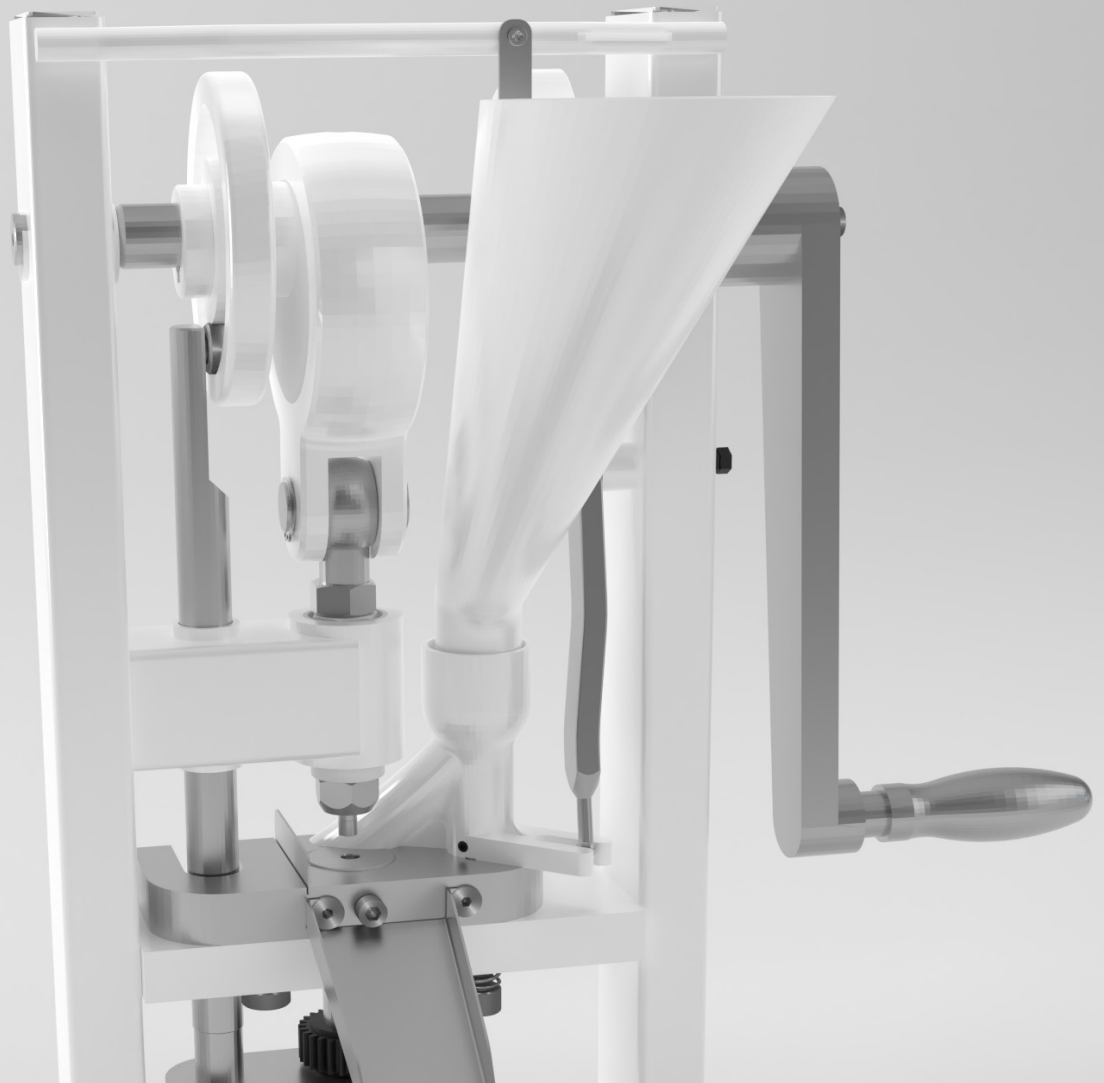




TDP 0[®] Tablet Press IQ/OQ



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

LFA Signature Identification



Prepared by	Name	Title	Date
Author	Callie Scott	Technical Writer	2022-02-08
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

LFA Signature Identification	2
Qualification Protocol	4
Purpose and Background	4
Scope	4
Qualification Protocol	5
Responsibilities	6
General Requirements	7
Codes and Abbreviations	8
Equipment and Process Description	9
Test Equipment	10
Document Qualification	11
Installation Qualification Protocol	11
Installation Position and Space Qualification	16
Equipment Appearance Qualification	22
Protocol Deviation Log	28

Comments:

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Date:

Qualification Protocol



Purpose and Background

The purpose of this Installation Qualification (IQ)/Operational Qualification (OQ) Protocol is to establish documented evidence that the TDP 0[®] 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	TDP 0/Desktop Tablet Press
Manufacturer	LFA Machines
Version Number	2
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:

Qualification Protocol



System Requirements

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

System Requirement	Target
Output Speed Target	30-50 tablets per minute
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:

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:

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
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
TDP®	LFA registered trademarked term meaning desktop tablet press

Comments:

Reviewed By: Date:



Equipment and Process Description

TDP 0[®] Process

The basic mechanism of the TDP 0[®] 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 Boot. As the Handle is manually operated, the Top Cam withdraws the Upper Punch from the Die and moves up the Lower Punch to the Die.

Compressing the Powder

After the powder is filled in the Tooling, the Top Cam drives the Upper Punch into the Die, and the Lower Punch is then raised by the Top Cam. Both punches then move together to compress the powder under high pressure.

Ejecting the Tablet

After both punches compress the powder into a tablet, the Top Cam withdraws the Upper Punch while the Lower Punch is pushed upward to expel the tablet. The tablet is then pushed out of the way by the Boot to prepare for the next tablet compression.

Comments:

Reviewed By: Date:

Qualification Protocol



Test Equipment

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

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Document Qualification



TDP 0[®] - 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



TDP 0[®] - 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



TDP 0[®] - 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



TDP 0[®] - Serial Number

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

TEST No.	MATERIAL CERTIFICATE		
TD0D01			
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 polypropylene (PP) plastic.		
2	Boot material is confirmed to be polypropylene (PP) plastic.		
3	Base Plate material is confirmed to be S45C carbon steel.		
4	Tooling is confirmed to be material that user specified.		
5	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



TDP 0[®] - Serial Number

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

TEST No. TDD04	PRODUCT MANUAL		
Purpose of Test			
To confirm the presence of product manual.			
Method			
1	Find the TDP 0 [®] 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

Installation Position and Space Qualification



TDP 0[®] - 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. TD0IS01	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 24 kg (around 53 lbs).		
2	Ensure the workspace surface supports an additional 10 kg (around 22 lbs).		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Workspace surface is sturdy enough to support 34 kg (around 75 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:

Installation Qualification Protocol

Installation Position and Space Qualification



TDP 0[®] - 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:

Installation Qualification Protocol

Installation Position and Space Qualification



TDP 0[®] - 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



TDP 0[®] - Serial Number

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

TEST No. TD0SM01	MOUNTING SECURITY		
Purpose of Test			
To confirm the machine is firmly bolted to the workspace surface.			
Method			
1	Ensure that the three bolts used to secure the machine to the workspace surface are the same ones that were used to attach the machine to the shipping container.		
2	Use a torque wrench to ensure the max tightening torque of the M6 bolts is 14.8 Nm.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	The three bolts used to secure the machine are M6.		
2	The max tightening torque of the bolts are 14.8 Nm.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Safety Measures Qualification



TDP 0[®] - 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:

Installation Qualification Protocol

Safety Measures Qualification



TDP 0[®] - Serial Number

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

TEST No. TD0SM02	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	Die's M6 bolt is 4.3 Nm.		
2	Base Plate's M10 bolt is 16.2 Nm.		
3	Lower Punch's M6 bolt is 4.3 Nm.		
4	Lower Drift Pin Assembly Locking Bar's M6 bolt is 4.3 Nm.		
5	Lower Drift Pin Assembly Lifting Bar's M20 bolt is 153 Nm.		
6	Boot Bolt and Spring is M10 and 8.1 Nm.		
7	Boot Timing Bar's M8 bolt is 9.7 Nm.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Equipment Appearance Qualification



TDP 0[®] - Serial Number

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

TEST No. TD0EA01	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.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Equipment Appearance Qualification



TDP 0[®] - Serial Number

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

TEST No. TD0EA02	MACHINE BODY		
Purpose of Test			
To confirm that the machine has no obvious damage to body.			
Method			
1	Inspect the machine body for obvious indentations, spots, scratches, cracks, or any other damages.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Machine body has no obvious damage.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Production and Output Qualification



TDP 0[®] - Serial Number

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

TEST No. TD00Q01	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 Drift Pin Assembly against the Base Plate.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum pressure produced is 3.1 kN (0.3 kN tolerance).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Production and Output Qualification



TDP 0[®] - Serial Number

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

TEST No. TD00Q02	MAXIMUM TABLET DIAMETER		
Purpose of Test			
To confirm that the machine's maximum tablet diameter is 10 mm.			
Method			
1	Install 10 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 10 mm (+/-5%).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Operational Qualification Protocol

Production and Output Qualification



TDP 0[®] - Serial Number

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

TEST No. TD00Q03	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:

Operational Qualification Protocol

Production and Output Qualification



TDP 0[®] - Serial Number

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

TEST No. TD00Q05	MAXIMUM TABLET PRODUCTION PER MINUTE		
Purpose of Test			
To confirm that the machine's maximum tablet production level is approximately no less than approximately 30-50 per minute.			
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.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum tablet production is approximately 30-50 pieces per minute (+/-5%).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:



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