Specification of Competency Standards
for the Testing, Inspection and Certification Industry
Unit of Competency

Functional Area - Testing Operations

Title	Perform chemical analysis on pharmaceutical products
Code	105782L5
Range	This unit of competency (UoC) covers the abilities to carry out chemical analysis on pharmaceutical products independently by applying knowledge of analytical chemistry and instrumental analysis, record accurate test data and critically evaluate test results in testing laboratories.
Level	5
Credit	4 （For Reference Only）
Competency	Performance Requirements 1. Possess knowledge of analytical chemistry and assays of pharmaceutical products • Apply the principles and concepts of chemical analysis for pharmaceutical products. • Specify the identification and assays of selected pharmaceutical products in relevant pharmacopoeia / test standards, e.g.: o British Pharmacopoeia (BP), o United States Pharmacopeia (USP), o European Pharmacopoeia (EP), o Pharmacopoeia of the People's Republic of China (ChP). • Determine pharmaceutical products and corresponding test methods routinely used in testing laboratories including: o purpose and principles of test, o properties of pharmaceutical products under test, o key preparation/measurement steps in test method, o calculation steps to give results in appropriate accuracy, precision, units and uncertainty, o expected values for sample type. • Explain the operation of equipment used for chemical analysis of selected pharmaceutical products, e.g. chromatography, spectrometry, electrochemical instruments. • Explain the importance of traceability of samples, test pieces, test data and results. • Describe the procedures for equipment calibration and performance check. 2. Perform chemical analysis on pharmaceutical products • Evaluate the test request and analyse sample characteristics that may affect selection and application of test methods. • Select and apply appropriate assay method and equipment in compliance with test requirements for selected pharmaceutical products. • Prepare a representative analytical portion of the laboratory sample to reduce the sample complexity and eliminate matrix effects. • Carry out routine performance check of equipment according to manufacturer's instruction and/or relevant standard to ensure it is ready for chemical tests of pharmaceutical products. • Set up, optimise and check the calibration status of equipment for measurements to suit sample/test requirements. • Carry out appropriate chemical tests on selected pharmaceutical product independently by measuring analyte response for calibration standards, validation and quality control checks, and the sample according to the requirements of test method. • Record accurate and reliable data and/or observations and evaluate test results for the compliance of pharmaceutical product.

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	3. Exhibit professionalism • Troubleshoot analytical procedures or equipment in case of any atypical observations/data/results being identified during sample analysis or performance check. • Ensure integrity and confidentiality of laboratory data and information by observing the code of conduct of the laboratory.
Assessment Criteria	The integrated outcome requirements of this UoC are the abilities to: • carry out chemical tests on selected pharmaceutical product independently by applying appropriate assay method and testing equipment according to the requirements of test request, • verify test results and observations by data validation, • critically evaluate test results to confirm the compliance of the pharmaceutical product against relevant specifications of test standard/method.
Remark	Practitioners are required to have prior knowledge of the following UoCs: • Apply atomic spectrometric