OPERATIONAL QUALIFICATION PROTOCOL

FOR

HI – CART 5”

Equipment ID	
Equipment Location	**PACKING AREA**
Equipment Make	**Pam-Pac Machines Pvt. Ltd.**
Document No.	
Reason For Qualification	**New Machine**

Table Content

1.0 PREAPPROVAL

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			

AUTHORISED BY:

Functional area	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 Hi-Cart 5" Machine meets all the acceptance criteria and is ready for PQ.

3.0 SCOPE

This protocol covers all aspects of Operational Qualification for the Hi-cart 5" Machine Tablets, Capsules, Dry Syrup & Dry Powder Injection Manufacturing. Scope incorporates qualification of all Hi-cart 5" Machine components like Carton magazine, Product feeding, Prefolded leaflet transfer, Product pushing, Embosing cum over printing station, Front & Rear sides flap closing, Empty carton ejection system.

This protocol will define the methods and documentation used to qualify the Hi-Cart 5" Machine for OQ. Successful completion of this protocol will verify that the Hi-Cart 5" Machine meets all acceptance criteria and is ready for Performance Qualification.

4.0 RESPONSIBILITIES

In accordance with protocol, following functions shall be responsible for the qualification of the system regardless of whether such work is performed by own staff or contract / consulting staff.

Department	Responsibilities
Quality Assurance	Prepare the Performance Protocol
	Distributes the finalized protocol for review and approval signatures.
	Execution of Performance protocol.
	Review of Protocol, the complied qualification data package, and final report.
Engineering	Review, approval and execution of Performance qualification protocol.
Quality Control	Review of protocol, testing of samples, recording of results and final result submission.
Production	Review and approval of protocol, operation of equipments and manufacture as per the batch manufacturing record and batch packing record.
Head Quality	Final authorisation of protocol

5.0 DATA COLLECTION

All personnel shall have suitable documented training or experience. 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, check sheets, Laboratory test results and certificates and retain for inclusion in the OQ File.

6.0 SYSTEM DESCRIPTION

The Hi-Cart 5" Machine, and its associated equipments are designed to process pharmaceutical products in accordance with cGMP principles. The purpose of carton packing machine is to open the carton automatically by the machine and products are packed into the cartons. Machine can handle
various carton ranges as specified by Pampac. Cartons are loaded in the magazine. The cartons are picked by the vacuum suckers and prebroken.
Prebroken cartons are dropped into the carton chain pockets.. Products are pushed into the cartons and both sides' flaps are closed. Finally cartons are delivered from the delivery end belt.

Complete system can be divided into following sub sections:

6.1 Carton magazine

6.2 Product feeding

6.3 Prefolded leaflet transfer

6.4 Product pushing

6.5 Embossing cum over printing station

6.6 Front & Rear sides flap closing

6.7 Empty carton ejection system

6.1 Carton magazine: This station is provided for loading various sizes of cartons as per range given by Pam Pac. At all places the adjustments are provided for setting various sizes of cartons with the Ganter scales. Cartons are picked by the vacuum suckers connected to the Dry Vacuum Pump and prebroken and placed into the carton chain.

6.2 Product feeding: The product feeding system depends on product. For Blister feeding system the blisters are transferred from belt conveyor to mouth piece of servo collator system. Blisters are stack in moth piece and magazine of servo collator system. And then blisters are transferred into product pockets with help of cam driven by servo motors. The movement of this collator system for Blister dropping into the product pockets is synchronised through PLC & Servo Drive. Also make up magazine collator provided with machine for feeding the blisters into the empty pockets cell & the blister which are diverted from machine which needs to feed again through collator. This system also synchronised through PLC & Servo Drive.

6.3 Prefolded leaflet unit: This station is provided for loading various sizes of pre-folded leaflets as per drawing given by ACG Pampac. Prefolded leaflets are picked by the vacuum suckers connected to the vacuum pump & the leaflets are transferred through turret unit & hold with angle lever by sponge rubber & then transfer into leaflets clamps provided on leaflet chain. The synchronization of leaflet clamps & cell angle pockets is done mechanically with chain drive.

6.4 Product pushing: This station is provided to push the product into the carton gradually with the help of product pusher. The movement of pushers are synchronized with the cell angle pockets while it travels. In this the product pusher is change part depending on the product size.

6.5 Embossing cum overprinting station: This station is used to give batch code embossing provision on the carton. The embossing letters are fixed on the embossing holder and the carton flap is passed through the embossing holder and pressure roller to get the impressions of the letters on the carton flap. For overprint the batch code on carton main flaps stereo roller & ink roller provided
with the machine. Rubber stereo is customer's scope.

6.6 Front & Rear side flaps closing: While cartons are moving through the carton chain pockets, the side flaps are closed. The drive for flap closed is synchronized with the machine drive. The main flap gets closed in three stages. First tuck in flap is folded. In second stage tuck in flap is just positioned into the carton body and finally tuck in flap is totally closed.

6.7 Empty carton ejection system: This system is provided to detect and eject the empty cartons from the line. Sensor is provided to sense the product presence in the carton. If the product is not available in the carton,

sensor will give feedback to PLC and PLC will give signal to the pneumatic cylinder for operating. With the pneumatic cylinder the particular carton will be ejected out from the conveyor.

7.0 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.

8.0 CHANGE CONTROL

Any changes or modifications to the system shall be performed in accordance with Change Control Procedure. 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 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 Hi-Cart 5" Machine has been executed and approved. IQ Protocol Document No:.....	Yes/No*		
2	Verify that Site Acceptance Tests (SAT) of the Hi-Cart 5" Machine has been executed and approved.	Yes/No*		
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 Hi-Cart 5" Machine are available.				
4	SOP of Hi-Cart 5"Machine Operation and Cleaning	Yes/No*		
5	SOP of Hi-cart 5" Machine Maintenance.	Yes/No*		
6	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	

10.0 TESTS AND CHECKS

10.1 SOP Verification

10.1.1 Purpose

To verify the accuracy of Standard Operating Procedures applicable to the Hi-Cart 5" 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 10.1.4 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
BP/	Hi-Cart 5" Machine Operation/Cleaning.		
BP/	Hi-Cart 5" Machine Maintenance.		

Comments:

Reviewed by		Date	

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	

Comments:

Reviewed by		Date	

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.

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 (level 0, level 1, level 2, level 3)	Three level password for Manager, Supervisor and Operator.			
Attempt to access PLC.	Physical restriction by lock to an unauthorised user is in place.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

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 section10.4.4 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 Hi-cart 5" 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 Hum Machine Interface (HMI):				
Switch "OFF" machine lamp	No lights will be provided to the machine.			
Switch "OFF" the mains	No Power distributed to electrical components. System returns to safe mode.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

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 HUM MACHINE INTERFACE (HMI)				
Observe Hi-Cart 5" Machine physically	Visual Inspection of Hi-Cart 5" Machine (Carton Magazine, Product feeding, Prefolded leaflet transfer, Product pushing, Embossing cum over printing station, Front & Rear sides flap closing and Empty carton ejection system).			
Start operation by turning on the main power isolator at the Hi-Cart 5" Machine.	Power is distributed to electrical components in control Panel. System returns to operation mode.			
Jumping of Screen	Select the keys for require parameters on screen, it immediately jump on selected menu.			
Data change with password	By using System function key for changing the data with password level for operating.			
Alarms	If any alarms indicate on screen it easily reset by correcting the alarms.			
Counter reset	In monitor function the counter can reset by pressing the reset key for 10 seconds.			

Equipment Operated By		Date	

Comments:
Signed: Date:

Reviewed by		Date	

10.5 System Emergency Shutdown Stop

10.5.1 Objective

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

10.5.2 Method

Ensure system is running under normal operating procedures. Press the emergency stop button and follow instructions in the Test Method column in section 10.5.4. Record all observations in the Actual Result column in section 10.5.4 and attach any raw data printouts as an appendix to this protocol.

10.5.3 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.

10.5.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial/Date
Emergency stop press on HMI	The Machine will stop immediately.			
Emergency stop press at discharge end	The Machine will stop immediately.			
Emergency stop press at Collator	The Machine will stop immediately.			
Low air pressure Minimum 3 bar	The Machine will stop immediately.			
Machine guards open	Machine will not start and prevents the system from starting.			
Hand wheel out	Machine will not start in run 7 set mode.			
Loading safety to product pusher	Machine will not stop immediately.			
Carton vacuum off	Machine will not start in run mode.			
Low level carton	Machine will stop immediately			
Blister not sensed	Leaflet will not be picked up			
Leaflet not sensed	Carton will not be picked up			
Carton not sensed	Product pusher will get diverted			
No continous Product	Machine will stop as per set count			

No continuous Leaflet	Machine will stop as per set count			
No continuous Carton	Machine will stop as per set count			
Empty Carton ejection	Carton will eject at discharge end			

10.6 Operator Interface and Screen Graphics Testing

10.6.1 Objective

To verify the operation of all push buttons, touch buttons, switches and screen graphics associated with the Hi-Cart 5" Machine.

10.6.2 Method

Verify that all push buttons, touch buttons and switches and screen graphics operate as defined in the tables. Document the results of the test in the table below.

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

10.6.3 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.

10.6.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Control panel:				
Alarm sounder reset: Generate an alarm and press the Alarm sounder reset	The Audible alarm silences, but raised alarm is still active.			
Reset alarm button: 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.			
Display or print each of the screens containing critical data, from the system MMI. Verify the screens against those specified. Append printouts to this protocol.	The screens printed or displayed from the system, accurately represent the screens specified by the vendor documentation			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.7 Automation Interface Tests

10.7.1 Objective

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

10.7.2 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.

10.7.3 Acceptance Criteria

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

10.7.4 Results

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

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

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	Input / Output (I/O) Test		
10.3	System Security Test		
10.4	System Start-up and Shutdown test		
10.5	System Emergency Shutdown Stop		
10.6	Operator Interface and Screen Graphics Testing		
10.7	Automation Interface Tests		

Comments:

Reviewed by		Date	

12.0 DEVIATION 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 EXCEPTIONS / DEVIATIONS = _____

Exception / Deviation No.	Exception / Deviation Title	Status

Comments:

Reviewed by		Date	

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:
<u>Corrective Action Implemented:</u>
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:

13.0 REFERENCES

The Principle Reference is the following

- 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.
- SOP "Handling of Deviations".
- SOP "Change Control Procedure".

14.0 LIST OF ANNEXURES

Appendix No.	Document Title

15.0 SUMMARY

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			