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Disintegration Tester Qualification

Practical 18 - Equipment qualification practical

Aim

To evaluate qualification evidence for a disintegration tester.

Principle

Qualification demonstrates fitness for an intended use. User requirements and risk assessment define the installation checks, operational challenges and performance evidence. Calibration of one sensor is only part of this evidence.

Materials and Requirements

- Equipment specification, user requirements and approved protocol
- Calibration, installation and maintenance records
- Supplied qualification readings and deviation forms
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Trace user requirements to design and installation checks, utilities, materials, safety systems and document availability.
3. Basket/tube/disc configuration, stroke, frequency, temperature, timing and endpoint observation.
4. Challenge the justified operating range with calibrated independent measurements and retain actual readings.
5. Verify physical operating parameters and apply the selected dosage-form method, including disc requirements and individual-unit records.
6. Assess performance with representative or worst-case loads or materials under the approved protocol.
7. Review deviations, acceptance criteria, requalification triggers and authorised release for the intended use.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Requirement / test	Method / challenge	Actual result	Criterion and decision
Installation	Specify	Record	Evaluate
Operating range	Specify	Record	Evaluate
Performance / load	Specify	Record	Evaluate

Calculations

- Timing error = indicated duration - reference duration.

Worked Example

Illustrative indicated 600 s and reference 598 s give +2 s. This check is distinct from a dosage-form disintegration result.

Result and Interpretation

- Provide a requirement-to-evidence matrix and a qualified-use statement with unresolved restrictions.

Precautions

- Use independent calibrated measurements.
- Set criteria before testing.
- Never bypass interlocks to perform a teaching challenge.

Viva Questions and Answers

What is IQ?

Documented verification of installation against requirements.

What distinguishes OQ and PQ?

OQ challenges operating functions; PQ demonstrates intended performance under justified use conditions.

When is requalification considered?

After relevant change, adverse trend or the approved periodic review.

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