Software Validation For Ion Chromatography

Worarat Wonglakorn[1], Orathai Tanrin[1], Pakamon Soontratanakul[2] , Thapanee Sarakonsri[1*], Runglawan Somsunan[1]

[1] Department of Chemistry, Faculty of Science, Chiang Mai University 50200,Thailand

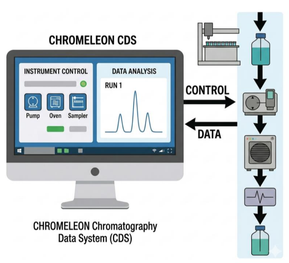
[2] Neocosmed Co., Ltd., 222 Moo 4 Rahaeng, Ladlumkaew, Pathumthani 12140, Thailand

ABSTRACT

The software validation of the Chromeleon system for Ion Chromatography (IC) at Neocosmed Co., Ltd. was conducted in accordance with US FDA 21 CFR Part 11 standards to ensure the accuracy and security of data for raw material and finished product analysis. The project involved testing user access controls across three levels Admin, Supervisor, and Analyst covering functional verification, method management, and signal processing . The results demonstrated that the system operates correctly according to all defined parameters. Notably, the Audit Trail records cannot be deleted, ensuring full traceability of the analytical data . Consequently, this validated software is reliable and suitable for use in a quality control laboratory under international standards.

INTRODUCTION

The United States Food and Drug Administration (FDA) has established 21 CFR Part 11



Chromeleon software controls the Ion Chromatography system



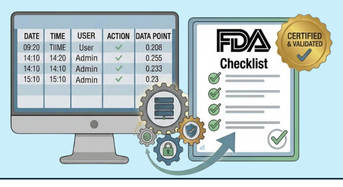
Validation required to ensure data integrity and traceability

OBJECTIVES

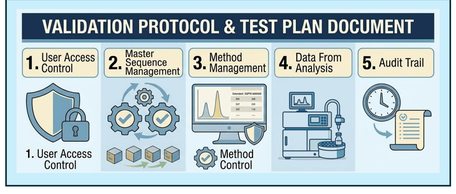
1. To verify and validate the Chromeleon software used in the Ion Chromatography system in compliance with U.S. FDA 21 CFR Part 11 regulations.
2. To prepare the Protocol and Report as documentary evidence to confirm the software's performance in accordance with regulatory requirements.

EXPERIMENTAL

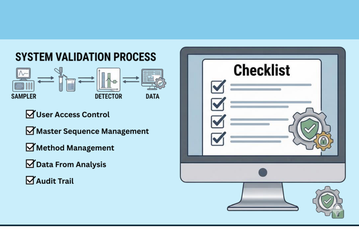
1 System Study and Guidelines



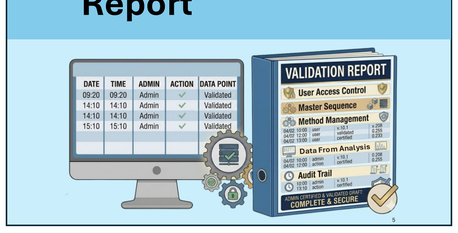
2 Define Validation Scope



3 Validation Testing



4 Documentation and Report



RESULTS AND DISCUSSION

Table 1. Results of Ion Chromatography System Validation

Main Menu	Authorize		Admin	Supervisor	Analyst
1. User Access Control	1.1 Create user		√	×	×
	1.2 User login		√	√	√
2. Master Sequence Management	2.1 Create and modify master sequence		√	√	×
	2.2 Use master sequence		√	√	√
3. Method Management	3.1 Create and modify method		√	√	×
	3.2 Use method		√	√	√
4. Data From Analysis	4.1 Integration	4.1.1 Setting integration	√	√	×
	4.2 Retention time	4.2.1 Modify retention time	√	√	×
	4.3 Calculation	4.3.1 Create and modify calculation	√	√	×
		4.3.2 Use calculation	√	√	×
	4.4 Report template	4.4.1 Create and modify report template	√	√	×
		4.4.2 Use report template	√	√	√
		4.4.3 Print report	√	√	√
	4.5 Delete data		√	×	×
5. Audit Trail	5.1 Delete data audit trail		×	×	×
	5.2 Delete instrument data audit trail		×	×	×

- ❑ User Access: Control Admin create users
- ❑ Method & Master sequence Management: Admin / Supervisor modify methods and master sequence
- ❑ Data Processing: Integration and calculation control
- ❑ Data Security: Only Admin delete data
- ❑ Audit Trail: Records cannot be deleted

ACKNOWLEDGMENT

The author would like to express sincere gratitude to Assoc. Prof. Dr. Thapanee Sarakonsri and Asst. Prof. Dr. Runglawan Somsunan from the Department of Chemistry, Faculty of Science, Chiang Mai University, for their invaluable guidance and mentorship throughout this project . Special thanks to Neocosmed Co., Ltd., the QC Manager, and all QC staff for their mentorship, expertise, and support during this internship.

CONCLUSION

The software validation confirms that the Chromeleon system fully complies with U.S. FDA 21 CFR Part 11. All tested parameters performed correctly, with formal Protocol and Report documents prepared as regulatory evidence. This validated system ensures accurate, reliable, and secure data, making it ready for routine use in Neocosmed's QC laboratory.

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