

Streamlining data compliance for multi-channel capillary electrophoresis

Featuring direct control of the BioPhase 8800 system with the BioPhase 8800 driver for Empower software

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This technical note highlights a streamlined workflow using the BioPhase 8800 driver for Empower software to control setup, operation and data acquisition on the BioPhase 8800 system. It provides seamless acquisition and analysis of capillary electrophoresis-sodium dodecyl sulfate (CE-SDS) and capillary isoelectric focusing (cIEF) data on the BioPhase 8800 system in both research and compliant environments.

Monoclonal antibodies have become one of the most successful therapeutic modalities as understanding disease-associated pathways has improved. However, due to increasing molecular, structural and functional complexity, more varieties of analytical instrumentation are needed to characterize molecules and analyze data fully. Therefore, a growing desire exists to operate and analyze data seamlessly to streamline data management in analytical development and regulated environments (GxP). Empower Chromatography Data System is a chromatography data system (CDS) widely used in the biopharmaceutical industry and allows instrument control and data processing from liquid chromatography, mass spectrometry, capillary electrophoresis and other analytical platforms. To minimize the need to train users on multiple software platforms and ensure seamless workflow transfer in a compliant and secure manner, SCIEX developed a driver which allows complete control of the BioPhase 8800 system.

BioPhase 8800 driver for Empower software¹ controls the BioPhase 8800 system hardware and data collection, allows for method and sequence editing and stores multi-capillary data in the Empower CDS with linked sample information. After data acquisition, users can analyze the data directly in Empower CDS and apply any necessary electronic signatures on reports using sign-off capabilities.

Key features of the BioPhase 8800 driver for Empower software

- **Seamless data acquisition:** The driver allows for direct control of the BioPhase 8800 system hardware, including method and sequence editing capabilities
- **High-throughput analysis:** Multi-channel data acquisition, storage and analysis (Figure 1)
- **Data integrity:** Direct transfer of data acquired on the BioPhase 8800 system with the ability to apply the 21 CFR Part 11 toolset in the Empower CDS to help satisfy GxP requirements
- **Streamlined data management:** Facilitate seamless data management from analytical development to quality control

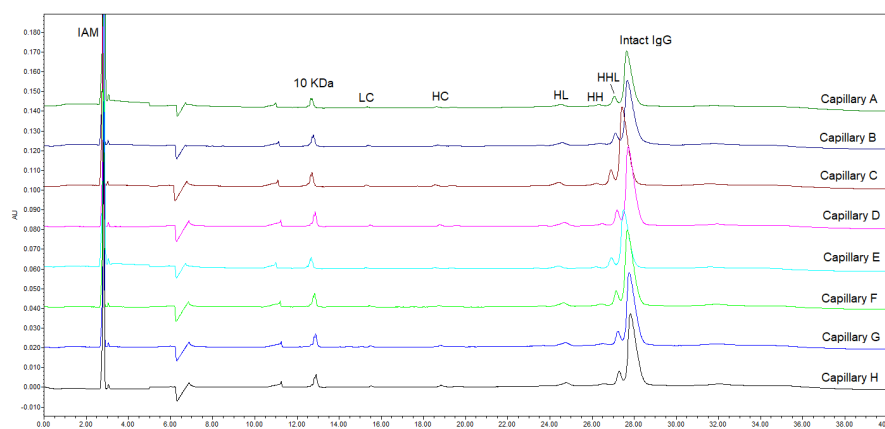


Figure 1. Overlay of 8 representative CE-SDS runs of IgG control standard (SCIEX) under non-reducing conditions. Peaks are labeled for the light chain (LC), heavy chain (HC), heavy-light (HL) chains, heavy-heavy (HH) chains and heavy-heavy-light (HHL) chains.

Methods

CE-SDS sample preparation: The IgG Control Standard, 3 pack (P/N: 391734) was from SCIEX (Framingham, MA) and was prepared under reducing conditions. Sample preparation was performed according to the guidelines published in the application guide for BioPhase CE-SDS Protein Analysis kit.²

cIEF sample preparation: The pI markers were from the cIEF Peptide Marker kit (SCIEX, P/N: A58481). The IgG reference standard (P/N: 1445539) test material was from USP (Rockville, MD). Sample preparation was performed according to the guidelines in the application guide for BioPhase Capillary Isoelectric Focusing (cIEF) kit.³

Capillary electrophoresis: The separations were performed using the BioPhase 8800 system (P/N: 5083590) from SCIEX. The BioPhase 8800 system was equipped with UV detection using 220 and 280 nm filters for CE-SDS and cIEF separations, respectively. The CE-SDS and cIEF separations were performed using the BioPhase BFS capillary cartridge - 8 x 30 cm (PN 5080121) and the BioPhase neutral capillary cartridge, 8 x 30 cm, 50 µm inner diameter (PN 5080119). BioPhase sample and reagent plates (PN 5080311) were from SCIEX (Framingham, MA). All separations were performed using the pre-loaded methods in the BioPhase 8800 driver for Empower software for capillary conditioning, sample separation and cartridge shutdown according to the instructions in the respective application guides.

Control software, data acquisition and processing: The BioPhase 8800 driver for Empower software was used to control the BioPhase 8800 system. Data analysis and reporting were performed using the tools of the Empower CDS.

Results and discussion

Workflow using the BioPhase 8800 driver for Empower software:

Create a CE method: There are 3 options to create a CE method for the BioPhase 8800 system. Users can download pre-made separation methods of interest from <https://www.SCIEX.com>. Alternatively, users can create or open a pre-loaded method using the BioPhase 8800 driver for Empower software. Finally, users can import a read-only copy of the method of interest into Empower CDS using the import function (Figure 2).

Create a sample set: A sample set can be created directly in the BioPhase 8800 driver for Empower software or using the sample set method editor within the BioPhase 8800 driver for Empower software. However, the plate layouts and sample set method for the BioPhase 8800 system must be defined or validated in the embedded method editor to avoid potential user errors (Figure 3).

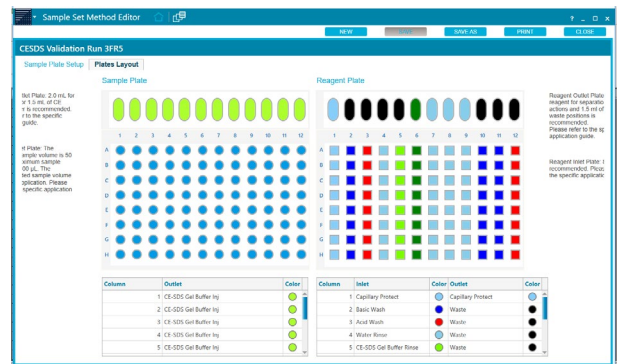


Figure 3. CE-SDS sample and reagent tray setup using the sample set method editor in the BioPhase 8800 driver for Empower software.

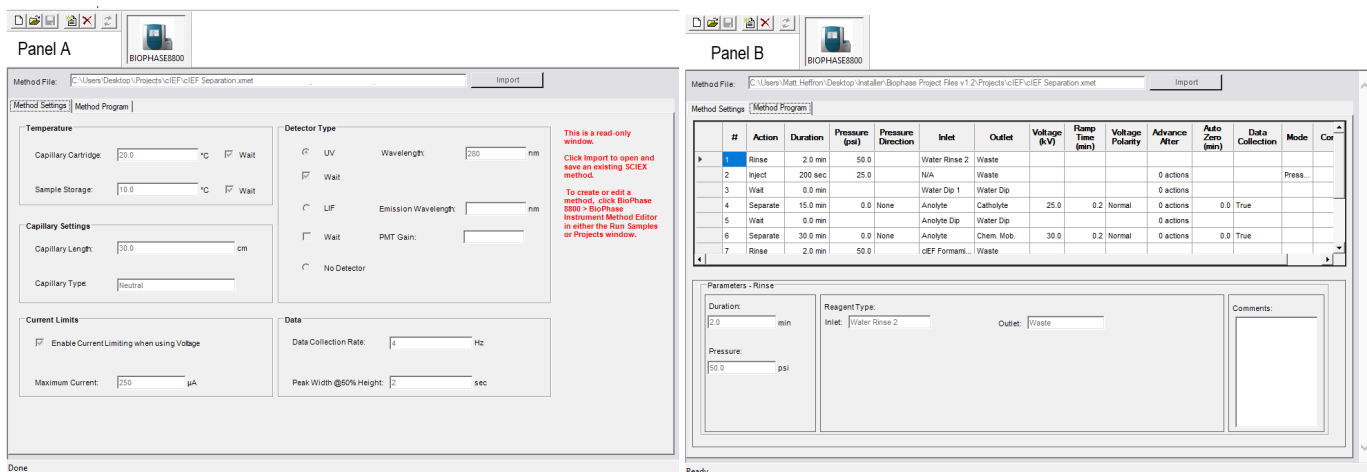


Figure 2. Embedded Empower CDS editor for method import (panel A) and BioPhase 8800 driver for Empower software (panel B). Panel A shows the method settings and Panel B the method time program.

Prepare the BioPhase 8800 system: The next step is to set up the BioPhase 8800 system with reagent and sample trays to run a sequence. This task can be easily accomplished using the direct control functions in the driver (Figure 4). Manual operations are also available in the driver, such as setting rinses, injections and separations, changing wavelength settings, modifying cartridge and sample compartment temperature, and obtaining cartridge information. Additionally, the system status can be monitored in real-time (Figure 4).

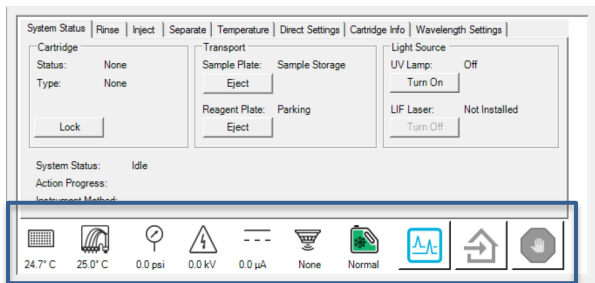


Figure 4. System status pane from the direct control screen in the driver. The bar at the bottom (highlighted in blue) shows the instrument status in real-time.

Submit the sample set for separation: The user can follow the functions in the Empower CDS to submit a sample set method, as shown in Figure 5.

Monitor the separations via direct control: The blue icon at the bottom of the direct control screen (Figure 4) allows users to monitor the separation status by opening the trace view option. The trace view can simultaneously display up to 3 electropherograms. The user can toggle between the optical, current, voltage and pressure traces. The user can also select which capillaries are displayed using the checkboxes at the bottom of the screen. Figure 6 shows the live view of UV absorption and current traces during a cIEF separation.

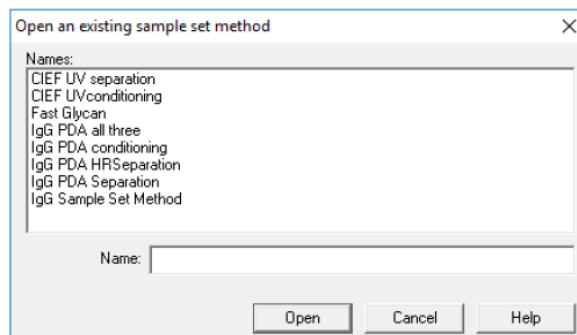


Figure 5. Options available to load a sample set method.

Analyzing the data, reporting and sign-off: The BioPhase 8800 driver for Empower software allows users to access the resources currently available in the Empower CDS, from data analysis to sign-off.

Multi-channel CE-SDS and cIEF assays using the BioPhase 8800 driver for Empower software

Figure 1 shows a representative CE-SDS separation of the IgG control standard under non-reduced conditions. The data analysis, reporting and sign-off features were performed using the software features in the Empower CDS. Figure 7 shows an example of a report sign-off commonly used in the compliant environment.

Figure 8 displays representative cIEF separations of the USP reference standard from capillaries A–H collected using the BioPhase 8800 driver for Empower software. These separations are comparable to data previously acquired using the BioPhase 8800 software.

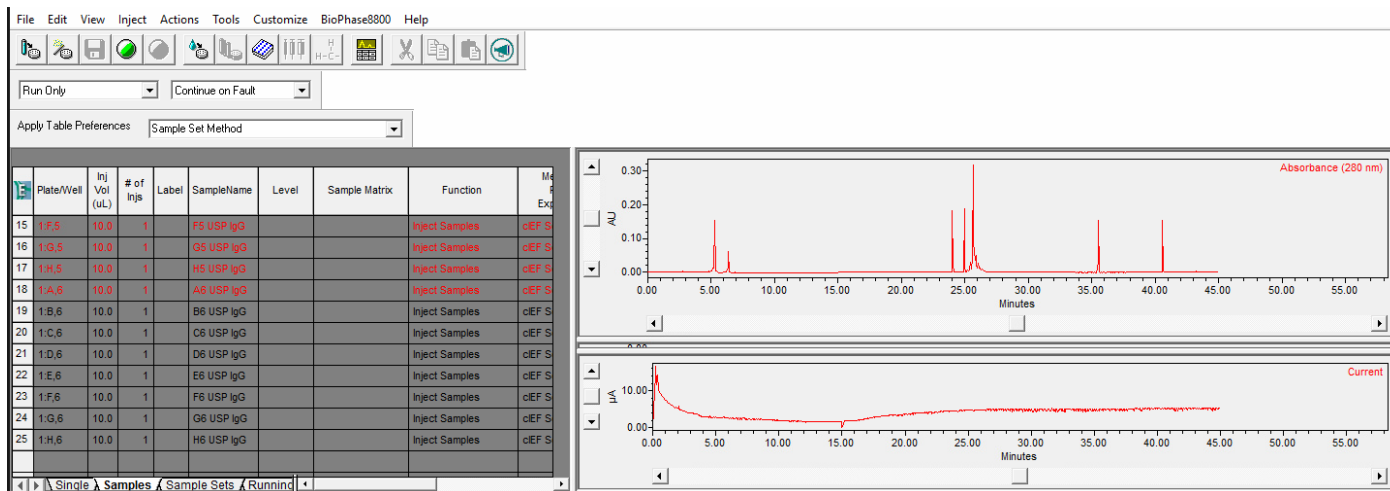


Figure 6. Sample set display on the BioPhase 8800 driver for Empower software showing the sample table and real-time separation profile with current trace.

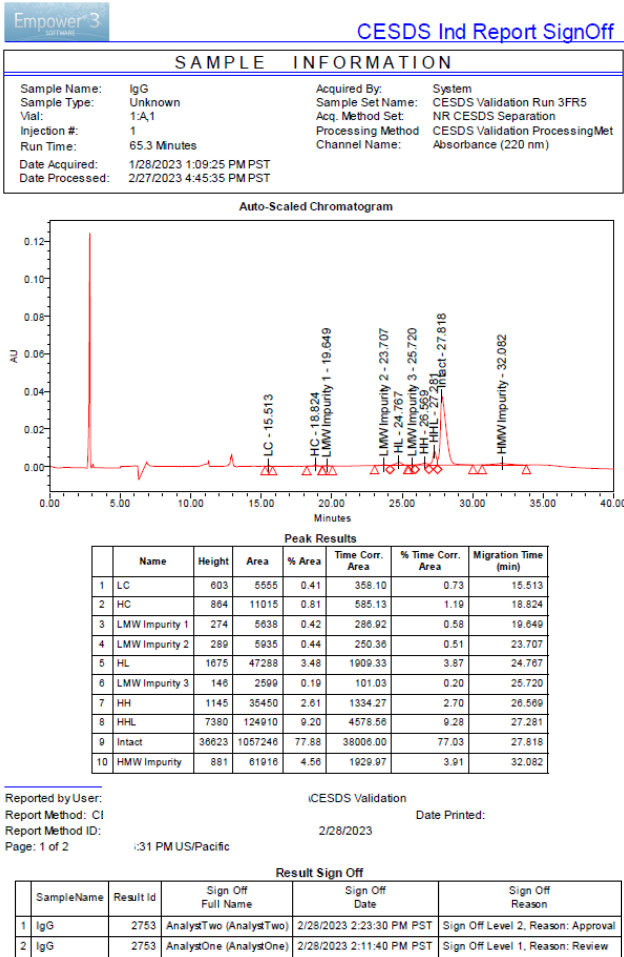


Figure 7. Example of a report generated by the BioPhase 8800 driver for Empower software. This report is generated using compliance features available in the Empower CDS.

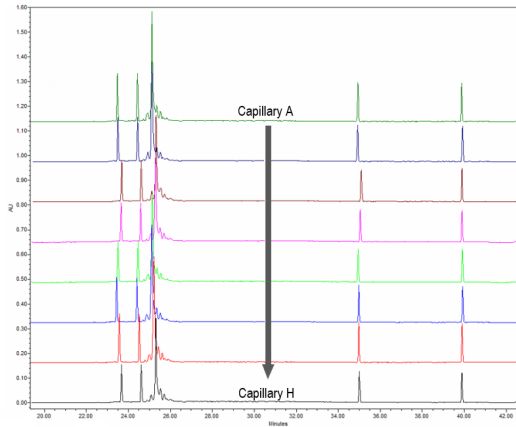


Figure 8. Overlay of 8 representative runs from capillaries A–H of the USP reference standard.

Conclusions

- The BioPhase 8800 driver for Empower software offers complete control of the BioPhase 8800 system to enable multi-channel data acquisition
- Streamlined data storage and analysis are achieved using Empower CDS
- The BioPhase 8800 driver for Empower software allows the use of compliance tools available in Empower CDS to help meet GxP requirements
- Seamless data management from analytical development to quality control is available for both CE-SDS and ciEF

References

1. BioPhase 8800 driver for Empower software – operator guide, [RUO-IDV-05-15014](#)
2. BioPhase CE-SDS Protein Analysis kit - application guide, [RUO-IDV-05-8662-C](#).
3. BioPhase Capillary Isoelectric Focusing (ciEF) kit - application guide, [RUO-IDV-05-8651-B](#)

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