Quality environment					
1	Asset no.	*			
2	Server Make	*			
3	Host Name	*			
4	Serial Number	*			

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Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
5	Gateway	*			
6	IP Address	*			
7	Domain Name System	*			
8	Make	*			
9	Model	*			
10	Processors	3.40GHz, 3.41GHz			
11	Central Processing Unit (CPU)	Intel® Xenon® E-2224 CPU			
12	Random Access Memory (RAM)	8 GB or higher			
13	Hard Disk Capacity	Minimum 50GB			

D. Verification of Data base Server Software Configuration for UAT/Quality environment

1	Server operating system	Windows Server 2016 Standard			
2	System type	32-bit or 64-bit			
3	OS Version	*			
4	Additional software (if any)	*			

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Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
5	License	Should be available			

Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
.					

E. Verification of Physical Dimension for Application Server & Data base server rack

1	Rack Number	*			
2	Height	*			
3	Depth	*			
4	Width	*			

Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
.					

F. Verification of Antivirus on Application server for UAT/Quality environment

1	Name of Antivirus	*			
2	Version Number of Antivirus	*			
3	Software License	Should be available			

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Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
4	Product Update	Immediate			
G. Verification of Antivirus on Data base Server for UAT/Quality environment					
1	Name of Antivirus	*			
2	Version Number of Antivirus	*			
3	Software License	Should be available			
4	Product Update	Immediate			

Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
H. Verification of Power Utility at Server room					
1	Type of Power Equipment	UPS			
2	Tag No.	*			
3	Make	*			
4	Model No.	*			
5	Serial No.	*			

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Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
6	Input Voltage & Frequency	400V			
		50Hz			
7	Output Voltage & Frequency	235V			
		50.1Hz			
8	Capacity of the System	20KVA			
9	Switch off mains incoming Power breaker of the UPS System	System should switch over to battery operation mode automatically			
I. Verification of Environmental Condition at Server room & Server room access					
1	Temperature	10°C-35°C			
2	Relative Humidity	10% - 80%			
3	Server room access	Biometric access to authorized user or lock and key			
J. Verification of Password and Account Lockout Policy at Server					
1	Minimum length	8 character			
2	Password complexity	Should be Enabled			

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Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
3	Facility for change password	Should be Enabled			
4	Lockout duration	3 Min.			
K. Verification of installed hardware and operating system and antivirus of client PC					
1.	Department	*			
2.	Asset no.	*			
3.	Host Name	*			
4.	Location	*			
5.	IP Address	*			
6.	Model	*			
7.	Capacity of HDD	50 GB free disk space or More			
8.	Processor	1.5 GHz or higher			
9.	RAM	4 GB or Higher			
10.	Operating System	Windows			
11.	Version	*			
12.	License	Yes			

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Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
13.	Name of Antivirus	*			
14.	Version	*			
15.	Update	Immediate			
16.	License	Should be available			
17.	Name of application server	*			
18.	Application Server's IP Address	*	13091		
19.	Connectivity	Should be Connected with client PC			
20.	Name of Database server	*			
21.	Database Server's IP Address	*			
22.	Connectivity	Should be Connected with client PC			
L. Verification of Password and Account Lockout Policy for client PC					
23.	Minimum length	8 character			

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Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
24.	Password complexity	Should be Enabled			
25.	Facility for change password	Should be Enabled			
26.	Maximum Password change	90 Days			
27.	Enforced password history	Should be Enabled			
28.	Lockout duration	3 Min			
29.	No. of invalid	3			

M. Verification of Network Components

1.	Location	Admin Server Room			
2.	Type	Switch			
3.	Asset No.	G/IT/NS/005			
4.	Make	CISCO			
5.	Model	SG300-52			
6.	Serial number	DNI2025092R			

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Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
7.	Ethernet connecter type	RJ-45			
8.	Power supply	UPS			
9.	Operating Temperature	10°C-35°C			

N. Verification of Peripheral devices configuration

Enterprise Tablet (ET51) Details:

1.	Make	*			
2.	Model	*			
3.	Total Nos	*			
4.	Serial No.	*			
5.	Display	Touch screen			
6.	Power	After pressing power button Tablet should be start			
7.	Operating System	Android 8.1.0			

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8.	Wi-Fi	Should be connected with Wi-Fi			
9.	Barcode Scan	Should be scan barcode			
10.	Storage	Minimum 32 GB			

Hand Held Terminal Details (Zebra Mobile Computer):

1.	Make	*			
2.	Model	*			
3.	Total Nos	*			
4.	Serial No.	*			
5.	Display	Touch screen			
6.	Power	After pressing power button Tablet should be start			
7.	Operating System	Android 8.1.0			

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Sr. No.	Check Points	Acceptance Criteria	Verification Result	Pass/Fail	Checked By Sign & Date
8.	Wi-Fi	Should be connected with Wi-Fi			
9.	Barcode Scan	Should be scan barcode			
10.	Storage	*			

Zebra thermal Printer Details

1.	Make	*			
2.	Model	*			
3.	Total Nos.	*			

Zebra thermal Printer hardware Configuration

1.	Mounting Details	Should be Connect with LAN			
2.	Printing Method	Thermal Transfer Printing			
3.	Power	After pressing power button Printer must start			

*Actual details to be recorded during execution.

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1	Verify configure the application by using Internet Information services (IIS)	IIS version: 10.0			
2	Verify SAP connectivity with application	Should be connected with SAP			
Verification of Database configuration					
1	IP Address of the database	172.16.200.30			
2	Database Name	AjantaDevGHT			
3	SQL Version	Server 2019 (RTM) - 15.0.2000.5 (X64)			

For the back end software installation procedure refer attached Annexure No.I

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16 DEVIATION SHEET

Sr. No.	Description of Deviation	GMP Criticality	Corrective Action	Need to be closed before OQ

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17 LIST OF ABBREVIATIONS

GMP	Good manufacturing practice
V	Volt
Hz	Hertz
Amp	Amperes
IQ	Installation qualification
PMMS	Pharmaceutical Manufacturing Management System

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18 SUMMARY AND CONCLUSION

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19 POST APPROVAL

In the list below all persons having participated in the execution of IQ and having signed on any of the tests are identified with their full name, department and function and their signature. With this signature the test participant confirms awareness of procedures to be followed in qualification tests and completion of associated documentation.

Ajanta Pharma Ltd :-				
--	Name	Department	Designation	Sign & Date
Reviewed By				
Reviewed By				
Reviewed By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				