



National Unit specification: general information

Unit title: Pharmaceutics: Prepare Pharmaceutical Preparations Aseptically

Unit code: FH2E 12

Superclass: PE

Publication date: December 2012

Source: Scottish Qualifications Authority

Version: 03

Summary

This Unit has been designed to develop knowledge, understanding and practical skills related to the procedures of aseptic preparation. This Unit is an optional Unit of the National Certificate in Pharmacy Services but can also be taken as a free-standing Unit.

It is designed primarily for staff working within the pharmacy sector. However it may also be suitable for somebody with an interest in the subject area.

Outcomes

- 1 Demonstrate knowledge and understanding of the principles and procedures to ensure safe aseptic preparation of pharmaceutical preparations.
- 2 Demonstrate knowledge and understanding of the principles and procedures related to the formulation, packaging, labelling, transport and waste disposal requirements for aseptic preparation.
- 3 Prepare an intravenous additive using aseptic technique.

Recommended entry

While entry is at the discretion of the centre, candidates would normally be expected to have knowledge and understanding of the basic principles of pharmacy practice. This could be demonstrated by candidates attaining:

- ◆ Pharmaceutics: Good Dispensing Practice
- ◆ Pharmaceutics: Legal and Ethical Controls
- ◆ Pharmaceutics: Preparation and Use of Pharmaceutical Dosage Forms

National Unit specification: general information (cont)

Unit title: Pharmaceutics: Prepare Pharmaceutical Preparations
 Aseptically

Credit points and level

1 National Unit credit at SCQF level 6: (6 SCQF credit points at SCQF level 6*)

**SCQF credit points are used to allocate credit to qualifications in the Scottish Credit and Qualifications Framework (SCQF). Each qualification in the Framework is allocated a number of SCQF credit points at an SCQF level. There are 12 SCQF levels, ranging from Access 1 to Doctorates.*

Core Skills

Opportunities to develop aspects of Core Skills are highlighted in the support notes of this Unit specification.

There is no automatic certification of Core Skills or Core Skill component in this Unit.

National Unit specification: statement of standards

Unit title: Pharmaceutics: Prepare Pharmaceutical Preparations Aseptically

Acceptable performance in this Unit will be the satisfactory achievement of the standards set out in this part of the Unit specification. All sections of the statement of standards are mandatory and cannot be altered without reference to SQA.

Outcome 1

Demonstrate knowledge and understanding of the principles and procedures to ensure safe aseptic preparation of pharmaceutical preparations.

Performance Criteria

- (a) The importance of quality assurance (QA) is described correctly.
- (b) The importance of documentation systems is described correctly.
- (c) The environmental requirements for aseptic preparation are described correctly.
- (d) The sources of contamination and ways to minimise contamination are identified correctly.
- (e) The environmental monitoring requirements in an aseptic facility are identified correctly.

Outcome 2

Demonstrate knowledge and understanding of the principles and procedures related to the formulation, packaging, labelling, transport and waste disposal requirements for aseptic preparation.

Performance Criteria

- (a) Formulation requirements for aseptic preparation of pharmaceutical preparations are described correctly.
- (b) Calculations for aseptic preparation of pharmaceutical preparations are correct.
- (c) Packaging and labelling requirements for aseptic preparation of pharmaceutical preparations are described correctly.
- (d) Stability requirements of aseptically prepared pharmaceutical preparations are described correctly.
- (e) Transportation and disposal arrangements for aseptically prepared pharmaceutical preparations are described correctly.

National Unit specification: statement of standards (cont)

Unit title: Pharmaceutics: Prepare Pharmaceutical Preparations
 Aseptically

Outcome 3

Prepare an intravenous additive using aseptic technique.

Performance Criteria

- (a) The calculation is correct.
- (b) The worksheet is prepared appropriately.
- (c) Aseptic technique is correct.
- (d) Labelling of the preparation is correct.

Evidence Requirements for this Unit

Evidence is required to demonstrate that candidates have achieved all Outcomes and Performance Criteria.

Written and/or oral evidence is required to demonstrate that the candidate has achieved all Outcomes and Performance Criteria.

Outcomes 1 and 2 should be assessed under controlled conditions by a single holistic closed-book assessment of one hour duration covering all of the above Performance Criteria. Candidates must be provided with the appropriate product information sheet(s) and the Pharmaceutical Handbook 19th edition pages 268–269 (or the equivalent) and should be allowed access to a non-programmable scientific calculator during assessment.

Outcome 1

- ◆ Candidates must correctly describe the importance of Quality Assurance in aseptic preparation.
- ◆ Candidates must correctly describe the importance of documentation systems in aseptic preparation.
- ◆ Candidates must correctly describe two environmental requirements for aseptic preparation.
- ◆ Candidates must correctly identify two sources of contamination and ways to minimise them in an aseptic facility.
- ◆ Candidates must correctly identify environmental monitoring requirements in an aseptic facility.

Outcome 2

- ◆ Candidates must correctly describe a formulation requirement for an aseptic pharmaceutical preparation.
- ◆ Candidates must correctly complete two different calculations in total, one for each of the two types of aseptic pharmaceutical preparations.
- ◆ Candidates must correctly describe packaging and labelling requirements for an aseptic pharmaceutical preparation.
- ◆ Candidates must correctly describe at least one stability requirement for aseptic pharmaceutical preparations.

National Unit specification: statement of standards (cont)

Unit title: Pharmaceutics: Prepare Pharmaceutical Preparations Aseptically

- ◆ Candidates must correctly describe transportation and disposal arrangements for aseptic pharmaceutical preparation.

Outcome 3 must be assessed by a single directly observed practical exercise preparing an intravenous additive and a checklist of the candidate's work must be produced to demonstrate that:

- ◆ The calculation is correct.
- ◆ The worksheet is prepared correctly.
- ◆ Aseptic technique is correct.
- ◆ Labelling of the preparation is correct.

National Unit specification: support notes

Unit title: Pharmaceutics: Prepare Pharmaceutical Preparations Aseptically

This part of the Unit specification is offered as guidance. The support notes are not mandatory.

While the exact time allocated to this Unit is at the discretion of the centre, the notional design length is 40 hours.

Guidance on the content and context for this Unit

Outcome 1

- (a) The importance of quality assurance (QA) is described correctly.
 - i The principles of Quality Assurance (QA).
 - ii The principles of Good Manufacturing Practice (GMP).
 - iii Aseptic Dispensing for NHS Patients.
 - iv The principles of aseptic preparation and terminal sterilisation.

- (b) The importance of documentation systems is described correctly.
 - i Standard Operating procedures (SOPs).
 - ii Worksheets.
 - iii Labelling.
 - iv Training and validation records.
 - v Cleaning and maintenance records.
 - vi Environmental monitoring records.

- (c) The environmental requirements for aseptic preparation are described correctly.
 - i The operation of the air handling unit.
 - ii Room classification: air changes, particle and microbial counts.
 - iii Requirements for changing rooms, preparation rooms, clean rooms including pressure differentials.
 - iv Isolators and Unidirectional Airflow Cabinets.
 - v Cleaning and disinfecting requirements.
 - vi Maintenance of equipment.

- (d) The sources of contamination and ways to minimise contamination are identified correctly.
 - i Atmosphere: dust, droplets, micro-organisms.
 - ii Personnel: hands, hair and clothing.
 - iii Equipment and starting materials.
 - iv Filtration and pressure differentials.
 - v Clothing types and properties.
 - vi Hygiene including hand-washing, make-up removal.
 - vii Behaviour in the cleanroom.

National Unit specification: support notes (cont)

Unit title: Pharmaceutics: Prepare Pharmaceutical Preparations Aseptically

- (e) The environmental monitoring requirements in an aseptic facility are identified correctly.
 - i Physical: pressure differentials, air flow velocity, air change rates, particle counts, temperature/humidity monitoring.
 - ii Microbiological: settle plate, contact plates, swabs, active air sampling, sterility testing.

Outcome 2

- (a) Formulation requirements for aseptic preparation of pharmaceutical preparations are identified correctly.
 - i Intravenous additives including cytotoxic preparations: volume, minimum/maximum concentration, compatibility.
 - ii Parenteral Nutrition (PN): components ie lipids, proteins, carbohydrates, electrolytes, vitamins and trace elements.

- (b) Calculations for aseptic preparation of pharmaceutical preparations are correct.
 - i Intravenous additives: volume, percentage, displacement values.
 - ii PN: millimoles from percentage and percentage from millimoles.

- (c) Packaging and labelling requirements for aseptic preparation of pharmaceutical preparations are described correctly.
 - i Labelling requirements for IV additives, intrathecal injections, cytotoxic preparations, radiopharmaceuticals and biopharmaceuticals.
 - ii PN.
 - iii Packaging requirements: protection from light, safe handling.
 - iv Storage requirements.
 - v Compatibility of container with products.

- d) Stability requirements of aseptically prepared pharmaceutical preparations are identified correctly.
 - Reference sources on stability data for IV additives eg. CIVAS handbook, Trissell, Data Sheets, Cytotoxics Handbook and BNF.

- (e) Transportation and disposal arrangements for aseptically prepared pharmaceutical preparations are described correctly.
 - i Transportation; cold chain, cytotoxic products, intrathecal products
 - ii Disposal; segregation, cytotoxic waste.

Outcome 3

Candidate checklist must demonstrate that:

- (a) The calculation is correct.
- (b) The worksheet is prepared correctly.
- (c) Aseptic technique is correct.
- (d) Labelling of the preparation is correct.

National Unit specification: support notes (cont)

Unit title: Pharmaceutics: Prepare Pharmaceutical Preparations Aseptically

Guidance on learning and teaching approaches for this Unit

The learning and teaching of this Unit is most effective when concepts, principles, and theories are set in a relevant context e.g. by making reference to applications of pharmaceutics in real life situations.

Learning and teaching approaches should include lectures, individual and group work reinforced by handouts and worksheets. Worksheets should be designed to encourage students to use a wide range of textbooks.

This Unit must be taught by either a pharmacist or pharmacy technician.

Opportunities for developing Core Skills

Although there is no automatic certification of Core Skills or Core Skills components, there may be an opportunity to develop the Core Skill of *Numeracy*, component Using Number at SCQF level 5.

Guidance on approaches to assessment for this Unit

It is recommended that Outcomes 1 and 2 are assessed under controlled conditions by a single holistic closed-book assessment, with access to the appropriate reference sources, of one hour duration.

Achievement of Outcomes 1 and 2 could be demonstrated by use of a cut-off score. Any cut-off score must be commensurate with the minimum evidence requirements of the Unit Specification.

Outcome 3 must be assessed by means of direct observation of aseptic technique together with completed checklist detailing the calculation(s), worksheet and labelling of the preparation.

Opportunities for the use of e-assessment

E-assessment may be appropriate for some assessments in this Unit. By e-assessment we mean assessment which is supported by Information and Communication Technology (ICT), such as e-testing or the use of e-portfolios or e-checklists. Centres which wish to use e-assessment must ensure that the national standard is applied to all candidate evidence and that conditions of assessment as specified in the Evidence Requirements are met, regardless of the mode of gathering evidence. Further advice is available in *SQA Guidelines on Online Assessment for Further Education (AA1641, March 2003)*, *SQA Guidelines on e-assessment for Schools (BD2625, June 2005)*.

National Unit specification: support notes (cont)

Unit title: Pharmaceutics: Prepare Pharmaceutical Preparations
 Aseptically

Disabled candidates and/or those with additional support needs

The additional support needs of individual candidates should be taken into account when planning learning experiences, selecting assessment instruments, or considering whether any reasonable adjustments may be required. Further advice can be found on our website www.sqa.org.uk/assessmentarrangements.

History of changes to Unit

Version	Description of change	Date
02	Amendments to wording within the 'Guidance on learning and teaching approaches in this unit', bottom paragraph.	10/10/2011
03	Clarification of the wording to avoid ambiguity and over/under assessment. Correction of typos and cut and paste errors in text.	10/12/2012

© Scottish Qualifications Authority 2012

This publication may be reproduced in whole or in part for educational purposes provided that no profit is derived from reproduction and that, if reproduced in part, the source is acknowledged.

Additional copies of this Unit specification can be purchased from the Scottish Qualifications Authority. Please contact the Business Development and Customer Support team, telephone 0303 333 0330.