

Qualification of laboratory Equipments

Hardness Tester

Basic Idea

- Measures the mechanical (crushing) strength of tablets by determining the force required to break them.
- Tablet hardness affects **disintegration, dissolution, friability, and drug release**.

Common Units

- Newton (N)
- Kilogram-force (kgf)
- Kilopond (kp)

User Requirement Specification (URS)

- Suitable hardness measuring range
- High accuracy and precision
- Digital display with easy calibration
- Compatible with different tablet shapes and sizes
- Software/printer for data recording (if required)
- Compliance with USP, IP, and Ph. Eur.

Qualification Stages

Installation Qualification (IQ)

- Verify equipment model and serial number.
- Install according to manufacturer guidelines.
- Verify power supply.
- Install software (if applicable).
- Review manuals and calibration certificates.
- Check accessories.

Operational Qualification (OQ)

Tests Include

- Force calibration using certified weights
- Force measurement accuracy
- Repeatability

- Display verification
- Zero adjustment
- Functional test

Performance Qualification (PQ)

- Test standard tablets.
- Verify consistent hardness measurements.
- Perform routine calibration.
- Monitor instrument performance.

Important Qualification Parameters

- Force accuracy
- Repeatability
- Precision
- Linearity
- Zero calibration
- Display accuracy

Documentation

- IQ, OQ, PQ reports
- Calibration certificates
- Maintenance records
- Instrument logbook
- Preventive maintenance records

Importance

- Ensures accurate hardness measurement.
- Maintains tablet quality.
- Prevents batch rejection.
- Ensures GMP compliance.

Friability Test Apparatus

Basic Idea

- Measures the ability of tablets to resist abrasion, shock, and mechanical stress during handling, packaging, and transportation.

- Tablets are rotated in a drum and % **friability** is calculated.

Formula

$$\text{Friability (\%)} = (\text{Initial Weight} - \text{Final Weight}) / \text{Initial Weight} \times 100$$

- **Acceptance Limit:** Generally $\leq 1.0\%$, unless otherwise specified.

User Requirement Specification (URS)

- Standard drum dimensions
- Adjustable rotation speed
- Accurate timer
- Digital display
- Compliance with USP/IP specifications

Qualification Stages

Installation Qualification (IQ)

- Verify installation.
- Check drum dimensions.
- Verify power supply.
- Review manuals.
- Check accessories.

Operational Qualification (OQ)

Tests Include

- Drum rotation speed (25 ± 1 rpm)
- Timer accuracy
- Number of revolutions
- Drum dimensions
- Functional operation

Performance Qualification (PQ)

- Test standard tablets.
- Verify % friability.
- Perform routine performance checks.
- Monitor repeatability.

Important Qualification Parameters

- Drum speed

- Timer accuracy
- Number of revolutions
- Drum dimensions
- Repeatability

Documentation

- IQ, OQ, PQ reports
- Calibration records
- Maintenance records
- Instrument logbook

Importance

- Ensures tablets withstand handling.
- Prevents excessive tablet breakage.
- Supports quality assurance.

Tap Density Tester

Basic Idea

- Determines the tap density of powders and granules by mechanically tapping a measuring cylinder until a constant volume is obtained.
- Used to evaluate **flow properties** and **compressibility**.

Formula

$$\text{Tapped Density} = \text{Weight of Powder} / \text{Tapped Volume}$$

User Requirement Specification (URS)

- Adjustable tapping height
- Standard tapping frequency
- Digital counter
- Compatible measuring cylinders
- Compliance with USP requirements

Qualification Stages

Installation Qualification (IQ)

- Verify installation.

- Check measuring cylinder.
- Verify power supply.
- Review manuals.
- Check tapping mechanism.

Operational Qualification (OQ)

Tests Include

- Tapping frequency
- Tapping height
- Counter accuracy
- Repeatability
- Mechanical operation

Performance Qualification (PQ)

- Test certified reference powders.
- Verify tap density.
- Monitor consistency.
- Perform routine verification.

Important Qualification Parameters

- Tapping height
- Tapping frequency
- Counter accuracy
- Repeatability
- Volume consistency

Documentation

- IQ, OQ, PQ reports
- Calibration records
- Maintenance records
- Instrument logbook

Importance

- Determines powder flow properties.
- Supports formulation development.
- Improves tablet compression.



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