

BTEC Nationals

IVA – LEARNER INSTRUCTIONS

Edexcel Level 3 BTEC National Certificate

Pharmacy Services

Unit 2: Pharmacy Law and Practice
Unit 7: Pharmaceutics

Issued June 2004

For use during the remainder of the duration of operation
of the specification issued August 2002



INSTRUCTIONS FOR LEARNERS COMPLETING IVAs

1. The Integrated Vocational Assignment (IVA) is a compulsory part of your qualification. If you do not complete the IVA you may not receive your certificate.
2. Your tutor(s) will tell you how long you have to complete the IVA and the access you may have to resources.
3. Read the IVA carefully and make sure that you understand the work you should hand in and what is required of you. If you are uncertain, discuss it with your tutor(s).
4. The IVA requires you to work by yourself and to produce original work. You should not share your work with any other learners. For example, if you produce an illustration or diagram electronically, you should not give it to another learner. Similarly, you should not accept and use such information from others. You are required to sign that the work submitted is your own.
5. If you work in a group at any stage, you must present your own responses to each task for assessment.
6. Information taken from sources for research, e.g. internet and textbooks, must be identified and not presented as your own work. You should list the sources used.
7. Some tasks may require Observation Records/Witness Statements. Your tutor(s) will organise for these to be completed and you must attach these to your submitted work.
8. In presenting your final work, you should not include draft work or reference materials such as handouts, notes and leaflets, unless the tasks specifically ask you to do so.
9. Presentation of your work:
 - Check that you have completed all tasks.
 - Label work with the appropriate task/sub task number.
 - Present tasks in the correct order.
 - Label each page with your name and page number.
 - Submit all electronic materials in paper format
 - Clearly label video or audio tapes submitted as part of your assignment.
 - All papers should be securely bound.
 - The completed IVA should NOT be presented in plastic envelopes, a box file or a lever arch file.

YOUR ASSIGNMENT TASKS

Scenario

This assignment provides the opportunity to demonstrate your knowledge of the laws relating to, or affecting, pharmacy and the professional role of the pharmacist. In conjunction with *Unit 7: Pharmaceuticals*, you need to demonstrate how medicines are regulated in Great Britain and in the European Community (EC) where appropriate. The assignment allows you to demonstrate knowledge of the major community pharmacy organisations and associations. It also covers the National Health Service (NHS) with particular reference to the pharmaceutical service.

The assignment provides you with an opportunity to demonstrate understanding of the pharmaceutical aspects of medicines and the dispensing process. It assesses your skills in fundamental procedures, processes, measurements and calculations. The assignment provides the opportunity for you to demonstrate safe and responsible practices in dispensing prescriptions. It enables you to demonstrate the theoretical aspects of and apply practical skills in the preparation of dispensed medicines.

In order to fulfil the requirements of this assignment, you will need to prepare products with the high degree of accuracy required for dispensed medicines. Your assessor(s) will be the final arbiter of this. The presentation of your work and products must demonstrate the professionalism in keeping with the expectations of the public and of the pharmacy profession.

Task 1

Legislation relating to the use of drugs and medicines

In responding to this task, you should consider:

- the Medicines Act 1968
- the licensing system
- sales promotion of medicinal products
- retail pharmacy business
- pharmacy, general sale and prescription only medicines
- containers and packaging
- wholesale dealing, homeopathic medicines, herbal remedies and veterinary drugs
- the Misuse of Drugs Act 1971
- control and treatment of addicts
- the Poisons Act 1972 (Lists and Rules)
- poisons rules
- schedule 1 poisons.

1.a.

Identify current legislation relating to the use of drugs and medicines.

1.b.

Define the main provisions of current legislation relating to the use of drugs and medicines.

1.c.

Explain the application of current legislation relating to the use of medicines and drugs.

This task provides evidence for unit 2 criteria P1, M1, D1.

Task 2

Dangerous substances and their control

Evidence for this task could be generated during the preparation of extemporaneous products. In responding to this task, as they apply to dangerous substances and their control, you should consider:

- Regulations
- Packaging and labelling
- COSHH.

2.a.

Show a knowledge and understanding of the control of dangerous substances.

2.b.

Competently and safely use dangerous substances according to agreed protocol.

2.c.

Accurately interpret COSHH (control of substances hazardous to health) safety data sheets.

This task provides evidence for unit 2 criteria P2, M2, D2.

Task 3

NHS and professional organisations

When responding to this task, you should consider:

- the structure and organisation of the NHS
- NHS bodies and organisations
- the structure and organisation of the Pharmaceutical Society
- ethics and professional conduct
- the Statutory Committee
- other professional organisations
- other professions.

3.a.

Describe the structure and function of the NHS and associated professional organisations.

3.b.

Discuss the effectiveness of the structure of the NHS and the associated professional organisations in achieving their stated functions and objectives.

3.c.

Evaluate the role of the organisation of the NHS and the activities of the Royal Pharmaceutical Society of Great Britain and associated professions and the effect they have on pharmacy.

This task provides evidence for unit 2 criteria P3, M3, D3.

Task 4

Miscellaneous legislation affecting pharmacy

When responding to this task, you should consider:

- miscellaneous Acts relating to trading, consumers and the environment
- laws relating to spirits and methylated spirits.

4.a.

Identify the range of miscellaneous legislation affecting pharmacy.

4.b.

Explain the provisions of miscellaneous legislation affecting pharmacy.

4.c.

Give an account of the implications of the miscellaneous legislation affecting pharmacy and say how it affects pharmacy services.

This task provides evidence for unit 2 criteria P4, M4, D4.

The evidence for Tasks 5 – 10 should be generated through the production of extemporaneous products. The number of products for dispensing should be sufficient to enable the range of practical dispensary techniques to be explored, this should **be at least five different** products. Your centre Assessor will provide you with the details of the products that you are required to produce. You will need to ensure that a suitably qualified, professionally competent assessor observes your practical activity.

When responding to these tasks you will need to consider:

- procedures and practices
- prescriptions
- reference sources
- calculations
- recording and regulatory systems.

Task 5

Dispensing procedures and practices

In preparing your extemporaneous products, you must generate evidence to show that you can

5.a.

Follow good dispensing procedures and practices.

5.b.

Interpret documented dispensing procedures and practices.

5.c.

Explain the need for good dispensary procedures and practices.

This task provides evidence for unit 7 criteria P1, M1, D1.

Task 6

Pharmaceutical products and medicines for dispensing

Using the prescription forms provided to you by your assessor, document the activity for this task. You must interpret and validate **at least five different** prescriptions.

6.a.

Read, interpret and dispense a range of prescription forms.

6.b.

Validate and issue a range of different prescriptions.

6.c.

Detect errors on prescriptions and follow remedial procedures before dispensing.

This task provides evidence for unit 7 criteria P4, M4, D4.

Task 7

Formulation of medicines including packaging materials

To provide the range of evidence required to complete this task, you will need to consider:

- formulation of the range of different medicines
- types of water used in the formulation of products
- physical properties of solutions
- clarification and filtration techniques
- mixing and comminution techniques
- product preparation
- microbiological aspects
- physical and chemical properties of medicines
- routes of administration.

7.a.

Identify the formulation of medicines that you are required to prepare extemporaneously.

7.b.

Describe the requirements for the formulation of the different medicinal products

7.c.

Explain the pharmaceutical formulation requirements of the extemporaneously prepared products.

This task provides evidence for unit 7 criteria P3, M3, D3.

Task 8

Weighings, measurements and calculations

You should use the requirements for preparing the extemporaneous products to provide evidence for this task.

Consider:

- systems and equipment for weights and measures
- special procedures
- equipment requirements.

8.a.

Identify the correct formulae for each of the products to be prepared extemporaneously and carry out a range of pharmaceutical calculations accurately.

8.b.

Identify the source of any possible errors.

8.c.

Calculate the magnitude of any possible errors and the limits of tolerance for those errors.

This task provides evidence for unit 7 criteria P2, M2, D2.

Task 9

Extemporaneous preparation

Prepare the extemporaneous products that you have been asked to produce to provide evidence for this task.

9.a.

Demonstrate basic manipulative skills in the dispensary.

9.b.

Competently and safely prepare medicines extemporaneously.

9.c.

Be highly skilled in the full range of manipulations required for extemporaneous preparation.

This task provides evidence for unit 7 criteria P5, M5, D5.

Task 10
Labelling and IT

In completing this task, you should consider generating the evidence required through labelling your extemporaneous products.

10.a.

Produce a label for a medicine using IT skills.

10.b.

Generate appropriate additional labels for a medicine using IT skills.

10.c.

Create and utilise a PMR system and relate that to labels generated for a particular prescription.

This task provides evidence for unit 7 criteria P6, M6, D6.

ASSESSMENT CRITERIA

For ease of reference, the assessment criteria from the unit specifications that are relevant to assessing and grading this IVA are repeated below. You should refer to the full unit specification for information on unit content.

Assessment Evidence Unit

Unit 2: Pharmacy Law and Practice		
To achieve a pass grade the evidence must show that the learner is able to:	To achieve a merit grade the evidence must show that the learner is able to:	To achieve a distinction grade the evidence must show that the learner is able to:
<ul style="list-style-type: none"> • show an awareness of current legislation relating to the use of drugs and medicines • show a knowledge and understanding of the control of dangerous substances • describe the structure and function of the NHS and associated professional organisations • demonstrate an awareness of miscellaneous legislation affecting pharmacy. 	<ul style="list-style-type: none"> • define the main provisions of current legislation relating to the use of drugs and medicines • competently and safely use dangerous substances according to agreed protocol • review the structure and function of the NHS and associated professional organisations • explain the provisions of miscellaneous legislation affecting pharmacy. 	<ul style="list-style-type: none"> • explain the application of current legislation relating to the use of medicines and drugs • accurately interpret COSHH (control of substances hazardous to health) data sheets • evaluate the role of the organisation of the NHS and the activities of the Royal Pharmaceutical Society of Great Britain and associated professions and how they impact on pharmacy • understand the implications of miscellaneous legislation affecting pharmacy.

ASSESSMENT CRITERIA

For ease of reference, the assessment criteria from the unit specifications that are relevant to assessing and grading this IVA are repeated below. You should refer to the full unit specification for information on unit content.

Assessment Evidence Unit

Unit 7: Pharmaceutics		
To achieve a pass grade the evidence must show that the learner is able to:	To achieve a merit grade the evidence must show that the learner is able to:	To achieve a distinction grade the evidence must show that the learner is able to:
<ul style="list-style-type: none"> • follow good dispensing procedures and practices • identify the correct formulae and carry out a range of pharmaceutical calculations accurately • have an understanding of the formulation of medicines • read, interpret and dispense a range of prescription forms • demonstrate basic manipulative skills in the dispensary • produce a label for a medicine using IT skills. 	<ul style="list-style-type: none"> • interpret documented dispensing procedures and practices • identify the correct formulae, carry out a range pharmaceutical calculations accurately and identify any possible errors • know the requirements for the formulation of different medicinal products • read, validate, accurately dispense and issue a range of different prescriptions • competently and safely prepare medicines extemporaneously • generate appropriate additional labels for a medicine using IT skills. 	<ul style="list-style-type: none"> • understand the need for good dispensary procedures and practices • identify the correct formulae, carry out a range pharmaceutical calculations accurately and identify/calculate any possible errors and limits of tolerance • have a thorough understanding of pharmaceutical formulation • detect errors on prescriptions and follow remedial procedures before dispensing • be highly skilled in the full range of manipulations required for extemporaneous preparation • create and utilise a PMR system and relate that to labels generated for a particular prescription.