Anton Paar

Vaccine Analysis

The Safest Way: Solutions for R&D and Quality Control of Vaccines

Vaccines are one of modern medicine's great success stories, from smallpox to SARS-CoV-2.

For therapeutic use, a vaccine must be carefully developed and equally thoroughly analyzed at every step of the formulation and production process before it is applied.

A simple jab prevents life-threatening diseases. In the same way, dedicated measuring solutions, along with advanced technical and software features, prevent inaccuracies and errors that can reduce the effectiveness, safety, and generally extremely high quality of these biopharmaceuticals.

Anton Paar develops and provides solutions for vaccine development, formulation, and quality control, including for the analysis of active agents, excipients, and final product formulations.

FIND OUT MORE

www.anton-paar.com/apb-vaccine-analysis

Vaccine Analysis

Solution Categories

The process of formulating vaccines, regardless of the specific active agent, is critical to ensure vaccine efficacy and stability throughout storage, distribution, and delivery.

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CONTENTS

VACCINES SAFETY, COMPLIANCE, AND DOSAGE CONSISTENCY

The concentration and clarity of incoming goods and final product formulations need to be analyzed for consistent parameters like: density, refractive index, specific optical rotation, clarity, and concentration. This ensures a safe and effective product.

Quality-control determination of these using Anton Paar's multiparameter measuring systems helps avoid contamination and satisfies pharmacopeia requirements.

Anton Paar's industry-leading array of laboratory instruments – with convenient modularity – provide super-accurate, highly reliable testing.

VACCINE STABILITY

Controlling the charge of the liposomes is critical to ensure that they remain stably suspended rather than aggregated or combined. To determine the zeta potential of liposomes, you can use electrophoretic light scattering (ELS), ensuring that the vaccine formulation will be electrostatically stable during the course of its shelf-life, transport, and delivery.

INJECTABILITY

A key aspect of vaccine delivery is comfort during the injection. Developing a vaccine formulation that has and maintains a low enough viscosity that can be easily delivered with a syringe is key. Many vaccine formulations often comprise a highly viscous liquid that is difficult and painful to inject. Thus, analyzing vaccine formulations for their viscosity is a needed step in both vaccine formulation development and quality control.

MRNA/LIPOSOME-BASED VACCINES

mRNA-based vaccines are often formulated in a lipid-based liposome carrier that helps to protect the RNA from RNA-cleaving enzymes. They also assist in delivering the mRNA molecules into the target cells.

Ensuring consistent liposome size is critical when formulating vaccines. Dynamic light scattering (DLS) is a useful technique for measuring the size and size distribution of liposomes, which ensures that the liposomes in the formulation are both consistent in size and stable over time.

DATA INTEGRITY FOLLOWING ALCOA+ PRINCIPLES

Vaccine production must conform to stringent pharma regulations on data integrity, traceability, and compliance, including 21 CFR Part 11 and ALCOA+.

A key factor for this is organizing, managing, and reviewing relevant data and metadata from materials, production, and quality control checks.

AP Connect is a lab execution software solution for connecting laboratory instruments to data management systems to enable digital and error-free data flow. Dedicated features in the Pharma Edition satisfy pharma industry regulations and data integrity requirements.

Vaccine Safety, Compliance, and Dosage Consistency

KEY PARAMETERS FOR FINAL QUALITY CONTROL, BATCH RELEASE, AND DOSAGE CONSISTENCY

CHALLENGE

There has been a lot of research into new vaccines. To assure a safe and effective product, thorough final quality control and batch release checks have to be performed. Measurements need to be completely traceable and comply with international regulations and guidelines.

SOLUTION

Anton Paar's density meters and viscometers are useful quality control instruments for assessing product quality. Key vaccine parameters can easily be checked.

BENEFITS

All instruments offer a combination of simple user interface and technological and software features to eliminate measurement errors. Modular extensions and automation possibilities are available. Measurement methods are according to pharmacopeia.

INSTRUMENTS

DMA 4501, DMA 5001, Lovis 2000 M/ME, Abbemat Performance refractometer series, MCP polarimeter series, ViscoQC 300

CHECKING TURBIDITY AS AN INDICATOR FOR PRODUCT CONTAMINATION

CHALLENGE

Buffers and saline for vaccine production and, of course, the final vaccines have to be checked for turbidity, which is a potential indicator for contamination.

SOLUTION

Check for the turbidity with a multiparameter measuring setup based on a density meter master instrument where you can add further modules like the Haze 3001 turbidity measurement.

BENEFITS

Perform turbidity measurements with simple handling and without scratched measuring cuvettes or calibration. The pharma compliance features of an Anton Paar density meter as a master instrument and its software solutions secure compliance and traceability for each measurement.

INSTRUMENTS

DMA Next-Level density meter series + Haze 3001

Vaccine Stability

VACCINE PARTICLE SIZE AND SURFACE CHARGE AFFECTING PRODUCT FORMULATION, SAFETY, AND STABILITY

CHALLENGE

Monitoring the particle size and surface charge of vaccine formulations during R&D, production, transportation, and storage is critical to ensure a safe and effective vaccine anywhere, anytime.

SOLUTION

DLS measurements with Litesizer 500 permit quality control of antiviral vaccines, while ELS measurements generate more insight into their aggregation behavior.

BENEFITS

Size and surface charge measurements of vaccines enable comparisons of different formulations, analysis of vaccine response to heat, transport, and agitation, as well as overall formulation stability and purity. The zeta potential provides an indication of the stability of the vaccine formulation.

INSTRUMENTS

Litesizer 500

INFLUENCE OF VARIABLE ENVIRONMENTAL CONDITIONS ON VACCINE STABILITY

CHALLENGE

The stability of vaccines and vaccine components under variable conditions during transportation and storage is crucial.

SOLUTION

Examine the integrity and aggregation behavior of the final product in response to cold chain disruptions with Litesizer. For components, perform homogeneity checks on in-vitro transcribed RNA, and conformation and aggregation behavior checks for recombinant antigens in between production steps.

BENEFITS

Produce an effective vaccine and safely deliver the vaccine to the patients.

INSTRUMENTS

Litesizer particle size analyzer series

Injectability

VISCOSITY CHECKS OF THE SAMPLE TO ENSURE INJECTABILITY/ADMINISTRABILITY

CHALLENGE

The viscosity of the injectable must be right to guarantee injectability of infusions. Whereas low viscosity injections are perceived to be more painful than injections with a higher viscosity, formulations with a too-high viscosity can lead to an injection system occlusion, which makes it difficult to complete the injection.

SOLUTION

Measure viscosity at multiple shear rates/speeds with ViscoQC 300 or Lovis 2000 M/ME. Analyze the flow behavior of the sample and use it to optimize the viscosity to ensure proper injection.

BENEFITS

ViscoQC 300 features and software, like digital automatic spindle and guard detection and V-Comply, ensure correct viscosity measurement. Lovis 2000 M/ME has short measurement times and sample volumes of only 0.1 mL. Both systems conform to 21 CFR Part 11 regulations and pharmacopeia.

INSTRUMENTS

ViscoQC 300, DMA M + Lovis 2000 ME

HOW SHEAR FORCES AFFECT VACCINE STABILITY

CHALLENGE

If the high forces that occur during vaccine injection are not measured and controlled, they can cause degradation or aggregation of the active agent in the vaccine formulation, potentially triggering an immunogenic response.

SOLUTION

Anton Paar's MCR directly measures how the shear forces that occur during an injection affect the structural and flow properties as well as the overall stability of vaccine formulations.

BENEFITS

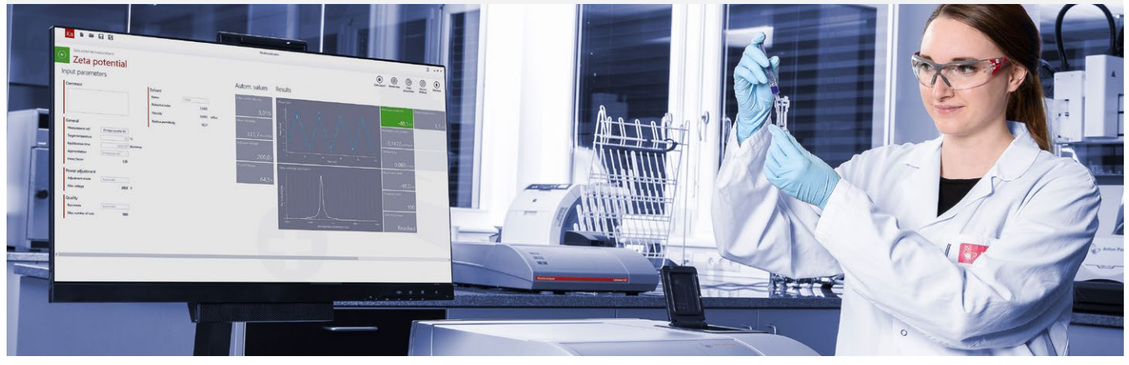
Accurately characterizing how a vaccine formulation responds to the shear stresses that occur during injections helps detect and avoid injection-induced aggregation or degradation of the formulation. This ensures a safe and complete dose for each patient.

INSTRUMENTS

MCR rheometer series

mRNA/Liposome-Based Vaccines

FORMATION AND STABILITY ANALYSIS OF LIPOSOMES



CHALLENGE

Many vaccines are formulated within liposomes. Care must be taken during the formation and processing to ensure that they are similar in size, remain in the nanometer size range, and stay stable during packaging, transport, and delivery – as there is a risk that they may combine to form multilayer vesicles rendering drug delivery ineffective.

SOLUTION

The Litesizer 500 particle size analyzer is an excellent tool for tracking and optimizing liposome formation as well as monitoring liposome size and stability over time and under different processing conditions (temperature, pH, etc.). DLS and ELS are used to measure liposome size and zeta potential, which are indicators of stability over time.

BENEFITS

Exact characterization of liposomes optimizes formation conditions and allows monitoring of size and stability over time and under a range of different storage and handling conditions. This supports the development and manufacturing of highly targeted drug delivery particles in vaccines.

INSTRUMENTS

Litesizer 500

Data Integrity Following ALCOA+ Principles

BEST PRACTICES FOR DATA MANAGEMENT

CHALLENGE

To ensure safety and consistency, vaccine manufacturing sites are required to perform quality control tests, not only on the final products, but on all excipients and APIs used to formulate the products. This means huge amounts of data need to be safely collected, organized, and reviewed.

SOLUTION

Anton Paar instruments used for quality control and characterization of the physical properties of excipients, APIs, and final formulations deliver data to the AP Connect software.

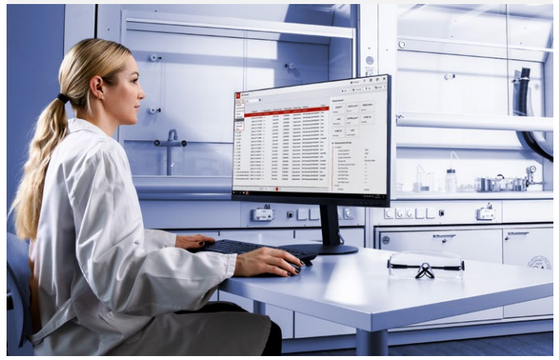
BENEFITS

The AP Connect software with its simple user interface ensures data quality according to the ALCOA+ principles for data integrity, centralizes data using an SQL database, optimizes electronic signature work flows, and has complete audit trail, review, and comment functions.

INSTRUMENTS

AP Connect Pharma edition + compatible measurement instruments

ELECTRONIC SIGNATURES – CHECK, REVIEW & APPROVAL



CHALLENGE

Paperless lab processes with digital records require tailored submission, review, and approval processes for a complete chain of responsibility.

SOLUTION

Anton Paar instruments are equipped with electronic signature features on the instruments, which enables users to put a verified signature on data items that are “reviewed” or even “approved” after initial submission.

BENEFITS

The use of electronic signatures ensures that all electronic records will be traceable and are equivalent to handwritten signatures – this way a chain of responsibility is established.

INSTRUMENTS

AP Connect Pharma edition + compatible measurement instruments

Anton Paar
Certified Service

“We're confident in the high quality of our instruments. That’s why we provide **a full warranty for three years**.”

All new instruments* include repair for three years.
You avoid unforeseen costs and can always rely on your instrument.
Alongside the warranty, we offer a wide range of additional services and maintenance options.

*Due to the technology they use, some instruments require maintenance according to a maintenance schedule. Complying with the maintenance schedule is a prerequisite for the three-year warranty.

Service and support directly from the manufacturer
Our comprehensive service provides you with the best individual coverage for your investment so that maximum uptime is ensured.

SAFEGUARDING YOUR INVESTMENT

Regardless of how intensively you use your instrument, we help you keep your device in good shape and safeguard your investment – including a three-year warranty.

THE SHORTEST RESPONSE TIMES

We know that sometimes it’s urgent. That’s why we provide a response to your inquiry within 24 hours. We give you straightforward help from real people, not from bots.

CERTIFIED SERVICE ENGINEERS

The seamless and thorough training of our technical experts is the foundation of our excellent service provision. Training and certification are carried out at our own facilities.

OUR SERVICE IS GLOBAL

Our large service network for customers spans 86 locations with a total of 350 certified service engineers. Wherever you're located, there's always an Anton Paar service engineer nearby.

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