

Application Solution



Focus on used analytical
instrument

Monoclonal Antibody/ Protein Industry



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Content

Monoclonal Antibody/Protein Industry

Protein routine method development

protein preparation purification

protein amount control (biopharmaceutical characterization)

protein impurity analysis

Monoclonal Antibody/Protein Industry

➤ Protein routine method development

HPLC,UPLC and GC



Waters e2695 HPLC



Agilent 1260 HPLC



Waters Acquity UPLC



Waters ARC HPLC



Agilent 7890 GC

During the drug development process, method development will go through different stages, usually involving complex and variable samples. Need to choose reliable and stable HPLC, UPLC to meet the needs of daily laboratory detection.

Monoclonal Antibody/Protein Industry

➤ Protein routine method development

Waters Acuity UPLC H-Class



More and more laboratories are equipped with UPLC systems, which have significant advantages over HPLC. Waters Acuity UPLC's three major advantages: 1. Increase speed (reduce analysis time); 2. Increase resolution; 3. Increase sensitivity.

Monoclonal Antibody/Protein Industry

➤ Protein routine method development

Waters ARC HPLC –comprehensive function and excellent performance



ACQUITY Arc

功能全面，性能优异

Through ACQUITY® Arc™ System, analysis scientists can really experience the compatibility of "plug and play" HPLC and UHPLC methods

High Performance Analytical Detectors

A wide range of high performance detection capabilities, optimized to support the diversity of applications. Includes photodiode array, UV/Vis, fluorescence, refractive index, evaporative light scattering, conductivity, and mass detection.

Gradient SmartStart

Adjust the injection relative to the gradient start to emulate other HPLC systems' dwell volumes, without the need to alter the gradient table. Successfully transfer most methods in just two injections.

Quaternary solvent management

Precise and accurate blending of up to four solvents with automated solvent compressibility compensation. Increase solvent flexibility with an optional, integrated solvent select valve, providing access to six additional solvents.



Negligible carryover

Advanced flow-through needle design minimizes carryover by continuously cleansing the needle during run. User-configurable wash settings provide capability to address even 'sticky' compounds to help ensure a clean analysis of the current target sample.

Column technology

Heating and cooling that supports columns up to 300 mm in a stable temperature environment for method repeatability from lab-to-lab. Optional and integrated column switching for up to three columns provides unattended column changeover. Simplify method screening and easily switch back and forth to support multiple methods on one system.

Auto-Blend™ Plus Technology

Program gradients directly in terms of pH and ionic strength to minimize manual mobile phase preparation and reduce potential for human error in routine analysis.

Designed for robustness

Integrated solvent degassing, seal wash, and fluidic path designed to reduce clogging associated with high salt content buffers for maximum uptime.

Holistic offerings

Benefit from an integrated offering of industry-leading columns, chemistry, and software solutions to meet the needs of virtually every HPLC application.

- Columns: The perfect pairing for high quality separations
- Informatics: Get more from your data for more confident decisions
- Global Services: Committed to your success

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➤ Protein routine method development

Waters new E2695 HPLC



FLEXIBILITY FOR YOUR APPLICATION DIVERSITY

Integrated leak management
For confident, unattended operation.

Simplified set-up
User-interface featuring automated system preparation (SystemPREP) functionality.

Flexible sample support
High sample capacity, at 120 vials, in a closed environment with optional temperature control and access to STAT samples.

Maximized uptime
Tool-free maintenance for common user-replaceable parts minimizes system down times.

Quaternary solvent blending
Consistent, predictable, and repeatable separations come from a fixed gradient delay volume and automated solvent compressibility.

Designed for robustness
Integrated solvent degassing, integrated seal wash, and PerformancePLUS™ check valves for maximum uptime.

Versatile detection

A wide range of detection capabilities, optimized to support the diversity of applications. Includes photodiode array, UV/Vis, fluorescence, refractive index, evaporative light scattering, electrochemical, conductivity, and mass detection.

Column management options

Heating or heating/cooling that supports columns up to 300 mm in a stable temperature environment for method repeatability from lab-to-lab. Optional and integrated column switching for up to six columns provides unattended column changeover.

Flow-through-needle injector

Supports injection volumes from 0.1 µL up to 2 mL and an active, user-definable needle wash sequence for consistently low carryover performance.

Auto-Blend Technology

Blend up to four solvents in any proportion and reduce the day-to-day variability associated with manual mobile phase preparation.

www.waters.com/alliance

Monoclonal Antibody/Protein Industry

➤ Antibody Purification for small and pilot Test

GE ÄKTA explorer

- ◆ Fully meet the biological inertness requirements of antibody purification.
- ◆ GE ÄKTATM explorer is available in two configurations depending on the pump head flow rate: one commonly used at 100 mL/min and the other at 10 mL/min. Both can be equipped with a Frac-950 fraction collector.
- ◆ The instrument is designed to be easy to use and suitable for different scales of purification. It should be said that it is an indispensable key equipment in the process of antibody purification.
- ◆ The instrument is designed to meet the stringent requirements of GLP/GMP for production equipment.



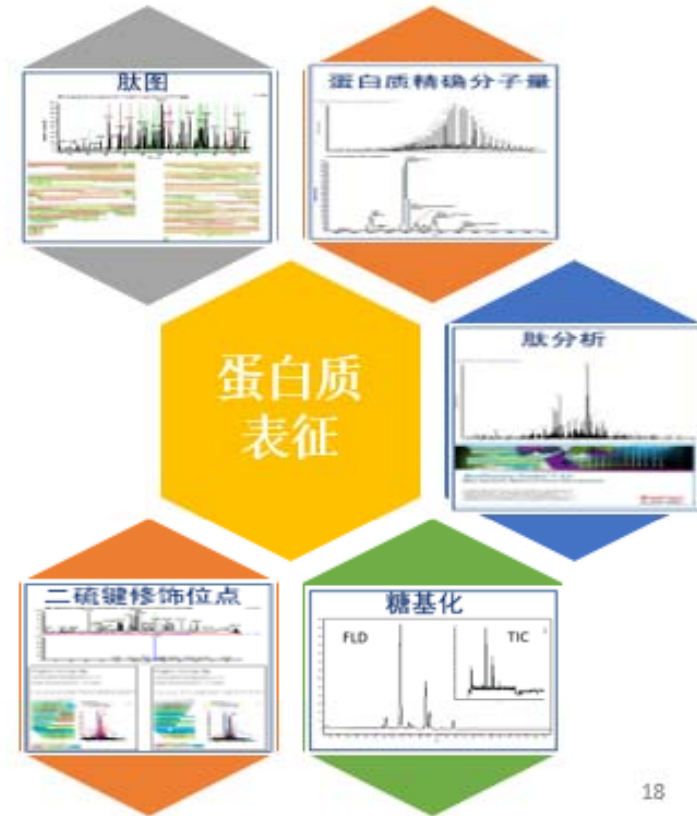
Monoclonal Antibody/Protein Industry

➤ Antibody Mass Analysis Structure Confirmation

Confirmation of Antibody Mass Analysis Structure----Biochemical Characterization Analysis



Thermo Q Exactive PLUSHRMS



Monoclonal Antibody/Protein Industry

➤ Antibody Mass Analysis Structure Confirmation

Beckman PA800 plus

- ◆ PA800 plus can separate various samples, including peptides, proteins, nucleic acids, ions, chiral compounds and drugs
- ◆ Capillary electrophoresis requires a smaller amount of samples than other analytical instruments (5-30 μ l, the amount of sample injection is only 5-50 nanol). It can provide more ideal analytical means than other separation technologies

Item	Overview
Determination of the isoelectric point of monoclonal antibody by cIEF method	The cIEF isocenter was focused on the sample and the known isoelectric point polypeptide as a reference using a CE (capillary electrophoresis apparatus), and the isoelectric point of the sample was calculated based on the relative migration time of the sample and the reference peptide.
Determination of charge heterogeneity purity of monoclonal antibody sample by cIEF method	The sample was subjected to cIEF iso-point focusing using a CE (capillary electrophoresis apparatus), and then the main peak purity was integrated to obtain the sample charge heterogeneity purity.
Determination of purity of monoclonal antibodies by CE-SDS method	After the sample was reduced, the purity and impurity content of the light chain or heavy chain were examined by SDS capillary electrophoresis and UV detector analysis.



Beckman PA800 plus

Monoclonal Antibody/Protein Industry

➤ Antibody Impurity Analysis

The newest technology for antibody impurity analysis---based on multi-dimensional liquid chromatography and high resolution mass spectrometry for impurity identification

- ◆ It can eliminate the limitation of flow relative to mass spectrometry, directly identify the impurities under the liquid phase conditions of non-volatile salts such as phosphate and ion-pairing reagents. The identification of impurities has never been so simple and convenient!
- ◆ Combined with high-resolution mass spectrometry for rapid on-line detection of molecular weights of related impurities isolated by any chromatographic method
- ◆ Combined with high-resolution mass spectrometry to quickly determine the type and site of amino acid residue modification of mAb product impurities
- ◆ Highly fast and large-scale separation and enrichment of product-related impurities for multiple testing services
- ◆ High-throughput screening monoclonal antibody clonal cell line



Waters 2D HPLC/UPLC online desalination technology platform



THANK YOU !

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