

12th World Congress on Chromatography

June 28-29, 2023 | Webinar

Volume : 14

Qualification of High-Performance Liquid Chromatography System

Muhammad Jehangir

Plant Manager, Novamed Group, Pakistan

Qualification is an important aspect which defines the efficacy of the system. The objective of performance qualification (PQ) is to verify the functions of the systems according to its design specifications and documents it whereas the operational qualification (OQ) involves the verification of working standards of the system. Qualification is an essential part of a pharmaceutical manufacturer's quality assurance system which should demonstrate that the facilities are suitable for their intended use and should also guarantee that the pharmaceutical products are of an appropriate quality. The OQ for the High-performance liquid chromatography (HPLC) are performed through wavelength accuracy test, detector linearity. For separation module it is performed through flow rate accuracy, gradient accuracy, temperature accuracy and carousel test. The PQ is performed through system reproducibility and injector linearity. The OQ and PQ protocols should be prepared, approved and performed as per qualification master plan. The qualification reports are approved by quality assurance and technical departments. For all the tests, the results were found to be as specified. Thus the HPLC system was qualified and released for use.

Biography

Muhammad Jehangir has 18 years diversified experience of Quality Control, Quality Assurance, Registration Affairs, Product development and Pharmaceutical manufacturing, Process Planning, Method development, Method validation, Statistical Methodology, Process & Cleaning Validation, and Equipment Validation etc. Certificate Courses on cGMP, cGLP, Process Validation, CTD Documents, ISO 9001:2015, 14001-2015 and 17025:2017 have strong scientific, analytical, statistical, managerial and training skills. Currently he is working as a Plant Manager for Novamed Pharmaceuticals. It is toll manufacturing-oriented company, manufacturing of companies like Abbot, Getz Pharma, ICI, SEARLE, Macter, Ray, and for Sanofi-Aventis. He is also looking after the Quality of Novamed Healthcare, the nutraceutical and cosmeceutical manufacturing plant.

m.jehangir@novamed.com.pk

Abstract received : January 2, 2023 | Abstract accepted : January 5, 2023 | Abstract published : 05-06-2023