HSTP 26® Tablet Press IQ/OQ

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we provide service.

Version 2.6 provided by Callie Scott

LFA Signature Identification

Prepared by	Name	Title	Date
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Approved by	**Name**	**Title**	**Date**
Manufacturing	Angus Wang	Purchasing	
Engineering			
Quality	Russell Crispin	Quality Control	

Disclaimer
This IQ/OQ is intended as a guide only and is not an exhaustive list. All qualification tests will need to be adapted to the industry and product, following industry regulations and the material safety data sheets that come with specific products. Please check with your Quality Control Manager/Department or other relevant internal departments at your company before using.

Comments:

Reviewed By: Date:

Contents

Comments:

Reviewed By: Date:

Qualification Protocol

Purpose and Background

The purpose of this Installation Qualification (IQ)/Operational Qualification (OQ) Protocol is to establish documented evidence that the HSTP 26® and its ancillary systems have been installed according to the system specifications, have been configured per applicable manufacturer's recommendations, design specifications, and process requirements, and performs the intended functions as specified in the protocol.

Scope

Equipment

This IQ/OQ Protocol applies to the following equipment:

Items	System Information
URS Reference	N/A
Factory Acceptance Testing (FAT) Reference	
Project Master Validation Plan Number	N/A
Site Master Validation Plan Number	N/A
Equipment Name/Description	HSTP 26/Rotary Tablet Press
Manufacturer	LFA Machines
Version Number	1
Serial Number	
Equipment ID Number or Asset Number	
Previous Qualification/Validation Number(s) (if applicable)	N/A
Is system new, modified, moved, periodic review, or revalidation?	
If revalidation, attach necessary change control document(s) and record attachment number. Provide reason for revalidation.	

Comments: .....

Reviewed By: ..... Date: .....

System Requirements

This IQ/OQ Protocol applies to the following system requirements:

System Requirement	Target
Output Speed Target	135,000 tablets per hour
Availability	90% (10% of potential availability taken up by cleaning, maintenance, etc.)
Quality Rate	+/-5% accuracy on tablet weight and hardness
Overall Equipment Effectiveness (OEE)	90-95%
Crew Target	1 person

Comments: .....

Reviewed By: ..... Date: .....

Responsibilities

The table below displays information regarding the individuals involved in developing this qualification protocol.

Department/Individual	Responsibilities
Validation Author	• Develops the process validation plan, protocol, and report. • Confirms accuracy and completeness of the validation and qualification deliverables.
Validation Project Leader	• Defines validation and qualification deliverables (i.e., process validation plan, protocol, and report, project monitoring, protocol execution). • Acquires inputs from any needed technical experts to determine the activities appropriate to the validation. • Identifies the resources required to conduct the validation.
Technical Representative	• Provides knowledge with regard to the equipment/process/product undergoing validation and qualification. • Provides assistance to the Validation Project Leader with respect to the technical aspects of the equipment/process/product. • Provides help with study designs, acceptance criteria, and statistical analysis, as necessary.
Quality Assurance/Quality Management	• Reviews and approves validation and qualification documentation. • Ensures that each document is complete, accurate, and compliant with applicable validation requirements. • Reviews and approves deficiencies that occur during validation.

Comments: .....

Reviewed By: ..... Date: .....

General Requirements

Completion of Installation Qualification (IQ) and Operational Qualification (OQ) shall be governed by the following general guidelines:

- Prior to starting any test case, the individual(s) involved in the test execution shall be trained on both the protocol and applicable procedure(s) required to execute the test cases.
- Except for the protocol approvers, each person who performs or reviews any section of tests within this document must complete the Signature Identification sheet.
- All tests that require the person executing the protocol to make a comparison, calculation or a judgment of satisfactory completion, will include a “Pass” or “Fail” column. This section will require the person executing the protocol to enter the disposition of each test or test step as appropriate.
- Any discrepancy encountered during execution will be documented as a deviation and will require analysis to determine the root cause, assessment of deviation risk, and corrective action recommendation, including repeat testing as appropriate. The deviation must be reviewed and approved prior to completing the associated test case. Each deviation shall be sequentially numbered and listed in a supported report log. The corresponding test case should reference the related deviation number.
- All test instruments used in the execution of this protocol must have a current calibration certification, traceable to NIST or applicable international standards. When the certificates for these instruments are held in the quality system (i.e., site calibration program), a verification of certification is sufficient. For all other instruments, current calibration must be demonstrated through calibration certificates.
- Any comments regarding the test case(s) will be recorded on the data sheets under the “Comments” section.
- The “Reviewed By” signature line will be signed by an independent reviewer who has read the respective test case and agrees with execution and conclusions.
- All supporting documentation and attachments must be identified or labeled with the minimum of the identification number, pagination (page of page), protocol number, and applicable test case(s).

General Acceptance Criteria

- The test case is successful and passes when all test steps meet the acceptance criteria.
- Successful completion of the protocol is achieved when all test cases have been successfully completed and all deviations resolved.

Comments: .....

Reviewed By: ..... Date: .....

Codes and Abbreviations

Code	Meaning
amps	Amperes
CE	Certification mark that indicates conformity with health, safety, and environmental protection standards sold within the European Economic Area
°C	Degree centigrade
Dev No.	Deviancy number
IQ	Installation Qualification
kg	Kilogram
kN	Kilonewton
mm	Millimeter
NIST	National Institute of Standards and Technology
Nm	Newton meter
OQ	Operational Qualification
PPE	Personal protective equipment
RH	Relative humidity
RTP®	LFA registered trademarked term meaning rotary tablet press

Comments: .....

Reviewed By: ..... Date: .....

Equipment and Process Description

HSTP 26® Process

The basic mechanism of the HSTP 26® involves filling the Tooling (Die, Upper Punch, and Lower Punch) with powder, compressing the powder, and ejecting the tablet.

Filling the Tooling with Powder

The dry materials are poured into the Hopper, which funnels the powder into the Fill Tray. As the machine operates, the Turret moves, which causes the Upper Punches to withdraw from the Dies. During this process, powder is moved by the Turret and is guided into the Die Bores by the Fill Tray.

Compressing the Powder

After the Die Bore is filled with powder, the Upper Punches are driven into the Dies. The Upper and Lower Punches then compress the powder under high pressure.

Ejecting the Tablet

After both punches compress the powder into a tablet, the Upper Tooling is withdrawn and the tablet is then pushed out of the Die Bore by the Lower Punch. Once the tablet has been ejected out of the Die Bore, it is slid out of the way by the Fill Tray's Take-Off Blade to prepare for the next tablet compression.

Comments: .....

Reviewed By: ..... Date: .....

Test Equipment

Equipment	Serial Number	Calibration Certificate Number	Calibration Date	Initial and Date
Compact force gauge				
Calipers				
Graduated steel ruler				
Indoor thermometer				
Hygrometer				
Multimeter				
Belt tension gauge				

Comments: .....

Reviewed By: ..... Date: .....

HSTP 26® - Serial Number

The objective of Document Qualification is to confirm the presence and validity of the appropriate documents.

TEST No. TDD01	PACKING LIST		
Purpose of Test			
To confirm the presence of the packing list with the appropriate information.			
Method			
1	Locate packing list with the shipping container.		
2	Confirm the package list includes description of products, quantity, net weight, and gross weight.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Description of products is present.		
2	Quantity of products is present.		
3	Net weight of shipment is present.		
4	Gross weight of shipment is present.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

HSTP 26® - Serial Number

The objective of Document Qualification is to confirm the presence and validity of the appropriate documents.

TEST No. TDD02	QUALIFICATION CERTIFICATE		
Purpose of Test			
To confirm the presence of CE qualification certificate.			
Method			
1	Inspect the CE certification.		
2	Confirm signature of authorized LFA personnel.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	CE qualification certificate is complete.		
2	Signature of authorized LFA personnel is present.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

HSTP 26® - Serial Number

The objective of Document Qualification is to confirm the presence and validity of the appropriate documents.

TEST No. TDD03	FACTORY ACCEPTANCE TEST REPORT AND QUALITY CONTROL CHECKLIST		
Purpose of Test			
To confirm the presence of factory acceptance test (FAT) report.			
Method			
1	Inspect the FAT report.		
2	Confirm quality control checklist from LFA Taiwan location is included.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	FAT report is complete.		
2	Quality control checklist from LFA Taiwan location is complete.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

Installation Qualification Protocol

Document Qualification

HSTP 26® - Serial Number

The objective of Document Qualification is to confirm the presence and validity of the appropriate documents.

TEST No. HS2D01	MATERIAL CERTIFICATE
Purpose of Test	
To confirm the presence of materials certificate.	
Method	
1	Point of contact materials are certified by third party.
2	Confirm materials are accurate to LFA standard.

Results

Test	Acceptance Criteria	Pass/Fail
1	Hopper material is confirmed to be SUS304 stainless steel.	
2	Turret material is confirmed to be cast iron 250.	
3	Interior Force Feeder material is confirmed to be SUS304 stainless steel.	
4	Fill Tray material is confirmed to be tin bronze QSN-6-3.	
5	Fill Tray Tail material is confirmed to be PTFE plate.	
6	Tooling is confirmed to be material that user specified.	
7	Ejection Tray material is confirmed to be SUS304 stainless steel.	

Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Disclaimer
This materials certificate does not come with the machine. The point of contact materials on the machine must be tested and certified by a third party.

Comments: .....

Reviewed By: ..... Date: .....

Installation Qualification Protocol

Document Qualification

HSTP 26® - Serial Number

The objective of Document Qualification is to confirm the presence and validity of the appropriate documents.

TEST No. TDD05	PRODUCT MANUAL		
Purpose of Test			
To confirm the presence of product manual.			
Method			
1	Find the HSTP® range product manual at https://www.lfatabletpresses.com/product-data in Product Manuals section.		
2	Confirm product manual link is accessible.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Product manual PDF is accessible and can be downloaded.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

Installation Qualification Protocol

Document Qualification

HSTP 26® - Serial Number

The objective of Document Qualification is to confirm the presence and validity of the appropriate documents.

TEST No. TDD06	ELECTRICAL WIRING DIAGRAM		
Purpose of Test			
To confirm the presence of electrical wiring diagram.			
Method			
1	Find the appropriate product manual at https://www.lfatabletpresses.com/product-data in Product Manuals section.		
2	Inspect the electrical wiring diagram in the product manual's appendix.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Electrical wiring diagram is accessible within the manual.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

Installation Qualification Protocol

Installation Position and Space Qualification

HSTP 26® - Serial Number

The objective of Installation Position and Space Qualification is to confirm the space and environmental conditions required for installation and operation.

TEST No. HS2IS01	WORKSPACE SURFACE		
Purpose of Test			
To confirm the workspace surface accounts for the machine's weight and force exerted by machine and user.			
Method			
1	Ensure workspace surface supports machine's weight of 1250 kg (around 2755 lbs).		
2	Ensure the workspace surface supports an additional 458 kg (around 1010 lbs).		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Workspace surface is sturdy enough to support 1708 kg (around 3765 lbs).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Disclaimer
Consult either a civil engineer or building manager to complete and verify the workspace surface qualification test.

Comments: .....

Reviewed By: ..... Date: .....

HSTP 26® - Serial Number

The objective of Installation Position and Space Qualification is to confirm the space and environmental conditions required for installation and operation.

TEST No. TDIS02	WORKSPACE TEMPERATURE		
Purpose of Test			
To confirm the workspace's temperature levels are acceptable for machine operation.			
Method			
1	Measure the workspace's temperature with an indoor thermometer.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Workspace temperature measures within 18-24 °C (64-75 °F).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

HSTP 26® - Serial Number

The objective of Installation Position and Space Qualification is to confirm the space and environmental conditions required for installation and operation.

TEST No. TDIS03	HUMIDITY		
Purpose of Test			
To confirm the workspace's relative humidity levels are acceptable for machine operation.			
Method			
1	Measure the workspace's humidity with a hygrometer.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Workspace relative humidity measures within 45-65% RH.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

HSTP 26® - Serial Number

The objective of Safety Measures Qualification is to confirm that machine installation meets requirements of safe production.

TEST No. HS2SM01	LIFTING EQUIPMENT		
Purpose of Test			
To confirm that the proper lifting equipment is available for mounting the machine.			
Method			
1	Ensure forklift and lifting strap are available.		
2	Ensure lifting strap supports the machine and does not induce any swinging or tilting of the machine.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Forklift and lifting strap are in position.		
2	Lifting strap is secure and supports the machine's weight in a balanced way.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

HSTP 26® - Serial Number

The objective of Safety Measures Qualification is to confirm that machine installation meets requirements of safe production.

TEST No. TDSM03	PERSONAL PROTECTIVE EQUIPMENT		
Purpose of Test			
To confirm user has access to the following items of personal protective equipment (PPE) for use during machine operation.			
Method			
1	Ensure protective equipment is on hand before using the machine.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Steel toe boots are in possession.		
2	Heavy duty grip gloves are in possession.		
3	Back support belt is in possession.		
4	Safety goggles are in possession.		
5	Disposable latex/rubber gloves are in possession.		
6	Hairnet and/or beard net are in possession (if applicable).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

HSTP 26® - Serial Number

The objective of Safety Measures Qualification is to confirm that machine installation meets requirements of safe production.

TEST No. TDSM04	MAX TIGHTENING TORQUE ON BOLTS		
Purpose of Test			
To confirm bolts on the machine are secure.			
Method			
1	Use a torque wrench to ensure the max tightening torque of major machine bolts are appropriate.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Dies' bolts are 4.3 Nm.		
2	Fill Tray Scraper's screw is 16.2 Nm.		
3	Upper Tracking's bolt is 153 Nm.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

HSTP 26® - Serial Number

The objective of Safety Measures Qualification is to confirm that machine installation meets requirements of safe production.

TEST No. HS2SM05	CORRECT LOCAL VOLTAGE		
Purpose of Test			
To confirm that the workspace has the correct local voltage for the machine.			
Method			
1	Ensure the workspace has the correct voltage.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Workspace electrics support 380 V or 220 V.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Disclaimer
Consult a licensed electrician to complete and verify the correct local voltage qualification test.

Comments:

Reviewed By: Date:

HSTP 26® - Serial Number

The objective of Equipment Appearance Qualification is to confirm no damage to the machine's appearance during installation.

TEST No. TDEA01	NAMEPLATE		
Purpose of Test			
To confirm that the nameplate is securely fixed onto the machine and its information is clear.			
Method			
1	Ensure that the nameplate is securely fitted to the machine.		
2	Ensure that the nameplate contains details that are pertinent to the operation of the machine.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Nameplate is present.		
2	Nameplate displays machine name.		
3	Nameplate displays version number.		
4	Nameplate displays serial number.		
5	Nameplate displays voltage and power requirements.		
6	Nameplate displays motor type.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

HSTP 26® - Serial Number

The objective of Equipment Appearance Qualification is to confirm no damage to the machine's appearance during installation.

TEST No. TDEA02	MACHINE BODY AND WIRING
Purpose of Test	
To confirm that the machine has no obvious damage to body and/or wiring.	
Method	
1	Inspect the machine body for obvious indentations, spots, scratches, cracks, or any other damages.
2	Inspect the wiring, cables, and electrical box for damage.

Results

Test	Acceptance Criteria	Pass/Fail
1	Machine body has no obvious damage.	
2	Machine's wiring, cables, and electrical box have no damage.	

Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

HSTP 26® - Serial Number

The objective of Production and Output Qualification is to confirm the maximum production and output values of the machine.

TEST No. HS2OQ01	ELECTRICAL OUTPUT LEVELS		
Purpose of Test			
To confirm that the machine's hertz, voltage, and kilowatt levels are correct.			
Method			
1	Use a multimeter to measure the machine for each unit.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum hertz is 50/60.		
2	Maximum volts is 380 or 220.		
3	Maximum kilowatts is 11.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Disclaimer
Consult a licensed electrician to complete and verify the electrical output levels qualification test.

Comments:

Reviewed By: Date:

HSTP 26® - Serial Number

The objective of Production and Output Qualification is to confirm the maximum production and output values of the machine.

TEST No. HS2OQ02	MAXIMUM PRESSURE		
Purpose of Test			
To confirm that the machine's maximum pressure level is accurate.			
Method			
1	Remove the Tooling from the press in accordance with product manual instructions (found at https://www.lfatabletpresses.com/product-data).		
2	Use a compact force gauge to record the maximum pressure exerted by the Upper Roller Cam.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum pressure produced is 100 kN (0.3 kN tolerance).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

HSTP 26® - Serial Number

The objective of Production and Output Qualification is to confirm the maximum production and output values of the machine.

TEST No. HS2OQ02	MAXIMUM PRESSURE		
Purpose of Test			
To confirm that the machine's maximum pre-pressure level is accurate.			
Method			
1	Remove the Tooling from the press in accordance with product manual instructions (found at https://www.lfatabletpresses.com/product-data).		
2	Use a compact force gauge to record the maximum pressure exerted by the Pre-Pressure Upper Roller Cam.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum pre-pressure produced is 20 kN (0.3 kN tolerance).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

HSTP 26® - Serial Number

The objective of Production and Output Qualification is to confirm the maximum production and output values of the machine.

TEST No. HS2OQ03	MAXIMUM TABLET DIAMETER		
Purpose of Test			
To confirm that the machine's maximum tablet diameter is 25 mm.			
Method			
1	Install 25 mm Tooling in press in accordance with product manual instructions (found at https://www.lfatabletpresses.com/product-data).		
2	Produce a test tablet using Firmapress as a control mix (purchase at https://www.lfatabletpresses.com/ready-mix-firmapress).		
3	Measure the test tablet with a set of calipers.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum tablet diameter produced is 25 mm (+/-5%).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

HSTP 26® - Serial Number

The objective of Production and Output Qualification is to confirm the maximum production and output values of the machine.

TEST No. HS2OQ04	MAXIMUM TABLET THICKNESS		
Purpose of Test			
To confirm that the machine's maximum tablet thickness 6 mm.			
Method			
1	Adjust Tooling to increase tablet thickness in accordance with product manual instructions (found at https://www.lfatabletpresses.com/product-data).		
2	Produce a test tablet using Firmapress as a control mix (purchase at https://www.lfatabletpresses.com/ready-mix-firmapress).		
3	Measure the test tablet with a set of calipers.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum tablet thickness produced is 6 mm (+/-5%).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

HSTP 26® - Serial Number

The objective of Production and Output Qualification is to confirm the maximum production and output values of the machine.

TEST No. HS2OQ05	MAXIMUM FILLING DEPTH		
Purpose of Test			
To confirm that the machine's maximum fill depth level is 16 mm.			
Method			
1	Adjust Tooling to increase fill depth in accordance with product manual instructions (found at https://www.lfatabletpresses.com/product-data).		
2	Turn the Handle until the Lower Punch is fully lowered.		
3	Insert a pipe cleaner (or anything similar that is non-abrasive) into the Die bore.		
4	Mark the point at which the pipe cleaner meets the Die bore's edge.		
5	Measure the fill depth with a graduated steel ruler.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum fill depth is 16 mm (+/-5%).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

HSTP 26® - Serial Number

The objective of Production and Output Qualification is to confirm the maximum production and output values of the machine.

TEST No. HS2OQ06	MAXIMUM HOURLY TABLET PRODUCTION		
Purpose of Test			
To confirm that the machine's maximum hourly tablet production level is approximately no less than approximately 135,000.			
Method			
1	Automatically operate the machine for one minute using Firmapress as a test mix (purchase at https://www.lfatabletpresses.com/ready-mix-firmapress).		
2	Record the tablet amount produced in one minute.		
3	Calculate the hourly output by multiplying the tablet amount by 60.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum hourly tablet production is approximately 135,000 (+/-5%).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Protocol Deviation Log

HSTP 26® - Serial Number

Record each of the deviations raised during the completion of the protocol and the date the deviation is resolved.

Deviation No.	Deviation Description	Date Resolved	Initial and Date

Comments:

Reviewed By: Date:

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