

Provantage® Services

Chemical Compatibility, Evaluation and Qualification Services

Introduction

A proper selection and qualification of equipment, filter devices and materials for use in a pharmaceutical manufacturing process should include a thorough assessment of the chemical compatibility of the product contact components. Failing to properly assess the compatibility of product contact components could lead to delays in the process development of product and could even lead to process failures and deviations that could compromise the quality of the drug product.

Despite these risks, it is often difficult to find detailed guidance on the necessary steps to demonstrate chemical compatibility because regulation and guidance documents are written to cover a wide array of products and processes. For instance, "PDA Technical Report 26" is a highly regarded guidance document for sterile filtration operations and states that chemical compatibility testing should be completed as part of the overall filter qualification package; however this guidance does not detail a specific method or procedure for demonstrating compatibility and instead only provides general guidance.

Our process validation team can assist you by providing chemical compatibility services to meet the needs of your specific process. Our validation project coordinators will work with you to understand your process, and by using our in-depth knowledge of our products, we can assist you in assessing the risk of your application and recommend the appropriate level of testing to mitigate this risk.

By selecting Provantage® Services to provide this service you can save the time and cost associated with developing validation protocols and test methods. We will provide you with a comprehensive compatibility assessment that will maintain your regulatory compliance and ensure that our products used in your process will perform as designed.

Service Description

Chemical compatibility testing can be provided for a wide array of our products that contact your product. These include, but are not limited to, sterilizing-grade filters, pre-filters, tangential flow filters, and Mobius® disposable process containers and components. The scope of the recommended chemical compatibility service offering is based on the following risk factors:

- Drug product or intermediate composition
- Device materials of construction
- Duration of product contact
- Temperature of product contact
- Maximum or worst-case process parameters

The recommended approach could range from a letter based on existing compatibility data to testing on full scale devices that compares product performance attributes before and after exposure to your product and processing conditions.



Chemical Compatibility Approach and Procedure

A project coordinator will be assigned and dedicated to your project from initiation to completion. A standard test protocol is customized for the needs of your specific process and submitted for your review. Once it is approved, testing begins. A standard report summarizing the test results is submitted to the client at the completion of testing. In the event that a chemical compatibility study or evaluation provides evidence that the process fluid is not compatible with the tested device, we will recommend an alternate device.

Our Validation Sciences Laboratories Service Specialists are committed to providing this service at validation labs in the U.S, Europe and Asia. We welcome and encourage client audits of our worldwide laboratory facilities. Let our years of filtration and process optimization experience save you valuable time and resources.

What you need to know to begin

- Exact filter or disposable assembly catalog numbers
- Product contact duration and temperature range
- Defined maximum or worst-case process conditions
- How much candidate test solution is available for testing, and when?
- Is there an MSDS for the candidate test solution?
- Is this a controlled drug? If so, what classification and code?

To Place an Order or Receive Technical Assistance

In Europe, please call Customer Service:

France: 0825 045 645

Germany: 01805 045 645

Italy: 848 845 645

Spain: 901 516 645 Option 1

Switzerland: 0848 645 645

United Kingdom: 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840

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