Title : Software Validation for Ion Chromatography

Author(s) :

1. Worarat Wonglakorn — **Student ID :** 650510186
2. Orathai Tanrin — **Student ID :** 650510199

Major : Chemistry

Advisor(s) :

1. Associate Professor Dr. Thapanee Sarakonsri
2. Assistant Professor Dr. Runglawan Somsunan

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ABSTRACT

The U.S. Food and Drug Administration has established Title 21 CFR Part 11 Regulations and the General Principles for Software Validation to guide the verification and certification of software used with analytical instruments. Neocosmed Co., Ltd.'s quality control laboratory utilizes ion chromatographs for the inspection of raw materials and products, operating with multiple software versions and user levels. Therefore, verification and validation are required to ensure the accuracy, reliability of the data, and compliance with international standards. This report aims to verify and certify the software used with the Chromeleon ion chromatograph software in accordance with Good Laboratory Practice and the standards of Title 21 CFR Part 11 Regulations, and to produce protocol and report that serves as evidence of the operation of the analytical instruments. The ion chromatography device using Chromeleon software, the test was conducted in the functional verification section. The inspection topics were Function, Interface and Challenge. All test results passed the criteria according to the expected parameters and were approved by the Quality Control Manager, demonstrating that the user rights control and prevention of access beyond the specified limits are accurate and reliable in accordance with international standards. Therefore, the ion chromatograph using Chromeleon software can work correctly according to the expected parameters. Suitable for use in the inspection of raw materials and products in the quality control laboratory of Neocosmed Co., Ltd. And can prepare the protocol and reports as evidence to confirm the operation of the analytical instruments.

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