International Journal of Research in Medical Sciences
Bhavsar R et al. Int J Res Med Sci. 2026 Feb;14(2):617-624
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20260251

Original Research Article

A comprehensive lot-to-lot variation assessment and comparative analysis of the Concerro CE-SDS kit against the Sciex CE-SDS kit for monoclonal antibody size variant analysis

Ravindra Bhavsar[1]*, Nikita Patel[2], Rani Jaiswal[2], Shailesh Agrahari[2], Husain Thanawala[2], Arati Patil[2]

[1]Pharmadesk Solutions Pvt. Ltd., Navi Mumbai, Maharashtra, India
[2]Department of Analytical Biopharma, Pharmadesk Solutions Pvt. Ltd., Navi Mumbai, Maharashtra, India

Received: 18 December 2025
Revised: 15 January 2026
Accepted: 21 January 2026

***Correspondence:**
Dr. Ravindra Bhavsar,
E-mail: ravindra.b@pharmadesk.com

ABSTRACT

Background: Monoclonal antibodies (mAbs) are complex biotherapeutics whose quality and integrity must be stringently monitored throughout development and manufacturing. Capillary electrophoresis sodium dodecyl sulfate (CE-SDS) is the definitive analytical technique used globally for assessing size heterogeneity, including the presence of low molecular weight (LMW) fragments, high molecular weight (HMW) species, and ensuring accurate estimation of size of protein's component. The objective of this study was to evaluate the analytical performance and manufacturing consistency of the newly introduced Concerro CE-SDS Kit against the established market innovator, the Sciex CE-SDS kit.
Methods: This study performed a head-to-head comparison utilizing the therapeutic monoclonal antibody Ipilimumab (Yervoi®). Analysis was conducted under both reduced and non-reduced conditions. Critical analytical performance indicators, including migration time, calculated peak area (mAu), calculated peak area percent (CPA%) were monitored during this study.
Results: The Concerro CE-SDS kit demonstrated analytical performance comparable to the Sciex CE-SDS kit, with similar precision and profile matching. Lot-to-lot variability for the Concerro CE-SDS kit showed %RSD values upto 10%.
Conclusions: The Concerro CE-SDS kit is affirmed as a robust, analytically equivalent alternative for high-precision size variant characterization in GxP/QC environments.

Keywords: Monoclonal antibody, CE-SDS kit, Size variant analysis, Ipilimumab

INTRODUCTION

As recombinantly produced monoclonal antibody (mAb) products usually contain size variants (e.g., aggregates, fragments) generated during their manufacture and storage, it is critical to monitor their levels.[1-3] As aggregates and fragments carry the potential to compromise product immunogenicity and potency, their quantification is a critical step typically performed during lot release, stability assessments, and product characterization.[4-6]

Capillary electrophoresis sodium dodecyl sulfate (CE-SDS) is the standard, globally utilized technology for the characterization of therapeutic antibodies and similar molecules across their entire product lifecycle.

Delivering fast, accurate, and reliable results for process and product-related impurities in the biopharma industry

necessitates a complete solution, one that integrates robust high-throughput analytical platforms with advanced chemistry.[7-9]

Concerro kits has developed a CE-SDS kit designed to be fully compatible with Sciex PA 800 plus and Agilent 7100 capillary electrophoresis instruments and methods. Concerro CE-SDS kit performance was evaluated with commercially available CE-SDS kit from Sciex.

Evaluating the analytical equivalence of new kits against established commercial standards is essential, particularly for techniques utilized in good manufacturing practice (GMP) environments or regulatory submissions. Comparative assessments ensure that alternative kits meet the performance requirements necessary for release or stability testing. In this study, we performed a head-to-head comparison between the Concerro CE-SDS Kit and the Sciex CE-SDS Kit using a representative therapeutic monoclonal antibody, Ipilimumab (Yervoi®). The evaluation included both reduced and non-reduced CE-SDS conditions and incorporated three Concerro CE-SDS kit lots to assess lot-to-lot variability.

METHODS

Study type, study place, and study period

This study was designed as a comparative analytical laboratory-based study to evaluate the performance and lot-to-lot consistency of a newly developed CE-SDS kit. All experimental work was conducted at the Analytical Laboratory of Pharmadesk Solutions Pvt. Ltd., Navi Mumbai, Maharashtra, India.

The study was performed over a period of six working days, including four days of laboratory experimentation followed by two days of data analysis and interpretation.

Sample selection criteria

No human subjects or patient-derived samples were involved in this study. A commercially available therapeutic monoclonal antibody, Ipilimumab (Yervoi®), was selected as a representative IgG1 molecule for size variant analysis due to its well-characterized structure and established use in CE-SDS method development and validation studies. The same material was used throughout the study to eliminate sample-related variability.

Reagents, kit components, and instrumentation

The therapeutic monoclonal antibody selected for this study was Ipilimumab (Yervoi®), chosen as a representative model for size variant analysis. For comparative evaluation, the SDS MW analysis kit (Lot No. M504008) served as the reference kit and obtained from Sciex. The testing kit material was the Concerro CE SDS-MW analysis kit (Lot no. CON-002-102025-01).

To perform an intermediate precision, three independent production lots of the Concerro, SDS MW analysis kit buffer components (SDS MW gel buffer, SDS MW sample buffer, acid wash, and basic wash) were used and same were used for comparative analysis with reference kit components of Sciex.

Iodoacetamide (IAM) (Part no. I6125) and 2-mercaptoethanol (BME) (Part no. M6250) were purchased from Sigma. CE capillary (Part No. G1600-63211) was purchased from agilent and analysis were performed using agilent 7100 capillary electrophoresis system equipped with a photodiode array (PDA) detector.

CE-SDS under reducing and non-reducing conditions

Capillary electrophoresis sodium dodecyl sulfate (CE SDS) analysis was conducted under both non reducing and reducing conditions, using inhouse established method.

For the non-reducing CE SDS, approximately 100 µg of sample was combined with 72 µl of SDS MW sample buffer containing Iodoacetamide (IAM). The mixture was incubated at 70 °C for 10 minutes, cooled to room temperature, and transferred into micro sample tubes for capillary injection.

Iodoacetamide (IAM) plays a critical role as an alkylating agent, effectively preventing disulfide bond reshuffling during the subsequent heat induced denaturation step. This stabilization is essential to ensure reliable quantification of the intact IgG monomer as well as any pre-existing high molecular weight (HMW) aggregates or low molecular weight fragments.

For the reducing CE SDS, approximately 100 µg of sample was mixed with 72 µl of SDS MW sample buffer containing 2-mercaptoethanol. The mixture was incubated at 70 °C for 10 minutes, subsequently cooled to room temperature, and transferred into micro sample tubes for injection.

This treatment ensured complete denaturation of the protein and cleavage of both inter and intrachain disulfide bonds. As a result, the individual polypeptide subunits including the light chain (LC), heavy chain (HC), and non-glycosylated heavy chain (NGHC) were resolved according to their molecular size during electrophoretic separation.

Electrophoresis and separation conditions

All separations were performed using Agilent 7100 capillary electrophoresis system equipped with a photodiode array (PDA) detector and a bare fused silica capillary (360 µm OD×50 µm ID×33 cm total length; effective separation length 24.5 cm).

The capillary electrophoresis system was operated under controlled laboratory conditions, with the capillary and

sample compartment maintained at a constant temperature of 25 °C. The instrument was housed in an environment meeting Agilent's specified requirements of ambient temperature between 15–35 °C and relative humidity below 60% (non-condensing), thereby ensuring stable performance and reproducibility of separations.

Prior to each analysis, a stringent capillary conditioning sequence was executed to establish consistent electroosmotic flow (EOF) and ensure proper capillary wall coating, which directly impacts the reproducibility of the migration time in multiple injection of samples. This sequence involved high-pressure flushing with 0.1 N NaOH solution for 10 minutes and 0.1 N HCL solution for 5 mins, followed by purified water, and a final equilibration with the SDS MW gel buffer.

Sample introduction was achieved by electrokinetic injection in reverse polarity at 5 kV for 10 seconds. Separation was carried out by applying 15 kV in reverse polarity for 35 minutes (for reduced samples) and 40 minutes (for non-reduced samples). Protein migration was monitored by detection at 220 nm.[10]

Statistical analysis

Statistical evaluation was performed to assess lot-to-lot intermediate precision and comparative analytical equivalence.

Mean values, standard deviation (SD), and percent relative standard deviation (% RSD) were calculated for migration time, corrected peak area, and corrected peak area percentage (CPA %).

Lot-to-lot precision was evaluated across three independent manufacturing lots of the Concerro CE-SDS kit, while comparative performance was assessed between the Concerro CE-SDS kit and the Sciex CE-SDS reference kit. % RSD values ≤10% for lot-to-lot studies and ≤5% for kit-to-kit comparison were considered analytically acceptable.

Data analysis and statistical methodology

Precision: lot-to-lot intermediate precision of the Concerro CE-SDS Kit

The overall precision of the Concerro CE-SDS kit across three independent manufacturing batches was assessed to establish lot to lot variability. Precision was determined by calculating the percent relative standard deviation (% RSD) from pooled analysis data obtained from the three Concerro CE-SDS kit lots.

The peaks selected for % RSD evaluation included: non reduced samples- main peak and HHL (heavy–heavy–light chain) impurity and reduced samples: LC (light chain) and HC (heavy chain) peaks.

Performance parameters analyzed were migration time, corrected peak area (mAu), and corrected peak area percent (CPA %).

Comparative analysis: Concerro CE-SDS Kit versus Sciex CE-SDS kit

Comparability between the Concerro CE-SDS kit and the Sciex CE-SDS kit was established by evaluating % RSD values for two critical performance indicators: migration time and corrected peak area percent (CPA %).

The peaks assessed for comparative analysis were: non reduced samples: main peak and HHL (heavy–heavy–light chain) impurity and reduced samples: LC and HC peaks.

This comparative evaluation provided a statistically relevant measure of similarity between the Concerro and Sciex CE-SDS kits, supporting the robustness and reliability of the Concerro CE-SDS kit for regulated analytical workflows.

RESULTS

The experimental design of this study was structured to comprehensively evaluate both the formulation consistency and analytical reliability of the Concerro CE SDS MW analysis Kit. Formulation consistency was assessed by analyzing IgG test samples under non reduced and reduced conditions across three independent manufacturing lots of the Concerro kit. To establish analytical comparability, a parallel experiment was conducted in which the same IgG samples were analyzed using the Sciex CE SDS reference kit and the second manufacturing lot of Concerro CE-SDS kit. This dual approach enabled a direct comparison of lot-to-lot reproducibility within the Concerro kit and performance equivalence against the established Sciex kit.

The study was completed over a period of six working days, with four days devoted to laboratory experimentation and instrument operation, followed by two days dedicated to data analysis and preparation of the final report. The subsequent sections present the detailed observations and findings derived from these experimental runs.

Lot to-lot performance evaluation of concerro CE kit

Figure 1 and 2 shows a good overlay of all non-reduced and reduced run of 3 lots of Concerro CE-SDS Kit respectively.

The non-reducing CE SDS (nrCE SDS) electropherograms (Figure 1) of Yervoi® (IgG) demonstrated clear resolution of the intact antibody (main peak) from lower molecular weight (LMW) species. The LMW species observed in the nrCE SDS profiles corresponded to antibody subunits, including light chain (LC), heavy chain (HC), heavy–light (HL), heavy–heavy (HH), and heavy–heavy–light (HHL). In the reducing CE SDS (rCE SDS) profiles (Figure 2),

complete denaturation and scission of inter and intrachain disulfide bonds resulted in the separation of individual polypeptide subunits. Distinct peaks corresponding to the light chain (LC), heavy chain (HC), and non-glycosylated heavy chain (NGHC) were consistently observed across all three Concerro kit lots. Identification of these subunits was achieved based on their relative migration patterns, with distinct separation observed across all profiles.

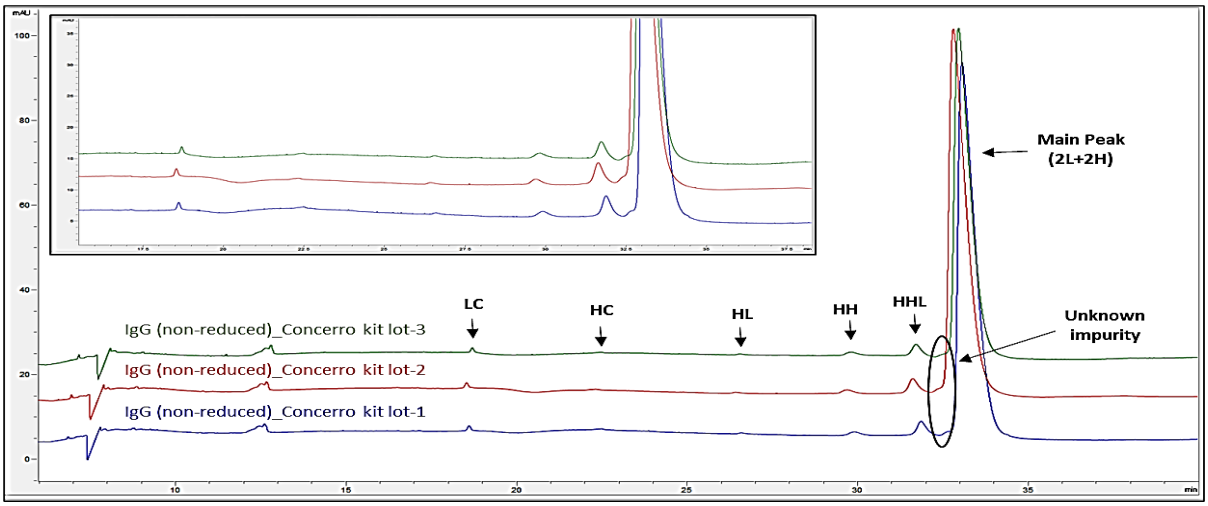

Figure 1: Overlay electropherograms of non-reduced samples obtained using three different manufacturing lots of the Concerro CE kit illustrate the comparative profiles across batches (LC: light chain, HC: heavy chain, HL: heavy-light chain, HH: heavy-heavy chain, HHL: heavy-heavy light chain, 2L+2H: 2 light chain-2 heavy chain) (full and zoomed view).

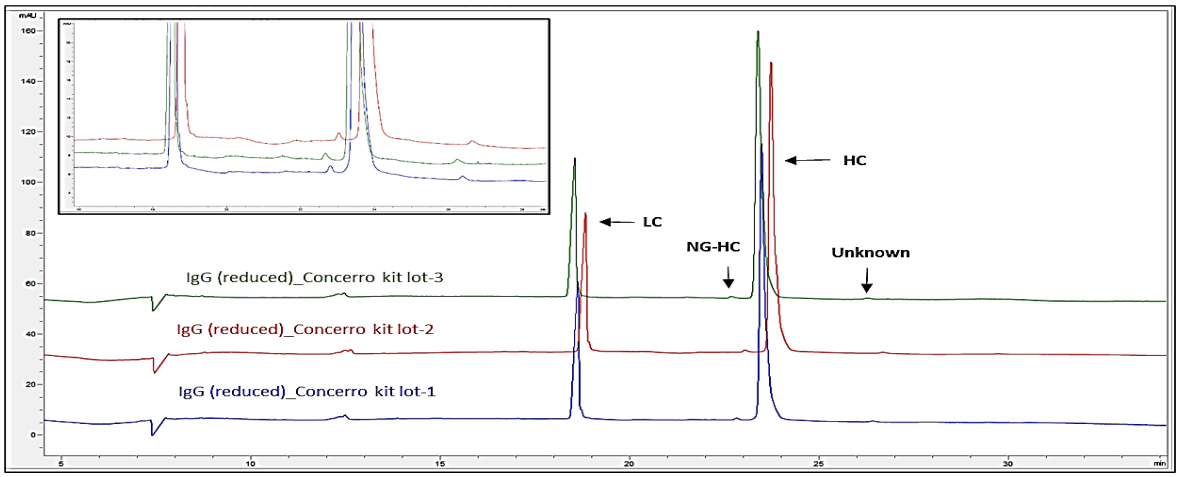

Figure 2: Overlay electropherograms of reduced samples obtained using different manufacturing lots of the Concerro CE kit illustrate the comparative profiles across batches (NG-HC: non-gycosylated heavy chain) (full and zoomed view).

To assess the lot-to-lot reproducibility of the Concerro CE SDS kit, several analytical parameters were systematically monitored. These included migration time (MT), corrected peak area (CPA), and the percentage CPA for the HHL and Main peak in non-reduced sample and LC and HC peak in reduced sample. These major species of monoclonal antibodies (IgG) detected in CE SDS runs are selected for evaluation and to establish the formulation consistency of the Concerro CE SDS Kit across 3 different manufacturing lots, the relative standard deviation (% RSD) values were calculated for these key species. The summarized results for non-reduced IgG samples are presented in Table 1, while the corresponding data for reduced IgG samples are provided in Table 2. As summarized in Tables 1 and 2, the maximum relative standard deviation (% RSD) observed was approximately 10%. This level of variability remains within acceptable analytical limits and demonstrates reproducibility of results across the three independent lots of the Concerro CE SDS kit.

Comparison of Concerro CE-SDS kit with the Sciex CE-SDS kit

To demonstrate analytical comparability, a parallel experiment was performed in which same IgG test samples were analyzed using both the Sciex CE SDS reference kit

and the second manufacturing lot of the Concerro CE SDS kit. The analyses were conducted under non reduced and reduced conditions to enable a direct comparison of performance between these two kits. Figures 3 and 4 shows a comparative overlay of non-reduced and reduced run of IgG sample using Sciex CE-SDS kit and Concerro CE-SDS kit.

Analytical parameters: migration time and the percentage CPA were systematically monitored, including for the major antibody species for Sciex versus Concerro CE-SDS kit performance evaluation. In the non-reduced profiles, the HHL and main intact antibody peaks were evaluated, while in the reduced profiles, the LC and HC peaks were selected for assessment.

Overlay comparisons of electropherograms generated using the Sciex CE-SDS kit and the Concerro CE-SDS kit (Lot 2) revealed highly similar profiles, with consistent resolution of all major species. Migration times and % CPA values aligned closely between the two kits (Tables 3 and 4) and the calculated % RSD values remained within acceptable analytical limits (<5%).

These findings demonstrate that the Concerro CE-SDS kit provides reliable performance under both non reducing and reducing conditions, enabling comprehensive characterization of monoclonal antibody subunit composition.

Table 1: %RSD of migration time, corrected peak area and corrected peak area % for non-reduced sample.

IgG1 sample (non-reduced)							
Parameter	**Peak name**	**Concerro kit Lot-1**	**Concerro kit Lot-2**	**Concerro kit Lot-3**	**Average**	**SD**	**% RSD**
Migration time (minutes)	HHL	31.84	31.37	31.43	31.55	0.25	0.8
	Main peak (2H+2L)	33.06	32.56	32.70	32.77	0.26	0.8
Corrected peak area (mAU)	HHL	0.0320	0.0320	0.0267	0.03	0.00	10.1
	Main peak (2H+2L)	1.4829	1.4752	1.2321	1.40	0.14	10.2
Corrected peak area %	HHL	2.07	2.08	2.08	2.08	0.01	0.3
	Main peak (2H+2L)	96.02	96.02	96.04	96.03	0.01	0.0

Table 2: %RSD of migration time, corrected peak area and corrected peak area % for reduced sample.

IgG1 sample (reduced)							
Parameter	**Peak N+name**	**Concerro kit Lot-1**	**Concerro kit Lot-2**	**Concerro kit Lot-3**	**Average**	**SD**	**% RSD**
Migration time (minutes)	LC	18.61	18.83	18.53	18.66	0.15	0.8
	HC	23.46	23.72	23.36	23.51	0.19	0.8
Corrected peak area (mAU)	LC	0.3931	0.4130	0.4139	0.41	0.01	2.9
	HC	0.8357	0.8793	0.8811	0.87	0.03	3.0
Corrected peak area %	LC	31.51	31.46	31.46	31.47	0.03	0.1
	HC	66.97	66.98	66.96	66.97	0.01	0.0

Table 3: Comparative CE SDS data for non-reduced IgG samples: Sciex reference kit versus Concerro CE kit.

IgG1 sample (non-reduced)						
Parameter	**Peak name**	**Sciex kit**	**Concerro kit data lot-2**	**Average**	**SD**	**% RSD**
Migration time (minutes)	HHL	30.45	31.41	30.93	0.68	2.2
	Main peak (2H+2L)	31.87	32.61	32.24	0.53	1.6
Corrected peak area %	HHL	2.07	2.05	2.06	0.02	0.9
	Main peak (2H+2L)	95.85	96.11	95.98	0.18	0.2

Table 4: Comparative CE SDS data for reduced IgG samples: Sciex reference kit versus Concerro CE kit.

IgG1 sample (reduced)						
Parameter	**Peak name**	**Sciex kit**	**Concerro kit data lot-2**	**Average**	**SD**	**% RSD**
Migration time (minutes)	LC	17.21	18.40	17.80	0.85	4.8
	HC	21.82	23.20	22.51	0.97	4.3
Corrected peak area %	LC	31.65	31.28	31.47	0.26	0.8
	HC	66.77	67.15	66.96	0.27	0.4

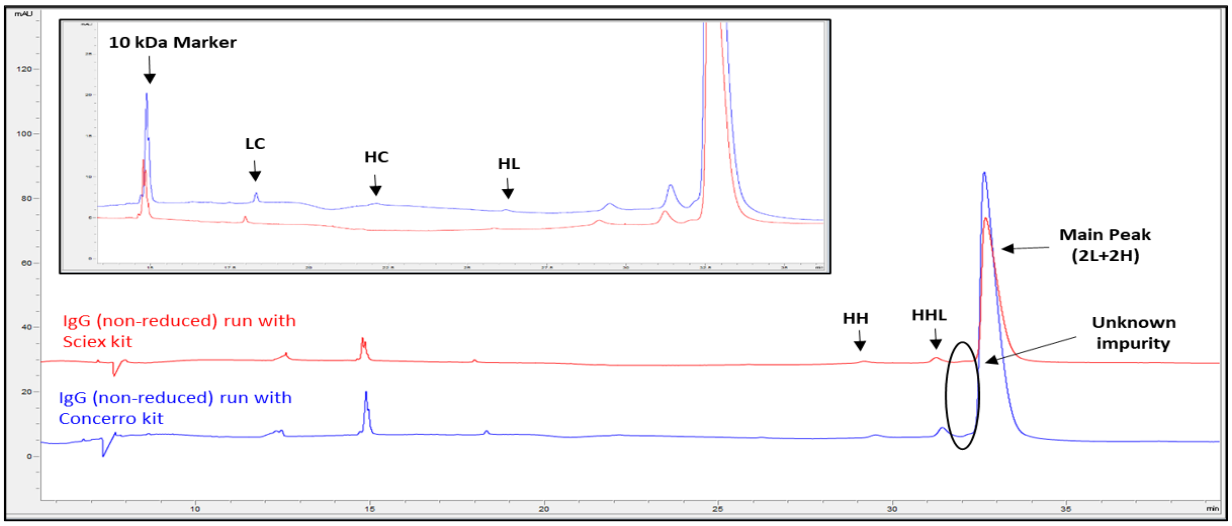

Figure 3: Overlay of electropherograms comparing non reduced IgG samples analyzed with the Sciex CE kit and the Concerro CE kit (full and zoomed view).

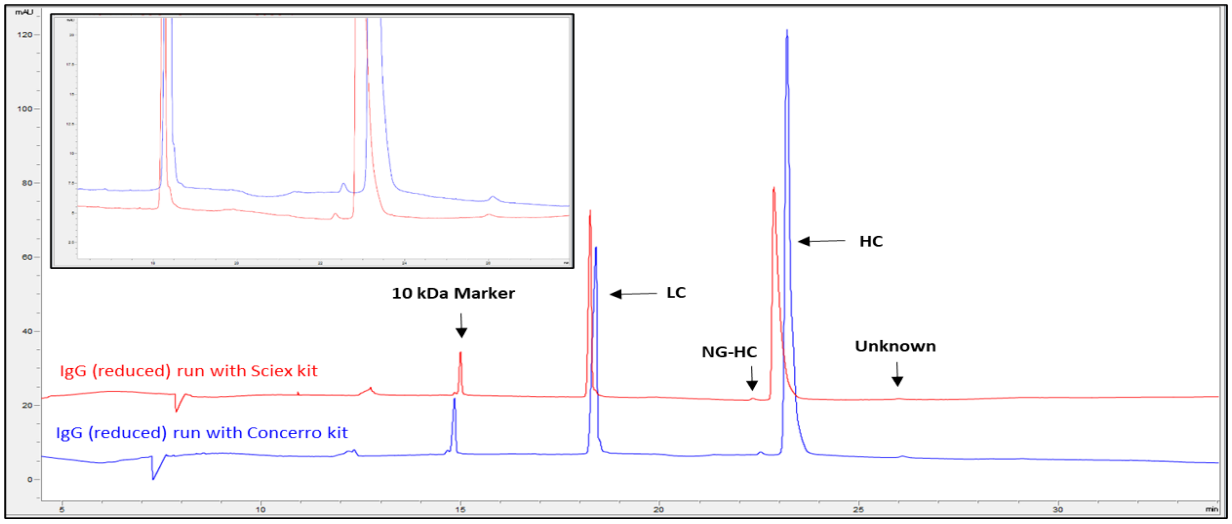

Figure 4: Overlay of electropherograms comparing reduced IgG samples analyzed with the Sciex CE Kit and the Concerro CE Kit, (Full and zoomed views).

DISCUSSION

A critical requirement for the adoption of new analytical reagents in the biopharmaceutical industry is the assurance of product robustness, particularly demonstrated through lot to lot consistency.[12] Lot-to-lot variation affecting calibrators and reagents is a frequent challenge that limits the laboratory's ability to produce consistent results over time.[13] In this study, the Concerro SDS MW analysis kit was evaluated across three independent production lots, with results showing consistent performance and % RSD values of upto 10%. These findings confirm the reproducibility and formulation stability of key buffer components (SDS MW gel buffer, SDS MW sample buffer, acid wash, and basic wash).[13,14] The demonstrated lot to lot consistency underscores the robustness of the Concerro kit and supports its suitability for integration into

regulated analytical workflows, thereby strengthening its potential for adoption in biopharmaceutical applications.

This level of consistency provides compelling statistical evidence of the stringent control maintained throughout the Concerro manufacturing process. Reliable lot to lot performance and assured long term availability position the Concerro SDS MW analysis kit as a dependable choice for biopharmaceutical laboratories. Such attributes are highly valued when selecting analytical reagents for critical QC applications, reinforcing the kit's suitability for adoption in regulated environments.[12]

Comparative overlay analysis: Sciex CE SDS MW kit versus Concerro CE SDS MW kit

Overlay comparisons of electropherograms from reduced and non-reduced test samples (Yervoi®) confirmed that the Concerro CE SDS kit profiles were highly similar to those obtained with the Sciex CE SDS kit, with equivalent resolution of key subunits (LC, HC, NGHC, HL, HH, and HHL). Migration times and corrected peak area percentages (% CPA) aligned closely between kits.

The peak intensities observed with the Concerro CE SDS kit appeared consistently higher than those obtained using the Sciex CE SDS kit. The observed difference could be attributed to the formulation of the Concerro buffers which may enhance protein denaturation and electrophoretic resolution, thereby leading to stronger and more stable signal responses. The higher peak intensity may indicate improved sensitivity of the Concerro kit components, suggesting its potential suitability for precise quantitative CE SDS analysis.

The relative standard deviation (% RSD) values obtained were consistently below 5% when comparing results generated using the Sciex CE kit and the Concerro CE kit. This low variability demonstrates a high degree of reproducibility and confirms that the analytical performance of the Concerro kit is comparable to that of the Sciex reference kit. These findings provide strong evidence for the reliability of the Concerro kit components and buffers in delivering accurate and robust results.

Taken together, the rigorous comparative study unequivocally demonstrated that the Concerro CE SDS kit achieves analytical performance similarity to the Sciex innovator kit, both in terms of precision (% RSD) and electropherogram profile similarity. These results confirm the robustness of the Concerro kit and support its suitability for regulated biopharmaceutical workflows requiring reproducible lot to lot performance.

Comparative evaluation against the Sciex CE-SDS reference kit revealed highly similar electropherogram profiles under both reducing and non-reducing conditions. Key antibody species, including intact IgG, HHL impurities, light chain, heavy chain, and non-glycosylated heavy chain, were consistently resolved with comparable migration times and relative abundances. These findings are in agreement with earlier reports demonstrating that CE-SDS kit chemistry plays a critical role in maintaining reproducible protein denaturation and separation efficiency.[7]

Notably, the Concerro CE-SDS kit exhibited slightly higher peak intensities compared to the Sciex kit. This may be attributed to differences in buffer formulation that enhance protein solubilization and SDS binding efficiency, leading to improved signal response. Similar observations have been documented in comparative CE-SDS evaluations where optimized gel and sample buffers resulted in enhanced detection sensitivity without compromising quantitative accuracy.[8]

Method compatibility and workflow integration

The experimental design was carefully controlled, with consistent separation parameters, sample preparation procedures, and instrumentation maintained throughout the comparative study. This ensured that the evaluation was robust and unbiased.

The consistency of % RSD values observed across three independent lots of the Concerro CE kit highlights the reproducibility of its components and ensures highly stable electrophoretic separations. This level of precision is a prerequisite for validated CE SDS methods and underscores the inherent quality and formulation consistency of the Concerro kit buffers.

As a result, it's integration into existing CE platforms can be achieved seamlessly, without the need for extensive re optimization of methods. This compatibility underscores the kit's utility in supporting reproducible and efficient biopharmaceutical analysis.

Although the Sciex PA 800 Plus system is widely used in the biopharmaceutical industry for CE-SDS analysis, this study demonstrates that the Agilent 7100 CE system delivers comparable and reliable performance.

Equivalent CE-SDS results were obtained using both Sciex CE SDS and Concerro CE-SDS kits on the Agilent 7100 platform, confirming the functional equivalence of the two kits and supporting the suitability of the Agilent 7100 for CE-SDS analysis in biopharmaceutical applications.

Limitations

The study focused exclusively on a single therapeutic IgG1 monoclonal antibody, Ipilimumab. While this provides a strong basis for comparison for standard mAb analysis, the performance characteristics demonstrated may require further verification by end-users when applied to significantly different molecular architectures, such as complex fusion proteins or bispecific antibodies.

CONCLUSION

This study demonstrates that the Concerro CE-SDS kit delivers robust, reproducible, and analytically equivalent performance when compared with the established Sciex CE-SDS kit. Consistent lot-to-lot precision across three independent manufacturing batches confirms the formulation stability and manufacturing control of the Concerro kit components. Comparative analysis under both reducing and non-reducing conditions showed excellent agreement in migration time, size variant profiles, and quantitative peak distribution between the two kits. These results support the suitability of the Concerro CE-SDS kit as a reliable alternative for monoclonal antibody size variant analysis in regulated GxP and QC environments.

ACKNOWLEDGEMENTS

Authors would like to acknowledge the analytical development team at Concerro for their assistance in providing the necessary reagent lots and technical support for this comparative study.

Funding: The study was funded by Pharmadesk Solutions Pvt. Ltd.
Conflict of interest: None declared
Ethical approval: Not required

REFERENCES

1. Cordoba-Rodriguez RV. Aggregates in MAbs and recombinant therapeutic proteins: a regulatory perspective. Bio Pharm Int. 2008;21:44-53.
2. Cordoba AJ, Shyong BJ, Breen D, Harris RJ. Nonenzymatic hinge region fragmentation of antibodies in solution. J Chromatogr B Analyt Technol Biomed Life Sci. 2005;818:115-21.
3. Xiang T, Lundell E, Sun Z, Liu H. Structural effect of a recombinant monoclonal antibody on hinge region peptide bond hydrolysis. J Chromatogr B Analyt Technol Biomed Life Sci. 2007;858:254-62.
4. Rosenberg AS. Effects of protein aggregates: an immunologic perspective. AAPSJ. 2006;8:E501-7.
5. Rosenberg AS, Worobec A. A risk-based approach to immunogenicity concerns of therapeutic protein products, part 2: considering host-specific and product specific factors impacting immunogenicity. Bio Pharm Int. 2004. Available at: http://www.biopharminternational.com/biopharm/21+CFR+Part+11/A-Risk-Based-Approach-to-Immunogenicity-Concerns-o/ArticleStandard/Article/detail/140695. Accessed on 04 November 2025.
6. Schenerman MA, Sunday BR, Kozlowski S, WebberK, Gazzano-Santoro H, Mire-Sluis A. CMC strategy forum report: analytical and structural characterization of monoclonal antibodies. Bio Process Int. 2004;2:42-52.
7. Rustandi RR, Washabaugh MW, Wang Y. Applications of CE SDS gel in development of biopharmaceutical antibody-based products. Electrophoresis. 2008;29:3612-20.
8. Zhang J, Burmana S, Gunturia S, Foley JP. Method development and validation of capillary sodium dodecyl sulfate gel electrophoresis for the characterization of a monoclonal antibody. J Pharm Biomed Analysis. 2010;53:1236-43.
9. Lacher NA, Roberts RK, He Y, Cargill H, Kearns KM, Holovics H, et al. Development, validation, and implementation of capillary gel electrophoresis as a replacement for SDSPAGE for purity analysis of IgG2 mAbs. J Sep Sci. 2010;33:1-10.
10. SDS-MW Analysis Kit For the PA 800 Plus Pharmaceutical Analysis System Application Guide. Available at: https://sciex.jp/content/dam/SCIEX/pdf/customer-docs/application-guide/pa-800-plus-system-sds-mw-analysis-kit-application-guide.pdf. 31-32. Accessed on 04 November 2025.
11. Agilent 7100 Capillary Electrophoresis System user manual. Available at: https://www.agilent.com/cs/library/usermanuals/public/7100_CE_System_User_Manual.pdf?srsltid=AfmBOooU2fg5aKT0BYx_gNoyPiDhQfA7yBZzECkVETr8b86NxZa7fZZ-. Accessed on 04 November 2025.
12. Ensuring Lot-to-Lot Consistency in Protein Reagents: A Guide for Reproducible Research and Drug Development. 2025. Available at: https://www.proteinqc.com/posts/ensuring-lottolot-consistency-in-protein-reagents-a-guide-for-reproducible-research-and-drug development?utm_source=copilot.com. Accessed on 04 November 2025.
13. Thompson S, Chesher D. Lot-to-Lot Variation. Clin Biochem Rev. 2018;39(2):51-60.

Cite this article as: Bhavsar R, Patel N, Jaiswal R, Agrahari S, Thanawala H, Patil A. A comprehensive lot-to-lot variation assessment and comparative analysis of the Concerro CE-SDS kit against the Sciex CE-SDS kit for monoclonal antibody size variant analysis. Int J Res Med Sci 2026;14:617-24.