



Extractables Analysis

A requirement of filter compatibility validation

An ideal filtration device is non-interactive. It does not adsorb or take out any active ingredients from the drug, nor impart extractables into the drug product. It is important to test the filtration device for its retention characteristics, non-interactive ability and safety under minimum and maximum operating conditions.

Drug products and filter components are typically organic in nature. Because most drugs contain a much greater concentration of organic material as compared to filters, it is often impossible to develop a practical analytical method to accurately detect and quantify extractables. Therefore, even the most precise analytical equipment employing the most accurate methods often cannot detect filter extractables when using actual drug product.

Approach/Procedure

Millipore proposes a rational systematic approach that simulates the worst-case conditions for a filtration device.

This approach detects and quantitates extractables, and is generic so it can be applied to any filtration device.

However, each application is evaluated on a case by case basis. No single analytical method can provide reliable extractables information for all filters. The specific model solvent streams tested and the specific analytical methodologies employed are specific to a filtration device.

Appropriate solvent streams are selected. Test protocols are developed, and analysis is performed. Detailed information about your specific drug product and how it is processed using Millipore filtration device(s) is needed to address your specific extractables testing needs.

The Millipore Advantage

Millipore's analytical and chromatography expertise was used to successfully develop Millipore's approach to extractables analysis. Our extensive knowledge of filtration technology and continued research has allowed us to provide technical expertise to our customers. Millipore's approach to extractables analysis is just one example of our constant participation in setting standards in the filtration industry.

- ▶ Use model stream test approach
- ▶ Perform trials under worst-case conditions
- ▶ Bases analytical method on filter materials of construction and model stream
- ▶ Tests performed by qualified experts
- ▶ Verify compatible filtration materials



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How to Request Extractables Analysis

A Millipore Validation Specialist can provide you with the technical expertise needed to conduct extractables analysis. To request extractables documentation or to get information on other validation services provided by Millipore, call your Millipore Applications Specialist or the Millipore office closest to you.

The Access Services program at Millipore is only one of many quality programs in place that ensure Millipore products meet the high standards of the pharmaceutical industry. Prior to product release, final lot release tests ensure released filters will meet Millipore's strict control parameters. Millipore produces validation guides for pharmaceutical-grade filters that contain complete extractables data.

To Receive More Information on Millipore's Access Services

For additional information call your nearest Millipore office:

In the U.S. and Canada, call toll-free **1-800-MILLIPORE (1-800-645-5476)**

In the U.S., Canada and Puerto Rico, fax orders to **1-800-MILLIFX (1-800-645-5439)**

Internet: <http://www.millipore.com>

E-mail: tech_service@millipore.com

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