Design Qualification

Friability Test Apparatus
Model: μFTCal$_{10}$

DESIGN QUALIFICATION

Protocol Number	**:**	ASIPL/DQ/
Company Name	**:**	
Location	**:**	
Instrument	**:**	Friability Test Apparatus
Model	**:**	µFTCal$_{10}$
Instrument Sr. No.	**:**	
Protocol Approved By	**:**	Analab Scientific Instruments Pvt. Ltd.

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

DESIGN QUALIFICATION

"Design qualification (DQ) defines the functional and operational specifications of the instrument ". DQ should ensure that instruments have all the necessary functions and performance criteria that will enable user to be successfully implemented for the intended application and to meet business requirements.

TECHNICAL SPECIFICATION

- **Speed** **:** Fix 25 RPM
- **Accuracy** **:** + 0.5 RPM
- **Timer** **:** Variable from 1 sec. to 9 hrs. 59 min 59 sec.
- **Counter** **:** 1 to 9999 revolutions
- **No. of drums** **:** Two
- **Display** **:** 16 x 2 Line Alphanumeric Backlit LCD
- **Keyboard** **:** **Membrane** waterproof polyester soft keypad compliance to UL/ROHS
- **Pharmacopeia Complies** **:** As per USP, IP, Ph. Eur.
- **Date** **:** 12/24 Hours Format
- **Time** **:** Real time clock
- **Tablet Discharge** **:** Automatic in the Sample tray from drum after completion of analysis.
- **10º tilt** **:** Manual with Tilting legs
- **Calculation of result** **:** Friability in %
- **Power failure detection** **:** Un-interrupted tablet testing after power resume
- **Power Supply** **:** 230VAC ± 10%, 50/60 Hz

The supplied Instrument is according to the Purchase Order and as per specification.

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

DESIGN QUALIFICATION

The Design Qualification (DQ) for the Friability Test Apparatus has been reviewed and found acceptable for use.

INSTRUMENT : Friability Test Apparatus
MODEL : $\mu FTCal_{10}$
SERIAL NUMBER :
FINAL REPORT REVIEWED AND ACCEPTED BY
(Name & Designation) :
DATE :

Customer	
Department	
Head of Dept.	
End User	
Date	
Signature	
Seal of the Company	

Analab Representative	
Date	
Signature	

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

Installation Qualification
&
Operational Qualification

Friability Test Apparatus
Model: μFTCal$_{10}$

INSTALLATION & OPERATIONAL QUALIFICATION

Protocol Number	**:**	ASIPL/IQ-OQ/
Company Name	**:**	
Location	**:**	
Instrument	**:**	Friability Test Apparatus
Model	**:**	µFTCal$_{10}$
Instrument Sr. No.	**:**	
Protocol Approved By	**:**	Analab Scientific Instruments Pvt. Ltd.

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

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Date :

Signature :

Name :
Designation :

Analab Representative | Checked by End User | Approved by Head of Department

1 INSTALLATION QUALIFICATION:-

Installation qualification establishes that the ordered instrument is received as designed and specified, that it is properly installed in the specified environment and environment is suitable for the operation & use of the instrument.

1.1. Instrument Identification & Verification

Customer Purchase Order No. _____ Date_____

Main System Contents.

Sr. No.	Description	PO Qty.	Received Qty.	Remark	
				Ok	Not ok
01	Friability Test Apparatus- Basic Unit μFTCal10	01			
02	Friability Drums : (Rosch Type) Sr. NO. _____ & _____	02			
03	Knobs for Drum fixing	01			
04	Tablet Collection Tray Holder MOC : Acrylic	02			
05	Tablet Collection Tray MOC : SS	02			
06	Power Supply Cable	01			
07	Instructional & Operational Manual	01			
08	Manufacturer test Certificate	01			
09	Warranty Card	01			
	Optional (if ordered)				
10	Abrasion Drum – Sr. No. _____	01			
11	IQ/OQ Documentation	01			
12	PQ Documentation	01			

The supplied Instrument is according to the Purchase Order and as per specification.

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

1.2. Pre-Installation Requisites & Verification

Check the installation place for fulfillment of manufacturer's recommendation. (Utilities such as Power requirement, necessary chemicals and environmental conditions such as humidity, temperature, light and dust etc. (Please refer Pre-Installation requisites attached with this document.)

Item	Condition	Observation		Remark	
		Ok	Not Ok	Pass	Fail
Instrument & Accessories appearance check	No Damage and Breakage to instrument & Accessories.				
Installation Table space Leveling & Vibration.	As per requirements.				
Power Requirements • Connections sockets • Supply Voltage • Earthing (Earth to Neutral Potential	• 5 Amps. 02 no. • 230 V AC +/- 10% • Not more than 3 (Three) Volts.				
Environment conditions. 1) Sunlight 2) Air Draft 3) Room Temp. 4) Humidity 5) Dust 6) Flammable, Toxic & Corrosive Vapors	 Away from sunlight No direct fan or AC 15 ° ~ 50° C 20 ~ 80 % Free from dust Free from vapor.				

Date :

Signature :

Name :
Designation :

Analab Representative | Checked by End User | Approved by Head of Department

1.3. Installation Qualification Verifications

1.3.1. Instrument Identification & Verification

SR. NO.	DESCRIPTIONS	RESULT		REMARK	
		Yes	No	Ok	Not Ok
A	Items received as per Purchase Order				

1.3.2. Pre-Requisites Inspection

SR. No.	DESCRIPTIONS	RESULT		REMARKS	
		Yes	No	Ok	Not Ok
A	Instruments & Accessories Checked for Damages				
B	Table Space & Leveling				
C	Power Supply Availability				
D	Environmental Requirements				

1.3.3. Standard & Optional Accessories (as ordered)

SR. NO.	DESCRIPTIONS	RESULT		REMARKS	
		Yes	No	Ok	Not ok
A	Friability Drums : (Rosch Type) – 02 Nos.				
B	Knobs for Drum fixing – 01 Nos				
C	Tablet Collection Tray Holder MOC : Acrylic - 02				
D	Tablet Collection Trays MOC : SS (02 Nos)				
E	Power Supply Cable				
F	Instructional & Operational Manual				
G	Warranty Card				
H	Manufacturer test Certificate				
I	Warranty Card				
J	Abrasion Drum (Optional)				
K	IQ/OQ Documentation (Optional)				
L	PQ Documentation (Optional)				

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

2 OPERATIONAL QUALIFICATION

Operational Qualification (OQ) is the process of demonstration that an instrument will function according to its operational specifications in the selected environment.

2.1. Customer Orientation & Training

Orientation for the end user/s will be performed as per the Instruction Manual.

Sr. No.	Orientation Topic	Status	Verified	
			Yes	No
1	Instrument Setup/Connectivity with Accessories, Peripherals and Mains etc.	Explained / Shown		
2	Instrument Front Panel – Key Function	Explained / Shown		
3	Instrument Back Panel – Connection	Explained / Shown		
4	Instrument Mode & its function • Utilities • Validation	Explained / Shown		
5	Instrument & Accessories Maintenance	Explained / Shown		

The Training on the above topics is given to following personnel

Personnel Trained	Designation	Location	Verified

The Instrument orientation and training were carried out in accordance with the Instruction Manual and found satisfactory.

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

2.2. Operational Checking & Verification

Ensure all the supplied drums are properly install with instrument with right and left side.

2.2.1. Power on Check

Requirement Condition & Observation	Remark	
	Pass	Fail
➢ Instrument will display Manufacturer's company name, Model Number, Version Number, Serial Number, and then holds at Customer Name, real date and time. ➢ Drums will detect home position		

2.2.2. Instrument Validation Check as per USP Guideline

Analab Friability is calibrated and validated as per USP guide line at factory. (Ref. Manufacturing Test certificate) All the tools/apparatus i.e. Stop Watch, Tachometer, Vernier Caliper and Digital protector used for validation are calibrated by authorized agencies.

2.2.2.1. RPM Validation

Press MODE and enter in Validation and select RPM validation. Select validation for 25 RPM

Set RPM	25
Expected Time between	0:57 00 & 1:03 00
Measured Time	
Result	□ Pass □ Fail
Expected Rotation between	24 & 26
Measured Rotation	
Result	□ Pass □ Fail

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

2.2.2.2. Time Validation

Press MODE and select Time validation with down keys. First Select validation for fix 4 & 10 minutes respectively and then select any Minute.

Time Validation				
Set Time	**4 Minutes**	**10 Minutes**	**User Selection**	**User Selection**
Expected Time between	3:50 00 & 4:10 00	9:50 00 & 10:10 00		
Measured Time				
Result	☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail

2.2.2.3. Count Validation

Press MODE and select Count validation with down key. First Select validation for fix 50 & 100 counts respectively and then select any count.

Count Validation				
Set Count	**50**	**100**	**User Selection**	**User Selection**
Expected count between	49 & 51	99 & 101		
Measured Count				
Result	☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail

2.2.2.4. Instrument Tilt Validation

Instrument Tilt (10° ± 1°) check	☐ Pass ☐ Fail

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

2.3. Summary of Operational Checking & Verification

SR NO.	DESCRIPTION	RESULT		REMARK	
		Yes	No	Pass	Fail
1	Power ON Check				
2	RPM Validation				
3	Time Validation				
4	Count Validation				
5	Instrument Tilt				

All system components and functions are operating satisfactorily.

Enclosed Records

1 Warranty Card
2

The Operational check and the verification were carried out in accordance with the Operating manual and found satisfactory.

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

INSTALLATION & OPERATIONAL QUALIFICATION

The Installation Qualification (IQ) & Operational Qualification (OQ) final reports for the Friability Test Apparatus has been reviewed and was found acceptable for use.

INSTRUMENT : Friability Test Apparatus

MODEL : $\mu FTCal_{10}$

SERIAL NUMBER :

FINAL REPORT REVIEWED AND ACCEPTED BY WITH (Name & Designation) :

DATE :

Customer	
Department	
Head of Dept.	
End User	
Date	
Signature	
Seal of the Company	

Analab Representative	
Date	
Signature	

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

Performance Qualification

Friability Test Apparatus
Model: μFTCal$_{10}$

PERFORMANCE QUALIFICATION DOCUMENT

Protocol Number	**:**	ASIPL/PQ/
Company Name	**:**	
Location	**:**	
Instrument	**:**	Friability Test Apparatus
Model Number	**:**	µFTCal1$_0$
Instrument Serial Number	**:**	
Protocol Prepared By	**:**	Analab Scientific Inst. Pvt. Ltd. Vadodara

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

PERFORMANCE QUALIFICATION

Performance Qualification is the process of demonstrating that an instrument consistently performs according to a specification appropriate for its use.

Note: PQ should always be performed under conditions that are similar to routine sample analysis.

1. Aim

To ensure that the Friability Test Apparatus is properly calibrated / Validated with traceable Instruments / System. The test will check and confirm that the correct parameter values are achieved.

2. Scope

Performance Qualification must be performed in the case of new installation of an instrument OR change in the location and / or as per FDA requirements.

3. Responsibility

The responsibility for the Performance Qualification lies with the system user.

4. Preparation for the Test

Standards Required along with Instrument & Accessories:-

Sr. No.	Standards and Accessories
01	Tablets having weight 650 mg
02	Clean Cloth
03	Friability Drums
04	Digital Electronics Balance – 0.1mg

Make sure:-

- That drums are clean.
- Drums should be at Home Position.

Date :

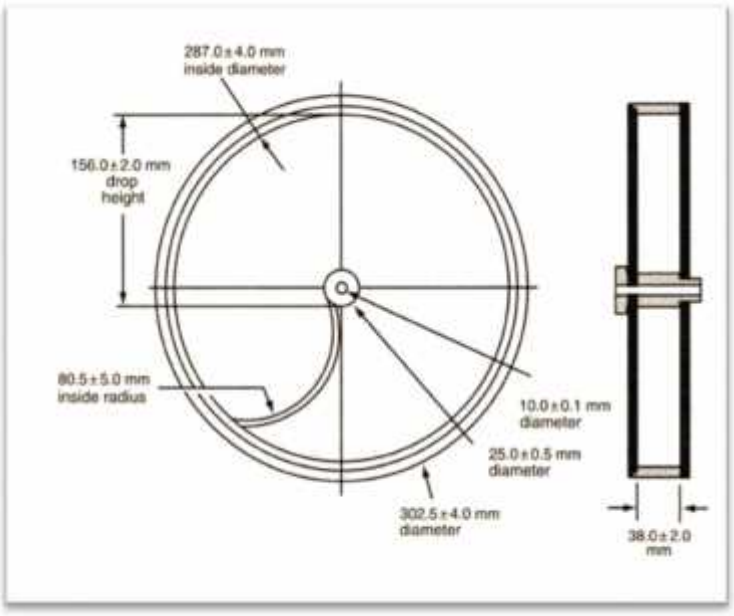
Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

5. Rosch Drums Validation Check as per USP Guideline

Drum 1 Serial No : _____ Drum 2 Serial No. : _____



Drum Parameter (mm)	Depth	Centre Hole Diameter	Centre disc Diameter	Outer Diameter	Inside Diameter	Inside Radius	Drop Hight
USP specification	**38.0 ± 2.0**	**10.0 ± 0.1**	**25.0 ± 0.5**	**302.5 ± 4.0**	**287.0 ± 4.0**	**80.5 ± 5.0**	**156.0 ± 2.0**
Measured Value Drum - 1							
Measured Value Drum - 2							

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

6. Standardization of Instruments with Tablets:-

- ❖ Connect Drums with the instrument
- ❖ Connect knobs to hold drums properly.
- ❖ Press COUNT or TIME keys to perform analysis with 25 RPM for 4 minutes or with 100 counts.
- ❖ If the tablet shape, size is irregular or whenever specified perform the friability test after tilting the instrument by 10 degrees.
- ❖ Put the weighed tablet in the drum (any one side) and enter the initial weight of sample and select the start to run test.
- ❖ After completion of test remove the tablets from the tray situated at the bottom of the acrylic pan of the instrument.
- ❖ Dedust the tablets and check for capping or breaking. Weigh the tablets and calculate its % friability by above given formula.
- ❖ Enter Final weight of tablets after analysis.
- ❖ Instrument will calculate % friability of tablets. % loss in weight should not more than 1%.

Formula to calculate % Friability:

% Friability = (Initial weight(g) - Final weight (g)) / Initial weight (g) x 100%

Acceptance criteria:

- ✓ For uncoated tablet the % friability should not more than 1%.
- ✓ For conventional compressed tablets % lose should be in between 0.5 % to 1%.
- ✓ For effervescent and chewable tablets in house limit will be set because they undergoes higher weight loss when subjected to friability test.

Note:

In general friability test is run only for single time, if any tablet found to be broken, cleaved or cracked after completion of test or if the % loss is greater than the targeted value it establishes that the sample fails the test, and the test should be repeated twice on the fresh samples mean of the three test shall be calculated and % loss should be not greater than 1% to meet the acceptance criteria.

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

7. Record of Tablets used:

Tablet Name	
Manufacturer	
Batch No / Quality	
Date of Opening	

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

PERFORMANCE QUALIFICATION

The instrument has been validated using traceable tools. The test protocols have been filled in correctly and test results are documented. The system can be released for appropriate use.

INSTRUMENT NAME : Friability Test Apparatus

MODEL : $\mu FTCal_{10}$

SR.NO. :

FINAL REPORT REVIEWED AND ACCEPTED BY (Name & Designation) :

DATE :

Customer	
Department	
Head of Dept.	
End User	
Date	
Signature	
Seal of the Company	

Analab Representative	
Date	
Signature	

Date :

Signature :

Name :

Designation :

Analab Representative	Checked by End User	Approved by Head of Department