

Acceptance Test for High Performance Liquid Chromatography – Mass Spectrometer (“HPLC-MS”).

The acceptance test should verify that the specifications declared by the manufacturer of the system are met at commissioning.

In particular, the following scopes shall be included in commissioning:

1. Setup of the HPLC-MS system with proper connection between each components and modules in the assigned space based on instrumentation design.
2. Ensure the flow rate, pump pressure, signal from wavelength detector, fraction collector is functional, stable and meets the specified range as denoted in the Tender Specifications. The injector, mixer, pump and solvent flow path must be leak free and verified with leakage test.
3. HPLC columns provided must be suitable for oligonucleotide/protein/peptide purification, with column properties meeting the Tender specifications or better.
4. Mass spectrometer provided must have stable performance and functional. Proper connection and communication must be established with HPLC and instrument computer. The specifications of mass spectrometer supplied must fulfill all Tender’s specifications or equivalent or better.
5. Demonstration trials must be performed with both oligonucleotide and protein standards to verify the normal function of each module. Certificate of commissioning must be provided for the instrument.
6. All samples, chemicals and solvents required for the commissioning of the HPLC-MS system must be provided without additional charge by the vendor. The vendor shall ensure that all tools necessary for the acceptance test are available at commissioning.
7. Installation of all relevant software in the computer with communication properly established between the software and the HPLC-MS system. Ensure the computer and software provide a stable data acquisition, with no sudden disruption or data loss during sample run.
8. Ensure data acquisition and processing is functional for both oligonucleotide and protein samples. On-site training must be provided to all potential users on the use of the data acquisition and acquisition software. Manuals for system software and hardware must be provided.
9. Demonstration and training shall be provided to all potential users for the use of the deconvolution software.

The contact of person-in-charge includes phone number and email must be provided on the instrument for any technical issue encountered within the warranty period.

If any of the specifications can only be tested at the manufacturer factory, the vendor shall specify and declare them at the tender stage.