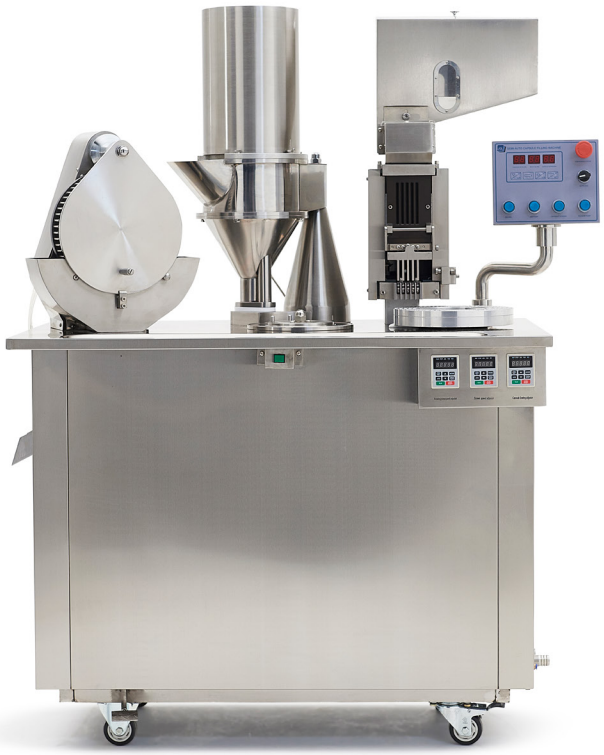
SACF 25®
Semi-Automatic Capsule Filler
IQ/OQ



We don’t just sell machines—
we provide service.

Version 1.4 provided by Callie Scott

LFA Signature Identification

Prepared by	Name	Title	Date
Author	Callie Scott	Technical Writer	2021-05-25
Approved by	**Name**	**Title**	**Date**
Manufacturing			
Engineering			
Quality			

Comments:

Reviewed By: Date:

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Comments:

Reviewed By: Date:

Purpose and Background

The purpose of this Installation Qualification (IQ)/Operational Qualification (OQ) Protocol is to establish documented evidence that the SACF 25® 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	SACF 25/Semi-automatic capsule filler
Manufacturer	LFA Machines
Model 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	25,000 capsules per hour (sizes #5, #4, #3, and #2) 21,400 capsules per hour (sizes #1 and #0) 17,850 capsules per hour (size #00)
Availability	90% (10% of potential availability taken up by cleaning, maintenance, etc.)
Quality Rate	+/-5% accuracy on capsule fill and dose
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
CE	Certification mark that indicates conformity with health, safety, and environmental protection standards sold within the European Economic Area
°C	Degree centigrade
Decibels	dB
Dev No.	Deviancy number
Hz	Hertz
IQ	Installation Qualification
kg	Kilogram
Megapascal	MPa
m	Meter
mm	Millimeter
NIST	National Institute of Standards and Technology
Nm	Newton meter
OQ	Operational Qualification
PPE	Personal protective equipment
RH	Relative humidity
SACF®	LFA registered trademarked term meaning semi-automatic capsule filler

Comments: .....

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

Equipment and Process Description

SACF 25® Process

The basic mechanism of the SACF 25® involves inserting the capsules into the Capsule Discs, separating the capsule halves, filling the capsule bodies, and sealing/ejecting the capsules

Inserting Capsules into the Tooling

Capsules are poured into the Capsule Hopper, which then distributes them to the Capsule Sewing Mechanism. The Capsule Magazine then orients the capsules in the correct position and sews them into the Capsule Discs. After the capsules' insertion, the vacuum pulls the capsule bodies from the caps. The operator then manually pulls apart the Capsule Discs, which each contain the capsule caps and bodies.

Filling the Capsule Bodies with Powder

The disc with capsule bodies is inserted onto the turntable in front of the Powder Hopper. After the Powder Hopper is filled with dry materials, the Auger and filling arm evenly distributes the powder onto all the capsule bodies inside the plate.

Capsule Sealing and Ejection

After excess powder has been removed, both Capsule Discs are manually rejoined. The Capsule Discs are then inserted into the Capsule Sealer and pushed against the Capsule Ejection Disc, which adheres both halves of the capsules together and ejects the filled capsules from the plates.

Comments: .....

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

Test Equipment

Equipment	Serial Number	Calibration Certificate Number	Calibration Date	Initial and Date
Indoor thermometer				
Hygrometer				
Multimeter				

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Document Qualification

SACF 25® - 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: .....

Installation Qualification Protocol

Document Qualification

SACF 25® - 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: .....

SACF 25® - 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

SACF 25® - Serial Number

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

TEST No. SACFD01	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	Capsule Discs material is confirmed to be LY12 aluminum alloy.		
2	Capsule Ejection Disc material is confirmed to be LY12 aluminum alloy and SUS304.		
3	Powder Hopper material is confirmed to be SUS304.		
4	Capsule Hopper material is confirmed to be SUS304.		
5	Alignment Tools material is confirmed to be SUS304.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

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

Installation Qualification Protocol

Document Qualification

SACF 25® - Serial Number

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

TEST No. SACFD02	**PRODUCT MANUAL**
Purpose of Test	
To confirm the presence of product manual.	
Method	
1	Find the SACF 25® product manual at https://www.lfacapsulefillers.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: .....

SACF 25® - Serial Number

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

TEST No. SACFD03	ELECTRICAL WIRING DIAGRAM		
Purpose of Test			
To confirm the presence of electrical wiring diagram.			
Method			
1	Find the appropriate product manual at https://www.lfacapsulefillers.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

SACF 25® - 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. SACFIS01	**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 330 kg (around 728 lbs).
2	Ensure the workspace surface supports an additional 92 kg (around 77 lbs).

Results			
Test	Acceptance Criteria		Pass/Fail
1	Workspace surface is sturdy enough to support 422 kg (around 805 lbs).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

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

SACF 25® - 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: .....

SACF 25® - 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:

Installation Qualification Protocol

Safety Measures Qualification

SACF 25® - Serial Number

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

TEST No. SACFSM01	LIFTING EQUIPMENT		
Purpose of Test			
To confirm that the proper lifting equipment is available for mounting the machine.			
Method			
1	Ensure forklift and pallet jack are available.		
2	Ensure pallet jack supports the machine and does not induce any movement.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Engine hoist and lifting strap are in position.		
2	Eye bolt is attached to top of machine with eye bolt thread fully screwed in.		
3	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: .....

SACF 25® - 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: .....

SACF 25® - Serial Number

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

TEST No. SACFSM02	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 240 V/220 V.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

SACF 25® - 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: .....

SACF 25® - 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: .....

SACF 25® - Serial Number

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

TEST No. SACFOQ01	ELECTRICAL OUTPUT LEVELS		
Purpose of Test			
To confirm that the machine's kilowatt, voltage, and ampere levels are correct.			
Method			
1	Use a multimeter to measure the machine for each unit.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum kilowatts is 2.2.		
2	Maximum volts is 240.		
3	Maximum amps is 9.2.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

SACF 25® - Serial Number

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

TEST No. SACFOQ02	MAXIMUM HOURLY CAPSULE PRODUCTION		
Purpose of Test			
To confirm that the machine's maximum hourly capsule production level is no less than approximately 17,850.			
Method			
1	Automatically operate the machine for one minute using Firmafill as a test mix (purchase at https://www.lfacapsulefillers.com/firmafill-capsule-powder).		
2	Record the capsule amount produced in one minute.		
3	Calculate the hourly output by multiplying the capsule amount by 60.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum hourly tablet production is approximately 17,850 pieces (+/-5%).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Protocol Deviation Log

SACF 25® - 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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