Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Applied Laboratory and Analytical Techniques for Pharmaceutical Manufacture

Unit Reference Number: M/652/4188

Level: Five (5)

Credit Value: 7

Minimum Guided Learning Hours: 45

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand laboratory safety, equipment and good scientific practice within pharmaceutical manufacturing	1.1 Evaluate laboratory safety requirements and their application to pharmaceutical analytical activities
	1.2 Evaluate the functions, operating principles and limitations of laboratory equipment used in pharmaceutical analysis
	1.3 Evaluate the principles of good scientific practice and data integrity in laboratory activities
	1.4 Assess the contribution of equipment calibration, maintenance and qualification to reliable analytical results
2. Be able to perform analytical techniques relevant to sterile and non-sterile pharmaceutical manufacture	2.1 Select and justify analytical methods appropriate to specified pharmaceutical samples and testing requirements
	2.2 Prepare pharmaceutical samples and analytical equipment in accordance with specified procedures
	2.3 Perform analytical tests in accordance with specified procedures and quality requirements
	2.4 Verify analytical results and record findings in accordance with laboratory quality and data-integrity requirements
3. Be able to interpret analytical results and investigate findings affecting pharmaceutical product quality	3.1 Analyse analytical results against specified acceptance criteria and product requirements

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	3.2	Evaluate the significance of out-of-specification and out-of-trend analytical findings
	3.3	Apply structured investigation methods to identify potential causes of analytical discrepancies
	3.4	Develop and communicate evidence-based conclusions and recommendations arising from analytical findings
4. Be able to apply laboratory quality management and documentation requirements	4.1	4.1 Complete laboratory records in accordance with good documentation and data-integrity requirements
	4.2	4.2 Apply relevant deviation and change control procedures to laboratory activities
	4.3	4.3 Evaluate the suitability of analytical method validation and verification arrangements
	4.4	4.4 Assess laboratory compliance risks and their potential implications for analytical reliability and product quality
	4.5	4.5 Develop justified recommendations to improve laboratory practices or analytical quality controls

Indicative Content	
LO1	1.1 must include relevant health and safety requirements; Control of Substances Hazardous to Health (COSHH); personal protective equipment (PPE); laboratory hazards and risk assessment; selection and justification of appropriate control measures. 1.2 must include operating principles, suitability, accuracy and limitations of relevant laboratory equipment; factors affecting equipment performance and analytical reliability. Other examples include analytical balances, pH meters, osmometers, microscopes and volumetric equipment. 1.3 must include good scientific practice; accurate and reproducible analytical work; appropriate sample identification and handling; traceability; ALCOA+ principles; reliability and integrity of analytical records. 1.4 must include calibration principles; equipment suitability and status; routine maintenance and performance checks; relevant qualification requirements; implications of equipment failures or inadequate controls for analytical accuracy and product quality.
LO2	2.1 must include consideration of sample characteristics, analytical objectives, relevant specifications, method suitability, equipment requirements and limitations; justification of the selected analytical methods.

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	2.2 must include appropriate sample preparation techniques; sample identification and traceability; preparation of analytical equipment; relevant calibration or performance checks; application of laboratory safety and contamination-prevention requirements. Other examples include sample dilution, weighing, volumetric preparation and appropriate sample handling. 2.3 must include practical application of relevant analytical techniques; adherence to standard operating procedures; appropriate use of equipment; control of factors affecting analytical accuracy; safe laboratory practice. Other examples include pH measurement, osmolality, clarity assessment, gravimetric analysis and volumetric analysis. 2.4 must include appropriate recording of results; relevant calculations and units; verification of results against procedural or analytical requirements; identification of potential errors; accurate, contemporaneous and traceable documentation.
LO3	3.1 must include interpretation of relevant analytical data; comparison with specifications and acceptance criteria; identification of compliant, atypical and non-compliant findings; consideration of measurement variability and uncertainty. 3.2 must include principles of out-of-specification (OOS) and out-of-trend (OOT) results; assessment of analytical findings and their potential significance; implications for product quality, patient safety and regulatory compliance; appropriate reporting and escalation. 3.3 must include review of analytical procedures and results; examination of relevant equipment, sample preparation, method and operator factors; identification of contributory factors and potential root causes; appropriate investigation documentation. 3.4 must include interpretation of investigation evidence; justified conclusions; recommendations for further testing, investigation or corrective action; accurate presentation and communication of results, limitations and potential quality implications.
LO4	4.1 must include accurate, legible and contemporaneous completion of laboratory records; sample and result traceability; appropriate identification and recording of equipment use; compliant correction of errors. Other examples include laboratory notebooks, analytical worksheets, equipment logbooks and electronic laboratory records. 4.2 must include identification and reporting of laboratory deviations; relevant investigation and escalation arrangements; principles of controlled changes to analytical methods, equipment or procedures; appropriate documentation and professional responsibilities. 4.3 must include the purpose and application of method validation and verification; relevant analytical performance characteristics; assessment of method suitability for intended use; implications for the reliability of analytical results. Other examples include accuracy, precision, specificity, linearity, range and robustness, where applicable to the method. 4.4 must include identification of risks associated with analytical procedures, equipment, documentation, personnel and laboratory controls; assessment of potential impacts on data reliability, product quality and regulatory compliance.

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	4.5 must include recommendations informed by identified risks or analytical findings; consideration of procedural, equipment, documentation or training improvements; anticipated impact on analytical reliability, laboratory compliance and product quality; appropriate measures for evaluating effectiveness.

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Assessment Requirements

Assessment must demonstrate the application of specialist laboratory and analytical knowledge and skills to activities relevant to sterile or non-sterile pharmaceutical manufacture.

Learners must demonstrate Level 5 capability through the selection and justification of analytical approaches, accurate performance of laboratory techniques, interpretation of results, investigation of discrepancies and evaluation of analytical reliability.

LO2 requires direct evidence of practical laboratory performance. Learners must prepare samples and equipment, undertake analytical testing and record results in accordance with specified procedures.

LO3 and LO4 require evidence of applying analytical, investigative and quality management skills.

Assessment must take place in an appropriately equipped laboratory or practical training environment, using relevant equipment, materials, procedures and safety controls.

Learners must undertake practical activities within their authorised scope of practice and with appropriate supervision.

The qualification does not confer occupational competence or professional authorisation in its own right.

Evidence may include:

- Laboratory risk assessments and equipment evaluations
- Analytical method selection and justification
- Direct observation of sample preparation and analytical testing
- Completed analytical worksheets and calculation records
- Laboratory results and verification records
- Evaluations of analytical method suitability
- OOS or OOT investigation reports
- Reviews of analytical equipment performance
- Laboratory documentation and deviation records
- Quality risk assessments
- Laboratory improvement recommendations
- Professional discussions supported by practical and technical evidence

LO1 – Laboratory safety, equipment and good scientific practice

Assessment should require learners to evaluate laboratory safety requirements, equipment suitability and the factors influencing analytical reliability.

Learners should demonstrate understanding of the relationship between equipment performance, good scientific practice, data integrity and product quality.

The assessment should go beyond identifying laboratory hazards or describing equipment functions. Learners should evaluate the suitability and limitations of equipment and controls within a relevant analytical context.

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LO2 – Practical analytical techniques

Learners must select and perform analytical techniques relevant to pharmaceutical manufacture.

Assessment should include practical performance of at least three analytical techniques, including:

- One physicochemical measurement, such as pH or osmolality
- One gravimetric or volumetric analytical procedure
- One additional technique appropriate to the learner's pharmaceutical context

The selection should enable learners to demonstrate sample preparation, equipment checks, procedural compliance, accurate measurement and verification of results.

The learner must justify the suitability of the chosen techniques for the specified samples and testing requirements.

Although the individual methods may be relatively straightforward, assessment should establish Level 5 demand through appropriate method selection, recognition of limitations, control of analytical variables and evaluation of result reliability.

Practical observation is required. Written assignments or professional discussions alone are insufficient.

LO3 – Analytical results and investigations

Learners must analyse analytical results against defined specifications and acceptance criteria.

Assessment should include an atypical, OOS or OOT finding requiring investigation.

Learners should consider potential sources of error and uncertainty, assess implications for product quality and develop evidence-based conclusions.

The assessment should require genuine interpretation and technical judgement rather than simply identifying whether a numerical result is within specification.

LO4 – Laboratory quality management

Learners must demonstrate compliant laboratory documentation and appropriate application of deviation and change control principles.

Assessment should include evaluation of analytical method validation or verification arrangements and laboratory compliance risks.

Learners are not required to undertake full analytical method validation, equipment qualification or formal approval of laboratory procedures.

An integrated laboratory assessment could generate evidence across LO2, LO3 and LO4, supported by a technical report or professional discussion where appropriate.

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