Qualification Specification for:

OCN NI Level 4 Certificate in Pharmaceutical Quality Control and Analysis

- **Qualification No: 610/1238/5**

Qualification Regulation Information

OCN NI Level 4 Certificate in Pharmaceutical Quality Control and Analysis
Qualification Number: 610/1238/5

Operational start date: 01 August 2022
Operational end date: 31 July 2027
Certification end date: 31 July 2031

Qualification operational start and end dates indicate the lifecycle of a regulated qualification. The operational end date is the last date by which learners can be registered on a qualification and the certification end date is the last date by which learners can claim their certificate.

All OCN NI regulated qualifications are published to the Register of Regulated Qualifications (**http://register.ofqual.gov.uk/**). This site shows the qualifications and awarding organisations regulated by CCEA Regulation and Ofqual.

OCN NI Contact Details

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Foreword

This document explains OCN NI's requirements for the delivery and assessment of the following regulated qualifications:

→ **OCN NI Level 4 Certificate in Pharmaceutical Quality Control and Analysis**

This specification sets out:

- Qualification features
- Centre requirements for delivering and assessing the qualification
- The structure and content of the qualification
- Unit details
- Assessment requirements for the qualification
- OCN NI's quality assurance arrangements for the qualification
- Administration

OCN NI will notify centres in writing of any major changes to this specification. We will also publish changes on our website at **www.ocnni.org.uk**

This specification is provided online, so the version available on our website is the most up to date publication. It is important to note that copies of the specification that have been downloaded and printed may be different from this authoritative online version.

Contents

About Regulation

OCN NI

Open College Network Northern Ireland (OCN NI) is a regulated Awarding Organisation based in Northern Ireland. OCN NI is regulated by CCEA Regulation to develop and award professional and technical (vocational) qualifications from Entry Level up to and including Level 5 across all sector areas. In addition, OCN NI is regulated by Ofqual to award similar qualification types in England.

The Regulated Qualifications Framework: an overview

The Regulated Qualifications Framework (RQF) was introduced on 1st October 2015: the RQF provides a single framework for all regulated qualifications.

Qualification Level
The level indicates the difficulty and complexity of the knowledge and skills associated with any qualification. There are eight levels (Levels 1-8) supported by three 'entry' levels (Entry 1-3).

Qualification Size
Size refers to the estimated total amount of time it could typically take to study and be assessed for a qualification. Size is expressed in terms of Total Qualification Time (TQT), and the part of that time typically spent being taught or supervised, rather than studying alone, is known as Guided Learning Hours (GLH).

Qualification Features

Sector Subject Area
2.1 Science

NOS - Cogent Laboratory Skills

Qualification Aim
The OCN NI Level 4 Certificate in Pharmaceutical Quality Control and Analysis will provide learners with the skills and knowledge to carry out different tests on laboratory pharmacological samples including quality analysis and control tests.

Qualification Objectives
The objectives of the OCN NI Level 4 Certificate in Pharmaceutical Quality Control and Analysis is to enable learners to carry out the following in line with pharmacopeia guidelines:

- titration to determine the concentration of a sample and analyse data
- different quality control tests on tablets
- ultraviolet-visible (UV-Vis) spectroscopy and dissolution tests

Grading
Grading for this qualification is pass/fail.

Qualification Target Group
This qualification is targeted at learners who are currently working in or who wish to work in laboratory based occupations in the pharmaceutical health, life science and related sectors.

Progression Opportunities
The OCN NI Level 4 Certificate in Pharmaceutical Quality Control and Analysis qualification will allow learners to progress to higher level qualifications in science and related areas.

Entry Requirements

The entry requirements for this qualification include the following:

- learners should be at least 18 years old
- have five GCSEs or equivalent including English and Maths at Grade C or above
- have a level 3 qualification or a level 2 qualification and in additional have at least one year's experience in a science related occupation

Resource Requirements

Learners must have access to appropriate equipment typically found in an industrial/scientific laboratory workplace.

Qualification Support

A Qualification Support pack is available for OCN NI centres within the login area of the OCN NI website (https://www.ocnni.org.uk/my-account/), which includes additional support for teachers, eg planning and assessment templates, guides to best practice, etc.

Delivery Languages

This qualification is available in English only at this time. If you wish to offer this qualification in Welsh or Irish (Gaeilge) then please contact OCN NI who will review demand and provide as appropriate.

Centre Requirements for Delivering the Qualification

Centre Recognition and Qualification Approval

New and existing OCN NI recognised centres must apply for and be granted approval to deliver the qualification prior to the commencement of delivery.

Centre Staffing

Centres are required to have the following roles in place as a minimum, although a member of staff may hold more than one role*:

- Centre contact
- Programme Co-ordinator
- Tutor
- Assessor
- Internal Verifier

*Note: A person cannot be an internal verifier for their own assessments.

Tutors

Tutors delivering the qualification should be occupationally competent and qualified to at least one level higher than the qualifications and have a minimum of one year's relevant experience.

Assessors

The qualification is assessed within the centre and is subject to OCN NI's quality assurance processes. Units are achieved through internally set, internally assessed, and internally verified evidence.

Assessors must:

- be occupationally competent to at least one level higher than the qualification
- have a minimum of one year's experience in the area they are assessing
- have direct or related relevant experience in assessment
- assess all assessment tasks and activities

Internal Verification

OCN NI qualifications must be scrutinised through the centre's internal quality assurance processes as part of the recognised centre agreement with OCN NI. The centre must appoint an experienced and trained centre internal verifier whose responsibility is to act as the internal quality monitor for the verification of the delivery and assessment of the qualifications.

The centre must agree a working model for internal verification with OCN NI prior to delivery of the qualifications.

Internal Verifiers must:

- have at least one year's occupational experience in the areas they are internally verifying
- attend OCN NI's internal verifier training if not already completed

Internal verifiers are required to:

- support tutors and assessors
- sample assessments according to the centre's sampling strategy
- ensure tasks are appropriate to the level being assessed
- maintain up-to-date records supporting the verification of assessment and learner achievement

Structure and Content

OCN NI Level 4 Certificate in Pharmaceutical Quality Control and Analysis

In order to achieve the qualification learners must complete 18 credits.

Total Qualification Time (TQT) for this qualification:	180 hours
Guided Learning Hours (GLH) for this qualification:	80 hours

Unit Reference Number	OCN NI Unit Code	Unit Title	Credit Value	GLH	Level
M/650/3488	CBF874	Pharmaceutical Analytical Quality Control and Analysis	18	80	Four

Unit Details

Title	Pharmaceutical Analytical Quality Control and Analysis
Level	Four
Credit Value	18
Guided Learning Hours (GLH)	80
OCN NI Unit Code	CBF874
Unit Reference No	M/650/3488
Unit purpose and aim(s): This unit will enable the learner to understand how to carry out different tests on laboratory pharmacological samples including quality analysis and control tests on tablets. Methods and Standard Operating Procedures (SOPs) used in analysis will align to guidelines found in the Pharmacopeias, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines and European Medicines Agency (EMA).	
Learning Outcomes	**Assessment Criteria**
1. Be able to perform titration to determine the concentration of a sample and analyse data.	1.1. Perform titration in line with pharmacopeia guidelines to determine the concentration of a given sample, accurately recording data on an analytical method sheet. 1.2. Calculate the percentage purity of the sample titrated in AC 1.1. 1.3. Analyse the results obtained in AC 1.2 and AC 1.3 including the following: a) trends in data b) possible sources of error and anomalies c) determining if data is valid and relevant. d) initiating further action for results out of specification
2. Be able to carry out quality control tests on friability of tablets.	2.1. Perform all steps in the appropriate SOP to determine the friability of tablets including: a) use of appropriate techniques to safely and effectively handle equipment and reagents b) accurate recording techniques c) critically review and evaluate SOP and provide a revised SOP if required. 2.2. Analyse results obtained in AC 2.1 including the following: a) trends in data b) possible sources of error and anomalies c) determining data validity and relevancy d) drawing conclusions with justification

3. Be able to carry out quality control tests on hardness of tablets.	3.1. Perform all steps in the SOP to determine the hardness of tablets including: a) use of appropriate techniques to safely and effectively handle equipment and reagents b) accurate recording techniques c) critically review and evaluate SOP to provide a revised SOP if required 3.2. Analyse results obtained in AC 3.1 including the following: a) trends in data b) possible sources of error and anomalies c) determining data validity and relevancy d) drawing conclusions with justification
4. Be able to carry out quality control tests on the uniformity of tablet weight.	4.1. Perform all steps in the SOP to determine the uniformity of tablet weight including: a) use of appropriate techniques to safely and effectively handle equipment and reagents b) accurate recording techniques c) critically review and evaluate SOP to provide a revised SOP if required 4.2. Analyse results obtained in AC 4.1 including the following: a) trends in data b) possible sources of error and anomalies c) determining data validity and relevancy d) drawing conclusions with justification
5. Be able to carry out quality control tests on the disintegration of tablets.	5.1. Perform all steps in the to determine the disintegration of tablets including: a) use of appropriate techniques to safely and effectively handle equipment and reagents b) accurate recording techniques c) critically review and evaluate SOP to provide a revised SOP if required 5.2. Analyse results obtained in AC 5.1 including the following: a) trends in data b) possible sources of error and anomalies c) determining data validity and relevancy d) drawing conclusions with justification

6. Be able to carry out ultraviolet-visible (UV-Vis) spectroscopy and dissolution tests.	6.1. Perform all steps in the SOP determine % dissolution by UV-Vis including: a) use of appropriate techniques to safely and effectively prepare five samples of various concentrations b) carry out UV-Vis analysis on test samples c) interpret results from UV-Vis analysis to produce a calibration curve d) carry out dissolution tests on samples e) Interpret results from dissolution tests to determine percentage dissolution 6.2. Analyse results obtained in AC 6.2 including the following: a) trends in data b) possible sources of error and anomalies c) determining data validity and relevancy d) drawing conclusions with justification

Assessment Guidance

The following assessment method/s may be used to ensure all learning outcomes and assessment criteria are fully covered.

Assessment Method	Definition	Possible Content
Portfolio of evidence	A collection of documents containing work undertaken to be assessed as evidence to meet required skills outcomes OR A collection of documents containing work that shows the learner's progression through the course	Learner notes/written work Learner log/diary Peer notes Record of observation Record of discussion
Practical demonstration/assignment	A practical demonstration of a skill/situation selected by the tutor or by learners, to enable learners to practise and apply skills and knowledge	Record of observation Learner notes/written work Learner log
Coursework	Research or projects that count towards a learner's final outcome and demonstrate the skills and/or knowledge gained throughout the course	Record of observation Learner notes/written work Tutor notes/record Learner log/diary
E-assessment	The use of information technology to assess learners' work	Electronic portfolio E-tests

Quality Assurance of Centre Performance

External Verification

All OCN NI recognised centres are subject to External Verification. External verification visits and monitoring activities will be conducted annually to confirm continued compliance with the conditions of recognition, review the centre's risk rating for the qualifications and to assure OCN NI of the maintenance of the integrity of the qualifications.

The External Verifier will review the delivery and assessment of the qualifications. This will include the review of a sample of assessment evidence and evidence of the internal verification of assessment and assessment decisions. This will form the basis of the EV report and will inform OCN NI's annual assessment of centre compliance and risk. The External Verifier is appointed by OCN NI.

Standardisation

As a process, standardisation is designed to ensure consistency and promote good practice in understanding and application of standards. Standardisation events:

- make qualified statements about the level of consistency in assessment across centres delivering a qualification
- make statements on the standard of evidence that is required to meet the assessment criteria for units in a qualification
- make recommendations on assessment practice
- produce advice and guidance for the assessment of units
- identify good practice in assessment and internal verification

Centres offering units of an OCN NI qualification must attend and contribute assessment materials and learner evidence for standardisation events if requested.

OCN NI will notify centres of the nature of sample evidence required for standardisation events (this will include assessment materials, learner evidence and relevant assessor and internal verifier documentation). OCN NI will make standardisation summary reports available and correspond directly with centres regarding event outcomes.

Administration

Registration

A centre must register learners within 20 working days of commencement of a qualification.

Certification

Certificates will be issued to centres within 20 working days of receipt of correctly completed results marksheets. It is the responsibility of the centre to ensure that certificates received from OCN NI are held securely and distributed to learners promptly and securely.

Charges

OCN NI publishes all up to date qualification fees in its Fees and Invoicing Policy document. Further information can be found on the centre login area of the OCN NI website.

Equality, Fairness and Inclusion

OCN NI has considered the requirements of equalities legislation in developing the specification for these qualifications. For further information and guidance relating to access to fair assessment and the OCN NI Reasonable Adjustments and Special Considerations policies, centres should refer to the OCN NI website.

Retention of Evidence

OCN NI has published guidance for centres on the retention of evidence. Details are provided in the OCN NI Centre Handbook and can be accessed via the OCN NI website.

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