Design Qualification

Tap Density Test Apparatus
Model: µTDCal$_{50}$

DESIGN QUALIFICATION

Protocol Number	**:**	ASIPL/DQ/
Company Name	**:**	
Location	**:**	
Instrument	**:**	Tap Density Apparatus
Model	**:**	µTDCal$_{50}$
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

- No. of Station : 1) USP1 (300 taps per min.)
  2) USP2 (250 taps per min.)
  3) USP3 (50 - 60 taps per min.).
- Stroke Height : 14 mm ± 2mm / 3mm ± 0.2 mm
- Stroke / Minute : 300 ± 15, 250 ± 15
- No. of taps : 1-9999
- Rotation and Tapping : Simultaneous
- Display of Strokes/min : Simultaneously Set & Actual
- Cylinder Supports : 100ml and 250 ml – Supplied without Cylinder
- Display : 20 x 4 Line Alphanumeric Backlit LCD
- Keypad : Membrane waterproof polycarbonate soft touch keypad compliance to UL/ROHS
- Pharmacopeia Complies : As per USP, IP, Ph. Eur.
- Method : 40 analysis method with View, Print & Delete facility
- **Password Protection : Delete Stored Protocol, Delete Stored Analysis Data, Date & Time**
- Date : 12/24 Hours Format
- Time : Real time clock
- Calculation of result : Bulk Density, Tapped density, Compressibility index and Haunser ratio
- Calibration Data Storage : Non-Volatile Memory which can store, print & view company name, standard name ,calibration done by, calibration status, instrument ID, serial number, model number etc.
- Searching of data : with record number, batch number, Date and by
- Report Formation : As per GLP Compliance

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

Technical Specifications cont.……

Analysis Data Storage	**: More than 1000** data can be store in non-Volatile Memory which can print & view test data with Batch No., username, sample name, instrument serial no., Instrument ID, model no., test date & time and test print date & time. **Secondly**, data can directly without saving test data in the instrument.
Printer Interface	: Centronics Parallel Port / Serial (RS-232 C) Port
Printer	: 40 / 80 Column Dot Matrix Printer
Power Supply	**:** 230VAC ± 10%, 50 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 Tap Density test apparatus has been reviewed and found acceptable for use.

INSTRUMENT : Tap Density Test Apparatus
MODEL : µTDCal$_{50}$
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

Tap Density Test Apparatus
Model: μTDCal$_{50}$

INSTALLATION & OPERATIONAL QUALIFICATION

Protocol Number	:	ASIPL/IQ-OQ/
Company Name	:	
Location	:	
Instrument	:	Tap Density Test Apparatus
Model	:	µTDCal$_{50}$
Instrument Sr. No.	:	
Protocol Approved By	:	Analab Scientific Instruments Pvt. Ltd.

Date :

Signature :

Name :

Analab Representative	Checked by End User	Approved by Head of Department

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Date :

Signature :

Name :

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	Tap Density Test Apparatus- Basic Unit μTDCal50	01			
02	Measuring Cylinders (250 & 100 mL)	02			
03	Cylinder Holders	02			
04	Power Supply Cable	01			
05	Operational & Instructional Manual with SOP	01			
06	Calibration test Certificate (without traceability documents)	01			
07	Warranty Card	01			
08	IQ/OQ Documentation	01			
09	PQ Documentation	01			

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

Date :

Signature :

Name :

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.				
Instrument to printer connectivity check	Printer should take command from Instrument				

Date :

Signature :

Name :

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	
		Yes	No
A	Items received as per Purchase Order		

1.3.2. Pre-Requisites Inspection

SR. No.	DESCRIPTIONS	RESULT	
		Yes	No
A	Instruments & Accessories Checked for Damages		
B	Table Space & Leveling		
C	Power Supply Availability		
D	Environmental Requirements		
E	Instrument to Printer Connectivity		

1.3.3. Standard & Optional Accessories (as ordered)

SR. NO.	DESCRIPTIONS	RESULT	
		Yes	No
A	Measuring Cylinders (250 & 100 mL)		
B	Cylinder Holders (02 Nos)		
C	Power Supply Cable		
D	Operational & Instructional Manual with SOP		
E	Calibration test Certificate (without traceability documents)		
F	Warranty Card		
G	IQ/OQ Documentation		
H	PQ Documentation		

Date :

Signature :

Name :

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 • Method • Analysis Data • Utilities • Service	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 :

Analab Representative	Checked by End User	Approved by Head of Department

2.2. Operational Checking & Verification

Ensure all the supplied cylinder holders are properly install with instrument.

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, instrument ID and then holds at Customer Name, real date and time.		

2.2.2. Instrument Validation Check as per USP Guideline

Analab tap density apparatus is calibrated and validated as per USP guideline at factory. (Ref. Manufacturing Test certificate) All the tools/apparatus i.e. Tachometer, Vernier Caliper and Balance used for validation are calibrated by authorized agencies.

2.2.2.1. 250 mL Cylinder (Readability : 2 mL)

	Weight in Gram	Acceptable Weight	Pass / Fail
Cylinder		176 – 264 Gram	
Cylinder Holder weight		440 - 460 Gram	

2.2.2.2. Drop Height Verification for 250 mL Cylinder

	USP 1				USP2			
ARM	Top Height mm	Base Height mm	Drop Height mm (HT-HB)	Acceptable Drop Height (12 to 16 mm)	Top Height mm	Base Height mm	Drop Height mm (HT-HB)	Acceptable Drop Height (2.8 to 3.2 mm)
	HT	HB	HD		HT	HB	HD	
1								
2								
3								

Date :

Signature :

Name :

Analab Representative	Checked by End User	Approved by Head of Department

2.2.2.3. 100 mL Cylinder (Readability : 1 mL)

	Weight in Gram	Acceptable Weight	Pass / Fail
Cylinder		114 – 146 Gram	
Cylinder Holder weight		228 - 252 Gram	

2.2.2.4. Drop Height Verification for 100 mL Cylinder

	USP 1				USP2			
ARM	Top Height mm	Base Height mm	Drop Height mm (HT-HB)	Acceptable Drop Height (12 to 16 mm)	Top Height mm	Base Height mm	Drop Height mm (HT-HB)	Acceptable Drop Height (2.8 to 3.2 mm)
	HT	HB	HD		HT	HB	HD	
1								
2								
3								

2.2.2.5. Number of Drops/Min

Method	Observed Drops/Minute	Deviation Limit	Pass / Fail
USP 1		294 to 306 Drops	
USP 2		245 to 255 Drops	
USP 3		50 to 60 Drops	

2.2.3. Printer Test

- Connect printer with instrument
- Go to Utility 2 i.e. Printer Test □ Pass □ Fail

Date :

Signature :

Name :

Analab Representative	Checked by End User	Approved by Head of Department

2.3. Summary of Operational Checking & Verification

SR NO.	DESCRIPTION	RESULT	
		Yes	No
1	Power ON Check		
2	Instrument Validation check as per USP Guideline		
3	Printer Test		

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 :

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 Tap Density Test Apparatus has been reviewed and was found acceptable for use.

INSTRUMENT : Tap Density Test Apparatus

MODEL : $\mu TDCal_{50}$

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 :

Analab Representative	Checked by End User	Approved by Head of Department

Performance Qualification

Tap Density Test Apparatus
Model: μTDCal$_{50}$

PERFORMANCE QUALIFICATION DOCUMENT

Protocol Number	**:**	ASIPL/PQ/
Company Name	**:**	
Location	**:**	
Instrument	**:**	Tap Density Test Apparatus
Model Number	**:**	µTDCal$_{50}$
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 Tap Density 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	Measuring Cylinder (100 mL)
02	Cylinder Holder
03	Powder to measure compressibility
04	Clean Cloth
05	Digital Electronics Balance – 0.1mg

Make sure:-

- That Cylinders are clean.
- Cylinder should be properly fix on cylinder holder.
- Connect dot matrix printer

Date :

Signature :

Name :
Designation :

Analab Representative	Checked by End User	Approved by Head of Department

5. Tap Density Tester Performance Test

Fill the material to be measured at an even flow rate into a tared 100mL graduated cylinder, filling the cylinder to between 70 to 90 mL. Enter the value in instrument.

Note : if the material in the graduated cylinder is not level, calculate the average volume by adding the high and low level and dividing by two.

Material Average volume : (High Volume + Low Volume) / 2
Suppose, High Volume is 82 and Low Volume is 80 then,

82+80 = 162 / 2 = 81 (Enter this value in instrument before starting first tapping)

After first tap completes, again measure the volume of sample and enter the value in instrument.

If difference between initial volume and first tap volume, is less than 2 ml, instrument will ask to save result other wise will ask to 2nd taps.

Save the reading and take the printout of result.

6. Record of Material used:

Material Name	
Manufacturer	
Batch No / Quality	
Date of Opening	

7. List of Attachment:

Sr. No	Attachments	Number of Pages
1	Sample Result Report	

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 : Tap Density Test Apparatus

MODEL : $\mu TDCal_{50}$

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