Viral Clearance Data Mining

Utilizing data from over 2200 viral clearance studies to support your process development efforts

ILLUSTRATION:
Example of virus

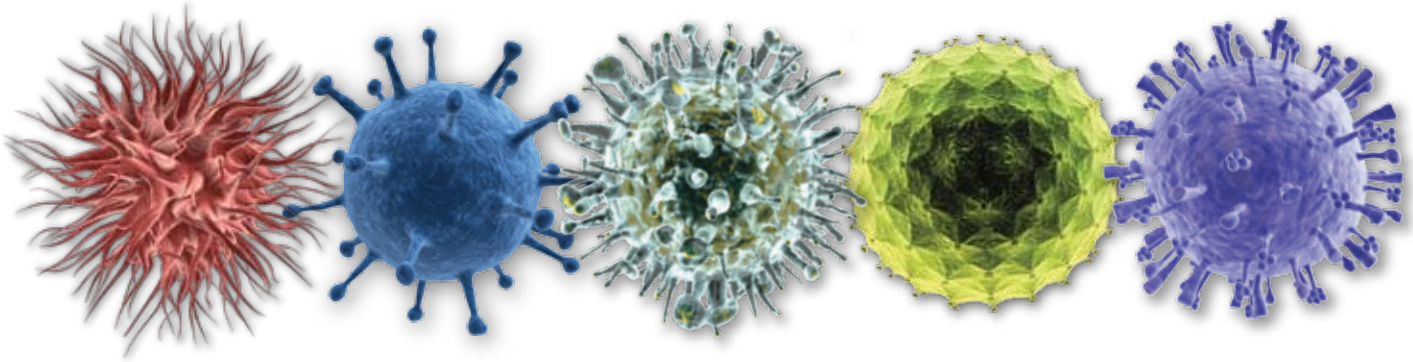
药明康德
WuXi AppTec

Viral clearance data mining leads to more informed decision-making for your process development efforts

Get the information you need from our vast database built on 20 years of testing results • 2200+ studies • 20,000+ data points

WuXi AppTec's Viral Clearance Database is a powerful tool allowing its users to query for information related to general or specific process step parameters and how those parameters affect viral clearance or inactivation.

Whether you are looking for information on different chemicals/detergents used for cleaning and inactivation steps or evaluating one of the many types of chromatography, membrane matrices and nanofilters that impact viral clearance, mining WuXi AppTec's database will help you make more informed decisions regarding your process development activities.



Supported Products Include:

- Recombinant proteins
- Monoclonal antibodies
- Tissue and plasma products
- Gene therapy vectors
- Vaccine
- Raw materials
- Devices

Database Features:

- More than 2200 different viral clearance or inactivation studies
- Information tabulated from 20,000 data points and continuously expanding
- Log reduction values obtained over a 20-year span
- Extensive library of inactivation and removal process steps

Multiple Search Criteria Include:

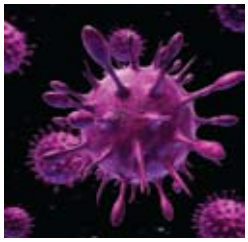
- Process step (AEX chromatography, solvent/detergent, nanofiltration)
- Virus used (over 30 different types)
- Process step parameters (pH, flow rate, conductivity)
- Protein and viral load
- Infectivity or PCR detection methodology
- General scale-down parameters for individual processes

Harness the power of 20 years of captured data

With database queries, WuXi AppTec clients are able to make informed decisions prior to or during critical process changes, which, in turn, allows them to fine-tune the processes – helping to avoid costly delays and the inclusion of unnecessary or non-ideal process steps in their viral clearance analysis. For example, a query might review the past results of a specific process step prior to implementing a change or as an alternative to an existing process. Alternatively, the database could be mined to examine the performance and effectiveness of specific conditions that could yield better viral clearance log reduction values.

Examples of Actual Client-Requested Queries of the WuXi AppTec Database

Process Step	Goal of Query	Parameters Evaluated	Data Findings / Conclusion
Chemical Inactivation	Data to support use of a specific nonionic surfactant prior to implementation of that step.	Effectiveness of the nonionic surfactant as a process step on inactivation of enveloped viruses. Parameters included concentration of the surfactant and virus type.	Optimal concentration of the surfactant that most consistently reduced virus to nondetectable levels (NDL) was determined.
Chemical Inactivation	Data to support a temperature change in the process step.	Concentration of the chemical and temperature used during inactivation steps and other processing conditions.	Support was provided for a change in the concentration of the chemical and the impact of the temperature change. The client enacted the changes suggested and higher log reduction values (LRVs) were obtained.
Chemical Inactivation	Viral inactivation data for three different chemicals.	The effectiveness of solutions used during various cleaning processes to inactivate parvovirus. Parameters included concentration, temperature and virus type.	Data indicated that two of the solutions were ineffective against parvovirus. The third solution was shown to achieve some level of clearance (≥3 log) if a specific temperature range is also incorporated into the cleaning process.
Chemical Inactivation	Determination of a pH range prior to execution of a process step.	Effectiveness of virus inactivation by low pH treatment in range of pH A +/- B for specific viruses. Evaluated only monoclonal antibody products derived from CHO cells	A specific pH range and other certain process parameters will yield high LRVs , thus making this process a robust step in the inactivation of both retroviruses and herpesviruses.
Chemical Inactivation	Data to support use of a specific detergent prior to implementation of a cleaning procedure.	Effectiveness of the detergent for inactivation of enveloped and non-enveloped viruses on materials used during CIP procedures.	Optimal dilution and time of exposure to the detergent for inactivating enveloped viruses was provided. Data suggested the detergent is not effective for the inactivation of small non-enveloped virus types. Thus, decontamination of contact parts during CIP procedures could be obtained.
Columns	After a viral clearance study, identification of conditions that may have given better results.	Anion exchange (AEX) steps and how process conditions (flow through vs. bind/elute, pH and conductivity) can impact clearance.	AEX was shown to be a robust process step in flow-through mode (in most cases).Data also suggested specific pH and conductivity conditions for optimal viral clearance results.
Columns	Demonstration of the effectiveness of virus removal via anion exchange column chromatography.	Anion exchange (AEX) chromatography in flow through mode for monoclonal antibodies derived from CHO cells. A three-virus panel was evaluated.	AEX was shown to be a robust process step in flow-through mode (in most cases). Data suggested both specific pH and conductivity parameters for optimal results as well as conditions that were not optimal.
Columns	Identification of alternative wash buffers for a column process.	The impact of specific wash buffers on the removal of parvoviruses during a column chromatography step. Additionally looked at what other wash buffers are commonly used for specific column chromatography processes.	Database generated a list of buffers that have been used in past column processes and the corresponding viral clearance data. Report was reviewed with client and suggested course of action was discussed.
Columns	Evaluation of the effectiveness of column chromatography in removing specific viruses.	Log Reduction Values for Virus A and Virus B model viruses via column chromatograph when operated in bind and elute mode for monoclonal antibodies produced in CHO cells.	Data demonstrated that Virus A is difficult to remove via this chromatography resin step. For Virus B, the results are variable, but most studies demonstrated at least 2 LRVs, with some studies obtaining ≥4 log clearance. Recommendations were discussed with client.
Columns	Evaluation of the impact of specific resins used in column chromatography on viral clearance values for non-enveloped viruses.	Viral clearance data on Resin A and Resin B for non-enveloped viruses.	No specific studies were noted using these resins. However, processing conditions for each resin, which were similar to conditions used in virus purification, were evaluated. Conclusion was that virus may bind to the resin and subsequently elute with the product using existing process conditions.
Columns	Determination of whether Hydrophobic Interaction Chromatography (HIC)is a reliable step for viral clearance.	Efficiency of virus removal via HIC for biological products.	Indications were that this process step can be quite variable.. Recommendations were discussed with the client.
Filters	Support for the change from current nanofilter (Filter A) to another filter (Filter B) prior to implementation.	Data from multiple Filter A and Filter B studies evaluated for parvovirus clearance data, including total viral load, LRVs, differences between virus types and purity grades.	Findings provided information to support a switch from Filter A to Filter B. Client has acted on WuXi AppTec's recommendation and has implemented the use of Filter B.



Viral Clearance Data Mining

Avoiding cost and time delays prior to IND/BLA/Market Approval

Benefits of Data Mining

- Help in selecting appropriate processes and technologies during process development efforts.
- Assist in determining whether process changes may affect viral clearance/inactivation.
- Provide understanding of appropriate or avoidable process parameters prior to viral clearance study.
- Determine up-front if necessary clearance levels could be achieved for an entire process.
- Set expectations for viral clearance from a given process technology or set of process parameters.
- Generate data for risk assessments or scientific justifications.

WuXi AppTec's Viral Clearance Studies

Experience

- Over 2200 custom viral clearance studies performed for IND, BLA, 501K, Marketing-Approval, and other.
- Over 30 human and animal viruses available as high-titer stocks.
- Experience with recombinant proteins, monoclonal antibodies, tissue and plasma product, vaccines, gene therapy vectors, and other product types.
- Many years of performing testing services based on global regulatory requirements – including FDA, ICH, ISO, CEN, AAMI, HIMA, USP, JMHLW, ANSI, WHO, and ASTM and applicable GLP and GMP guidelines.

Program Features

- Large-volume testing to improve log reduction claims.
- Experienced staff can perform entire study for Sponsor, including scale-down and resin cycling, or can work with client to execute the study.
- Regulatory advice, consulting and risk assessments utilizing WuXi AppTec's database.
- Twelve fully-equipped suites and 12 AKTA and AVANT systems available for custom studies, enabling easy scheduling of customer on-site validations.
- Senior staff study directors and dedicated project managers with extensive experience on hundreds of custom studies.

SS978-11-04.11.13

Contact WuXi AppTec to learn more about our viral clearance data mining services:
(1) 651-675-2000 / 888-794-0077 • www.wuxiapptec.com • www.virologyexperts.com