INSTALLATION QUALIFICATION

FOR

TABLET HARDNESS TESTER

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

INSTALLATION QUALIFICATION FOR TABLET HARDNESS TESTER

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1.0 Pre-Approval:

Signing of this Approval page of Installation Qualification Protocol No. ..... indicates agreement with the Installation Qualification approach described in this document. Should Modifications to the Installation Qualification become necessary, an addendum will be prepared and approved.

Written By	Signature	Date
Quality Control		

Checked By	Signature	Date
Production		
Quality Assurance		

Approved By	Signature	Date
Quality Assurance		
Plant Head		

INSTALLATION QUALIFICATION FOR TABLET HARDNESS TESTER

2.0 Overview:

2.1 Purpose:

The purpose of this protocol is to provide an outline for the Installation Qualification of the instrument for static attributes to verify that:

- Each installed sub component complies with the instrument data sheets / specifications, agreed upon with the manufacturer.
- All supporting utilities are connected.
- The instrument is installed as per the laid down specifications.
- No unauthorized or unrecorded modifications have taken place.
- Required testing reports are available.
- A *draft* Standard Operating Procedures (SOP) have been identified and listed.

2.2 Scope:

This protocol covers the installation qualification of the Tablet Hardness Tester.

2.3 Responsibility:

The validation group comprising of a representative from each of the following departments shall be responsible for the overall compliance with this protocol:

- Quality Control Department
- Production Department
- Quality Assurance Department

Quality Control shall be responsible for checking proper installation and recording installation data as per the procedures outlined in this protocol.

The Quality Assurance shall be responsible for the final review of the qualification documents and its compliance to meet the acceptance criteria of the Installation Qualification protocol.

The summary report shall be approved by the Plant Head, and Head Quality Assurance.

2.4 Requalification:

Installation Qualification to be requalified on:

- Replacement of major component of the Instrument with a new component.
- Any major modification in the existing Instrument.
- Shifting of the Instrument from one location to another.

2.5 System Description:

Hardness is one of the most important aspect while compression of Tablets, it gives brief idea about the tablet's resistance to crushing. Hardness also has a significant impact on the dissolution rate of the Tablet. Hence determination of the tablet hardness is one of the most important parameters while compression.

Tablet Hardness Tester Dr. Schleuniger Pharmatron - 8M will allow to measure tablet Hardness in Newtons, Kiloponds, Strong cobbs or user defined unit of measure. It can also measure tablet diameter and thickness in either mm or inches . It also has a function of measuring weight in either g or mg. Up to 100 measurement of each parameters can be taken and / or stored for statistical analysis.

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This hardness tester calculate the mean, maximum, minimum, range, absolute standard deviation and relative standard deviation of data. Statistical data may be printed in graphical form using one of the graph option. It can define both tolerance (T1 and T2) ranges and valid range for measurement, which eliminates unacceptable values from the statistics

Tablet Hardness Tester Dr. Schleuniger Pharmatron - 8M has ten input / output ports for external communications.

1. The host / terminal port allows the tester to be attached to any serial terminal, allowing information to be passed between the tester and the host computer. This could be used to enter configuration information as well as collect data for external analysis.

2. The centronics printer port allows the user to connect the tester to any compatible parallel printer.

3. The RS232C port 1 connection allows the user to connect the tester to any compatible serial printer.

4. The RS232C port 2 allows the user to connect the tester to additional test equipment.

5. The CAN in port is used for networking local CAN compatible devices.

6. The CAN out port is used for networking local CAN compatible devices.

7. The thickness port is the data port through which data from the external thickness gauge is transferred to the tester.

8. The balance port is the data port through which data from the balance is transferred to the tester.

9. The optional keyboard port allows the entry of product information, limits and configuration information from a keyboard.

10. The external start port is for a removes switch that can be used for functional equivalent to the Run button on the front plate.

The tester has powerful micro-processor based control board. The Micro-Processor controls the operations of the machines, and computes the statistics for the tablet measurements. The hardness reading are taken via a load cell, and converted into the appropriates units. Available unit scales are Newtons, Kiloponds, Strong cobbs or the User Defined unit of measure . Diameter and the Thickness (internal) data readings are taken by using the load cell in conjunction with a stepper motor. Both sets of units are programmed via the 8M software.

Operators can enter the Product Name. Number, Batch ID, Press ID, Container Number, Operator and Comments with a keyboard, Up to 100 samples of weight, Thickness, diameter and hardness can be collected, reported and stored (excluding Product 0) in a single test sequence. The data can not, however, be stored for batch (multiple test) evaluation purposes.

3.0 Instrument Specification:

Detailed Instrument Specifications are as follows:

ITEM	SPECIFICATIONS
Physical Dimensions	420 x 150 x 185 mm
Weight	10 Kg
Environmental requirements	32° to 100° F 0° to 38° C Up to 90% RH
Power Supply	115 / 230 V, 50/60 cycles, auto switch
Hardness Capacity and Tolerance	50 Newtons ± 1% of full scale 400 Newtons ± 1% of full scale 500 Newtons ± 1% of full scale 800 Newtons ± 1% of full scale 1000 Newtons ± 1% of full scale
Sample Diameter	33 mm. (max)
Cycle Time	25 Tablets / 3 minutes (typical)
Measuring Unit	Hardness
	N (Newton's)
	Kp (Kilopond, 1 Kp = 9.81N)
	Sc (Strocobb, 1 Kp = 1.43 Sc)
	Diameter
	mm or Inch
Voltage	220V / 50-60 Hz or 110V / 50-60 Hz
Test Method	Manual or Automated

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4.0 Instrument Identification:

The subjected instrument is identified as ***Tablet Hardness Tester,***

Dr. Schleuniger Pharmatron AG

Model: **8M**

Serial No. : **01921**

In-house Instrument No. : .....

Name of the Supplier : ***Dr. Schleuniger Pharmatron AG***

Purchase Order No. : _____**Dated**_____

5.0 Instrument Location:

Facility	:	Oral formulation
Area	:	Process Area
Room / Lab. Identification	:	In-process Quality Control (IPQC)

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6.0 Installation Qualification Procedure:

6.1 Inspection Checklist:

Instructions:

6.1.1 Check the Instrument physically for any damage and record the observation in the Data Sheet of section 6.2.

6.1.2 Identify the utility supplies required for instrument operation. Verify that utilities are as per the specification mentioned in the Check Point and record the observation in the Data Sheet of section 6.2.

6.1.3 Identify the critical accessories supplied with the instrument or installed on the utility supply line. Verify that instruments are as per the desired specifications.

6.1.4 Check the installation of instrument:

- To verify the proper assembly of the components as per the instrument manual. Record the installation location and verification of assembly in Test Data section 6.2.

6.1.5 Identify the SOPs and assign SOP Numbers, record the SOP Title and Number in Section No. 6.2.

6.1.6 Record the deficiency (if any) in section number 6.2 and report the details of action taken.

Note:

1. *Record all the observations against the respective specifications, mentioned in the specific checkpoints, under section 6.2 (The specifications are extracted from the Purchase order / Manual / Manufacturer's Recommendations).*
2. *Incase of non-compliance, give the explanation / justification in the deficiency and corrective action report format under section 6.2.*
3. *When more than one unit of the same type exist, replicate the corresponding data sheet to match and uniquely identify each page.*
4. *Incase of multiple options; clearly identify the one, which has been supplied.*
5. *The calibration certificates of the instruments shall be traceable to National / International standards.*
6. *Define all technical terms and abbreviations in the appendix under section 10.0.*

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6.2 Installation Qualification:

6.2.1 Physical verification of the instrument / Environment

Objective: - To verify that any physical damage of the instrument and Environmental condition for the operation of the Instrument.

S.No.	Test Particulars	Specifications	Observations	Acceptance Yes/No
Physical Verification				
1.	Check the Instrument for any damages.	There should not be any damages.		
Environmental Conditions				
1.	Room Temperature	15° C to 30°C		
2.	Relative Humidity	45% to 70%		
3.	Away from the Sunlight	-		
5.	No corrosive Gases	-		
6.	The table holding the instrument should be dry, horizontal.	-		
7.	Free from excess dust and moisture	-		
8.	Stability of input power (± 10% of 230 v AC 50 Hz)	-		

Checked by
(Quality Control)

Name	Sign.	Date

Verified by
(Quality Assurance)

Name	Sign.	Date

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6.2.2 Major Component Verification

Objective: - To verify that major components as identified below are complying as per the desired specifications.

S. No	Name	Qty. Supplied	Observation	Acceptance Yes / No
1	Tablet Hardness Tester – main Unit (Dr. Schleuniger Pharmatron AG)	01		
2	Load Cell Compartment (attached to the main Unit)	01		
3	Keyboard	01		
4.	Operators manual	01		
5.	5 kg Cast iron Weight with certificate	01		
6.	Power supply cord	01		
7.	10.0 mm mechanical tablet	01		
8.	Plastic collection tray	01		
9.	Hand held brush	01		

	Name	Sign.	Date
Checked by (Quality Control)			
Verified by (Quality Assurance)			

6.2.3 Verification of Utility Supply

Objective: To verify that necessary utility supplies required for instrument operation are as per the desired specification and connected properly.

S.No.	Utility	Specifications	Observations	Connected and Identified (Yes / No)
1.	Power	Single Phase, 230V ± 10% 50 Hz		

Note: *Power Supply to be checked with a Multimeter.*

Checked by (Quality Assurance)	**Name**	**Sign.**	**Date**
Verified by (Quality Assurance)	**Name**	**Sign.**	**Date**

6.2.4 Standard Operating Procedures (SOP's) Identification:

SOP's	Number	Title
Operation, Calibration and Cleaning		Operation, Calibration and Cleaning of Tablet Hardness Tester

6.2.5 Deficiency (if any) and Corrective Action Report:

If there is no deficiency, then write NA.

Description of deficiency and date observed:

_____
_____
_____
_____
_____

Person, responsible for corrective action and date assigned:

_____
_____
_____
_____

Corrective actions taken and date conducted:

_____
_____
_____
_____
_____
_____
_____
___

Conducted By : _____ Approved By : _____

Date : _____ Date : _____

Comments (if any):

_____

_____

Verified By:

Name: _____ Signature: _____ Date: _____

7.0 Acceptance Criteria:

Installation Qualification shall be considered acceptable when all the conditions specified in various forms under section 6.0 have been met.

Any deviation from the acceptance criteria of the specific check point shall be reported and decision should be taken for the rejection, replacement or rectification of the instrument / component.

8.0 Remarks (if any) :

_____

_____

_____

_____

_____

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9.0 Summary:

Checks	Observations	Remarks
Whether acceptance criteria of the protocol and Specific check points are met.	Yes/No	

9.1 Conclusion:

Tablet Hardness Tester (8M) bearing Instrument Number **is** / **is not** qualifying the Installation Qualification tests as per the Protocol ....., hence the instrument **can** / **cannot** be tested for its Operational Qualification as per Protocol No. .....

9.2 Post-Approval Signatures:

Name	Signature	Date
Quality Control		
Quality Assurance		
Plant Head		

10.0 Appendix:

10.1 Abbreviations and Definitions:

IQ	- Installation Qualification
mm	- Millimeter
V	- Volt
cm	- Centimeter
S. No.	- Serial Number
Sr.	- Senior
°C	- Degree Centigrade
AC	- Alternate Current
DC	- Direct Current
g	- Gram
RH	- Relative Humidity
Hz	- Hertz
Kg	- Kilogram
Nos.	- Numbers
Amp	- Amperes
Eq.	- Equipment

Acceptance criteria	:	The product, instrument., and / or process specifications and limits, such as acceptable quality level and unacceptable quality level, that are necessary for making a decision to accept or reject.
Installation qualification	:	The documented verification that all aspects of a facility, utility or equipment that can affect product quality adhere to approved specifications (e.g., construction, materials) and are correctly installed?
Validation	:	Establishing documented evidence that a system does what it purports to do.
Revalidation	:	Repetition of the validation process or a specific portion of it

10.2 List of Documents:

1. Instrument manual
2. Purchase Order No. Dated is attached.
3. Calibration Certificates
4. Draft SOP – .....