

Product Specifications

Vibrac

PRECISION TEST SYSTEMS

Documentation:

- Validation Guide:
 - IQ Installation Qualification
 - OO Operational Qualification
 - PQ Process Qualification
- Gold Bottle Calibration Certificates:
- Measurement Accuracy Manual:

Software:

- Gage R & R Study:
 - Repeatability Calculations
 - Reproducibility Calculations
 - Input Data Form

Hardware:

- 2 Gold Bottles

GOLD STANDARD BOTTLE VALIDATION GUIDE



Another Quality
Engineered Solution
For Production
Testing

The Worldwide Gold Standard
in Torque Measurement and
Validation

Vibrac
PRECISION TEST SYSTEMS

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Vibrac

As the industry leader in the precision torque test equipment market serving both the packaging and motion control industry, Vibrac remains committed to supplying state of the art products and documentation to meet the requirements of the 21st century.

Process Validation Definition:

“Process validation is the documented evidence that the process, operated within established parameters, can perform effectively and reproducibly to produce a product meeting its pre-determined specifications and quality attributes.”

Validation Master Plan:

The Master Plan described below comes from the Pharmaceutical Inspection Convention.

- **Design Specification Qualification**
- **Installation Qualification**
- **Operational Qualification**
- **Performance Qualification**
- **Change Control**

Validation Guide

This Document package will guide the user step by step through the implementation of the IQ, OQ and PQ elements of the Master Plan.

Installation Qualification (IQ):

This element contains all the check off lists for receipt, power up, and calibration.

Operational Qualification (OQ):

This element contains a list of user supplied documentation and training requirements.

Performance Qualification (PQ):

This element contains all the necessary information and documentation for performing a Gage R & R Study.



Performing a Gage Study (Gage R & R):

The Gage Study is used to demonstrate that the Cap Inspector is capable of providing the required accuracy, repeatability and reproducibility of measurements for the current application.

Input Data Screen:

Part	Appraiser	Trial	Reading
1	A	1	16.44
2	A	1	16.50
3	A	1	16.41
4	A	1	16.47
5	A	1	16.47
6	A	1	16.53
7	A	1	16.44
8	A	1	16.50
9	A	1	16.41
10	A	1	16.47

R & R Industry Standards:

- R&R < 10% Excellent
- R&R 10-20% Adequate
- R&R 21-30% Marginal
- R&R > 31% Inadequate

Test Results:

Source of Variability	Percent of Tolerance	99% Index
Repeatability (Equipment Variation)	1.32%	0.13245
Reproducibility (Appraiser Variation)	0%	0
Repeatability & Reproducibility	1.32%	0.13245
Part Variation	1.38%	0.1377
Total Variation	1.91%	0.19106

Repeatability

Is the variability of the measurements obtained by one person while measuring the same item repeatedly.

Reproducibility

Is the variability of the measurement system caused by differences in operator behavior.

The Gage Study is performed by having 3 operators test each Gold Bottle 10 times and record the data.

This data must then be typed into the computer that the supplied software has been installed on.