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Version 2.4 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:

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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 RTP 33[®] 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	RTP 33/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:

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Qualification Protocol



System Requirements

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

System Requirement	Target
Output Speed Target	118,800 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

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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.

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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:

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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

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Qualification Protocol



Equipment and Process Description

RTP 33[®] Process

The basic mechanism of the RTP 33[®] 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:

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Test Equipment

Equipment	Serial Number	Calibration Certificate Number	Calibration Date	Initial and Date
Compact force gauge				
Calipers				
Graduated steel ruler				
Indoor thermometer				
Hygrometer				
Multimeter			1	
Belt tension gauge				

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Document Qualification



RTP 33[®] - 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	of Te	est		
To confirm	n the	e presence (of the packing list with the appro	priate information.
Method				
1	Lo	cate packin	g 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		Descriptior	n 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)

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Document Qualification



RTP 33[®] - 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	of To	est		
To confirm	the	e presence (of CE qualification certificate.	
Method				
1	Ins	pect 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:

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Document Qualification



RTP 33[®] - 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 o	of To	est			
To confirm	the	presence o	of factory acceptance test (FAT)	report.	
Method					
1	Ins	pect the FA	T report.		
2	Co	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:

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Document Qualification



RTP 33[®] - Serial Number

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

TEST No. RT3D01		MATERIAL CERTIFICATE			
Purpose of	of To	est			
To confirm	n the	e presence	of materials certificate.		
Method					
1	Po	int of contac	ct materials are certified by third	party.	
2	Co	nfirm mater	ials are accurate to LFA standard	I.	
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		Fill Tray ma bronze QS	aterial is confirmed to be tin N-6-3.		
4		Tooling is o user speci	confirmed to be material that fied.		
5		-	ay material is confirmed to be ainless steel.		
6	Fill Tray Scraper and Take-Off Blade are confirmed to be bakelite and copper coat Zn, respectively.				
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:

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Document Qualification



RTP 33[®] - Serial Number

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

TEST No. TDD05		PRODUCT MANUAL			
Purpose o	of To	est			
To confirm	the	e presence	of product manual.		
Method					
1	Find the RTP 33 [®] product manual at <u>https://www.lfatabletpresses.com/</u> product-data in Product Manuals section.				
2	Confirm product manual link is accessible.				
Results	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:

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Document Qualification



RTP 33[®] - 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 o	of To	est			
To confirm	the	presence	of electrical wiring diagram.		
Method					
1	1		priate product manual at <u>https://</u> n Product Manuals section.	www.lfatabletpresses.com/	
2	Ins	pect the ele	ectrical wiring diagram in the prod	duct 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)		Completed by (Initial/Date)	Verified by (Initial/Date)	

Comments:

Reviewed By:



Installation Position and Space Qualification

RTP 33[®] - 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. RT3IS01		WORKSPACE SURFACE			
Purpose of	of Test				
	the workspa e and user.	ce surface accounts for the mach	ine's weight and force exerted		
Method					
1	Ensure work lbs).	space surface supports machine'	s weight of 927 kg (around 2043		
2	Ensure the v lbs).	orkspace surface supports an ac	lditional 339 kg (around 747		
Results					
Test		Acceptance Criteria	Pass/Fail		
1		Workspace surface is sturdy enough to support 1266 kg (around 2790 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.

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Installation Position and Space Qualification

RTP 33[®] - 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 o	of To	est			
To confirm	the	workspace	e's temperature levels are accept	able for machine operation.	
Method					
1	Me	asure the w	orkspace's temperature with an	indoor thermometer.	
Results					
Test			Acceptance Criteria	Pass/Fail	
1	Workspace temperature measures within 15-24 °C (64-75 °F).		-		
Result		Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)	

Comments:

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Installation Position and Space Qualification

RTP 33[®] - 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 o	of Te	est			
To confirm	the	workspace	e's relative humidity levels are ac	ceptable for machine operation.	
Method					
1	Me	asure the w	orkspace's humidity with a hygro	ometer.	
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:

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Safety Measures Qualification



RTP 33[®] - Serial Number

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

TEST No. RT3SM01		LIFTING EQUIPMENT			
Purpose o	f Te	est			
To confirm	that	t the proper	lifting equipment is available for	mounting the machine.	
Method					
1	En	sure forklift	and lifting strap are available.		
2		nsure lifting strap supports the machine and does not induce any swinging 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)	

Reviewed By:





RTP 33[®] - 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 o	of Te	est		
		er has acce machine o	ss to the following items of perso peration.	onal protective equipment (PPE)
Method				
1	En	sure protect	tive equipment is on hand before	using the machine.
Results				
Test			Acceptance Criteria	Pass/Fail
1		Steel toe b	oots are in possession.	
2		Heavy duty	v grip gloves are in possession.	
3		Back supp	ort 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:

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Safety Measures Qualification

RTP 33[®] - 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 o	of Te	est			
To confirm	ı bo	lts on the m	achine are secure.		
Method					
1		e a torque v Its are appre	vrench to ensure the max tighten opriate.	ing torque of major machine	
Results					
Test			Acceptance Criteria	Pass/Fail	
1		Dies' bolts	are 4.3 Nm.		
2		Fill Tray Sc	raper's screw is 16.2 Nm.		
3		Take-Off Blade's screw is 4.3 Nm.			
4		Upper Cam Housing's bolts are 4.3 Nm.			
5		Upper Tracking's bolt is 153 Nm.			
Result		Dev No. Completed by (Initial/Date)		Verified by (Initial/Date)	

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RTP 33[®] - Serial Number

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

TEST No. RT3SM05		CORRECT LOCAL VOLTAGE			
Purpose of	f Te	st			
To confirm	that	the worksp	ace has the correct local voltage	e for the machine.	
Method					
1	En	sure the wo	rkspace has the correct voltage.		
Results					
Test			Acceptance Criteria	Pass/Fail	
1		Workspace electrics support 220 V or 440 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:

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Equipment Appearance Qualification

RTP 33[®] - 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 o	of Te	est			
To confirm clear.	tha	t the name	plate is securely fixed onto the m	achine and its information is	
Method					
1	En	sure that the	e nameplate is securely fitted to t	the machine.	
2		sure that the	e nameplate contains details that e.	are pertinent to the operation	
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:



Equipment Appearance Qualification

RTP 33[®] - 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 o	of To	est			
To confirm	tha	at the machi	ne has no obvious damage to bo	dy and/or wiring.	
Method					
1	1	pect the ma any other d	achine body for obvious indentati amages.	ons, spots, scratches, cracks,	
2	Ins	pect the wir	ring, cables, and electrical box fo	or 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)	

Reviewed By:



Production and Output Qualification

RTP 33[®] - Serial Number

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

TEST No. RT3OQ01		ELECTRICAL OUTPUT LEVELS			
Purpose o	f Te	st			
To confirm	that	the machir	e's kilowatt, voltage, and ampere	e levels are correct.	
Method					
1	Us	e a multime	ter to measure the machine for e	ach unit.	
Results					
Test			Acceptance Criteria	Pass/Fail	
1		Maximum I	kilowatts is 2.2.		
2	2 Maximum volts is 220 or 440.				
3		Maximum amps is 32.			
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.

Reviewed By:



Production and Output Qualification

RTP 33[®] - Serial Number

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

TEST No. RT3OQ02		MAXIMUM PRESSURE			
Purpose of	f Te	st			
To confirm	that	the machir	e's maximum pressure level is a	ccurate.	
Method					
1			oling from the press in accordar ound at <u>https://www.lfatabletpres</u>	-	
2		e a compac per Roller (t force gauge to record the maxi Cam.	mum pressure exerted by the	
Results					
Test			Acceptance Criteria	Pass/Fail	
1	Maximum pressure produced is 40 kN (0.3 kN tolerance).				
Result		Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)	

Comments:

Reviewed By:



Production and Output Qualification

RTP 33[®] - Serial Number

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

TEST No. RT3OQ02		MAXIMUM PRESSURE			
Purpose of	Purpose of Test				
To confirm	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 <u>https://www.lfatabletpresses.com/product-data</u>).			
2		Use a compact force gauge to record the maximum pressure exerted by the Pre-Pressure Upper Roller Cam.			
Results					
Test	Test		Acceptance Criteria	Pass/Fail	
1	Maximum pre-pressure produced is 40 kN (0.3 kN tolerance).				
Result		Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)	

Comments:

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Production and Output Qualification

RTP 33[®] - Serial Number

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

TEST No. RT3OQ03		MAXIMUM TABLET DIAMETER				
Purpose of	Purpose of Test					
To confirm	that	the machin	e's maximum tablet diameter is 1	l 2 mm.		
Method	Method					
1		Install 12 mm Tooling in press in accordance with product manual instructions (found at <u>https://www.lfatabletpresses.com/product-data</u>).				
2		Produce a test tablet using Firmapress as a control mix (purchase at <u>https://</u> <u>www.lfatabletpresses.com/ready-mix-firmapress</u>).				
3	Me	Measure the test tablet with a set of calipers.				
Results						
Test		Acceptance Criteria		Pass/Fail		
1		Maximum tablet diameter produced is 12 mm (+/-5%).				
Result		Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)		

Reviewed By:



Production and Output Qualification

RTP 33[®] - Serial Number

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

TEST No. RT3OQ04	MAXIMUM TABLET THICKNESS				
Purpose o	f Te	st			
To confirm	that	t the machir	e's maximum tablet thickness 6	mm.	
Method	Method				
1		Adjust Tooling to increase tablet thickness in accordance with product manual instructions (found at <u>https://www.lfatabletpresses.com/product-data</u>).			
2	Produce a test tablet using Firmapress as a control mix (purchase at <u>https://</u> <u>www.lfatabletpresses.com/ready-mix-firmapress</u>).				
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)	

Reviewed By:



Production and Output Qualification

RTP 33[®] - Serial Number

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

TEST No. RT3OQ05		MAXIMUM FILLING DEPTH				
Purpose of	Purpose of Test					
To confirm	that	the machin	e's maximum fill depth level is 1	5 mm.		
Method						
1		Adjust Tooling to increase fill depth in accordance with product manual instructions (found at <u>https://www.lfatabletpresses.com/product-data</u>).				
2	Tur	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	Ма	Mark the point at which the pipe cleaner meets the Die bore's edge.				
5	Me	Measure the fill depth with a graduated steel ruler.				
Results						
Test		Acceptance Criteria		Pass/Fail		
1	Maximum fill depth is 15 mm (+/-5%).		ill depth is 15 mm (+/-5%).			
Result		Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)		

Reviewed By:



Production and Output Qualification

RTP 33[®] - Serial Number

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

TEST No. RT3OQ06		MAXIMUM HOURLY TABLET PRODUCTION			
Purpose of	Purpose of Test				
To confirm that the machine's maximum hourly tablet production level is approximately no less than approximately 118,800.					
Method					
1	Automatically operate the machine for one minute using Firmapress as a test mix (purchase at <u>https://www.lfatabletpresses.com/ready-mix-firmapress</u>).				
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	1 Maximum hourly tablet production is approximately 118,800 pieces (+/-5%).				
Result		Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)	

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Protocol Deviation Log



RTP 33[®] - 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:

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