

Process Specific Filter Validation

Introduction

Pall fully appreciates the stringent regulatory demands for filter validation documentation in the Biopharmaceutical industry and maintains a comprehensive global filter validation service to help meet these demands.

Many of Pall's Validation Laboratories are stand alone facilities where specialists working to GLP principles perform specific customer tests. To date, in excess of 2000 customer validation studies have been completed in these facilities.

First time regulatory approval of the filtration validation package is our mission. Pall's close links with industry and the regulatory agencies ensure we are up-to-date with the latest thinking, so helping to achieve this goal.

Validation Objectives

The objective is to prove the suitability of the filter for the process by answering the following questions:

- Does the product affect the filter
- Does the filter affect the product
- Does the product affect microbial retention by the filter

To achieve these objectives, Pall uses a Parametric Approach to ensure that filter validation is performed taking into account all critical product attributes and process parameters. This is in line with regulatory expectations and the recommendations of PDA Technical Report 26.



The Filter Validation Package

The filter validation package will be tailored to meet your specific needs and will probably include some or all of the following:

- Compatibility assessment
- Challenge viability study
- Bacterial, mycoplasma or bacteriophage retention study
- Extractables analysis
- Evaluation of adsorptive effects
- Generation of product wet integrity test data

We can also develop customized microbiological procedures using your specific process isolates.

Prior to the start of any test, a protocol detailing the test methodology and acceptance criteria will be issued for approval.

At the conclusion of testing, a comprehensive report including all experimental data will be provided.

Test Summary

Compatibility assessment

To be suitable for use in the manufacture of a pharmaceutical drug product, a filter cartridge must be both chemically and physically resistant to the process stream and operating conditions. Laboratory tests can be used to establish chemical compatibility.

Product viability study

Many pharmaceutical products are bactericidal. This test verifies the survival capacity of the organism selected for microbial challenge testing, in the whole product or a suitable product simulant, for the process time.

Microbial retention study

This is to qualify the ability of the filter media to produce sterile filtrate in the process. A solution of the product or simulant will be inoculated with the challenge organism at a concentration $>1 \times 10^7$ viable organisms/cm² of filter membrane area. The challenge is carried out on three filter membranes from different production batches, with at least one being at minimum specification.

Extractables analysis

Both quantitative and qualitative information on extracted materials must be generated. Commonly extractables cannot be evaluated directly in the actual product, but a "Model Solvent" approach must be developed. The Pall Validation Laboratories use a filter cartridge tested with the appropriate "Model Solvent" to reproduce a worst case situation.

Evaluation of adsorptive effects

It is critical that filters are selected to minimize adsorption and loss of product components. Laboratory scale tests can be used to generate adsorption profiles to help with filter selections and process qualification.

Generation of product wet integrity test parameters

Integrity tests performed on critical filters immediately before and after batch filtration give filter security. In order to optimize processing it may be more convenient to integrity test the filter cartridge wet with the product. Pall Validation Services Groups can provide users with the integrity test data for these specific products.

Test Requirements

- Full process information
- Full product composition
- Approximately 2000mL of product

- Full process information
- Full product composition
- Approximately 200mL of product

- Full process information
- Full product composition
- Approximately 1000mL of product

- Full process information
- Full product composition

- Full process information
- Full product composition
- Approximately 1000mL of product
- Analytical test methods

- Full product composition
- Approximately 1000mL of product

Part Numbers

PTS01CA

PTS01VA (Basic)
PTS01VB (Mid)
PTS01VC (Complex)

PTS01BA (Basic)
PTS01BB (Mid)
PTS01BC (Complex)

PTS01EA (Generic)
PTS01EB (Lab tests)

PTS01AA

PTS01PA

Charges

Wherever possible, we provide a fixed price in advance for the project. Where this is not possible, we will give an estimate to assist you in budgeting and cost control. The final invoice gives details on items such as labor, materials etc.

What's the Next Step ?

Simply contact your local Pall representative. They will discuss your specific requirements with you and forward your enquiry to Pall's Validation Services Teams. We recommend you do this well in advance of a regulatory audit to ensure there is adequate time to generate appropriate test data.



New York - USA

+1 516 484 5400 phone
+1 516 625 3610 fax
pharmafilter@pall.com e-mail


Portsmouth - Europe

+44 (0)23 9230 3303 phone
+44 (0)23 9230 2506 fax
BioPharmUK@pall.com e-mail

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