



PHARMA DEVILS

**OPERATIONAL QUALIFICATION PROTOCOL
FOR
AIR JET MACHINE**

PROTOCOL No.:

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PROTOCOL No.:

1.0 PRE- APPROVAL

Signing of this Operational 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	Signature	Date
Production			

CHECKED BY:

Organization	Name	Signature	Date
Engineering			
Production			
Quality assurance			

APPROVED BY:

Organization	Name	Signature	Date
Head Engineering			
Head Manufacturing			

AURTHORISED BY:

Organization	Name	Signature	Date
Head Quality			



2.0 OBJECTIVE

The objectives of this Operational Qualification (OQ) are as follows:

- To verify that the equipment operates 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 operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

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 Air jet machine meets all the acceptance criteria and is ready for PQ.

3.0 SCOPE

This protocol covers all aspects of Operational Qualification for the Air jet Machine serving components. This protocol will define the methods and documentation used to qualify the Air jet machine. Successful completion of this protocol will verify that the Air jet machine meets all acceptance criteria and is ready for Performance Qualification.

4.0 RESPONSIBILITIES

All work is to be performed under oversight and according to approved procedures.

Engineering Validation Personnel

The following are the responsibilities of Engineering Validation Personnel:

- Preparation, Review and submission of OQ Protocol.
- 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.

The following are the primary responsibilities of the Validation Personnel.

- Overall cGMP compliance for OQ
- Review and Pre-Approval of OQ Protocol
- Execution of this OQ protocol
- Document Control of OQ Protocol until such document is completed, approved and after.
- Regulatory Compliance Review of the completed OQ Protocol
- Review and Approval of the executed OQ Protocol.

5.0 SYSTEM DESCRIPTIONS

Very High Speed Air jet machine has following major components.

5.1 Conveyor Belt

The container moving on conveyor belt are separated by in feed worm and transferred to the infeed turn table which then transfer it to the air jet line.

5.2 Air jet machine

Very High Speed Air jet machine is versatile self supported on with height adjustable adjustment system. In this equipment two AC drive, two motor, dust collector, ionized unit, air pressure switch are fitted. The main



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working of this system to cleaning of bottle. Air jet system rotates the bottle and air cleaning is to be done. High voltage is given through ionized unit to protect the contamination. Dust is automatically collect in dust collector.

6.0 DOCUMENTATION REQUIREMENTS

The OQ File should include:

- This OQ Protocol.
- All printouts and handouts generated during the qualification procedure.
- Any laboratory test results or their referenced location.
- A Signature Sheet where all people, performing the qualification tests, are listed.
- Any change control actions that may have occurred during the qualification activities.
- Any variances, exceptions or investigation reports generated during the qualification activities.

7.0 DATA COLLECTION

All individuals executing this Protocol shall complete the *Signature Sheet*. All personnel shall have suitable documented training or experience.

All approvals shall be made in *BLACK* ink.

All data entry shall be made in *BLACK* ink.

All corrections to this Protocol, which are not retyped, are to be made in *BLACK* 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 printouts and certificates and retain for inclusion in the OQ File. If more Data Sheets or Variance Sheets are required, they are to be attached to this Protocol as *Annexure* and to be listed in *Section 13. List of Annexure*.

8.0 CHANGE CONTROL

Any changes or modifications to the system shall be performed in accordance with the Project Change Control Procedure (SOP No:).

Change Control Forms raised during the execution of this OQ 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.

9.0 PRE-QUALIFICATION REQUIREMENTS

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

9.1 System Pre-requisites

S. No.	Description of Pre-requisite	Completed Yes or No	Verified By	Date
1	Verify that the IQ of the Air jet machine has been executed and approved. IQ Protocol Document No:	Yes/No*		
2	Verify that Site Acceptance Tests (SAT) of the Air jet machine has been executed and approved.	Yes/No*		



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3	Verify that the safety walk through has been completed and that the system is safe to use.	Yes/No*		
Verify that authorised drafts of the following procedures (SOP / PMI) relevant to operation of the Air jet machine are available.				
4	SOP of Air jet machine.	Yes/No*		
5	SOP of Air jet machine Maintenance.	Yes/No*		
6	SOP of Air jet machine Cleaning /Washing	Yes/No*		
7	Verify that all critical instruments associated with the system will be in a calibrated state during OQ execution.	Yes/No*		

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

9.2 Test Equipment Calibration

Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below.

All equipment / instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment Name	Equipment Owner	Equipment Number	Due Date	Signature	Date

Reviewed by		Date	
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10.0 TESTS AND CHECKS

10.1 SOP Verification

10.1.1 Purpose

To verify the accuracy of Standard Operating Procedures applicable to the Air jet machine

10.1.2 Method

Obtain a controlled copy of each SOP referenced within section 10.1.4. During the course of OQ testing, perform each operation according to the instruction indicated within the appropriate SOP. Mark with a highlighter pen each instruction or statement within the SOP which is verified and in accordance with the actual practice. Write any differences from actual practice in red ink on the copy of the SOP. On completion, write "Operational Qualification - SOP Verification" on the marked-up copy of the SOP, sign & date it and attach as an appendix to the OQ protocol together with any other raw data such as printouts.

Ensure all SOP's identified in Section 10.1.4 are evaluated and checked.

10.1.3 Acceptance Criteria

At the completion of OQ testing, all standard operating procedures referenced within section 9.1.4 will be annotated to correctly reflect the applicable method instruction(s) required to obtain intended operation or function result.

10.1.4 Results

Enter the SOPs into the table below and verify that they have been evaluated and checked. Incorporate the marked up SOPs as an appendix to the OQ report together with any other raw data such as printouts.

SOP Number	SOP Description	SOP accurate after check [Y/N]	Initial / Date
.....	Operation & Cleaning of Dry syrup Bottle Air jet machine.		

Equipment Operated by		Date	
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Comments:

Reviewed by		Date	
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10.2 Input/Output (I/O) Test

10.2.1 Objective

To verify that PLC Inputs and Outputs (I/Os) are connected to the correct field device.

10.2.2 Method

Input/output checks have been carried out as part the site acceptance/commissioning process, as such, results are documented in Site Acceptance Test (SAT) document. Ensure that all tasks have been completed and signed off as correct.

Check the machine operation either by sequence of operation by forcing the signal and record the result.

10.2.3 Acceptance Criteria

SAT must show that all field devices operate and communicate correctly with the control system in agreement with the electrical schematics. Therefore, verify that all testing was witnessed, completed and signed off as correct.

Where Digital I/Os have been re-tested, verify that all field devices operate and communicate in accordance with the control system and in agreement with associated electrical schematics.

10.2.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Verify Digital Input/Output Tests have been Completed as specified in SAT document	Tests have been witnessed, completed and signed off as correct.			

Equipment Operated by		Date	
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Comments:

Reviewed by		Date	
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PROTOCOL No.:

10.3 System Security Test

10.3.1 Objective

To verify that access to system programs and data are protected in an adequate manner.

10.3.2 Method

Follow instructions in the Test Method column in section 10.3.4 to test security of the system. Record all observations in the actual results column in section 10.3.4 and attach any raw data printouts as an appendix to this protocol.

10.3.3 Acceptance Criteria

Access to control system and software is to authorised personnel only. Specific acceptance criteria for each test are provided in section 10.3.4.

10.3.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Enter test methods for testing in-built security access to the control system (for operator, supervisor and maintenance)	Maintenance, Manual and Auto.			
Attempt to access PLC.	No Physical restriction by lock to an unauthorised user is in place.			

Equipment Operated by		Date	
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Comments:

Reviewed by		Date	
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10.4 System Start-Up and Shutdown Test

10.4.1 Objective

To verify that the system components will power-up and start as defined by the design documentation.

10.4.2 Method

Follow instructions in the Test Method column of section 10.4.4 to test the start-up and shutdown of each system component. Obtain approval from the Production, Electrical and Mechanical Departments (where applicable) prior to this test and attach the approval slip as an appendix to this protocol. Record all observations in section 10.4.4 and attach any raw data printouts as an appendix to this protocol.

10.4.3 Acceptance Criteria

All Start-up and Shutdown functions operate correctly as specified in the following document:

- System Operating and Maintenance Manual Air jet machine:

Specific acceptance criteria for each test are provided in the tables in section 10.4.4.

10.4.4 Results

10.4.4.1 Shutdown Procedure

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
While the system is operating, cease operation by assigning the following mode on the Man Machine Interface (MMI):				
Stop Compressed air supply to the equipment	Reading drops to zero in pressure gauge mounted on FRL unit inside structure of Air jet machine			
Switch "OFF" the mains	No Power distributed to electrical components. System returns to safe mode.			

Equipment Operated by		Date	
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Comments:

Reviewed by		Date	
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10.4.4.2 Power-Up and Start Test

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
The system is operating, by assigning the following mode on the Man Machine Interface (MMI)				
Observe Air jet machine physically	Visual Inspection of Air jet machine			
Switch "ON" the mains	Power is distributed to electrical components in control Panel. System returns to operation mode			
Compressed air supply to the equipment.	Reading appears in pressure gauge mounted on FRL unit inside structure of Air jet machine.			
Operate different system component in sequence	All the system component starts functioning as per the sequence mentioned in point no. 4 (system description)			

Equipment Operated By		Date	
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Comments:

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PROTOCOL No.:

10.5 Operator Data Entry Test

10.5.1 Objective

To verify system response following Operator Data Entry and to ensure that the system will only accept approved inputs and that all other inputs are rejected in a controlled manner.

10.5.2 Method

Follow the instruction within the test method column of section 10.5.4 to test the data entry of the system. Record all observations in the actual results in section 10.5.4 and attach any raw data printouts as an appendix to this protocol.

Ensure that upon test conclusion, all parameter set points are returned to normal operating status.

10.5.3 Acceptance Criteria

Operator inputs with limits / formats associated with them will accept values as stated in column "System accepts Input as Valid". Entered value or format stated in column "System rejects Input as invalid" will be rejected by the system.

10.5.4 Results

System Variable	Limits		Value Smaller than Min	Value Greater than Max	Expected Result Met? [Yes/No]	Initial / Date
	Min	Max				
Expected Result	System accepts Input as Valid		System rejects Input as Invalid			
Pressure Gauge				NA		

Equipment Operated by		Date	
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Comments:

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10.6 System Functionality Tests

10.6.1 Objective

To verify Air jet machine components functionality.

10.6.2 Method

Prior to this test, power up and start-up each component as described in Section 10.6.4: *Power up and Start Test*. Operate each item as described in Section 10.6.4 to test the functionality of the system. Record all observations in the Actual Results column in Section 10.6.4.

10.6.3 Acceptance Criteria

All aspects of control for individual components integrated within the Air jet machine shall function as specified in the expected results column in Section 10.6.4.

10.6.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Switching on the Power and Utilities to the System				
Switch on the power & utilities to Air jet machine.				
Monitor and Log the readings.	Log the following readings: 1. Voltage. 415 ± 10 % Volts 2. Amperage in Amp meter 3. Compressed air pressure – 4 bar.			
Observe Air jet machine physically	Visual Inspection of Air jet machine.			
Switch “ON” the mains	Power is distributed to electrical components in control Panel. System returns to operation mode			
Compressed air supply to the equipment.	Reading appears in pressure gauge mounted on FRL unit inside structure of Air jet machine.			

Equipment Operated by		Date	
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Comments:

Reviewed by		Date	
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10.7 System Alarm and Interlocks Test

10.7.1 Objective

To verify that operation of system alarms and interlocks are functioning correctly.

10.7.2 Method

Air jet machine Alarm Tests have been carried out as part the site acceptance/commissioning process, as such, results are documented in Site Acceptance Test (SAT) document Ensure that all tasks have been completed and signed off as correct. State this in the section below and refer to the relevant supporting documentation in the Actual results column.

With a copy of the SAT document and relevant sections of the Software Design Specification for the Air jet machine, re-test 10% of all alarms in accordance with the method described in the SAT. List down the names of individual alarms and interlocks re-tested on a check sheet. Verify on the check sheet that the alarm/ interlock has passed or failed.

If there are no failures when testing 10% of the alarms, then alarms testing are complete. Record results in section 10.7.4. Should there be a failure of one or more alarm proceed to re-test 50% of all alarms in the manner described above. If no failures are found while checking 50% of the alarms, then alarms testing are complete. Record results in section 10.7.4. If there are one or more failures while testing 50% of the Alarms, proceed to test 100% of the Alarms in the manner described above.

Note: Only test the alarms / interlocks that will not result in any physical/ structural damage to the system as a result.

Ensure that all instruments or equipment used to conduct this test are calibrated. Attach copies of calibration certificates as an appendix to this protocol, and record details as necessary in Section 10.2.

Attach a copy of the alarms and Interlocks test check sheet as an appendix to the protocol. Record all observations in the Actual Results in section 10.7.4 and attach any raw data printouts to the alarms and Interlocks test check sheet.

10.7.3 Acceptance Criteria

SAT document must show that the system alarms/ interlocks activate in the correct situation and with the correct effect. Alarm / Interlock retesting must activate in the correct situation and with the correct effect as described in the SAT document.

System cannot be started when critical alarms are activated.

Record of alarms/interlocks testing check sheet is attached in the appendix



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10.7.4 Results

Item	Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Clear all the alarms. Press the alarm reset key. Press the drive on. Then follow the test method.					
Door	Ensure that door is not in bypass mode. Open the door one at a time.	On each opening of the door , the machine should stop.			
Air pressure low	Forcefully lower down the air pressure to less than 6 bar.	The machine should stop.			
Emergency stop	Press the emergency off switch. PLC INPUT X16 will switch off.	When the machine trips, it should display "EMERGENCY STOP BUTTON PRESSED".			
Motor clutch trip	Forcefully keep the motor clutch trip proximity switch in ON condition for one second.	The machine should stop and display "MOTOR CLUTCH TRIP"			
Main motor drive trip	Forcefully switch OFF the power to the A.C. drive.	The machine should stop and display "MAIN MOTOR DRIVE TRIP"			
Bottle Jam	Jam the bottle through sensor	The machine should stop and give alarm			

Equipment Operated by		Date	
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Comments:

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10.8 System Emergency Shutdown Stop

10.8.1 Objective

To verify that the emergency stop function activation shuts down the system in an appropriate manner.

10.8.2 Method

Ensure system is running under normal operating procedures. Press the emergency stop button and follow instructions in the Test Method column in section 10.8.4. Record all observations in the Actual Result column in section 10.8.4 and attach any raw data printouts as an appendix to this protocol.

10.8.3 Acceptance Criteria

Component comprising the system shut down in a safe and controlled manner when the emergency stop button is pressed. All pumps and motors will trip. An alarm condition is registered with audible alarm.

10.8.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial /Date
Press Emergency Stop Button while the system is running in normal operating mode	The system shuts down in a safe and controlled manner.			

Equipment Operated by		Date	
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Comments:

Reviewed by		Date	
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10.9 System Power Failure and Recovery Test

10.9.1 Objective

To ensure that system integrity is maintained in the event of power loss, that the system operates in accordance with specified acceptance criteria during failure and that the system can be recovered back to a satisfactory operational state without the loss of data

10.9.2 Method

Perform a simulated power loss while the systems operating normally without any faults. Verify the capability of the system to safely recover and resume normal operation. Verify that the system is able to retain the original program without data corruption. Also, verify that the system can prevent loss or corruption of stored data.

Follow instructions in the Test Method column in Section 10.9.4. Record all observations in the Actual Results column in section 10.9.4 and attach any raw data printouts as an appendix to this protocol.

10.9.3 Acceptance Criteria

Upon loss of power the system shuts down safely without causing damage to equipment components and can automatically restart following a power failure event without the need for application of additional resetting procedures. The system is able to retain the original program upon a loss of power.

The system is able to prevent the loss or corruption of stored data during a power failure.

10.9.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Pressure Gauge				

10.9.4.1 Parameter settings

System Variable	Prior to Power Failure	Following power restoration	Initial / Date
Pressure Gauge			

Equipment Operated by		Date	
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Comments:

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10.10 Operator Interface and Screen Graphics Testing

10.10.1 Objective

To verify the operation of all push buttons, switches associated with the Air jet machine.

10.10.2 Method

Verify that all push buttons, switches operate as defined in the tables. Document the results of the test in the table below. Record the results in section 10.11.4 of this protocol.

Verify and mark-up a copy of the following operator screens and attach the copy to the protocol

10.10.3 Acceptance Criteria

The push buttons touch buttons and switches operate as defined in the tables. The screen graphics appear as defined in the table.

The actual results meet the expected results as defined in the test table(s) provided.

10.10.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Control panel:				
<u>Alarm sounder reset:</u> Generate an alarm and press the Alarm sounder reset	The Audible alarm silences, but raised alarm is still active.			
<u>Reset alarm button:</u> Generate an alarm and press the Reset alarm button when the alarm condition has been lifted.	The alarm is reset and the alarm disappears from the alarm status 'active alarms' screen.			

Equipment Operated by		Date	
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Comments:

Reviewed by		Date	
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10.11 Loss of Utilities

10.11.1 Objective

To verify the loss of utilities supplies will not affect or damage the Air jet machine and that the subsequent return of any failed utility does not pose a threat to the system, the system’s operator and the product quality.

10.11.2 Method

• **Compressed Air Supply to the Air jet machine**

Run the Air jet machine in normal operation.

Isolate the supply of compressed air to the Air jet machine. Record the system’s reactions and any alarms generated in the result table below.

Reinstate the supply of compressed air and record the systems reactions in the result table 10.14.4 as the system returns to normal operation.

10.11.3 Acceptance Criteria

The Rotocone Vacuum Dryer shall raise an alarm and revert to the scenarios listed in the results section below on the isolation of:

- Compressed air

10.11.4 Results

Test method	Expected Result	Actual Result	Acceptable [Y/N]	Initial/Date
Turn off compressed air supply to the Air jet machine by closing valve Record the system’s reactions in the “actual result” column.	Air pressure low			
	All actuated valves fail-safe			
	System shuts down			
Restore compressed air supply to the Air jet machine by opening valve Record the system’s reactions as the system returns to normal operation.	System reverts to normal status			

Equipment Operated by		Date	
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Comments:

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10.12 Automation Interface Tests

10.12.1 Objective

To verify that the interface between the control system and other automation is as defined.

10.12.2 Method

Follow the instructions in the Test Method column in the table to test the interface between the control system and other automation. Record all observations in the Actual Results section of the table.

10.12.3 Acceptance Criteria

The interface between the control system and other automation must be as defined in the expected result column within the table

10.12.4 Results

Test method	Expected Result	Actual Result	Acceptable [Y/N]	Initial/Date
Disconnect the control panel communication cable.	Control panel to become blank and message will appear that communication signal is missing.			

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11.0 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
10.1	SOP Verification		
10.2	Digital Input & Output Test		
10.3	Air Jet machine Security Test		
10.4	Air Jet machine Start-Up and Shutdown Test		
10.5	Operator Data Entry Test		
10.6	Air Jet machine Functionality Test		
10.7	Air Jet machine Alarm and Interlocks Test		
10.8	Air Jet machine Emergency Shutdown Test		
10.9	Air Jet machine Power Failure and Recovery Test		
10.10	Operator interface and Screen Graphics Testing		
10.11	Loss of utilities		
10.12	Automation Interface test		

Comments:

Reviewed by

Date



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12.1 DEVIATION AND CORRECTIVE ACTION REPORT FORM

This Deviation and Corrective Action Report Form shall be completed for each result that does not meet the expected or as designed condition encountered during the execution of the protocol. Each form shall be numbered sequentially and tracked on the Deviation Sheet within the protocol.

Deviation Report Number:		
PROTOCOL SECTION NO.:	DATE OF TEST:.....	
Description Of Test Result:		
IMMEDIATE ACTION TAKEN:		
Corrective Action Taken / Planned:		
Deviation Reported By:		
Name:	Signature:	Date:
Corrective action must be taken prior to approval of IQ or OQ? :		
HEAD - ENGG. SIGNATURE	DATE:	
Head-User dept. signature	Date	
QA Signature:	Date:	
Corrective Action Implemented:		
Corrective Action Implemented By:		
Name:	Signature:	Date:
(Attach comments and supporting documentation as necessary)		
Was a re-test or amendment necessary due to the Deviation?	Date of re-test:	
Is Deviation Closed (Yes/No):		
QA Signature:	Date:	



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16.0 POST APPROVALS

The following approvals signify that the OQ is complete and acceptable and that the system is ready for PQ Execution.

PREPARED BY:

Functional area	Name	Signature	Date
Production			

CHECKED BY:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality assurance			

APPROVED BY:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			

AUTHORISED BY:

Functional area	Name	Signature	Date
Head Quality			