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www.cityandguilds.com
centresupport@cityandguilds.com
### Version and date | Change detail | Section
---|---|---
1.2 September 2014 | Amendments to range in **all** units. Please see individual units in this document for detail. There are now **two** versions of assessment for **each** unit (Version A and Version B). Please note that Version A tests for all units have been updated and the new version should be used from 1 September 2014. The existing Version A tests will not be available after this date. Version B tests are new. Please see p11 of this document for further information. | All units

1.3 October 2014 | Amendment to 5356-312 Version A Assessment document. Q14 - Replaced incorrect ‘Counselling Points’ table with ‘Mode of Action’ table. Question remains the same. | 5356-312 Version A (v1-1)

1.4 April 2015 | Additional guidance on mark allocation added. | - Qualification handbook (p11) - Assessor guidance document - Marking guides

1.5 May 2015 | Amendment to 5356-304 Version A Assessment document. Q18 - Added missing label for fifth key structure. | 5356-304 Version A (v1-1)

2.0 November 2015 | Various minor amendments / updates to Assessment packs following review. | Assessment packs 5356-301 to 319 Version A & B (v1-2)

2.1 August 2017 | Adding GLH and TQT details Removing QCF | Introduction to the qualification Summary of units
## Contents

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Introduction to the qualification</td>
<td>5</td>
</tr>
<tr>
<td>1.1</td>
<td>Qualification structure</td>
<td>5</td>
</tr>
<tr>
<td>1.2</td>
<td>Opportunities for progression</td>
<td>7</td>
</tr>
<tr>
<td>1.3</td>
<td>Qualification support materials</td>
<td>7</td>
</tr>
<tr>
<td>1.4</td>
<td>Centre requirements</td>
<td>8</td>
</tr>
<tr>
<td>2</td>
<td>Resource requirements</td>
<td>8</td>
</tr>
<tr>
<td>2.1</td>
<td>Initial assessment and induction</td>
<td>9</td>
</tr>
<tr>
<td>2.2</td>
<td>Recommended delivery strategies</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>Course design and delivery</td>
<td>10</td>
</tr>
<tr>
<td>3.1</td>
<td>Assessment</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>Summarized assessment methods</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>Units</td>
<td>20</td>
</tr>
<tr>
<td>Unit 301</td>
<td>Chemical principles for pharmacy technicians</td>
<td>21</td>
</tr>
<tr>
<td>Unit 302</td>
<td>Biological principles for pharmacy</td>
<td>22</td>
</tr>
<tr>
<td>Unit 303</td>
<td>Microbiology for pharmacy</td>
<td>26</td>
</tr>
<tr>
<td>Unit 304</td>
<td>Human physiology for pharmacy</td>
<td>31</td>
</tr>
<tr>
<td>Unit 305</td>
<td>Action and uses of medicines</td>
<td>36</td>
</tr>
<tr>
<td>Unit 306</td>
<td>Gastrointestinal and nutritional medicines</td>
<td>42</td>
</tr>
<tr>
<td>Unit 307</td>
<td>Cardio-respiratory medicines</td>
<td>46</td>
</tr>
<tr>
<td>Unit 308</td>
<td>Central nervous system medicines and anaesthesia</td>
<td>50</td>
</tr>
<tr>
<td>Unit 309</td>
<td>Infections, immunological products and vaccines</td>
<td>54</td>
</tr>
<tr>
<td>Unit 310</td>
<td>Endocrine and genito-urinary medicines</td>
<td>59</td>
</tr>
<tr>
<td>Unit 311</td>
<td>Malignant disease, immunosuppressive and musculoskeletal medicines</td>
<td>62</td>
</tr>
<tr>
<td>Unit 312</td>
<td>Eye, ear, nose and dermatological medicines</td>
<td>66</td>
</tr>
<tr>
<td>Unit 313</td>
<td>Community pharmacy practice</td>
<td>70</td>
</tr>
<tr>
<td>Unit 314</td>
<td>Professional development in pharmacy</td>
<td>76</td>
</tr>
<tr>
<td>Unit 315</td>
<td>Communicating in pharmacy</td>
<td>80</td>
</tr>
<tr>
<td>Unit 316</td>
<td>Dispensing and supply of medicines</td>
<td>85</td>
</tr>
<tr>
<td>Unit 317</td>
<td>Pharmaceutics</td>
<td>90</td>
</tr>
<tr>
<td>Unit 318</td>
<td>Pharmacy law, ethics and practice</td>
<td>94</td>
</tr>
<tr>
<td>Unit 319</td>
<td>Making medicines for pharmacy</td>
<td>99</td>
</tr>
</tbody>
</table>
City & Guilds
Believe you can

www.cityandguilds.com
1 Introduction to the qualification

This document contains the information that centres need to offer the following qualification:

<table>
<thead>
<tr>
<th>Qualification title and level</th>
<th>Level 3 Diploma in Pharmaceutical Science</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLH</td>
<td>720</td>
</tr>
<tr>
<td>TQT</td>
<td>1200</td>
</tr>
<tr>
<td>City &amp; Guilds qualification number</td>
<td>5356-03</td>
</tr>
<tr>
<td>Qualification accreditation number</td>
<td>500/9959/0</td>
</tr>
<tr>
<td>Last registration date</td>
<td>31/12/2015</td>
</tr>
<tr>
<td>Last certification date</td>
<td>31/12/2018</td>
</tr>
</tbody>
</table>

This knowledge qualification has been designed for those wishing to work in a pharmacy setting, either in the community or in a hospital. The qualification can be used as a stand alone knowledge qualification or, taken in conjunction with the City & Guilds Level 3 NVQ Diploma in Pharmacy Service Skills, will contribute to the Level 3 Apprenticeship in Pharmacy as specified by Skills for Health.

1.1 Qualification structure

To achieve the Level 3 Diploma in Pharmaceutical Science, learners must complete all 19 units from the mandatory groups to achieve a total of 120 credits.

The diagram below illustrates the unit titles, the credit value of each unit and the title of the qualification which will be awarded to candidates successfully completing the required number of units and/or credits. It also shows any excluded combination of units.

<table>
<thead>
<tr>
<th>Unit accreditation number</th>
<th>City &amp; Guilds unit number</th>
<th>Unit title</th>
<th>Mandatory/optional for full qualification</th>
<th>Credit value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y/601/7562</td>
<td>Unit 301</td>
<td>Chemical principles for pharmacy technicians</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>M/601/7566</td>
<td>Unit 302</td>
<td>Biological principles for pharmacy</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>L/601/9177</td>
<td>Unit 303</td>
<td>Microbiology for pharmacy</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>K/601/7789</td>
<td>Unit 304</td>
<td>Human physiology for pharmacy</td>
<td>Mandatory</td>
<td>10</td>
</tr>
<tr>
<td>Code</td>
<td>Unit</td>
<td>Title</td>
<td>Type</td>
<td>Credits</td>
</tr>
<tr>
<td>---------</td>
<td>-------</td>
<td>-------------------------------------------------</td>
<td>---------------</td>
<td>---------</td>
</tr>
<tr>
<td>L/601/9180</td>
<td>305</td>
<td>Action and uses of medicines</td>
<td>Mandatory</td>
<td>10</td>
</tr>
<tr>
<td>A/601/7568</td>
<td>306</td>
<td>Gastrointestinal and nutritional medicines</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>T/601/7570</td>
<td>307</td>
<td>Cardio-respiratory medicines</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>J/601/7573</td>
<td>308</td>
<td>Central nervous system medicines and anaesthesia</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>L/601/7574</td>
<td>309</td>
<td>Infections, immunological products and vaccines</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>Y/601/7576</td>
<td>310</td>
<td>Endocrine and genito-urinary medicines</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>D/601/7577</td>
<td>311</td>
<td>Malignant disease, immunosuppressive and musculoskeletal medicines</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>T/601/7794</td>
<td>312</td>
<td>Eye, ear, nose and dermatological medicines</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>R/601/9181</td>
<td>313</td>
<td>Community pharmacy practice</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>A/601/7795</td>
<td>314</td>
<td>Professional development in pharmacy</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>Y/601/9182</td>
<td>315</td>
<td>Communicating in pharmacy</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>J/601/7797</td>
<td>316</td>
<td>Dispensing and supply of medicines</td>
<td>Mandatory</td>
<td>5</td>
</tr>
<tr>
<td>A/601/7800</td>
<td>317</td>
<td>Pharmaceutics</td>
<td>Mandatory</td>
<td>10</td>
</tr>
<tr>
<td>L/601/7803</td>
<td>318</td>
<td>Pharmacy law, ethics and practice</td>
<td>Mandatory</td>
<td>10</td>
</tr>
<tr>
<td>Y/601/7805</td>
<td>319</td>
<td>Making medicines for pharmacy</td>
<td>Mandatory</td>
<td>10</td>
</tr>
</tbody>
</table>
Total Qualification Time

Total Qualification Time (TQT) is the total amount of time, in hours, expected to be spent by a Learner to achieve a qualification. It includes both guided learning hours (which are listed separately) and hours spent in preparation, study and assessment.

<table>
<thead>
<tr>
<th>Title and level</th>
<th>GLH</th>
<th>TQT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 3 Diploma in Pharmaceutical Science</td>
<td>720</td>
<td>1200</td>
</tr>
</tbody>
</table>

1.2 Opportunities for progression

This knowledge qualification has been designed to prepare candidates wishing to work in a pharmacy setting. It can be taken as a stand alone qualification or, with the City & Guilds Level 3 NVQ Diploma in Pharmacy Service Skills, as part of the Apprenticeship for Pharmacy at Level 3. The completion of the two qualifications will also satisfy the requirements for registration to work as a Pharmacy Technician, as required by the General Pharmaceutical Council.

1.3 Qualification support materials

City & Guilds also provides the following publications and resources specifically for this qualification:

<table>
<thead>
<tr>
<th>Description</th>
<th>How to access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment documents</td>
<td><a href="http://www.cityandguilds.com">www.cityandguilds.com</a></td>
</tr>
<tr>
<td>Assessment marking guides</td>
<td><a href="http://www.cityandguilds.com">www.cityandguilds.com</a></td>
</tr>
</tbody>
</table>
Centre requirements

1.4 Resource requirements

Human resources
Staff delivering this qualification must be able to demonstrate that they meet the following occupational expertise requirements. They should:

- be technically competent in the area for which they are delivering training and have experience of providing training. This means they should be a pharmacy technician or pharmacist for pharmacy specific units. Their knowledge must be at least to the same level as the training being delivered
- have recent relevant experience in the specific area they will be assessing
- have credible experience which is clearly demonstrable through continuing learning and development

Centre staff may undertake more than one role, e.g. tutor and assessor or internal quality assurer, but must never internally quality assure their own assessments.

Assessors and internal quality assurers

Assessors must:

- hold or be working towards the appropriate Assessor qualification as identified by the qualifications regulators. Assessors holding older qualifications must be able to demonstrate that they are assessing to current standards
- have credible experience which is clearly demonstrable through continuing learning and development.

Internal Quality Assurers must:

- be a registered and practising Pharmacist or a practising Pharmacy Technician
- other than in Northern Ireland, pharmacy technicians must be registered or eligible to register with the Pharmacy regulator
- understand the nature and context of the assessors’ work and that of their candidates due to the critical nature of the work and the legal and other implications of the assessment process
- have a working knowledge of pharmacy and/or GP dispensing settings, the regulation, legislation and codes of practice for the service (where applicable), and the requirements of national standards at the time any assessment is taking place
- occupy a position that gives them authority and resources to co-ordinate the work of assessors, provide authoritative advice, call meetings as appropriate, visit and observe assessments and carry out all the other internal quality assurance roles as defined by the relevant national occupational standard
- hold or be working towards the appropriate Internal Quality Assurer qualifications as identified by the qualifications regulators. Internal quality assurers holding older qualifications must be able to demonstrate that they are assessing to current standards.
- have undertaken the appropriate assessor qualification identified by the regulator and practised as an assessor prior to undertaking the IQA role.

It is recognised that internal quality assurers are expected to quality assure the assessment process and not reassess the evidence provided.
Co-ordinating Assessors and Lead Assessors

In order that the requirements for occupational competence of assessors can be met while allowing flexibility of delivery, candidates may have more than one assessor involved in the assessment process.

Where more than one assessor is involved in the qualification there must be a named assessor who is responsible for the overall co-ordination of the assessment for each candidate. This person will be responsible for integrating, planning and directing assessment for the whole qualification.

Where more than one assessor is involved in a unit, there must be named assessor who is responsible for the overall coordination of the assessment for that unit. The lead assessor must ensure that the best use is made of all available evidence and will make the final judgment of competence in each unit where other assessors have been involved.

It is expected that all assessors will work closely with internal quality assurers to ensure standardised practice and judgments within the assessment process.

Qualification consultants

Qualification consultants must:

- be a registered and practising Pharmacist or a practising Pharmacy Technician
- other than in Northern Ireland, be registered or eligible to register with the Pharmacy regulator.
- have working knowledge of pharmacy and/or GP dispensing settings, the regulation, legislation and codes of practice for the service (where applicable), and the requirements of national standards at the time any assessment is taking place
- hold, or be working towards, the appropriate Qualification consultant qualification as identified by the qualifications regulators. Qualification consultants holding older qualifications must be able to demonstrate that they are assessing to current standards
- who are not yet qualified against the appropriate competences but have the necessary occupational competence and experience, can be supported by a qualified external verifier who does not necessarily have the occupational expertise or experience.
- have credible experience which is clearly demonstrable through continuing learning and development.

Assessment centres

Assessment centres will be responsible for maintaining up-to-date information on assessors, internal verifiers and expert witnesses and for ensuring the currency of the competence of internal verifiers and all those involved in the assessment process.

Continuing professional development (CPD)

Centres are expected to support their staff in ensuring that their knowledge remains current of the occupational area and of best practice in delivery, mentoring, training, assessment and verification, and that it takes account of any national or legislative developments.

Candidate entry requirements

Candidates should not be entered for a qualification of the same type, content and level as that of a qualification they already hold.

Centres should review the entry profile of learners to consider ability to progress to and achieve a L3 qualification. The General Pharmaceutical Council expect learners to have the equivalent of four GCSEs at grade C or above, including mathematics, English language, science and one other subject. Please note, however, that this is a guide only and that centres must have processes in place to review candidates’ qualifications and experience in order to ensure that they have the potential and opportunity to gain the qualification successfully.
2 Course design and delivery

2.1 Initial assessment and induction
Centres will need to make an initial assessment of each candidate prior to the start of their programme to ensure they are entered for an appropriate type and level of qualification.

The initial assessment should identify:
- any specific training needs the candidate has, and the support and guidance they may require when working towards their qualification. This is sometimes referred to as diagnostic testing.
- any units the candidate has already completed, or credit they have accumulated which is relevant to the qualification they are about to begin.

City & Guilds recommends that centres provide an induction programme to ensure the candidate fully understands the requirements of the qualification they will work towards, their responsibilities as a candidate, and the responsibilities of the centre. It may be helpful to record the information on a learning contract.

2.2 Recommended delivery strategies
Centre staff should familiarise themselves with the structure, content and assessment requirements of the qualification before designing a course programme.

Centres may design course programmes of study in any way which:
- best meets the needs and capabilities of their candidates
- satisfies the requirements of the qualification.

When designing and delivering the course programme, centres might wish to incorporate other teaching and learning that is not assessed as part of the qualification. This might include the following:
- literacy, language and/or numeracy
- personal learning and thinking
- personal and social development
- employability.

Where applicable, this could involve enabling the candidate to access relevant qualifications covering these skills.
3 Assessment

3.1 Summary of assessment methods
For this qualification candidates will be required to complete the following assessments:

- one test for each unit.

For each unit City & Guilds has provided two versions of the test (Version A and Version B). The two versions should be used for multiple cohorts of candidates and to enable resits (eg candidates who fail the Version A test must take the Version B for the resit and vice versa). Centres may use either version for the first paper.

The tests should be taken under supervised conditions. This means that all activities will be completed with the assessor, or other designated supervisor, present. Strict exam regulations do not apply; it is envisaged that most candidates will take the short-answer questions in their normal learning environment with their own tutor present. No word count applies.

City & Guilds has provided marking guides for all tests. The tests must be marked by the centre using the marking and grading criteria provided. Only whole marks should be awarded, half marks are not permitted.

The tests and marking guides are available to download from www.cityandguilds.com. All documents are password protected. The password can be found on the Walled Garden.

All documents must be held securely by centres and not made available to candidates until the time of exam. All completed tests should be securely stored by the centre for verification by City & Guilds, and under no circumstances should candidates be allowed to take question papers away with them.

Using the assessment marking guides
Only the knowledge required by the unit may be considered for marking and grading. Any additional skills displayed but which are not required for the unit (eg high levels of presentation) should not influence the marking or grading. For unit specific grading please see individual marking guides.

The answers supplied in the marking guides should be used as a guide and assessors should use professional judgement if a candidate’s answers differ from those provided. Answers supplied may not provide an exhaustive list of correct answers in all cases. Where the candidate has given an answer which in the professional opinion of the assessor is correct, the allocated marks can be awarded.

Time constraints
The following time constraints must be applied to the assessment of this qualification:

- each paper has a recommended time allowance; Please note this is a guide only. Candidates should not be penalised if they take longer to complete the test. However, centres should adhere to the recommended duration where possible. Please see individual marking guides for durations
- candidates must be assessed within the lifespan of the qualification
- all assignments must be completed and assessed within the candidate’s period of registration. Centres should advise candidates of any internal timescales for the completion and marking of individual assignments.
Resits
Candidates who have failed an assessment are permitted two more attempts only. Please note on resits candidates may only achieve a pass overall. The centre must provide appropriate feedback and support to enable the candidate to re-sit. If a candidate has failed and does not meet the assessment criteria in the third re-sit, the candidate has failed the unit and the centre should either:
- guide the candidate towards a more suitable qualification, or
- inform the candidate of the right to appeal.

Use of resources
The assessment has been designed to assess the ability of candidates to cover a range of knowledge associated with each unit. City & Guilds expects candidates to have a good understanding of the basic principles of the main medicines used in each therapeutic area. The BNF will be available as an allowed reference source in assessments where it would be appropriate. Please see Assessor guidance for the conditions on the use of the BNF.

For further guidance on assessment requirements please refer to Assessor guidance document which can be downloaded from www.cityandguilds.com.
### 3.2 Test specifications

The test specifications for the units and qualifications are below:

#### Unit 301: Chemical principles for pharmacy technicians

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of Marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>301</td>
<td>1. Understand how the atomic and electronic structure of elements influences the arrangement of the periodic table and bonding</td>
<td>15</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>2. Understand the principles behind chemical reactions</td>
<td>17</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>3. Carry out calculations involving quantities and concentrations</td>
<td>10</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>42</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

#### Unit 302: Biological principles for pharmacy

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>302</td>
<td>1. Understand the basic structure and function of carbohydrates, lipids and proteins</td>
<td>21</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>2. Understand the structure and functions of enzymes</td>
<td>11</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>3. Understand the structure and functions of nucleic acids</td>
<td>23</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>4. Understand the biological significance of water</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>57</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

#### Unit 303: Microbiology for pharmacy

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>303</td>
<td>1. Understand the structure and function of micro-organisms, including their classification</td>
<td>14</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>2. Understand the growth of micro-organisms including the biological, chemical, and physical requirements for growth</td>
<td>18</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>3. Understand microbial control of the environment</td>
<td>9</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>4. Understand the transmission of infectious disease</td>
<td>12</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>53</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>
## Unit 304: Human physiology for pharmacy

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>304</td>
<td>1. Know different types of human cells and tissue</td>
<td>32</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>2. Understand the structure and function of musculoskeletal system and the digestive system</td>
<td>33</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>3. Understand the cardiovascular, respiratory and lymphatic systems in the human body</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>4. Know how the human body’s nervous system and sensory organs function</td>
<td>24</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>5. Know how the endocrine system and the genitourinary system function</td>
<td>26</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>131</td>
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</table>

## Unit 305: Action and uses of medicines

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>305</td>
<td>1. Understand the basic principles of how medicines work in the human body</td>
<td>19</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>2. Know about the uses and limitations of medicines including their management in practice</td>
<td>16</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>3. Know how to use standard pharmacy resources to research answers to pharmaceutical queries</td>
<td>12</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>47</td>
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</table>

## Unit 306: Gastrointestinal and nutritional medicines

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>306</td>
<td>1. Understand how medicines are used to treat disorders of the gastrointestinal tract</td>
<td>28</td>
<td>52</td>
</tr>
<tr>
<td></td>
<td>2. Understand how medicines are used to treat nutritional disorders</td>
<td>13</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>3. Understand how medicines are used in the treatment of blood disorders</td>
<td>13</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>54</td>
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</table>
### Unit 307: Cardio-respiratory medicines

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>307</td>
<td>1. Understand how medicines are used to treat disorders of the respiratory systems</td>
<td>28</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>2. Understand how medicines are used to treat disorders of the cardiovascular system</td>
<td>42</td>
<td>51</td>
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<td>3. Understand how to advise patients to manage their conditions</td>
<td>12</td>
<td>15</td>
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### Unit 308: Central nervous system medicines and anaesthesia

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>308</td>
<td>1. Know how medicines are used to treat disorders of the central nervous system</td>
<td>28</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>2. Understand how medicines are used to treat mental health disorders</td>
<td>28</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>3. Understand how medicines are used in the treatment and management of pain</td>
<td>13</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>4. Understand how medicines are used in anaesthesia</td>
<td>9</td>
<td>11</td>
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<td></td>
<td>Total</td>
<td>78</td>
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### Unit 309: Infections, immunological products and vaccines

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>309</td>
<td>1. Understand how medicines are used to treat infections</td>
<td>41</td>
<td>77</td>
</tr>
<tr>
<td></td>
<td>2. Understand the uses of commonly available immunological products</td>
<td>12</td>
<td>23</td>
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<tr>
<td></td>
<td>Total</td>
<td>53</td>
<td>100</td>
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</table>
### Unit 310: Endocrine and genito-urinary medicines

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>310</td>
<td>1. Understand how medicines are used to treat disorders of the endocrine system</td>
<td>42</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>2. Understand how medicines are used to treat gynaecological disorders and in obstetrics</td>
<td>51</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>3. Understand how medicines are used to treat genito-urinary disorders</td>
<td>46</td>
<td>33</td>
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<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>139</strong></td>
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</table>

### Unit 311: Malignant disease, immunosuppressive and musculoskeletal medicines

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>311</td>
<td>1. Know the behavioural difference between normal cells and malignant cells</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>2. Understand the treatments used for malignant diseases</td>
<td>39</td>
<td>44</td>
</tr>
<tr>
<td></td>
<td>3. Understand how medicines are used to treat musculoskeletal disorders</td>
<td>42</td>
<td>47</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>89</strong></td>
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</table>

### Unit 312: Ear, eye, nose and dermatological medicines

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>312</td>
<td>1. Know how medicines are used to treat disorders of the eye</td>
<td>33</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>2. Know how medicines are used to treat disorders of the ear</td>
<td>14</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>3. Know how medicines are used to treat disorders of the nose</td>
<td>14</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>4. Know how medicines are used to treat disorders affecting the mouth and throat</td>
<td>28</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>5. Know how medicines are used in the treatment of dermatological disorders</td>
<td>30</td>
<td>25</td>
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<tr>
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<td><strong>Total</strong></td>
<td><strong>119</strong></td>
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### Unit 313: Community pharmacy practice

<table>
<thead>
<tr>
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<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>313</td>
<td>1. Understand how to assist in the provision of appliances, dressings and other non-medicinal products</td>
<td>26</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>2. Understand how to assist in the provision of services outside of the Pharmacy</td>
<td>9</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>3. Know the national and local regulations and policies regarding supply of medicines to patients in care</td>
<td>17</td>
<td>33</td>
</tr>
<tr>
<td></td>
<td>Total</td>
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</table>

### Unit 314: Professional development in pharmacy

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>314</td>
<td>1. Understand the importance of effective communications with the customers of the pharmacy</td>
<td>23</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>2. Know how to perform as part of an effective pharmacy team</td>
<td>14</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>3. Understand the importance of supporting own learning and that of others</td>
<td>25</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>4. Understand the importance of continuing professional development</td>
<td>19</td>
<td>23</td>
</tr>
<tr>
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</table>

### Unit 315: Communicating in pharmacy

<table>
<thead>
<tr>
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<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>315</td>
<td>1. Understand how to provide relevant information and advice on medicines and products</td>
<td>7</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>2. Understand the correct procedures for the sale and supply of over-the-counter medicines</td>
<td>20</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>3. Know about health and health promotion</td>
<td>15</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>4. Understand how to prepare for a review of medicines taken by an individual</td>
<td>11</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>53</td>
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</table>
### Unit 316: Dispensing and supply of medicines

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>316</td>
<td>1. Understand the organisational policies and standard operating procedures with the pharmacy working environment</td>
<td>27</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>2. Understand the processes involved when dispensing prescriptions</td>
<td>14</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>3. Know how to order, receive, store and maintain pharmaceutical stock</td>
<td>29</td>
<td>41</td>
</tr>
<tr>
<td></td>
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<td>70</td>
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</table>

### Unit 317: Pharmaceutics

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>317</td>
<td>1. Understand how to perform accurate calculations for pharmaceutical formulae</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>2. Understand how to accurately weigh and measure ingredients for pharmaceutical products</td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>3. Understand factors that affect the formulation of pharmaceutical products</td>
<td>19</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>4. Know how to prepare pharmaceutical products</td>
<td>32</td>
<td>45</td>
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<tr>
<td></td>
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<td>71</td>
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</table>

### Unit 318: Pharmacy law, ethics and practice

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>318</td>
<td>1. Understand the laws regulating the sale and supply of medicines and non-medicinal poisons</td>
<td>38</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>2. Understand the laws governing the supply of controlled drugs</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>3. Know other laws that relate to the legal and safe delivery of pharmacy services</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>4. Know the organisations and staff groups relating to the delivery of pharmacy services</td>
<td>20</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>5. Understand the factors affecting standards in pharmacy services</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td></td>
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</table>
## Unit 319: Making medicines for pharmacy

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Outcome</th>
<th>No. of marks</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>319</td>
<td>1. Understand the legislation and guidelines controlling pharmaceutical manufacture</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>2. Know about the environment and equipment for pharmaceutical manufacture</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>3. Understand how medicines are manufactured</td>
<td>39</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>4. Understand the principles of quality assurance and quality control</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>5. Understand the aspetic preparation of pharmaceutical products</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>102</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>
Units

Availability of units
The units for this qualification follow. They may also be obtained from the centre resources section of the City & Guilds website.

The learning outcomes and assessment criteria are also viewable on the Ofqual Register of Regulated Qualifications [http://register.ofqual.gov.uk/](http://register.ofqual.gov.uk/)

Structure of units
The units in this qualification are written in a standard format and comprise the following:

- City & Guilds reference number
- unit accreditation number
- title
- level
- credit value
- unit aim
- relationship to NOS, other qualifications and frameworks
- endorsement by a sector or other appropriate body
- information on assessment
- learning outcomes which are comprised of a number of Assessment criteria
- notes for guidance.
### Summary of units

<table>
<thead>
<tr>
<th>City &amp; Guilds unit number</th>
<th>Title</th>
<th>Unit number</th>
<th>Credits</th>
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<tbody>
<tr>
<td>301</td>
<td>Chemical principles for pharmacy technicians</td>
<td>Y/601/7562</td>
<td>5</td>
</tr>
<tr>
<td>302</td>
<td>Biological principles for pharmacy</td>
<td>M/601/7566</td>
<td>5</td>
</tr>
<tr>
<td>303</td>
<td>Microbiology for pharmacy</td>
<td>L/601/9177</td>
<td>5</td>
</tr>
<tr>
<td>304</td>
<td>Human physiology for pharmacy</td>
<td>K/601/7789</td>
<td>10</td>
</tr>
<tr>
<td>305</td>
<td>Action and uses of medicines</td>
<td>L/601/9180</td>
<td>10</td>
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<tr>
<td>306</td>
<td>Gastrointestinal and nutritional medicines</td>
<td>A/601/7568</td>
<td>5</td>
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<tr>
<td>307</td>
<td>Cardio-respiratory medicines</td>
<td>T/601/7570</td>
<td>5</td>
</tr>
<tr>
<td>308</td>
<td>Central nervous system medicines and anaesthesia</td>
<td>J/601/7573</td>
<td>5</td>
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<tr>
<td>309</td>
<td>Infections, immunological products and vaccines</td>
<td>L/601/7574</td>
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<tr>
<td>310</td>
<td>Endocrine and genito-urinary medicines</td>
<td>Y/601/7576</td>
<td>5</td>
</tr>
<tr>
<td>311</td>
<td>Malignant disease, immunosuppressive and musculoskeletal medicines</td>
<td>D/601/7577</td>
<td>5</td>
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<tr>
<td>312</td>
<td>Eye, ear, nose and dermatological medicines</td>
<td>T/601/7794</td>
<td>5</td>
</tr>
<tr>
<td>313</td>
<td>Community pharmacy practice</td>
<td>R/601/9181</td>
<td>5</td>
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<tr>
<td>314</td>
<td>Professional development in pharmacy</td>
<td>A/601/7795</td>
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<td>315</td>
<td>Communicating in pharmacy</td>
<td>Y/601/9182</td>
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<tr>
<td>316</td>
<td>Dispensing and supply of medicines</td>
<td>J/601/7797</td>
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<td>317</td>
<td>Pharmaceutics</td>
<td>A/601/7800</td>
<td>10</td>
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<td>318</td>
<td>Pharmacy law, ethics and practice</td>
<td>L/601/7803</td>
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<tr>
<td>319</td>
<td>Making medicines for pharmacy</td>
<td>Y/601/7805</td>
<td>10</td>
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</tbody>
</table>
Unit 301  Chemical principles for pharmacy technicians

Level:  3
Credit value:  5
UAN number:  Y/601/7562

Unit aim
This aim of this unit is to give learners the underpinning knowledge of the fundamental principles of chemistry needed by Pharmacy Technicians.

Learning outcomes
There are three learning outcomes to this unit. The learner will be able to:
1. Understand how the atomic and electronic structure of elements influences the arrangement of the periodic table and bonding
2. Understand the principles behind chemical reactions
3. Carry out calculations involving quantities and concentrations

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 301 Chemical principles for pharmacy technicians
Outcome 1 Understand how the atomic and electronic structure of elements influences the arrangement of the periodic table and bonding

Assessment criteria
The learner can:
1. explain the periodic table in terms of the **atomic structure** of the **elements**
2. explain **inter** and **intra** molecular forces of attraction
3. explain **chemical bonding** between atoms and between molecules.

Range
- **Atomic structure**: protons, neutrons, electrons, arrangements of electrons around the nucleus, atomic number, mass number, periodicity of physical and chemical properties, isotopes
- **Elements**: the first 20 plus iron
- **Inter**: polar bonding and hydrogen bonding
- **Intra**: chemical bonding
- **Chemical bonding**: covalent and ionic
Unit 301  Chemical principles for pharmacy technicians
Outcome 2  Understand the principles behind chemical reactions

Assessment criteria
The learner can:
1. explain how chemical and physical factors affect the rates of reactions
2. explain the concept of PH
3. categorise the different functional groups for homologous series.

Range
- **Chemical and physical factors**: changes in concentration, temperature, pressure, surface area and catalysts
- **Concept of pH**: acid based reaction, pH scale
- **Categorise**: structural formulae, displayed formulae, isomers
- **Functional groups**: alkanes, alkenes, alkynes, aromatic hydrocarbons, aldehydes, ketones, alcohols, carboxylic acids, amines, amides, esters
- **Homologous series**: up to a 10 carbon chain
Unit 301  Chemical principles for pharmacy technicians
Outcome 3  Carry out calculations involving quantities and concentrations

Assessment criteria
The learner can:
1. accurately balance chemical equations
2. accurately carry out calculations involving molar quantities.

Range
- **Balance chemical equations:**
  - proportions in chemical reactions
  - balanced equations for chemical reactions
  - reacting masses
- **Calculations:** weights, volumes, concentrations, percentages
  - chemical quantities: relative atomic mass and relative molecular mass, relationship between atomic quantities and grams
- **Molar quantities:** the mole concept, molarity, calculation of amounts of substance in moles using equations eg moles = mass/relative molecular mass
  - Molar concentrations - mol/l, mmol/l, mmol/ml
Unit 302  Biological principles for pharmacy

Level: 3  Credit value: 5  UAN number: M/601/7566

Unit aim
The aim of this unit is for learners to develop knowledge of biological principles applicable to pharmacy. The unit will give the learner knowledge and understanding of the basic structure and functions of biological chemicals.

Learning outcomes
There are four learning outcomes to this unit. The learner will be able to:
1. Understand the basic structure and function of carbohydrates, lipids and proteins
2. Understand the structure and functions of enzymes
3. Understand the structure and functions of nucleic acids
4. Understand the biological significance of water

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 302 Biological principles for pharmacy

Outcome 1 Understand the basic structure and function of carbohydrates, lipids and proteins

Assessment criteria
The learner can:
1. describe the basic structure of carbohydrates, lipids and proteins
2. explain the functions of carbohydrates
3. explain the functions of lipids
4. explain the functions of proteins.

Range
- **Carbohydrates, lipids and proteins:**
  - Carbohydrates - mono, di, polysaccharides, glycosidic bonds
  - Lipids - saturated and unsaturated fatty acids, triglycerides, phospholipids
  - Proteins - essential and non essential amino acids, peptide bonds
- **Functions of carbohydrates:** source of energy
- **Functions of lipids:** energy, structure, insulation, protection
- **Functions of proteins:** enzyme transport, contractile, immuno, membrane, structural, hormones
Unit 302 Biological principles for pharmacy
Outcome 2 Understand the structure and functions of enzymes

Assessment criteria
The learner can:
1. describe the structure of enzymes
2. explain the role, functions and actions of enzymes.

Range
- Structure of enzymes: proteins, active sites, lock and key, induced fit
- Functions and actions of enzymes: biological catalysts, inhibitors, activators, common examples
Unit 302 Biological principles for pharmacy
Outcome 3 Understand the structure and functions of nucleic acids

Assessment criteria
The learner can:
1. explain the formation and structure of DNA and RNA
2. describe the functions of nucleic acids
3. describe the causes of mutations and their effects on the human body.

Range
- **Structure**: nucleotides, phosphate sugar backbone
- **Functions**: transcription, translation and basic protein synthesis
- **Causes**: evolution, chemical, radiation, infection
- **Effects**: beneficial, neutral, harmful
Unit 302 Biological principles for pharmacy
Outcome 4 Understand the biological significance of water

Assessment criterion
The learner can:
1. explain the biological functions of water in the human body.

Range
• Biological functions: solvent, lubrication, transport, temperature regulation
Unit 303  Microbiology for pharmacy

Level: 3  
Credit value: 5  
UAN number: L/601/9177

Unit aim  
The aim of this unit is to give learners an understanding of the relevance of microbiology to pharmacy.

Learning outcomes  
There are four learning outcomes to this unit. The learner will be able to:
1. Understand the structure and function of micro-organisms, including their classification
2. Understand the growth of micro-organisms, including the biological, chemical, and physical requirements for growth
3. Understand microbial control of the environment
4. Understand the transmission of infectious disease

Guided learning hours  
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body  
This unit is endorsed by Skills for Health.

Assessment  
This unit will be assessed by:
- an assignment based knowledge test.
Unit 303  Microbiology for pharmacy
Outcome 1  Understand the structure and function of microorganisms, including their classification

Assessment criteria
The learner can:
1. explain the classification of micro-organisms
2. explain how the structure of micro-organisms relates to their function.

Range
- **Micro-organisms**: bacteria, viruses, microscopic fungi, protozoa
- **Structure**: size, shape, cell arrangements, cellular structure
Unit 303 Microbiology for pharmacy
Outcome 2 Understand the growth of micro-organisms, including the biological, chemical, and physical requirements for growth

Assessment criteria
The learner can:
1. explain the growth and reproduction of micro-organisms
2. explain the factors that affect the growth of micro-organisms
3. explain the uses of different growth media.

Range
• Growth and reproduction of micro-organisms: binary fission, asexual reproduction, growth curves, bacterial counting including viable and total counts
• Micro-organisms: bacteria, viruses, microscopic fungi, protozoa
• Factors: pH, temperature, osmotic and atmospheric pressure, water, carbon, nitrogen, energy, trace nutrients
• Growth media: liquid, semi solid, selective/differential, enriched
Unit 303 Microbiology for pharmacy
Outcome 3 Understand microbial control of the environment

Assessment criteria
The learner can:
1. explain methods used to control and monitor the microbial content of the environment, including environment and personal hygiene
2. describe the different groups of disinfectants.

Range
- **Control and monitor**: bacterial counting including viable and total counts, basic principles of hygiene, anti-microbial agents, sterilisation, settle plates, surface swabs, finger dabs
- **Groups of disinfectants**: oxidising, non-oxidising
**Unit 303**  
**Microbiology for pharmacy**  
Outcome 4  
Understand the transmission of infectious disease

**Assessment criteria**
The learner can:
1. describe diseases caused by **pathogenic micro-organisms**
2. explain the role of micro-organisms in the **transmission** of disease and infections.

**Range**
- **Pathogenic micro-organisms**: bacteria, viruses, microscopic fungi, protozoa (with common examples of diseases caused)
- **Transmission**: airborne, direct contact, indirect contact
Unit 304 Human physiology for pharmacy

Level: 3
Credit value: 10
UAN number: K/601/7789

Unit aim
This unit aims to provide the learner with a broad knowledge of the structure and function of the human body as a basis for learning about the use of medicines.

Learning outcomes
There are five learning outcomes to this unit. The learner will be able to:
1. Know different types of human cells and tissue
2. Understand the structure and function of the musculoskeletal system and the digestive system
3. Understand the cardiovascular, respiratory and lymphatic systems in the human body
4. Know how the human body’s nervous system and sensory organs function
5. Know how the endocrine system and the genitourinary system function

Guided learning hours
It is recommended that 60 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 304  Human physiology for pharmacy
Outcome 1  Know different types of human cells and tissue

Assessment criteria
The learner can:
1. describe the **structure of human cells**
2. describe the **main types of human tissues**
3. describe the function of the **main human tissue types**.

Range
• **Structure of human cells:**
  - cell wall
  - nucleus
  - cytoplasm
  - mitochondria
  - rough and smooth endoplasmic reticulum
  - golgi body
  - lysosomes
• **Main types of human tissues:** epithelial, connective, muscle, nerve
Unit 304  Human physiology for pharmacy
Outcome 2  Understand the structure and function of the musculoskeletal system and the digestive system

Assessment criteria
The learner can:
1. describe the structure of the **musculoskeletal system**
2. explain the **function** of the **musculoskeletal system**
3. describe the structure of the **digestive system**
4. explain the **function** of the **digestive system**.

Range
- **Musculoskeletal system**: bones, muscles, cartilage, tendons, membranes, joints
- **Function**: movement, support, protection, blood cell production, storage of minerals (calcium)
- **Digestive system**: mouth, pharynx, oesophagus, stomach, pancreas, liver, gall bladder, small intestine, large intestine, rectum, anus
- **Function**: break down and absorption into the body of nutrients, elimination of waste products from the body
Unit 304  Human physiology for pharmacy
Outcome 3  Understand the cardiovascular, respiratory and lymphatic systems in the human body

Assessment criteria
The learner can:
1. describe the structure of the cardiovascular system
2. explain the function of the cardiovascular system
3. explain how the structure of the respiratory system aids gaseous exchange
4. explain how the structure of the lymphatic system contributes towards the body's defence mechanisms.

Range
• **Cardiovascular system**: blood, heart, blood vessels (arteries, veins, arterioles, venules, capillaries)
• **Function**: transport, defence, temperature regulation
• **Respiratory system**: nasal cavities, pharynx, larynx, trachea, bronchi, bronchioles, alveoli, capillary network
• **Lymphatic system**: lymphatic vessels, lymph nodes, spleen, drainage of tissue fluid, formation of lymph
Unit 304  Human physiology for pharmacy
Outcome 4  Know how the human body's nervous system and sensory organs function

Assessment criteria
The learner can:
1. describe how the organisation of the nervous system affects its function
2. describe the structure of the body's sensory organs
3. explain the function of the sensory organs.

Range
- **Nervous system**: central nervous system, peripheral nervous system, somatic and autonomic control, sympathetic and parasympathetic, structure of a neuron, sense organs, effector organs, initiation and transmission of nerve impulse, synapses, sensory and motor neurones, reflex arc
- **Sensory organs**: eyes, ears, mouth, nose, skin
- **Function**: sight, hearing, taste, smell, touch
Unit 304  Human physiology for pharmacy
Outcome 5  Know how the endocrine system and the genitourinary system function

Assessment criteria
The learner can:
1. describe the structure of the endocrine system
2. explain the function of each endocrine gland
3. define homeostasis
4. describe how the urinary system assists the regulation of body fluids in the body
5. describe the structure of the reproductive system
6. explain the function of the reproductive system
7. describe foetal development from conception to birth.

Range
• Endocrine system:
  o pituitary gland
  o hypothalamus
  o thyroid
  o parathyroid
  o pancreas
  o adrenal medulla
  o adrenal cortex
  o gonads
• Function: homeostatic regulation of hormones, hormone characteristics, endocrine control and feedback, hormones produced by each gland
• Urinary system:
  o kidney
  o ureters
  o urethra
  o bladder
  o nephron
• Regulation: filtration, absorption, urine production, storage and release, electrolyte, pH balance
• Reproductive system:
  o Male (testis, epididymis, scrotum, sperm duct, penis, accessory glands)
  o Female (ovary, oviducts, uterus, vagina, external genitalia, mammary glands)
• Function: production of gametes, hormonal regulation of sperm production in male and female ovarian and menstrual cycles, fertilisation, pregnancy and birth, lactation
• Foetal development: fertilisation, stages of development (trimesters), birth
Unit 305  Action and uses of medicines

Level:  3  
Credit value:  10  
UAN number:  L/601/9180

Unit aim
This unit provides learners with basic information and concepts to help them understand how medicines work. It relates physiological function with disease and eventual treatment to help learners with their work in the pharmacy.

Learning outcomes
There are three learning outcomes to this unit. The learner will be able to:
1. Understand the basic principles of how medicines work in the human body
2. Know about the uses and limitations of medicines including their management in practice
3. Know how to use standard pharmacy resources to research answers to pharmaceutical queries

Guided learning hours
It is recommended that 60 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 305  Action and uses of medicines
Outcome 1  Understand the basic principles of how medicines work in the human body

Assessment criteria
The learner can:
1. describe the basic modes of actions of medicines on the human body
2. explain the reasons for using different routes for the administration of medicines.

Range
- Modes of actions:
  - receptors
  - agonists
  - antagonists
  - partial agonists
  - competition
  - reversibility
  - enzymes
  - ion channels with common examples

- Routes:
  - oral
  - intravenous
  - subcutaneous
  - intra-muscular
  - topical
  - nasal
  - rectal
  - vaginal
  - eyes
  - ears
  - buccal
  - transdermal
  - inhaled
Unit 305  Action and uses of medicines
Outcome 2  Know about the uses and limitations of medicines including their management in practice

Assessment criteria
The learner can:
1. describe the common drug/drug and drug/food interactions
2. describe factors which lead to the successful medicinal treatment of disorders.

Range
- **Interactions**: drug/drugs (absorption, distribution, metabolism, elimination, additive and antagonistic) with common examples, drug/food (St Johns Wort, grapefruit juice, green leafy vegetables, MAOI)
- **Factors**: adherence, patient knowledge, adverse drug reactions
Unit 305  Action and uses of medicines
Outcome 3  Know how to use standard pharmacy resources to research answers to pharmaceutical queries

Assessment criteria
The learner can:
1. describe the main sources of pharmaceutical information
2. describe how to select the appropriate sources of information to correctly answer a pharmaceutical query.

Range
- Main sources/sources of information: British National Formulary (BNF), British National Formulary for Children (BNFc), Martindale, Stockley’s drug interactions, pharmacy journals, local formularies, British Pharmacopoeia, online resources, medicines information departments in community and hospital (eg NPA, local medicines information)
Unit 306  Gastrointestinal and nutritional medicines

Level: 3  
Credit value: 5  
UAN number: A/601/7568

Unit aim
This unit examines the main medicine categories and their actions in the treatment of gastrointestinal, nutritional and blood disorders.

Learning outcomes
There are three learning outcomes to this unit. The learner will be able to:
1. Understand how medicines are used to treat disorders of the gastrointestinal tract
2. Understand how medicines are used to treat nutritional disorders
3. Understand how medicines are used in the treatment of blood disorders

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 306  

Gastrointestinal and nutritional medicines

Outcome 1  
Understand how medicines are used to treat disorders of the gastrointestinal tract

Assessment criteria
The learner can:
1. describe common disorders affecting the gastrointestinal tract
2. explain how common medicines are used in each of the gastrointestinal tract disorders
3. summarise common side effects of medicines used to treat disorders of the gastrointestinal tract
4. explain the information that must be given to patients about their gastrointestinal medicines.

Range
- **Common disorders**: indigestion, peptic ulcer disease, gastro-oesophageal reflux disorders (GORD), diarrhoea, constipation, irritable bowel syndrome, inflammatory bowel disease, haemorrhoids, anal fissures, nausea and vomiting
- **Common medicines**: refer to current edition of BNF for common medicines for the disorders listed
- **Common side effects**: refer to current edition of BNF for common side effects of the disorders listed
Unit 306  Gastrointestinal and nutritional medicines
Outcome 2  Understand how medicines are used to treat nutritional disorders

Assessment criteria
The learner can:
1. describe the problems arising from nutritional disorders
2. compare the routes used to provide artificial nutrition
3. explain how common medicines or foods are used in each of the nutritional disorders
4. summarise common side effects of medicines used to treat nutritional disorders.

Range
- Nutritional disorders: vitamin and mineral deficiencies, intolerances (gluten, lactose, glucose), metabolic disorders
- Routes: enteral (naso gastric, oral, percutaneous endoscopic gastrostomy), parenteral (central line and peripheral line)
- Common medicines: refer to current edition of BNF for common medicines for the disorders listed
- Common side effects: refer to current edition of BNF for common side effects of the disorders listed
Unit 306  Gastrointestinal and nutritional medicines
Outcome 3  Understand how medicines are used in the treatment of blood disorders

Assessment criteria
The learner can:
1. describe common disorders affecting the blood
2. explain how common medicines are used in each of the blood disorders
3. summarise common side effects of medicines used to treat blood disorders
4. explain the information that must be given to patients about their blood disorder medicines.

Range
• Common blood disorders: anaemia (iron, pernicious, megaloblastic), platelet disorders, glucose 6-phosphate dehydrogenase deficiency (G6PD), neutropenia, fluid and electrolyte imbalances
• Common medicines: refer to current edition of BNF for common medicines for the disorders listed
• Common side effects: refer to current edition of BNF for common side effects of the disorders listed
Unit 307  Cardio-respiratory medicines

Level: 3
Credit value: 5
UAN number: T/601/7570

Unit aim
This unit examines the main medicine categories and their actions in the treatment of cardiovascular and respiratory disorders.

Learning outcomes
There are three learning outcomes to this unit. The learner will be able to:
1. Understand how medicines are used to treat disorders of the respiratory system
2. Understand how medicines are used to treat disorders of the cardiovascular system
3. Understand how to advise patients to manage their conditions

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 307  Cardio-respiratory medicines
Outcome 1  Understand how medicines are used to treat disorders of the respiratory system

Assessment criteria
The learner can:
1. describe **common disorders** affecting the respiratory system
2. explain how **common medicines** are used in each of the respiratory disorders
3. summarise **common side effects** of medicines used to treat disorders of the respiratory system
4. explain information that must be given to patients about their respiratory medicines.

Range
- **Common disorders:**
  - asthma
  - COPD
  - cough
  - common cold
  - influenza
  - allergies, including hay fever
- **Common medicines:** refer to current edition of BNF for common medicines for the disorders listed
- **Common side effects:** refer to current edition of BNF for common side effects of the disorders listed
Unit 307  Cardio-respiratory medicines

Outcome 2  Understand how medicines are used to treat disorders of the cardiovascular system

Assessment criteria
The learner can:
1. describe common disorders affecting the cardiovascular system
2. explain how common medicines are used in each of the cardiovascular disorders
3. summarise common side effects of medicines used to treat disorders of the cardiovascular system
4. explain information that must be given to patients about their cardiovascular medicines.

Range
• Common disorders:
  o congestive heart failure
  o hypertension
  o hypotension
  o cardiac arrhythmias
  o angina
  o hypercholesterolaemia
  o hyperlipidaemia
  o myocardial infarction
  o cardiac arrest

• Common medicines: refer to current edition of BNF for common medicines for the disorders listed

• Common side effects: refer to current edition of BNF for common side effects of the disorders listed
Unit 307    Cardio-respiratory medicines
Outcome 3  Understand how to advise patients to manage their conditions

Assessment criteria
The learner can:
1. safely and accurately demonstrate the use of devices used in airways disease
2. produce a safe and effective plan to improve the lifestyle of a selected patient.

Range
- **Devices**: common inhaler devices, spacers, nebulisers, peak flow meters
- **Lifestyle**: smoking cessation, dietary changes, exercise, lipid lowering products
Unit 308 Central nervous system medicines and anaesthesia

Level: 3
Credit value: 5
UAN number: J/601/7573

Unit aim
This unit examines the main medicine categories and their actions affecting the central nervous system.

Learning outcomes
There are four learning outcomes to this unit. The learner will be able to:
1. Know how medicines are used to treat disorders of the central nervous system
2. Understand how medicines are used to treat mental health disorders
3. Understand how medicines are used in the treatment and management of pain
4. Understand how medicines are used in anaesthesia

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 308  Central nervous system medicines and anaesthesia

Outcome 1  Know how medicines are used to treat disorders of the central nervous system

Assessment criteria
The learner can:
1. describe common disorders affecting the central nervous system
2. explain how common medicines are used in each of the central nervous system disorders
3. summarise common side effects of medicines used to treat disorders of the central nervous system
4. explain the information that must be given to patients about their central nervous system medicines.

Range
- **Common disorders:**
  - epilepsy
  - Parkinson’s disease and related disorders
  - Attention Deficit Hyperactivity Disorder
  - narcolepsy
  - obesity
  - dementia

- **Common medicines:** refer to current edition of BNF for common medicines for the disorders listed

- **Common side effects:** refer to current edition of BNF for common side effects of the disorders listed
Unit 308  Central nervous system medicines and anaesthesia

Outcome 2  Understand how medicines are used to treat mental health disorders

Assessment criteria
The learner can:
1. describe common disorders affecting mental health, including addiction and substance misuse
2. explain how common medicines are used in each of the mental health disorders
3. summarise common side effects of medicines used to treat mental health disorders
4. explain the information that must be given to patients about their mental health medicines.

Range
- Common disorders:
  - anxiety and sleep disorders
  - affective disorders (unipolar, bipolar, depression)
  - psychotic disorders (schizophrenia, delusional disorders, mania)
  - addiction and substance misuse
- Common medicines: refer to current edition of BNF for common medicines for the disorders listed
- Common side effects: refer to current edition of BNF for common side effects of the disorders listed
Unit 308  Central nervous system medicines and anaesthesia

Outcome 3  Understand how medicines are used in the treatment and management of pain

Assessment criteria
The learner can:
1. discuss the prescribing of **pain control** in relation to the analgesic ladder
2. summarise **common side effects** of medicines used in the treatment and management of pain
3. explain the information that must be given to patients about their medicines for pain treatment and management.

Range
- **Pain control:**
  - Analgesics:
    - pain mechanism
    - psychological aspect of chronic pain
    - the need for regular pain control and the analgesic ladder
    - action and use of non opioids and opioids
    - action and use of adjuvant drugs
    - limitations of analgesia
    - dangers and treatment of overdose
    - action and use of treatments used for migraine
    - medicine and treatments for nausea and vertigo
- **Common side effects:** refer to current edition of BNF for common side effects
Unit 308  Central nervous system medicines and anaesthesia

Outcome 4  Understand how medicines are used in anaesthesia

Assessment criteria
The learner can:
1. explain the requirement for combination drug use in general anaesthesia
2. explain the reasons for different administration routes for local anaesthetics.

Range
- Combination drug use:
  o intravenous anaesthetics
  o inhalation anaesthetics
  o anti-muscarinic
  o anxiolytic, analgesia
  o antiemetic
  o perioperative drugs
  o muscle relaxants
  o reversal
- Local anaesthetics:
  o epidural and intrathecal
  o use of vasoconstrictors
  o action of local anaesthetic
Unit 309  Infections, immunological products and vaccines

Level: 3
Credit value: 5
UAN number: L/601/7574

Unit aim
This unit will provide learners with an understanding of the main medicine categories, including immunological products and vaccines used in the treatment and prevention of infections.

Learning outcomes
There are two learning outcomes to this unit. The learner will be able to:
1. Understand how medicines are used to treat infections
2. Understand the uses of commonly available immunological products

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 309  Infections, immunological products and vaccines

Outcome 1 Understand how medicines are used to treat infections

Assessment criteria
The learner can:
1. describe common infections and their associated symptoms
2. explain how common medicines are used to treat infections, giving examples of those in common use
3. summarise common side effects of medicines used to treat infections
4. explain the information that must be given to patients about their infection-treating medicines
5. discuss the factors that influence the selection of antimicrobial medicines.

Range
• Common infections:
  o bacterial (tuberculosis, UTI, lower respiratory tract infection, conjunctivitis, impetigo)
  o viral (influenza, common cold, herpes simplex, HIV)
  o fungal (aspergillosis, candidiasis (oral and vaginal), nail and skin fungal infections)
  o protazoal (malaria)
  o infestations (roundworm, tapeworm)
• Common medicines: refer to current edition of BNF for common medicines
• Common side effects: refer to current edition of BNF for common side effects
• Factors: type of micro-organism, type of infection, patient factors, interacting medicines taken
**Unit 309**  
**Infections, immunological products and vaccines**

**Outcome 2**  
Understand the uses of commonly available immunological products

**Assessment criteria**  
The learner can:

1. explain the **general principles** and **benefits** of vaccination
2. discuss vaccines in the **current UK vaccination schedule**, giving examples of the current schedule
3. explain why **correct storage** of immunological products is vital, providing examples of best practice and workplace policies.

**Range**

- **General principles**: production of antibodies, types of vaccine (live attenuated, inactivated, detoxified exotoxins, extracts of microorganisms), acquisition of immunity
- **Benefits**: to individual, to community
- **Current UK vaccination schedule**: childhood vaccination, travel vaccination, as described in current edition of BNF
- **Correct storage**: refrigeration, protection from light
Unit 310  Endocrine and genito-urinary medicines

Level: 3  
Credit value: 5  
UAN number: Y/601/7576

Unit aim
This unit examines the main medicine categories and their actions in the treatment of endocrine genito-urinary disorders.

Learning outcomes
There are three learning outcomes to this unit. The learner will be able to:
1. Understand how medicines are used to treat disorders of the endocrine system
2. Understand how medicines are used to treat gynaecological disorders and in obstetrics
3. Understand how medicines are used to treat genito-urinary disorders

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 310  Endocrine and genito-urinary medicines
Outcome 1  Understand how medicines are used to treat disorders of the endocrine system

Assessment criteria
The learner can:
1. describe common disorders affecting the endocrine system
2. explain how common medicines are used in each of the endocrine system disorders
3. summarise common side effects of medicines used to treat disorders of the endocrine system
4. explain the information that must be given to patients about their endocrine medicines.

Range
• Common disorders:
  o Adrenal: excess and deficiency
  o Thyroid: hypothyroidism, hyperthyroidism
  o Pancreas: diabetes, hypoglycaemia, pancreatitis
  o Sex hormone: excess and deficiency, Poly Cystic Ovarian Syndrome, menopause, hormone replacement therapy and its use in osteoporosis
  o Hypothalamic and pituitary: adrenal insufficiency
  o Tumours of endocrine glands
• Common medicines: refer to current edition of BNF for common medicines for the disorders listed
• Common side effects: refer to current edition of BNF for common side effects of the disorders listed
Unit 310  Endocrine and genito-urinary medicines

Outcome 2  Understand how medicines are used to treat gynaecological disorders and in obstetrics

Assessment criteria

The learner can:
1. describe common gynaecological and obstetric disorders
2. explain how common medicines are used in each of the gynaecological and obstetric disorders
3. summarise common side effects of medicines used to treat gynaecological and obstetric disorders
4. explain the information that must be given to patients about their gynaecological or obstetrics medicines.
5. describe the use, limitations and side effects of the main methods of contraception.

Range

- **Common gynaecological and obstetric disorders:**
  - Endometriosis
  - Polycystic Ovarian Syndrome
  - Pre-menstrual Syndrome
  - Pelvic Inflammatory Disease
  - Dysmenorrhea
  - Amenorrhea
  - Menopausal symptoms
  - Bacterial Vaginosis
  - induction of abortion
  - induction of labour
  - haemorrhage
  - premature labour

- **Common medicines:** refer to current edition of BNF for common medicines for the disorders listed

- **Common side effects:** refer to current edition of BNF for common side effects of the disorders listed

- **Main methods of contraception:**
  - combined hormonal contraceptives
  - progestogen-only contraceptives
  - spermicidal contraceptives
  - intra-uterine devices
  - contraceptive caps
  - contraceptive diaphragms
  - emergency contraception - hormonal, IUD
Unit 310  Endocrine and genito-urinary medicines
Outcome 3  Understand how medicines are used to treat genito-urinary disorders

Assessment criteria
The learner can:
1. describe **common disorders** affecting the genito-urinary system
2. explain how **common medicines** are used in each of the genito-urinary disorders
3. summarise **common side effects** of medicines used to treat genito-urinary disorders
4. explain the information that must be given to patients about their genito-urinary medicines
5. describe the **effect** that renal dialysis will have on patient medication.

Range
- **Common disorders:**
  - genital infection
  - sexually transmitted diseases
  - candidiasis
  - urinary retention
  - urinary incontinence
  - nocturnal enuresis
  - benign prostatic hyperplasia
  - erectile disorders
  - kidney disease
- **Common medicines:** refer to current edition of BNF for common medicines for the disorders listed
- **Common side effects:** refer to current edition of BNF for common side effects of the disorders listed
- **Effect:**
  - type of dialysis
  - dialysis equipment used
  - molecular weight of drugs
  - water solubility of drugs
  - protein binding
  - affective volume of distribution
  - usual route of clearance
  - body weight
Unit 311  Malignant disease, immunosuppressive and musculoskeletal medicines

Level: 3
Credit value: 5
UAN number: D/601/7577

Unit aim
This unit aims to provide learners with knowledge of the action and uses of drugs in the treatment of malignancy, immunosuppressive and musculoskeletal disorders.

Learning outcomes
There are three learning outcomes to this unit. The learner will be able to:
1. Know the behavioural difference between normal cells and malignant cells
2. Understand the treatments used for malignant diseases
3. Understand how medicines are used to treat musculoskeletal disorders

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 311  Malignant disease, immunosuppressive and musculoskeletal medicines

Outcome 1  Know the behavioural difference between normal cells and malignant cells

Assessment criterion
The learner can:
1. describe the **behavioural differences** between normal and malignant cells.

Range
- **Behavioural differences**: normal cells growth, malignant cells growth, metastasis
Unit 311 Malignant disease, immunosuppressive and musculoskeletal medicines

Outcome 2 Understand the treatments used for malignant diseases

Assessment criteria
The learner can:
1. describe the common malignant diseases
2. explain how common treatments are used in the treatment of malignant diseases
3. summarise common side effects of treatments used for malignant diseases
4. explain the information that must be given to patients about their medicines for the treatment of malignant diseases.

Range
- Common malignant diseases:
  - carcinoma
  - sarcoma
  - leukaemia
  - lymphoma
  - germ cell tumours
  - blastomas
  - gliomas
  - melanomas
- Common treatments:
  - different types of surgery
  - radiotherapy
  - refer to current edition of BNF
- Common side effects:
  - side effects of radiotherapy
  - refer to current edition of BNF for common side effects of the diseases listed
Unit 311 Malignant disease, immunosuppressive and musculoskeletal medicines

Outcome 3 Understand how medicines are used to treat musculoskeletal disorders

Assessment criteria
The learner can:
1. describe common disorders affecting the musculoskeletal system
2. explain how common treatments are used in the treatment of musculoskeletal disorders
3. summarise common side effects of treatments used for musculoskeletal disorders
4. explain the information that must be given to patients about their musculoskeletal medicines.

Range
- **Common disorders:**
  - osteoarthritis
  - rheumatoid arthritis
  - osteoporosis
  - Paget’s disease
  - gout
  - soft tissue injuries (i.e., sprains, strains, ruptures, deep bruising)
  - multiple sclerosis
  - myasthenia gravis
- **Common treatments:**
  - OTC rubefacients
  - topical anti-rheumatics
  - OTC treatment of soft tissue injury (including rest, ice, compression, elevation)
  - refer to current edition of BNF
- **Common side effects:** refer to current edition of BNF for common side effects of the disorders listed
Unit 312  Eye, ear, nose and dermatological medicines

Level: 3
Credit value: 5
UAN number: T/601/7794

Unit aim
This unit examines the main medicine categories and their actions in the treatment of gastrointestinal, nutritional and blood disorders.

Learning outcomes
There are five learning outcomes to this unit. The learner will be able to:
1. Know how medicines are used to treat disorders of the eye
2. Know how medicines are used to treat disorders of the ear
3. Know how medicines are used to treat disorders of the nose
4. Know how medicines are used to treat disorders affecting the mouth and throat
5. Know how medicines are used in the treatment of dermatological disorders

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 312  Eye, ear, nose and dermatological medicines
Outcome 1  Know how medicines are used to treat disorders of the eye

Assessment criteria
The learner can:
1. describe common disorders affecting the eye
2. explain how common medicines are used in each of the disorders of the eye
3. summarise common side effects of medicines used to treat disorders of the eye
4. explain the information that must be given to the patient about their eye medicines.

Range
- **Common disorders:**
  - glaucoma
  - infective and allergic conjunctivitis
  - tear deficiency
  - inflammatory disorders
  - myopia
  - hypermetropia
  - astigmatism
  - cataracts
  - floaters
- **Common medicines:** refer to current edition of BNF for common medicines for the disorders listed
- **Common side effects:** refer to current edition of BNF for common side effects of the disorders listed
Unit 312  

Eye, ear, nose and dermatological medicines

Outcome 2  
Know how medicines are used to treat disorders of the ear

Assessment criteria

The learner can:
1. describe the problems arising from **ear disorders**
2. explain how **common medicines** are used in each of the disorders of the ear
3. outline **common side effects** of medicines used to treat disorders of the ear
4. explain information that must be given to the patient about their ear medicines.

Range

- **Ear disorders**: otitis externa, otitis media, ear wax
- **Common medicines**: refer to current edition of BNF for common medicines for the disorders listed
- **Common side effects**: refer to current edition of BNF for common side effects of the disorders listed
Unit 312  Eye, ear, nose and dermatological medicines
Outcome 3  Know how medicines are used to treat disorders of the nose

Assessment criteria
The learner can:
1. describe the problems arising from disorders of the nose
2. explain how common medicines are used in each of the disorders of the nose
3. outline common side effects of medicines used to treat disorders of the nose
4. explain the information that must be given to the patient about their nose medicines.

Range
• Disorders of the nose: allergic rhinitis, rhinitis, nasal congestion, staphylococcal infections
• Common medicines: refer to current edition of BNF for common medicines for the disorders listed
• Common side effects: refer to current edition of BNF for common side effects of the disorders listed
Unit 312  
**Eye, ear, nose and dermatological medicines**

**Outcome 4**  
Know how medicines are used to treat disorders affecting the mouth and throat

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**Assessment criteria**

The learner can:

1. describe the problems arising from *disorders of the mouth and throat*
2. explain how *common medicines* are used in each of the disorders of the mouth and throat
3. outline *common side effects* of medicines used to treat disorders of the mouth and throat
4. explain the information that must be given to the patient about their mouth and throat medicines.

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**Range**

- **Disorders of the mouth and throat:**
  - gingivitis
  - mouth ulcers
  - cold sores
  - oral thrush
  - dry mouth
  - sore throat

- **Common medicines:** refer to current edition of BNF for common medicines for the disorders listed

- **Common side effects:** refer to current edition of BNF for common side effects of the disorders listed
Unit 312  
Eye, ear, nose and dermatological medicines

Outcome 5  
Know how medicines are used in the treatment of dermatological disorders

Assessment criteria
The learner can:
1. describe the common disorders affecting the skin, hair and nails
2. explain how common medicines are used in each of the disorders of the skin, hair and nails
3. outline common side effects of medicines used to treat disorders of the skin, hair and nails
4. explain information that must be given to the patient about their skin, hair and nail medicines.

Range

- **Common disorders:**
  - eczema
  - dermatitis
  - psoriasis
  - dry skin
  - acne
  - rosacea
  - dandruff
  - impetigo
  - tinea
  - athletes foot
  - ringworm
  - onychomycosis
  - lice
  - scabies
  - warts
  - verrucas
  - pruritus
  - bites
  - stings
  - rashes
  - burns, including sunburn

- **Common medicines:** refer to current edition of BNF for common medicines for the disorders listed

- **Common side effects:** refer to current edition of BNF for common side effects of the disorders listed
Unit 313  Community pharmacy practice

Level:          3
Credit value:  5
UAN number:    R/601/9181

Unit aim
This unit provides the knowledge required to assist in the supply of appliances, dressings and other non-medicinal products, and the provision of services outside of the pharmacy.

Learning outcomes
There are three learning outcomes to this unit. The learner will be able to:
1. Understand how to assist in the provision of appliances, dressings and other non-medicinal products
2. Understand how to assist in the provision of services outside of the pharmacy
3. Know the national and local regulations and policies regarding supply of medicines to patients in care

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 313  Community pharmacy practice
Outcome 1  Understand how to assist in the provision of appliances, dressings and other non-medicinal products

Assessment criteria
The learner can:
1. explain how to prepare for the supply of appliances, dressings and surgical hosiery, meeting individual and prescriber requirements
2. explain the information required by an individual or Healthcare Professional when supplying appliances, dressings or surgical hosiery.

Range
• Appliances:
  o bandages
  o ostomy
  o continence equipment
  o catheters
  o compression hosiery
  o lymphoedema garments
  o inhaler spacer devices
  o trusses
  o compliance aids

• Information required:
  o products allowable on prescription
  o endorsements required
  o purpose of the appliance
  o how to use the appliance
  o range available
Unit 313  Community pharmacy practice
Outcome 2  Understand how to assist in the provision of services outside of the pharmacy

Assessment criteria
The learner can:
1. explain how to prepare for and deliver a service to individuals that are unable to attend the pharmacy
2. describe health and safety risks when delivering services outside the pharmacy.

Range
- **Service**: collection and delivery, MURs at home
Unit 313  Community pharmacy practice
Outcome 3  Know the national and local regulations and policies regarding supply of medicines to patients in care

Assessment criteria
The learner can:
1. describe the regulations and policies for the supply of medicines to care homes
2. describe the use of monitored dosage system.

Range
- Care homes: residential, nursing, mixed, children's, mental health, elderly care
- Monitored dosage system: available products, purpose, SOPs, MAR sheets
Unit 314 Professional development in pharmacy

Level: 3
Credit value: 5
UAN number: A/601/7795

Unit aim
This unit aims to provide the learner with the knowledge and understanding to function as a professional in the pharmacy environment and give them the necessary skills to support their own learning and that of others.

Learning outcomes
There are four learning outcomes to this unit. The learner will be able to:
1. Understand the importance of effective communications with the customers of the pharmacy
2. Know how to perform as part of an effective pharmacy team
3. Understand the importance of supporting own learning and that of others
4. Understand the importance of continuing professional development

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 314  Professional development in pharmacy
Outcome 1  Understand the importance of effective communications with the customers of the pharmacy

Assessment criteria
The learner can:
1. identify the different customers that use the pharmacy service
2. explain the key features of effective communication in pharmacy settings
3. describe customers’ needs and how to respond appropriately
4. explain how to deal with complaints or conflict in pharmacy settings
5. explain the importance of customer confidentiality in a pharmacy setting.

Range
- Customers: internal, external
- Effective communication: verbal, non-verbal, listening skills, questioning skills, consultation skills, face to face, telephone, electronic, written
- Customers’ needs: urgent requests, special requirements, the need for information and advice
- Complaints: internal, external, service/product related, formal, informal, standard operating procedures
- Conflict: within pharmacy team, outside pharmacy team, personal differences, poor communication, bullying and harassment
- Customer confidentiality: legal and ethical requirements, GPhC Guidance on Patient confidentiality
Unit 314  Professional development in pharmacy  
Outcome 2  Know how to perform as part of an effective pharmacy team

Assessment criteria  
The learner can:
1. explain the principles of **effective team working** in a pharmacy setting  
2. recognise **styles of interactions** between pharmacy team members  
3. outline **strategies** for handling problem relationships within the pharmacy team.

Range  
- **Effective team working**: organisation, objectives, communication, respect, clearly defined roles, training, pharmacy profession code of ethics, standard operating procedures  
- **Styles of interactions**: Belbin, Myers Briggs  
- **Strategies**: grievance procedure, performance management, mediation, discussion
Unit 314  Professional development in pharmacy
Outcome 3  Understand the importance of supporting own learning and that of others

Assessment criteria
The learner can:
1. describe different learning styles
2. compare different learning environments
3. explain the use of different instructional techniques
4. describe how demonstrations are structured.

Range
- Learning styles: VARK, Kolb, Honey and Mumford
- Learning environments: classroom, workplace, e-learning
- Different instructional techniques: lecture, guided discussion, tutorial, demonstration, role play, simulation, individualised instruction, structured lesson
- Demonstrations: assess trainee's current knowledge level, explain what will be covered, use SOPs to break into logical steps, demonstrate, summarise, assess understanding
Unit 314 Professional development in pharmacy
Outcome 4 Understand the importance of continuing professional development

Assessment criteria
The learner can:
1. discuss development opportunities to improve practice
2. review successful interventions and learn from these
3. explain how to learn from errors, critical incidents and enquiries into serious failings
4. describe how to record their CPD.

Range
- **Development opportunities:**
  - lectures
  - audit
  - study days
  - meetings
  - projects
  - discussion with colleagues
  - work shadowing
  - reading
  - learning by doing
  - research
  - distance learning
  - conferences
  - e-learning
  - presentations
- **Learn:** group or individual reflection, root cause analysis, audits, risk assessments, CHAPS (GPhC Responding to Complaints and Concerns)
- **CPD:** reflection, planning, action, evaluation, on-line CPD recording system, local and national support for CPD activities, GPhC CPD professional standards
Unit 315  Communicating in pharmacy

Level: 3  
Credit value: 5  
UAN number: Y/601/9182

Unit aim
This unit delivers the knowledge required by Pharmacy Technicians to effectively communicate in a pharmacy environment.

Learning outcomes
There are four learning outcomes to this unit. The learner will be able to:
1. Understand how to provide relevant information and advice on medicines and products
2. Understand the correct procedures for the sale and supply of over the counter medicines
3. Know about health and health promotion
4. Understand how to prepare for a review of medicines taken by an individual

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 315  Communicating in pharmacy
Outcome 1  Understand how to provide relevant information and advice on medicines and products

Assessment criteria
The learner can:
1. explain how to advise patients to take their medicines in a way that ensures cost-effective compliance, concordance and safe use
2. explain how to work within the parameters of own role when providing information and advice to individuals.

Range
• Advise patients: explaining, demonstrating, instructing
• Medicines: general sales list medicines, pharmacy medicines, prescription only medicines
• Information: side/adverse effects, storage requirements, safe and effective use of medicines, compliance aids, PILs
• Individuals: patients, representatives, carers, healthcare professionals
Unit 315  Communicating in pharmacy
Outcome 2  Understand the correct procedures for the sale and supply of over the counter medicines

Assessment criteria
The learner can:
1. describe the different classes of medicines
2. describe the Pharmacy Protocol
3. discuss the questions and techniques used to obtain relevant information before recommending products or referring to an appropriate authority.

Range
- Classes of medicines: general sales list medicine, pharmacy medicines, prescription only medicines
- Pharmacy Protocol: requests for symptoms, requests for medicines by name, when to refer, abused/misused medicines, staff training, refusal of sales
- Questions: open, closed, leading, compound, questions to avoid, prompts, funnel and inverted funnel
- Techniques: 2WHAM, question sequencing
Unit 315  Communicating in pharmacy
Outcome 3  Know about health and health promotion

Assessment criteria
The learner can:
1. define the term ‘health promotion’
2. define the components of a healthy lifestyle
3. describe the predictors used for managing common conditions.

Range
- **Health promotion**: health education, health protection, health prevention, primary, secondary and tertiary health education
- **Healthy lifestyle**: diet, exercise, stress reduction, alcohol, drug misuse
- **Predictors**: blood pressure, exercise, alcohol intake, BMI, blood glucose, cardiac risk factor analysis
Unit 315 Communicating in pharmacy

Outcome 4 Understand how to prepare for a review of medicines taken by an individual

Assessment criteria
The learner can:
1. explain the purpose of reviewing an individual’s medication
2. explain the importance of the completion and maintenance of documentation and records
3. discuss legal and ethical requirements when preparing for a “Medicines Use Review” (MUR).

Range
• Documentation and records: PMR, MUR form, intervention form, hospital records
• Legal and ethical requirements: consent, confidentiality, who can undertake an MUR
Unit 316  Dispensing and supply of medicines

Level: 3  
Credit value: 5  
UAN number: J/601/7797

Unit aim
This unit aims to provide the learner with the knowledge and understanding to dispense prescriptions appropriately and to be able to order, receive, dispose and return pharmaceutical stock.

Learning outcomes
There are three learning outcomes to this unit. The learner will be able to:
1. Understand the organisational policies and standard operating procedures within the pharmacy working environment
2. Understand the processes involved when dispensing prescriptions
3. Know how to order, receive, store and maintain pharmaceutical stock

Guided learning hours
It is recommended that 30 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 316  Dispensing and supply of medicines
Outcome 1  Understand the organisational policies and standard operating procedures within the pharmacy working environment

Assessment criteria
The learner can:
1. explain the principles and practices for dispensing, including organisational policies
2. explain the importance and use of SOPs
3. describe the consequences of near misses and dispensing errors
4. explain the importance of recording errors within the pharmacy working environment
5. explain the importance of keeping accurate records within the pharmacy working environment.

Range
- Principles and practices: induction, mandatory training, assembly of medicines, roles and responsibilities, referral process
- Policies:
  - Standards of Conduct, Ethics and Performance
  - Control of Substances Hazardous to Health (COSHH)
  - Medicine, Ethics and Practice
  - The Human Medicines Regulations 2012
  - General Pharmaceutical Council (GPhC)
  - Health and Safety at Work etc Act 1974
  - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR)
  - Misuse of Drugs Act 1971
  - current pharmacy professional regulation
  - error reporting procedures – roles and responsibilities, referral process
- Errors: near misses, incidents, factors which cause errors, implications of errors, dispensing errors
- Records: accountable officer, clinical trials, patient medication records (PMR), prescriptions, ward transcription, Controlled Drugs register
Unit 316  Dispensing and supply of medicines
Outcome 2  Understand the processes involved when dispensing prescriptions

Assessment criteria
The learner can:
1. explain the processes for prescription receipt
2. discuss the types of checks that need to be performed on a prescription
3. define branded and generic medicines
4. explain the processes for prescription collection
5. describe automated supply procedures.

Range
• **Prescription receipt:** identification, special requirements, allergies, exemptions, transactions, validation
• **Types of checks:** clinical, in-process, final (accuracy), validation
• **Prescription collection:** identification, information provision, referral, sundries, confirmation of understanding
• **Automated supply:** original pack-dispensing systems, repackaging systems, ward-based automated dispensing systems
Unit 316  Dispensing and supply of medicines
Outcome 3  Know how to order, receive, store and maintain pharmaceutical stock

Assessment criteria
The learner can:
1. outline procedures for the ordering and receipt of stock
2. describe appropriate storage conditions for stock
3. explain the guidelines for stock control
4. describe the procedures for dealing with breakages/spillages
5. describe the process for stock rotation and dealing with expired items
6. describe the process for returns and disposal of stock.

Range
• Procedures: organisational, ethical and legal requirements, national and local guidelines and contracts, standard operating procedures, waste disposal policies and procedures, COSHH
• Storage conditions: low temperature, room temperature, secured area, ventilated area, isolated area
• Stock control: national and local guidelines and contracts, ethical and legal requirements, suppliers, ordering, receipt, storage, maintenance, issue
• Procedures: waste disposal policies and procedures, COSHH
• Process: stock taking, expiry date checking, waste disposal policies
• Returns and disposal: drug alerts and recalls, COSHH, waste disposal policies
Unit 317  Pharmaceutics

Level: 3  
Credit value: 10  
UAN number: A/601/7800

Unit aim
This unit prepares the learner to be able to produce extemporaneous medicinal products for patients. The learner will be able to calculate formulae and use techniques that will ensure a safe and accurate product is produced.

Learning outcomes
There are four learning outcomes to this unit. The learner will be able to:
1. Understand how to perform accurate calculations for pharmaceutical formulae
2. Understand how to accurately weigh and measure ingredients for pharmaceutical products
3. Understand factors that affect the formulation of pharmaceutical products
4. Know how to prepare pharmaceutical products

Guided learning hours
It is recommended that 60 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 317  Pharmaceutics
Outcome 1  Understand how to perform accurate calculations for pharmaceutical formulae

Assessment criteria
The learner can:
1. explain the importance of performing accurate calculations
2. explain how to calculate accurate dosages and quantities for patients in accordance with prescriptions.

Range
• **Calculate**: weights, volumes, percentages, ratios, dilutions, displacement values, small quantity calculations, concentrations, use of formulae for extemporaneous dispensing
• **Dosages and quantities**: based on age, weight, surface area and blood volume, quantity of medicine based on number of prescribed doses and time intervals
Unit 317  Pharmaceutics
Outcome 2  Understand how to accurately weigh and measure ingredients for pharmaceutical products

Assessment criteria
The learner can:
1. explain the importance of selecting the correct weighing and measuring equipment
2. describe weighing and measuring procedures
3. describe how to use metric system and SI system accurately.

Range
- Weighing and measuring equipment: metric system (SI units), balances, measuring cylinders, conical measures, pipettes, syringes, maintenance of equipment, setting up balances, limitation of errors and limits of tolerance
- Procedures: setting up balances, maintenance of equipment, weighing, measuring, checking
- Metric system/SI system: litres, grams, moles
Unit 317  
Pharmaceutics

Outcome 3  
Understand factors that affect the formulation of pharmaceutical products

Assessment criteria
The learner can:
1. describe **types of water** used in pharmaceutical products
2. discuss the properties of different forms of **pharmaceutical products**
3. describe different pharmaceutical **compounding techniques**
4. describe **factors** affecting the quality and stability of pharmaceutical products
5. list the **chemical and physical properties of ingredients** for pharmaceutical products.

Range
- **Types of water**: potable, distilled, deionised, purified, for preparations, water for injections, sterile water, pyrogen free
- **Pharmaceutical products**: solutions, suspensions, mixtures, linctuses, elixirs, emulsions, ointments, creams, pastes, capsules, suppositories, pessaries, lotions, liniments, mouth washes, gargles, powders
- **Compounding techniques**: mixing, comminution, levigation, trituration
- **Factors**: solubility, solute, solvent, saturated, super saturated, isotonicity, factors effecting rate of solution, characteristics of emulsions, suspensions, solid dose forms, chemical and physical purity of raw materials, contamination of raw materials, quality standards
- **Chemical and physical properties of ingredients**: solubility, hydro\lipophilicity, density, melting point, compatibility
Unit 317  Pharmaceutics
Outcome 4  Know how to prepare pharmaceutical products

Assessment criteria
The learner can:
1. describe different types of pharmaceutical equipment used in compounding
2. describe how to prepare a range of pharmaceutical products
3. describe how to produce accurate labels
4. describe storage requirements for pharmaceutical products
5. explain how to complete and store accurate records.

Range
- **Equipment**: pestle and mortar, tile, palette knife, conical measure, balance, stirrer
- **Pharmaceutical products**: solutions, suspensions, mixtures, linctuses, elixirs, emulsions, ointments, creams, pastes, capsules, suppositories, pessaries, lotions, liniments, mouth washes, gargles, powders
- **Labels**: legal requirements, expiry dates, storage requirements, warnings
- **Storage requirements**: packaging, temperature, humidity, light
Unit 318  Pharmacy law, ethics and practice

Level:  3  
Credit value:  10  
UAN number:  L/601/7803

Unit aim
This unit will ensure that the learner will have the necessary knowledge and understanding to be able to supply and issue medicines ethically, legally and safely.

Learning outcomes
There are five learning outcomes to this unit. The learner will be able to:
1. Understand the laws regulating the sale and supply of medicines and non-medicinal poisons
2. Understand the laws governing the supply of controlled drugs
3. Know other laws that relate to the legal and safe delivery of pharmacy services
4. Know the organisations and staff groups relating to the delivery of pharmacy services
5. Understand the factors affecting standards in pharmacy services

Guided learning hours
It is recommended that 60 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 318 Pharmacy law, ethics and practice
Outcome 1 Understand the laws regulating the sale and supply of medicines and non-medicinal poisons

Assessment criteria
The learner can:
1. describe the key principles and requirements of current legislation relating to the use of drugs and medicines
2. explain the uses of the Drug Tariff
3. describe the main requirements of current legislation relating to the sale or supply of non-medicinal poisons
4. outline the current legal requirements for the sale or supply of veterinary medicines
5. summarise the current legal requirements relating to the provision of denatured alcohol.

Range
- Uses of the Drug Tariff: payment for supply of medicines, appliances and services, allowable products, endorsing
- Current legislation relating to the sale or supply of non-medicinal poisons: Poisons Act 1972
- Legal requirements for the sale or supply of veterinary medicines: classification, prescription requirements, labelling, records, the veterinary medicines cascade
- Legal requirements relating to the provision of denatured alcohol: sale, supply, records
- Denatured alcohol: completely denatured, industrial denatured, trade specific denatured
Unit 318  Pharmacy law, ethics and practice
Outcome 2  Understand the laws governing the supply of controlled drugs

Assessment criteria
The learner can:
1. describe the key principles and requirements of current legislation relating to the use of controlled drugs
2. describe the additional requirements for use of controlled drugs in hospitals
3. explain how drug dependence treatments are supplied to drug misusers.

Range
- **Current legislation relating to the use of controlled drugs**: Misuse of Drugs Act 1971, Misuse of Drugs Regulations 2001
- **Controlled Drugs (CD):**
  - Schedule 1
  - Schedule 2
  - Schedule 3
  - Schedule 4
  - Schedule 5
- **How drug dependence treatments are supplied**: instalment prescriptions and supply, supply of paraphernalia, supervised consumption, needle exchange schemes
Unit 318  Pharmacy law, ethics and practice
Outcome 3  Know other laws that relate to the legal and safe delivery of pharmacy services

Assessment criteria
The learner can:
1. summarise the key principles of legislation within the pharmacy context
2. explain how legislation impacts on pharmacy services.

Range
- Legislation:
  o Trade Descriptions Act 1968
  o Consumer Protection Act 1987
  o Weights and Measures Act 1985
  o Data Protection Act 1998
  o Freedom of Information Act 2000
  o Control of Substances Hazardous to Health (COSHH)
  o The Complete Health Improvement Program (CHIP)
  o The CLP Regulation
  o Health and Safety at Work etc Act 1974
  o Equality Act 2010
  o Safeguarding Children and Vulnerable Adults
  o Employment Law
Unit 318  Pharmacy law, ethics and practice
Outcome 4  Know the organisations and staff groups relating to the delivery of pharmacy services

Assessment criteria
The learner can:
1. describe the structure and function of the National Health Service and other NHS bodies and organisations connected with pharmacy
2. explain the role of the professional regulator for Pharmacy Technicians
3. describe the role of the professional leadership bodies for Pharmacists and Pharmacy Technicians
4. compare the roles and responsibilities of the Pharmacist, pharmacy support staff and other healthcare professionals within pharmacy practice.

Range
- Other NHS bodies and organisations:
  o Scotland (Regional NHS boards, Special NHS boards, Healthcare Improvement Scotland)
  o Wales (Local Health Boards, NHS trusts, Community Health Councils)
  o Northern Ireland (Department of Health, Social Services & Public Safety, Health & Social Care board, Health & Social Care trusts)
- Role of the professional regulator: registration, standards, guidance, Fitness to Practice
- Professional leadership bodies: APTUK, RPS
- Pharmacy support staff and other healthcare professionals:
  o Superintendent Pharmacist
  o Pharmacist prescribers
  o Responsible Pharmacist
  o Pre-registration Trainee Pharmacist
  o Pharmacy Technician
  o Pre-registration Trainee Pharmacy Technician
  o Pharmacy Assistants
  o Accuracy Checking Technicians
Unit 318  Pharmacy law, ethics and practice
Outcome 5  Understand the factors affecting standards in pharmacy services

Assessment criteria
The learner can:
1. describe the **requirements** for conducting a retail pharmacy business
2. explain the principles of clinical governance
3. explain the importance of standard operating procedures
4. describe the **key principles** of audit and quality improvement
5. explain how **National Health Care Standards** contribute to improving patient care.

Range
- **Requirements**: owning a pharmacy, restricted titles, Pharmacy Contract (Essential, Advanced & Enhanced services), inspection
- **Key principles**: the audit cycle
- **National Health Care Standards**: NICE, CQC, NPSA
Unit 319  Making medicines for pharmacy

Level: 3  
Credit value: 10  
UAN number: Y/601/7805

Unit aim
The unit will ensure the learner will have the necessary knowledge and understanding to be able to work safely in the pharmaceutical manufacturing environment.

Learning outcomes
There are five learning outcomes to this unit. The learner will be able to:
1. Understand the legislation and guidelines controlling pharmaceutical manufacture
2. Know about the environment and equipment for pharmaceutical manufacture
3. Understand how medicines are manufactured
4. Understand the principles of quality assurance and quality control
5. Understand the aseptic preparation of pharmaceutical products

Guided learning hours
It is recommended that 60 hours should be allocated for this unit, although patterns of delivery are likely to vary.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
• an assignment based knowledge test.
Unit 319 Making medicines for pharmacy
Outcome 1 Understand the legislation and guidelines controlling pharmaceutical manufacture

Assessment criteria
The learner can:
1. explain the legislation and guidelines governing the manufacture of pharmaceutical products
2. discuss an individual's responsibility in relation to current health and safety regulations
3. explain the difference between dispensing and manufacturing in pharmacy
4. explain error reduction strategies in a manufacturing context
5. explain the legislation on manufacture and supply of clinical trial materials.

Range
- **Legislation and guidelines:**
  - EEC Directive on Good Manufacturing Practice for Human Medication
  - European Medicines Agency (EMEA) and Medicines and Healthcare products Regulatory Agency (MHRA)
  - Medicines Act 1968, licensing, marketing authorisation, manufacturers license, environmental and waste regulations
  - The Human Medicines Regulations 2012
  - current Rules and Guidance for Pharmaceutical Manufactures and Distributors – the ‘orange guide’
  - Quality Assurance of Aseptic Preparation Services
  - current Health & Safety policies
  - Chemicals (Hazard Information and Packaging for Supply) regulations (CHIP4): Classification, Labelling and Packaging of Substances and Mixtures (CLP regulations)
  - Control of Substances Hazardous to Health (COSHH)
  - local Standard Operating Procedures (SOPs)

- **Health and Safety regulations:**
  - Health and Safety at Work etc Act 1974
  - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR)
  - Control of Substances Hazardous to Health (COSHH)
  - Standard Operating Procedures – hygiene requirements
  - protective clothing
  - equipment
  - spillages
  - fire

- **Dispensing:** unlicensed unit, direct to a named patient, one week shelf life, records and documentation, audits

- **Manufacturing:** licensed unit, batch manufacture to external customers, extended expiry dates, records and documentation, audits, Qualified Person

- **Error reduction strategies:** quality assurance, quality control, risk assessment, employee training

- **Legislation:** Investigational Medicinal Product (IMP) manufacturing license, role of MHRA, role of Qualified Person
Unit 319  Making medicines for pharmacy
Outcome 2  Know about the environment and equipment for pharmaceutical manufacture

Assessment criteria
The learner can:
1. describe the different environments used for pharmaceutical manufacturing
2. explain the importance of basic and personal hygiene in pharmaceutical manufacture
3. explain the potential consequences of different sources of contamination within pharmaceutical manufacturing
4. describe the importance of planned preventative maintenance in pharmaceutical manufacturing.

Range
- **Different environments:**
  - Grade A - Laminar air flow cabinets and isolators
  - Grade B - The aseptic room
  - Grade C - The preparation room
  - Grade D - Support, filling and isolator rooms
- **Basic and personal hygiene:** hygiene requirements in accordance with SOPs for personnel assisting in medicines manufacture
  - hand washing / hand hygiene
  - changing procedures
  - personal protective equipment
  - personal presentation – jewellery, make-up, nail varnish, hair
  - eating, drinking, smoking
- **Sources of contamination:** microbial, chemical, physical
- **Importance:** improved equipment reliability, decrease cost of replacement, decreased equipment downtime, increased efficiency, prevention of contamination
Unit 319  Making medicines for pharmacy
Outcome 3  Understand how medicines are manufactured

Assessment criteria
The learner can:
1. describe the procedures for preparing the manufacturing environment of medicines
2. explain the difference between sterile and non-sterile manufacturing
3. describe documentation used in the manufacturing of medicines
4. state the principles of labelling and packaging
5. describe the principles of waste disposal
6. describe the different methods of sterilisation
7. describe the principles for the storage and supply of manufactured products.

Range
• Preparing the manufacturing environment: cleaning, equipment tests, environmental monitoring, protective clothing
• Sterile: manufacturing environment, products, sterilisation
• Non-sterile: manufacturing environment, products
• Documentation: procedures, batch manufacture records/worksheets, product specification, equipment checks, cleaning, environmental monitoring, error monitoring
• Labelling: requirements for manufactured products
• Packaging: primary packaging, secondary packaging, transport packaging
• Waste disposal:
  o The Hazardous Waste (England and Wales) Regulations 2005
  o Health Technical Memorandum HTM-07-01
  o sharps, product waste
  o general clean room waste
• Methods of sterilisation: heating with bactericide, autoclave, dry heat, filtration, gaseous, radiation, chemical
• Storage: cold chain, maintenance of storage environments, shelf life, stability, exposure to light, secure storage
• Supply: transport, cold chain, documentation, special transport arrangements, labelling and packaging
Unit 319  Making medicines for pharmacy
Outcome 4  Understand the principles of quality assurance and quality control

Assessment criteria
The learner can:
1. explain the difference between quality assurance and quality control
2. describe how manufactured products are tested
3. explain product formulation in pharmacy manufacturing
4. discuss the importance of validation and record keeping in quality assurance
5. explain total quality management
6. explain the importance of quarantine in pharmacy manufacturing.

Range
- **Tested**: chemical analysis of raw materials and final products, examination of packaging materials, in-process tests, sterility and pyrogen testing
- **Product formulation**: compatibility with other substances, physical, chemical and mechanical properties of a drug, polymorphism, particle size, pH and solubility
- **Validation**: competence validation (broth tests and process validation), staff training
- **Total quality management**: system of management based on the principle that every member of staff must be committed to maintaining high standards of work in every aspect of a company’s operations
- **Quarantine**: records, segregation, release
Unit 319 Making medicines for pharmacy
Outcome 5 Understand the aseptic preparation of pharmaceutical products

Assessment criteria
The learner can:
1. describe the different types of products made by Aseptic Units
2. explain the safe disposal of hazardous materials and waste
3. explain the importance of validation in aseptic preparation.

Range
- **Types of products**: eye drops, injections, antibiotic reconstitutions, cytotoxic, total parenteral nutrition, radiopharmaceuticals, centralised intravenous additive services, intrathecal, syringe drivers, analgesia
- **Disposal**:
  - The Hazardous Waste (England and Wales) Regulations 2005
  - Health Technical Memorandum HTM-07-01
  - sharps
  - product waste
  - general waste
- **Validation**: competence validation (broth tests and process validation), staff training
Useful contacts

**UK Centres**
Registrations, Exam entries (Dated/On-Demand/e-volve Scheduling), invoices, Missing or late exam materials, Results entries, Certification. Publication enquiries: logbooks, centre documents, forms, free literature.

E: centresupport@cityandguilds.com

**Quality support (new centres)**
For Sales advice and support
For quality assurance

E: directsales@cityandguilds.com
E: csdirect@cityandguilds.com

E: Techbac@cityandguilds.com

**International centres**
Quality assurance, sales advice, results, entries, enrolments, invoices, missing or late exam materials

Please contact your local office: www.cityandguilds.com/aboutus/international

**UK centres**
General e-assessment (e-volve) support
Enquiries

E: evolvesupport@cityandguilds.com

**UK learners**
General qualification information

E: learnersupport@cityandguilds.com

**International learners**
General qualification information

E: learnersupport@cityandguilds.com

**Employer**
Employer solutions including, Employer Recognition: Endorsement, Accreditation and Quality Mark, Consultancy, Mapping and Specialist Training Delivery

E: business@cityandguilds.com

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