

-SQA-SCOTTISH QUALIFICATIONS AUTHORITY

**Hanover House
24 Douglas Street
GLASGOW G2 7NG**

NATIONAL CERTIFICATE MODULE DESCRIPTOR

-Module Number- 7210031 **-Session-** 1991-92
-Superclass- PE

-Title- **PHARMACEUTICS 3**

-DESCRIPTION-

Purpose This module introduces the student to pharmaceutical manufacture and sterile dispensing.

It is intended primarily for student pharmacy technicians.

Preferred Entry Level 69080 Microbiology 1
Pharmaceutics 1
Pharmaceutics 2

Outcomes The student should:

1. explain the requirements of the guide to good pharmaceutical manufacturing practice with regard to sterile and non-sterile medicines;
2. describe the formulation and procedures and perform relevant calculations underlying the manufacture of sterile pharmaceutical preparations;
3. demonstrate the principles and processes underlying the aseptic dispensing of pharmaceutical preparations;
4. prepare, package, sterilise and label pharmaceutical preparations.

Assessment Procedures Acceptable performance in the module will be satisfactory achievement of the performance criteria specified for each Outcome.

The following abbreviations are used below:

PC Performance Criteria
IA Instrument of Assessment

Note: The Outcomes and PCs are mandatory and cannot be altered. The IA may be altered by arrangement with SQA. (Where a range of performance is indicated, this should be regarded as an extension of the PCs and is therefore mandatory.)

OUTCOME 1**EXPLAIN THE REQUIREMENTS OF THE GUIDE TO GOOD PHARMACEUTICAL MANUFACTURING PRACTICE WITH REGARD TO STERILE AND NON-STERILE MEDICINES**

PCs

- (a) The explanation of the principles of "The Guide to Good Pharmaceutical Manufacturing Practice" is correct in relation to the manufacture of pharmaceutical preparations.
- (b) The explanation of the principles of quality assurance is correct in relation to the provision of pharmaceutical service.

IA Restricted Response Questions

The student will be presented with 15 restricted response questions to test the knowledge required to explain the requirements of the guide with regard to sterile and non-sterile medicine.

The exercise will consist of 15 restricted responses questions as follows.

For PC (a), 10 questions will be set.

For PC (b), 5 questions will be set.

Satisfactory achievement of the Outcome will be based on the student answering 12 questions correctly:

For PC (a), 8 questions must be correct.

For PC (b), 4 questions must be correct.

**OUTCOME 2 DESCRIBE THE FORMULATION AND PROCEDURES
AND PERFORM RELEVANT CALCULATIONS
UNDERLYING THE MANUFACTURE OF STERILE
PHARMACEUTICAL PREPARATIONS**

- PCs
- (a) The description of different methods of sterilisation is correct in relation to the manufacture of pharmaceutical products and the sterilisation of equipment.
 - (b) All calculations are correct.
 - (c) The description of the formulation and procedures is appropriate to the manufacture of parenteral pharmaceutical preparations.
 - (d) The description of the formulation and procedures is appropriate to the manufacture of ophthalmic and other topical preparations.

IA Restricted Response Questions

The student will be presented with 30 restricted response questions to test the knowledge required to describe the formulation and procedures underlying the manufacture of sterile pharmaceutical products.

The exercise will consist of 30 restricted response questions as follows:

For PC (a), 10 questions will be set.

For PC (b), 4 questions will be set.

For PC (c), 8 questions will be set.

For PC (d), 8 questions will be set.

Satisfactory achievement of the Outcome will be based on the student answering 24 questions correctly.

For PC (a), 8 questions must be correct.

For PC (b), 4 questions must be correct.

For PC (c), 6 questions must be correct.

For PC (d), 6 questions must be correct.

OUTCOME 3 DEMONSTRATE THE PRINCIPLES AND PROCESSES UNDERLYING THE ASEPTIC DISPENSING OF PHARMACEUTICAL PREPARATIONS

PCs

- (a) The description of the principles of an aseptic dispensing service is correct for pharmaceutical preparations.
- (b) Demonstration of aseptic technique is appropriate to the aseptic dispensing of pharmaceutical preparations.

IA Assignment

The student will be presented with an assignment to test the knowledge and skills required to demonstrate the principles and processes underlying aseptic dispensing.

The assignment will consist of 2 parts:

- (i) the student will be presented with 12 restricted response questions for PC(a) to test the knowledge required to demonstrate the principles of an aseptic dispensing service.
- (ii) for PC(b) the student will be presented with a practical exercise to allow them to carry out aseptic dispensing techniques.

Satisfactory achievement of the Learning Outcome will be based on the student answering 10 out of 12 questions correctly for PC(a) and meeting the performance criteria for PC(b). The assessment for PC (b) should be carried out with the aid of an observation checklist.

OUTCOME 4 PREPARE, PACKAGE, STERILISE AND LABEL PHARMACEUTICAL PREPARATIONS

PCs

- (a) The preparation, packaging, sterilising and labelling of a parenteral is correct for a given prescription.
- (b) The preparation, packaging, sterilising and labelling of an ophthalmic preparation is correct for a given prescription.

IA Practical Exercise

The student will be presented with a prescription to test the application of knowledge and skills required to prepare, package, sterilise and label parenteral and ophthalmic preparations.

An observation checklist should be used.

Satisfactory achievement of the Outcome will be based on all the performance criteria being met.

**The following sections of the descriptor are offered as guidance.
They are not mandatory.**

CONTENT/CONTEXT

1. The requirements of the "Guide to Good Pharmaceutical Manufacturing Practice" in relation to sterile and non-sterile preparations.

Principles of quality assurance.
 2. Principles of sterilisation by a variety of methods to ensure production of sterile pharmaceutical preparations. Calculations to include isotonicity and molar concentrations (millimoles).
 3. Aseptic dispensing is dealt with in relation to TPN, IV additives, cytotoxic drugs, and radiopharmaceuticals. Students should be able to demonstrate basic aseptic techniques in the laboratory whilst being aware of the limitations of this environment.
 4. The sterile production of injections/eyedrops.
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SUGGESTED LEARNING AND TEACHING APPROACHES

Background information should be introduced by exposition, reinforced by hand-outs and supported by the use of models, videos, slides and demonstration of practical techniques. This should then be reinforced by the use of worksheets which should incorporate problem solving exercises and calculations. A record of practical exercises should be kept.

It is recommended that this module be taught by a pharmacist.

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