



FACF 400[®]
Fully Automatic Capsule Filler
IQ/OQ



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

LFA Signature Identification



Prepared by	Name	Title	Date
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Approved by	Name	Title	Date
Manufacturing			
Engineering			
Quality			

Comments:

Reviewed By:

Date:

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Qualification Protocol



Purpose and Background

The purpose of this Installation Qualification (IQ)/Operational Qualification (OQ) Protocol is to establish documented evidence that the FACH 400® 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	FACH 400/Fully automatic capsule filler
Manufacturer	LFA Machines Taiwan Ltd.
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:

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Qualification Protocol



System Requirements

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

System Requirement	Target
Output Speed Target	180 capsules per minute (size #000) 360 capsules per minute (sizes #00, #00el, #0el) 400 capsules per minute (sizes #0, #1, #2, #3, #4, #5)
Availability	
Quality Rate	
Overall Equipment Effectiveness (OEE)	
Crew Target	

Comments:

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Qualification Protocol



Responsibilities

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

Department/Individual	Responsibilities
Validation Author	<ul style="list-style-type: none">• Develops the process validation plan, protocol, and report.• Confirms accuracy and completeness of the validation and qualification deliverables.
Validation Project Leader	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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:

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Qualification Protocol



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
FACF®	LFA registered trademarked term meaning fully automatic capsule filler

Comments:

Reviewed By: Date:



Equipment and Process Description

FACF 400® Process

The basic mechanism of the FACF® range involves orienting, separating, filling, closing, and ejecting capsules.

Orienting and Inserting Capsules into the Capsule Die Segments

When the machine begins operation, the capsules in the Hopper are fed into the magazine vertically. With each movement of the machine, the gate of the Capsule Magazine releases one capsule, and the horizontal forks orientate it. Then, the vertical forks push the capsules into the Capsule Die Segments with all caps in the upward position.

Filling the Capsule Bodies with Powder

After the vacuum system separates the capsule bodies and capsule caps, the lower Capsule Die Segment with the capsule bodies is extended. The filling rod then pushes the pressed powder slug in the capsule bodies.

Capsule Sealing and Ejection

Once defective capsules have been rejected, the capsules are snapped shut. After that, the finished capsules are ejected and then cleaned by the vacuum cleaner and compressed air.

Comments:

Reviewed By: Date:

Qualification Protocol



Test Equipment

Equipment	Serial Number	Calibration Certificate Number	Calibration Date	Initial and Date
Indoor thermometer				
Hygrometer				
Multimeter				
Pressure gauge				
Decibel reader				

Comments:

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Installation Qualification Protocol

Document Qualification



FACF 400® - 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



FACF 400® - 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:

Installation Qualification Protocol

Document Qualification



FACF 400[®] - 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



FACF 400[®] - Serial Number

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

TEST No. FACFD01	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	Tooling Plates and Molds material is confirmed to be LY12 aluminum alloy.		
2	Powder Hopper material is confirmed to be SUS304.		
3	Capsule Hopper material is confirmed to be SUS304.		
4	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



FACF 400[®] - Serial Number

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

TEST No. FACFD02	PRODUCT MANUAL		
Purpose of Test			
To confirm the presence of product manual.			
Method			
1	Find the FACF [®] Range 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:

Installation Qualification Protocol

Document Qualification



FACF 400® - Serial Number

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

TEST No. FACFD03	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

Accessories Qualification



FACF 400® - Serial Number

The objective of Accessories Qualification is to confirm the presence of the appropriate accessories provided.

TEST No. FACFA01	ACCESSORIES		
Purpose of Test			
To confirm the presence of appropriate Tooling parts provided.			
Method			
1	Inspect the contents of the Tooling case.		
Results			
Test	Acceptance Criteria	Pass/Fail	
1	Dosing Disk is present.		
2	(2) Dosing Disk Alignment Pins are present.		
3	(2) Capsule Segment Alignment Pins are present.		
4	(2) Capsule Magazine Alignment Pins are present.		
5	(9) Capsule Sealing Pins are present.		
6	(9) Capsule Ejection Pins are present.		
7	(9) Tamping Pins are present.		
8	(2) Capsule Sealing Alignment Pins are present.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Accessories Qualification



FACF 400® - Serial Number

The objective of Accessories Qualification is to confirm the presence of the appropriate accessories provided.

TEST No. FACFA02	TOOLS		
Purpose of Test			
To confirm the presence of appropriate tools provided.			
Method			
1	Inspect the contents of the toolbox.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Wrench for Dosing Disk is present.		
2	Flathead screwdriver is present.		
3	Crosshead screwdriver is present.		
4	6 mm-24 mm wrench set is present.		
5	(3) double-end wrenches are present.		
6	Allen key set is present.		
7	0.02-1 mm feeler gauge is present.		
8	Upper Mold Frame Dismount Tool is present.		
9	T-shaped wrench is present.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Accessories Qualification



FACF 400® - Serial Number

The objective of Accessories Qualification is to confirm the presence of the appropriate accessories provided.

TEST No. FACFA03	ACCESSORIES (CONTINUED)		
Purpose of Test			
To confirm the presence of appropriate accessories provided.			
Method			
1	Inspect the accessories of the container.		
Results			
Test	Acceptance Criteria	Pass/Fail	
1	(3) 32 x 44 clamps are present.		
2	(3) door keys are present.		
3	Capsule removal needle is present.		
4	Brush is present.		
5	Spring sheet is present.		
6	(12) M6 x 16 outer hexagonal bolts are present.		
7	(8) M6 x 12 outer hexagonal bolts are present.		
8	(2) M8 x 35 outer hexagonal bolts are present.		
9	Feeding Hopper is present.		
10	(4) Anchors and bolts are present.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Installation Position and Space Qualification



FACF 400® - 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. FACFIS01	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 600 kg (around 1322 lbs).		
2	Ensure the workspace surface supports an additional 167 kg (around 368 lbs).		
3	Ensure the workspace surface supports the machine's static floor loading limit of 6.18 kN/m ² .		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Workspace surface is sturdy enough to support 767 kg (around 1690 lbs) and a static floor loading limit of 6.18 kN/m ² .		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:



Installation Qualification Protocol

Installation Position and Space Qualification

FACF 400® - 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. FACFIS02	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:

Installation Qualification Protocol

Installation Position and Space Qualification



FACF 400® - 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. FACFIS03	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



FACF 400® - Serial Number

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

TEST No. FACFSM01	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	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:

Installation Qualification Protocol

Safety Measures Qualification



FACF 400® - Serial Number

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

TEST No.	PERSONAL PROTECTIVE EQUIPMENT		
TDSM03			
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:

Installation Qualification Protocol

Safety Measures Qualification



FACF 400® - Serial Number

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

TEST No. FACFSM02	CORRECT LOCAL VOLTAGE		
Purpose of Test			
To confirm that the workspace has the correct local voltage for the machine and supports the correct ampere levels.			
Method			
1	Ensure the workspace has the correct voltage.		
2	Ensure that the workspace supports the correct ampere levels.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Workspace electrics support 220 V or 380 V.		
2	Workspace electrics support 17 AMPs.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Safety Measures Qualification



FACF 400® - Serial Number

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

TEST No. FACFSM03	SAFETY SENSORS		
Purpose of Test			
To confirm that the machine's safety sensors work properly.			
Method			
1	Test the emergency stop, door sensors, and isolator switch's functions during machine operation.		
Results			
Test	Acceptance Criteria	Pass/Fail	
1	Machine stops operation whenever emergency stop button is pushed.		
2	Machine stops operation whenever perspex doors are opened.		
3	Machine cuts off when isolator switch is turned.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Equipment Appearance Qualification



FACF 400® - 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:

Installation Qualification Protocol

Equipment Appearance Qualification



FACF 400® - 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:

Installation Qualification Protocol

Lubrication Qualification



FACF 400® - Serial Number

The objective of Lubrication Qualification is to confirm that all lubrication points are properly greased.

TEST No. FACFL01	LUBRICATION		
Purpose of Test			
To confirm that the machine is properly lubricated.			
Method			
1	Inspect the machine's lubrication points.		
2	Apply lubrication to machine if needed.		
Results			
Test	Acceptance Criteria	Pass/Fail	
1	The chain in the Driving Part Assembly is lubricated with oil or grease.		
2	The cam bearing, needle bearing, and cam in the rejection driving assembly are lubricated with NLGI Grade 1 grease.		
3	The cam bearing, needle bearing, and cam in the press driving assembly are lubricated with NLGI Grade 1 grease.		
4	The deep groove ball bearing and spherical surface ball bearing in the main shaft support assembly are lubricated with NLGI Grade 1 grease.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Lubrication Qualification



FACF 400® - Serial Number

The objective of Lubrication Qualification is to confirm that all lubrication points are properly greased.

TEST No. FACFL01	LUBRICATION (CONTINUED)		
Purpose of Test			
To confirm that the machine is properly lubricated.			
Method			
1	Inspect the machine's lubrication points.		
2	Apply lubrication to machine if needed.		
Results			
Test	Acceptance Criteria	Pass/Fail	
6	The needle bearing, cam, linear bearing, and cam bearing in the end production press driving assembly are lubricated with NLGI Grade 1 grease.		
7	The cam bearings, needle bearings, and cam in the dosing driving assembly are lubricated with NLGI Grade 1 grease.		
8	The cam bearing, needle bearing, cam, linear bearing, and pin end bearing in the vacuum driving assembly are lubricated with NLGI Grade 1 grease.		
9	The cam bearing, needle bearing, cam, and pin end bearing in the sequence driving assembly are lubricated with NLGI grade 1 grease.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Lubrication Qualification



FACF 400® - Serial Number

The objective of Lubrication Qualification is to confirm that all lubrication points are properly greased.

TEST No. FACFL01	LUBRICATION (CONTINUED)		
Purpose of Test			
To confirm that the machine is properly lubricated.			
Method			
1	Inspect the machine's lubrication points.		
2	Apply lubrication to machine if needed.		
Results			
Test	Acceptance Criteria		Pass/Fail
10	The disk cam in the round table assembly is lubricated with NLGI Grade 1 grease.		
11	The feeding decelerator on top of the Powder Hopper is filled with hydraulic oil ISO VG 46 or H1 NSF for food grade products.		
12	The main drive decelerator inside the machine body near the motor is filled with hydraulic oil ISO VG 46 or H1 NSF for food grade products.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Control Panel Function Qualification



FACF 400® - Serial Number

The objective of Control Panel Function Qualification is to confirm that the touch screen is responsive and works properly.

TEST No. FACFCF01	START-UP INTERFACE		
Purpose of Test			
To confirm that the touch screen control panel's start-up interface functions work well.			
Method			
1	Turn on the machine.		
2	Enter the following user login information: Username: 1 Password: 111 OR Username: 2 Password: 222		
3	Press the Enter button to go to the main menu.		
Results			
Test	Acceptance Criteria	Pass/Fail	
1	The user login information is correct.		
2	Entering login information initiates the main menu screen.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Control Panel Function Qualification



FACF 400® - Serial Number

The objective of Control Panel Function Qualification is to confirm that the touch screen is responsive and works properly.

TEST No. FACFCF02	MAIN MENU INTERFACE		
Purpose of Test			
To confirm that the touch screen control panel's operational interface functions work well.			
Method			
1	Press each button on the main menu interface.		
Results			
Test	Acceptance Criteria	Pass/Fail	
1	Pressing the Running button initiates the operation screen.		
2	Pressing The Fault Picture button displays the machine errors.		
3	Pressing the System Parameter button displays different machine settings.		
4	Pressing the Recipe Data button allows the user to enter relevant information and stores it.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Control Panel Function Qualification



FACF 400® - Serial Number

The objective of Control Panel Function Qualification is to confirm that the touch screen is responsive and works properly.

TEST No. FACFCF03	RUNNING SCREEN INTERFACE		
Purpose of Test			
To confirm that the touch screen control panel's operational interface functions work well.			
Method			
1	Press the menu buttons on the operational interface.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Pressing the Pump Off button starts and stops the vacuum.		
2	Pressing the Run button begins machine operation.		
3	Pressing the Jog button operates the machine when the button is pressed and stops operation when the button is released.		
4	Pressing the Speed Up and Speed Down buttons increases or decreases operation speed.		
5	Pressing the Brake Off button turns the motor break on and off.		
6	Pressing the Running Mode button switches from operation mode to maintenance mode and vice versa.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Control Panel Function Qualification



FACF 400® - Serial Number

The objective of Control Panel Qualification is to confirm that the touch screen is responsive and works properly.

TEST No. FACFCF04	FAULT PICTURE SCREEN INTERFACE		
Purpose of Test			
To confirm that the touch screen control panel's error screen interface functions work well.			
Method			
1	Turn off the motor.		
2	Turn off the vacuum pump motor.		
3	Turn off the feeding motor.		
4	Operate the machine with no capsules.		
5	Operate the machine with no powder.		
6	Inspect the fault picture screen displayed information.		
Results			
Test	Acceptance Criteria	Pass/Fail	
1	Main motor overload red light comes on when motor is turned off.		
2	Pump motor overload red light comes on when vacuum pump motor is turned off.		
3	Feed motor overload red light comes on when feeding motor is turned off.		
4	No Capsule red light comes on when machine operates with no capsules.		
5	No Powder red light comes on when machine operates with no powder.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Control Panel Function Qualification



FACF 400® - Serial Number

The objective of Control Panel Qualification is to confirm that the touch screen is responsive and works properly.

TEST No. FACFCF04	FAULT PICTURE SCREEN INTERFACE (CONTINUED)		
Purpose of Test			
To confirm that the touch screen control panel's error screen interface functions work well.			
Method			
1	Open the Perspex Casing's doors.		
2	Press the Emergency Stop button.		
3	Set Preset output on the Running screen to 0 and operate machine.		
4	Set Preset time on the Running screen to 0 and operate machine.		
5	Inspect the fault picture screen displayed information.		
Results			
Test	Acceptance Criteria	Pass/Fail	
1	Glass door open red light comes on when Perspex Casing doors are open.		
2	Emergency Stop red light comes on when the button is pushed.		
3	The Preset output red light comes on when it is set to 0 during operation.		
4	The Preset time red light comes on when it is set to 0 during operation.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Control Panel Display Qualification



FACF 400® - Serial Number

The objective of Control Panel Qualification is to confirm that the touch screen is responsive and works properly.

TEST No. FACFCD01	SYSTEM PARAMETER DISPLAY		
Purpose of Test			
To confirm that the touch screen control panel's parameter setting display interface looks correct.			
Method			
1	Inspect the system parameter screen's displayed information.		
Results			
Test	Acceptance Criteria	Pass/Fail	
1	Automatic feed start/stop delay is displayed.		
2	Low powder/capsule delay is displayed.		
3	Capsule loader startup/stop delay is displayed.		
4	Powder recycle level is displayed.		
5	Machine model is 400.		
6	Number holes in each segment is displayed.		
7	Velocity coefficient is displayed.		
8	Current protection is displayed.		
9	Time setup and date setup is displayed.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Equipment Noise Qualification



FACF 400® - Serial Number

The objective of Equipment Noise Qualification is to confirm that the decibel levels put out a specific level.

TEST No. FACFEN01	DECIBEL LEVEL		
Purpose of Test			
To confirm that the machine's decibel level is at an adequate level.			
Method			
1	Use a decibel reader to measure the machine's decibel level during operation.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	The machine's noise level is less than 78 dB.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Segment Qualification



FACF 400® - Serial Number

The objective of Segment Qualification is to confirm that machine's segments work normally.

TEST No. FACFSQ01	UPPER CAPSULE DIE SEGMENTS		
Purpose of Test			
To confirm that the machine's upper Capsule Die Segments function properly.			
Method			
1	Inspect the upper Capsule Die Segments during operation.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	The upper Capsule Die Segment lifts before the Tamping Station.		
2	The upper Capsule Die Segment returns to its original place between the rejection station and Capsule Sealing Station.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Segment Qualification



FACF 400® - Serial Number

The objective of Segment Qualification is to confirm that the machine's segments work normally.

TEST No. FACFSQ02	LOWER CAPSULE DIE SEGMENTS		
Purpose of Test			
To confirm that the machine's lower Capsule Die Segments function properly.			
Method			
1	Inspect the lower Capsule Die Segments during operation.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	The lower Capsule Die Segment pushes out after the upper Capsule Die Segment lifts.		
2	The lower Capsule Die Segment returns to its original place between the Rejection Station and Capsule Sealing Station.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Capsule Sorting Qualification



FACF 400® - Serial Number

The objective of Capsule Sorting Qualification is to confirm that the Capsule Sewing Station orients capsules properly.

TEST No. FACFCS01	CAPSULE SORTING		
Purpose of Test			
To confirm the capsules are being sorted correctly during operation.			
Method			
1	Inspect the Capsule Sewing Station during operation.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Capsules smoothly go into the Capsule Magazine without getting stuck.		
2	Capsules go through the rectifier and into the segments without issue.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Capsule Separation Qualification



FACF 400® - Serial Number

The objective of Capsule Separation Qualification is to confirm that the Capsule Separating Station separates the capsules into caps and bodies properly.

TEST No. FACFCP01	CAPSULE SEPARATION		
Purpose of Test			
To confirm the capsules are being separated correctly during operation.			
Method			
1	Inspect the Capsule Separating Station during operation.		
Results			
Test	Acceptance Criteria	Pass/Fail	
1	All capsules are oriented with the cap at the top and the body at the bottom and are aligned with the segment bores.		
2	The vacuum pump produces negative pressure that separate the capsules without losing the caps, damaging them, etc.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Capsule Rejection Qualification



FACF 400® - Serial Number

The objective of Capsule Rejection Qualification is to confirm that the Capsule Rejection Station ejects everything but caps in the segment.

TEST No. FACFCR01	CAPSULE REJECTION		
Purpose of Test			
To confirm that defective capsules are discarded out of the machine during operation.			
Method			
1	Manually insert a capsule cap, sealed capsule, unseparated capsule, and double-caps into the segments.		
2	Inspect the Capsule Rejection Station during jogging operation.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	The machine expels the sealed capsule, the unseparated capsule, and the double-caps, and the single cap stays in the segment.		
2	The rejected capsules are collected by the vacuum nozzle.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Capsule Sealing Qualification



FACF 400® - Serial Number

The objective of Capsule Sealing Qualification is to confirm that the machine is correctly locking caps and bodies.

TEST No. FACFCE01	CAPSULE SEALING		
Purpose of Test			
To confirm that caps and bodies are being sealed into capsules during machine operation.			
Method			
1	Inspect the Capsule Sealing Station during operation.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	The sealing pins move up against the block and seals the capsule.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Capsule Ejection Qualification



FACF 400® - Serial Number

The objective of Capsule Ejection Qualification is to confirm that the machine is correctly locking caps and bodies.

TEST No. FACFCJ01	CAPSULE EJECTION		
Purpose of Test			
To confirm that sealed capsules are being properly discharged from the machine.			
Method			
1	Inspect the Capsule Ejection Station during operation.		
Results			
Test	Acceptance Criteria	Pass/Fail	
1	The ejection pins move up against the block and the capsules are ejected.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Production and Output Qualification



FACF 400® - Serial Number

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

TEST No. FACFOQ01	ELECTRICAL OUTPUT LEVELS		
Purpose of Test			
To confirm that the machine's kilowatt, voltage, and hertz 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 3.75.		
2	Maximum volts is 220 or 380.		
3	Maximum hertz is 50.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Production and Output Qualification



FACF 400[®] - Serial Number

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

TEST No. FACFOQ02	VACUUM AIR PRESSURE OUTPUT LEVELS		
Purpose of Test			
To confirm that the machine vacuum's air supply pressure is correct.			
Method			
1	Use a pressure gauge to measure the vacuum's air supply.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Vacuum air pressure is 0.6-0.8 MPa.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Production and Output Qualification



FACF 400® - Serial Number

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

TEST No. FACFOQ03	MAXIMUM HOURLY CAPSULE PRODUCTION		
Purpose of Test			
To confirm that the machine's maximum hourly capsule production level is no less than approximately: <ul style="list-style-type: none"> • 10,800 (#000) • 21,600 (#00, #00el, #0el) • 24,000 (#0, #1, #2, #3, #4, #5) 			
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 10,800/21,600/24,000 pieces (+/-5%).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Protocol Deviation Log



FACF 400® - 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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