

Qualification of Integrity Test Equipment

Introduction

Filter integrity testing can be one of the most critical procedures in a filtration process and may be an essential requirement for batch release of a product. The increasing requirement for accuracy and documentation has resulted in a wider use of automated integrity test equipment.

Such equipment must be qualified to ensure that it satisfies both process and regulatory requirements.

How Can Pall Assist?

Expertise

We have over twenty years experience in the design, manufacture and qualification of Palltronic® integrity test equipment.

Time and cost saving

Our approach to instrument qualification minimizes time and costs.

Quite simply, we make instrument qualification easier for you.

Qualification Tests

Installation Qualification IQ

We check all the equipment components and documentation. The suitability of the testing environment and services are also checked if the instrument is qualified on your site.

Operational Qualification OQ

We offer two options.

1. GAMP* guidelines state that the OQ of standard instruments such as integrity test units can be divided into two parts. A completed OQ1 containing extensive qualification studies on a reference instrument. A shorter OQ2 protocol on



your specific instrument is then performed, saving both time and cost.

2. Alternatively, all OQ tests in the form of a standard system acceptance test (SAT) can be performed on your specific instrument. A customized SAT protocol can also be prepared for you if required.

Performance Qualification PQ

We can also assist in generating customized PQ protocols and if required, perform the tests.

Features and Benefits

- Pall's experience and expertise ensures instrument qualification of the highest standard meeting the latest industry and regulatory requirements
- All materials, measuring equipment and labor supplied by Pall for trouble-free testing
- Completed OQ1 document on reference instruments saves time and costs
- Tests can be performed on site or off-site for maximum flexibility
- The ultimate benefit to you is a faster and more secure qualification process to meet regulatory requirements

* Good Automated Manufacturing Practice guidelines issued by the ISPE

Where are Tests Performed?

At a Pall site

We perform the tests in our purpose-designed laboratories. If required, you can view the testing.

On your site

We set up and perform the tests at your location.

Equipment and Materials

We have all the necessary equipment to ensure that qualification tests are performed accurately and reliably. We also supply materials such as filters. This capability means that we can offer a fast, professional and cost-effective service.

Range of Qualification Service

The service covers the **Palltronic Flowstar™** and **Palltronic AquaWIT™** instruments. Specialized versions of these instruments can also be qualified as appropriate.

Documentation

Standard Qualification & Validation Documents

Standard protocols for IQ/OQ2 or SAT can be purchased from Pall. Completed OQ1 documents are also available together with validation support documentation based on GAMP guidelines. Full details and part numbers are published in Pall datasheet USD 2170.

Customized Protocols

We work closely with your specialists to ensure that the format and content of customized protocols meet your requirements.

Reports

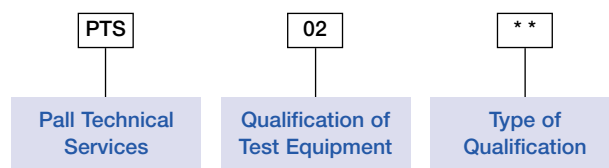
On completion of the tests, the final reports are reviewed, approved and signed by a competent Pall specialist. The full documentation is then submitted to you for approval.

Charges

In most cases, we can provide a fixed price in advance for the service.

For some special requirements, we provide an estimate to assist you in budgeting and cost control. The final invoice will itemise actual costs for labor, materials etc.

Part Number Structure



Typical Part Number PTS02AB IQ/OQ2 Qualification at Pall Site



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