

Provantage® Services

Catalogue No. VSLEAGC00

Service Description: Leachables Gas Chromatography (GC) Study

Scope

Determine the level and nature of filter leachables using actual pharmaceutical drug product or placebo under simulated process conditions.

Minimum Customer Product Sample

Millipak® filter: ~ 500 mL unfiltered

Opticap® filter: ~ 6 L unfiltered

Cartridge: ~ 8 L unfiltered

Mobius® Assemblies: ~2 L unfiltered

The exact quantity of product sample will be established during development of the protocol.

Test Materials

One filter device each from three lots of filter device manufacturing lots per drug product.

Methodology

- Review of process conditions and drug product formulation.
- Simulate actual use filter preparation and process conditions
- Static or dynamic soak in drug product
- Identification and quantitation of leachables using Gas Chromatography/Mass Spectrometry (GC/MS)

Outcome

Report will include study conditions, identification and quantitation of leachables.



Deliverables

- Provantage® Laboratories will provide a specific test protocol to the Customer once the project has been initiated. This protocol must be reviewed and endorsed by the Customer and a copy returned to Provantage® Laboratories prior to initiation of the laboratory work. Requests for multiple protocol revisions or customization before or after approval may be billed for.
- Provantage® Laboratories will not provide a protocol for the feasibility study which is a standard preliminary study performed according to our internal procedure.
- The final report will be issued after review and customer approval of the draft (by phone, fax or email). The number of revision of the draft report following Customer recommendations is limited to one (1). Requests for additional report revisions or customization may be billed for.
- Final deliverables will be issued electronically in a PDF format. Requests for original hard copy reports may be billed per report.
- Final deliverables can be re-issued (without any modification compared to the initial ones) within a 10-year time frame. Requests for additional copies of reports will be charged for and will include any associated archive retrieval costs.
- Deliverables are provided in a format suitable for submission to regulatory authorities.

Execution

Provantage® Laboratories performs this study with trained personnel in appropriate laboratory space with validated, calibrated and maintained equipment suitable for the proposed study. Studies may include use of qualified sterilization facilities and contract testing laboratories. Temperature monitoring systems are in-place for all storage and testing locations. There is complete traceability of your data.



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Scheduling

- Laboratory space for this study is scheduled on a first available basis. The copy of the final signed protocol approval page as well as the samples (except if the product has an expiration < 7 days) must be received before Wednesday lunch time, the week prior to initiation of study. Failure to provide these items in a timely manner may result in postponing test start date.
- The average timeline for this study is 16 - 20 weeks starting when the copy of the final signed protocol approval page and the samples are received and ending with draft report being sent. Estimated timeline may be confirmed upon receipt of the Purchase Order.

Cancellation

If Services are terminated by the Customer before its completion, the following application fees will be applied:

- 15% if protocol development has been initiated
- 50% if protocol has been submitted to the customer
- 100% if the test has already been initiated

Merck Millipore will put on-hold projects for which there no communication happening for more than two months. After six months, if there is no response to at least two attempts to re-initiate contact with the customer, the project will be cancelled by Merck Millipore. The project will be subject to cancellation fees corresponding to the stage of the project. The project may be re-opened by the Customer at any time. Re-opening will be initiated with a new Services Questionnaire and PO.

To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645

Germany: 069 86798021

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

Or visit: www.merckmillipore.com/offices

For Technical Service visit:

www.merckmillipore.com/techservice