

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Science in Aseptic Processing

Unit Reference Number: Y/617/0961

Level: Three (3)

Credit Value: 12

Minimum Guided Learning Hours: 70

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand the basics of Chemistry	1.1 Explain the relation and composition of: <ul style="list-style-type: none"> a) Electrons b) Protons c) Neutrons d) Atomic number e) Atomic mass
	1.2 State the characteristics and physical and chemical properties of the groups of elements in the Periodic Table
	1.3 Describe the bonding that occurs between elements to form compounds
	1.4 Explain the relation between <ul style="list-style-type: none"> a) relative atomic mass b) relative molecular mass c) molar quantities
	1.5 State how changes in conditions affect reaction rates
	1.6 Identify the common SI units used in pharmaceutical science and the Greek symbols for small quantities
	1.7 Explain the principles of balanced equations for chemical reactions
	1.8 Explain the typical drug breakdown reactions related to chemical structure
	1.9 Explain protein chemistry and the impact on stability

	1.10	Explain factors affecting solubility
	1.11	Explain Partition Chemistry
	1.12	Explain Rate Kinetics
	1.13	State the reference sources available to use for information on pharmaceutical products
2. Understand the basics of Pharmaceutics and Formulation	2.1	State the main presentations of Aseptic Pharmaceuticals
	2.2	Explain the routes of administration for different types of formulations
	2.3	Explain the function of typical excipients
	2.4	Compare the devices for compounding and presenting injectable medicines
	2.5	List the physical properties of solutions
	2.6	Describe the following: a) Standards of water b) Preparation of water
	2.7	Identify the functions of water
3. Understand the basics of Radio Pharmacy	3.1	Outline the types of Radioactivity in Radio Pharmacy
	3.2	Describe nuclear decay and half life, decay cascades and in-growth
4. Understand the basics of Materials Science	4.1	Describe the structure and nature of materials used in pharmaceutical containers and devices
	4.2	Explain Leaching Chemistry
	4.3	Explain container-drug interactions
	4.4	Compare the structure and function of different filters
5. Understand the basic structure of Biological Chemicals	5.1	Explain the structure and function of: a) Carbohydrates b) Proteins c) Lipids
	5.2	Explain the structure, action and properties of the enzymes that speed up digestion
	5.3	Describe the processes of a) Metabolism b) Anabolism c) Catabolism

	5.4	Describe the structure and function of Nucleic Acids
6. Describe the structure and function of Nucleic Acids	6.1	Describe the process of: a) Diffusion b) Osmosis c) Active transport across a semi-permeable membrane
	6.2	Describe the impact of the tonicity of solutions on body fluids and tissues
	6.3	Describe the principles of Homeostasis
	6.4	Describe the structure and function of different biological systems and organs and how they support the body
7. Understand the basics of Clinical Pharmacy	7.1	Define the major classes of drugs
	7.2	Explain the use of Parenteral Nutrition and the effect on body fluids and electrolytes
	7.3	Demonstrate how doses are calculated
8. Understand the basics of Microbiology	8.1	For common types of microorganisms, describe: a) The structure b) The key characteristics c) Defence mechanisms d) The life cycle e) The requirements for growth
	8.2	State the types of infectious diseases caused by microorganisms
	8.3	Describe the routes and modes of transmission of infection
	8.4	State the difference between pathogenic and non-pathogenic micro-organisms
	8.5	Describe the roles and functions of: a) White blood cells b) Antibodies c) Normal human flora in resisting infectious diseases
	8.6	Explain how the processes of sterilisation and disinfection affect microorganisms
	8.7	Explain processes used to analyse microbiological samples and identify cultures
	8.8	Explain processes to analyse and report microbiological data

Indicative Content

LO1	<p>1.2 Elements include:</p> <ul style="list-style-type: none">• Groups• Periods• Alkali metals• Alkaline metals• Non-metals• Transitional metals <p>1.4 Bonding includes:</p> <ul style="list-style-type: none">• Ionic• Covalent• Hydrogen <p>1.5 Conditions include:</p> <ul style="list-style-type: none">• Concentration• Temperature• Pressure• Particle size• Catalysts <p>1.9 Reactions include:</p> <ul style="list-style-type: none">• oxidation,• hydrolysis,• free radical reactions• catalysis• Acid based (pH)• Light• Drug/Drug (compatibility) <p>1.10 Protein chemistry includes:</p> <ul style="list-style-type: none">• 2y, 3y, 4y structures <p>1.12 Partition chemistry includes:</p> <ul style="list-style-type: none">• Lipophilic• Hydrophilic <p>1.13 Rate Kinetics:</p> <ul style="list-style-type: none">• chemical degradation• effect of temperature• concentration <p>1.15 Reference sources:</p> <ul style="list-style-type: none">• Martindale• British Pharmacopoeia (B.P.)• Stabilis• Radiopharmacy textbooks• SPC reference sources
LO2	<p>2.2 Formulations include:</p> <ul style="list-style-type: none">• Emulsions,• Suspensions,• Colloids• Solubilised systems• Powder systems

	<ul style="list-style-type: none"> • Freeze-dried systems <p>Routes of administration could include: injectable topical eyedrops</p> <p>2.3 Excipient types include:</p> <ul style="list-style-type: none"> • Water for Injections • pH adjusters • Tonicity adjusters • Preservatives • Co-solvents • Emulsifier • Surface-active agents – micelles • Liposomes • Cyclic complexing agents • Protein stabilisers <p>2.5 Physical properties:</p> <ul style="list-style-type: none"> • Solubility, solute, solvent • Saturated, supersaturated • Isotonicity • Factors affecting the rate of solution <p>2.6 Types of water should include:</p> <ul style="list-style-type: none"> • Water for injection • Water for irrigation • Potable water <p>2.7 The functions of water as a:</p> <ul style="list-style-type: none"> • Solvent • Vehicle • Temperature buffer
LO3	<p>3.1 Types of radioactivity include:</p> <ul style="list-style-type: none"> • Alpha, • Beta, • Gamma
LO4	<p>4.1 Materials include:</p> <ul style="list-style-type: none"> • Plastics • Clinical rubbers (eg syr bungs) • Glass · Silicone lubricants • Metals <p>4.3 Should include adsorption and absorption</p> <p>4.4 Filters include:</p> <ul style="list-style-type: none"> • HEPA • Membrane (hydrophilic & hydrophobic)
LO5	<p>5.1</p> <p>a) Carbohydrates include:</p> <ul style="list-style-type: none"> • Simple ring and straight chain forms of monosaccharides • Disaccharides • Polysaccharides <p>b) Protein function includes:</p> <ul style="list-style-type: none"> • Enzymes • Transport proteins • Contractile proteins • Antibodies / Immuno-proteins • Membrane proteins

	<ul style="list-style-type: none"> • Structural proteins • Hormones • Refer also to Polypeptides <p>5.1 Protein structure includes reference to:</p> <ul style="list-style-type: none"> • Amino acids • Primary, secondary, tertiary & quaternary structure • Metallo-proteins <p>c) Lipids include:</p> <ul style="list-style-type: none"> • Glycerol • Saturated and unsaturated fatty acids • Triglycerides • Phospholipids <p>5.4 Nucleic acids include: Nucleotides Deoxyribonucleic acid (DNA) Ribonucleic acid (RNA)</p>
LO6	<p>6.2 Tissues include:</p> <ul style="list-style-type: none"> • Epithelial tissue • connective tissue • muscle tissue • Nerve tissue <p>6.3 Homeostasis includes:</p> <ul style="list-style-type: none"> • Importance of the body's need to maintain an optimal internal environment for cell function • Role of negative and positive feedback mechanisms • Function of the digestive system in maintaining homeostasis • Causes and effects of homeostatic disorders <p>6.4 Systems and organs include:</p> <ul style="list-style-type: none"> • Cardiovascular system • Circulatory system • Eye • Respiratory system • Lymphatic system • Digestive system • Urinary system • Skeletal system • Muscular system • Skin
LO7	<p>7.1 Major classes of drugs include:</p> <ul style="list-style-type: none"> • Controlled drugs • Antibiotics • MABs (monoclonal antibodies) • Chemotherapy • Radiopharmacy <p>7.2 Parenteral nutrition:</p> <ul style="list-style-type: none"> • Body fluids • Risks • Electrolytes <p>7.3 Calculations include:</p> <ul style="list-style-type: none"> • BMI • Dose per kg • Clearance-based calculations
LO8	<p>8.1 Microorganisms include:</p>

- Bacteria
- Fungi
- Protozoa
- Viruses
- Prokaryotic cells
- Eukaryotic cells

8.1 Defence mechanisms include:

- Spore formation
- Resistance
- Capsid transfer
- Biofilm formation

8.4 Requirements for growth include:

- Media,
- Oxygen,
- Temperature,
- Pathogens,
- Environmental microorganisms

8.7 Processes include:

- sample handling,
- incubation,
- identification by morphological, chemical and automated methods

8.8 Analyse & report should include:

- statistical analysis,
- control limits,
- presentation & reporting

Uned Cymhwyster

Mae'r uned hon yn rhan o gymhwyster rheoleiddiedig.

Teitl yr Uned: Gwyddoniaeth mewn Prosesu Aseptig

Lefel: Three (3)

Gwerth Credyd: 12

GLH Lleiafswm: 70

Deilliant Dysgu (Bydd y Dysgwr yn):	Maen Prawf Asesu (Gall y Dysgwr):
1. Deall hanfodion cemeg	1.1 Egluro perthynas a chyfansoddiad: a) Electronau b) Protonau c) Niwtronau d) Rhif Atomig e) Màs Atomig
	1.2 Nodi nodweddion a phriodweddau ffisegol a chemegol y grwpiau o elfennau yn y Tabl Cyfnodol
	1.3 Disgrifio'r bondio sy'n digwydd rhwng elfennau i ffurfio cyfansoddion
	1.4 Egluro'r berthynas rhwng: a) Màs Atomig cymharol b) Màs moleciwlaidd cymharol c) Symiau molar
	1.5 Nodi sut mae newidiadau mewn amodau yn effeithio ar gyfraddau adwaith
	1.6 Nodi'r unedau SI cyffredin a ddefnyddir mewn gwyddor fferyllol a'r Symbolau Groegaidd ar gyfer symiau bach
	1.7 Egluro egwyddorion hafaliadau cytbwys ar gyfer adweithiau cemegol
	1.8 Egluro'r adweithiau ymddatod cyffuriau nodweddiadol sy'n gysylltiedig ag adeiledd cemegol
	1.9 Egluro cemeg protein a'r effaith ar sefydlogrwydd

	1.10	Egluro ffactorau sy'n effeithio ar hydoddedd
	1.11	Egluro cemeg ymrannu
	1.12	Egluro Cineteg Cyfradd
	1.13	Nodi'r ffynonellau cyfeirio sydd ar gael i'w defnyddio i gael gwybodaeth am gynhyrchion fferyllol
2. Deall hanfodion Fferylliaeth a Fformiwleiddiad	2.1	Nodi prif gyflwyniadau Cynhyrchion Fferyllol Aseptig
	2.2	Egluro'r llwybrau gweinyddu ar gyfer gwahanol fathau o fformiwleiddiau
	2.3	Egluro swyddogaeth llenwyddion nodweddiadol
	2.4	Cymharu'r dyfeisiau ar gyfer cymysgu a chyflwyno meddyginiaethau chwistrelladwy
	2.5	Rhestru priodweddau ffisegol hydoddiannau
	2.6	Disgrifio'r canlynol: a) Safonau dŵr b) Paratoi dŵr
	2.7	Nodi swyddogaethau dŵr
3. Deall hanfodion Fferylliaeth Radio	3.1	Amlinellu'r mathau o Ymbelydredd sydd mewn Fferylliaeth Radio
	3.2	Disgrifio ddadfeiliad niwclear a hanner oes, rhaedrau dadfeiliad a mewn-dwf
4. Deall hanfodion Gwyddor Deunyddiau	4.1	Disgrifio strwythur a natur deunyddiau a ddefnyddir mewn cynwysyddion a dyfeisiau fferyllol
	4.2	Egluro Cemeg Trwytholchi
	4.3	Egluro rhyngweithiadau cynhwysydd-cyffur
	4.4	Cymharu adeiledd a swyddogaeth gwahanol hidlyddion
5. Deall strwythur sylfaenol Cemegau Biolegol	5.1	Egluro strwythur a swyddogaeth : a) Carbohydradau b) Proteinau c) Lipidau
	5.2	Egluro adeiledd, gweithred a phriodweddau'r ensymau sy'n cyflymu treuliad

	5.3	Disgrifio prosesau: a) Metaboledd b) Anaboledd c) Cataboledd
	5.4	Disgrifio strwythur a swyddogaeth Asidau Niwclêig
6. Deall Anatomeg a Ffisioleg dynol	6.1	Disgrifio prosesau: a) Trylediad b) Osmosis c) Cludiant actif Ar draws pilen lled-athraidd
	6.2	Disgrifio effaith tonigrwydd hydoddiannau ar hylifau a meinweoedd y corff
	6.3	Disgrifio egwyddorion Homeostatis
	6.4	Disgrifio adeiledd a swyddogaeth gwahanol systemau biolegol ac organau a sut maent yn cynnal y corff
7. Deall hanfodion Fferylliaeth Glinigol	7.1	Diffinio'r prif ddsbarthiadau o gyffuriau
	7.2	Egluro'r defnydd o Faeth Parenterol a'r effaith ar hylifau'r corff ac electrolytau
	7.3	Dangos sut mae dosau yn cael eu cyfrifo
8. Deall hanfodion Microbioleg	8.1	Ar gyfer mathau cyffredin o ficro- organebau, disgrifio: a) Y strwythur b) Y nodweddion allweddol c) Mecanweithiau amddiffyn d) Y cylch bywyd e) Y gofynion ar gyfer twf
	8.2	Nodi'r mathau o glefydau heintus a achosir gan ficro-organebau
	8.3	Disgrifio llwybrau a dulliau trosglwyddo haint
	8.4	Nodi'r gwahaniaeth rhwng mico- organebau pathogenig a di-bathogenig
	8.5	Disgrifio rolau a swyddogaethau: a) Celloedd gwyn b) Gwrthgyrff c) Fflora dynol arferol Mewn gwrthsefyll clefydau heintus
	8.6	Egluro sut mae prosesau sterileiddio a diheintio yn effeithio ar ficro-organebau
	8.7	Egluro prosesau a ddefnyddir i samplau microbiolegol a nodi cyfryngau meithrin

Cynnwys Mynegol

LO1

AC 1.2

Mae elfennau yn cynnwys:

- Grwpiau
- Cyfnodau
- Metel Alcalïaidd
- Metelau Alcalïaidd
- Anfetelau
- Metelau Trawsffurfiol

AC 1.4

Mae Bondio yn cynnwys:

- Ionig
- Cyfalent
- Hydrogen

AC 1.5

Mae Amodau yn Cynnwys:

- Crynodiad
- Tymheredd
- Pwysedd
- Maint Gronynnau
- Catalyddion

AC 1.9

Mae Adweithiau yn Cynnwys:

- Ocsidiad
- Hydrolysis
- Adweithiau radical rhydd
- Catalyddion
- Bas asid (pH)
- Golau
- Cyffur / Cyffur (cydweddoldeb)

AC 1.10

Mae Cemeg Protein yn Cynnwys:

- strwythurau 2y, 3y, 3y

AC 1.13

Cineteg Cyfradd:

- Diraddiad Cemegol
- Effaith Tymheredd
- Crynodiad

AC 1.15

Ffynonellau Cyfair:

- Martindale
- British Pharmacopoeia (B.P)

	<ul style="list-style-type: none"> • Stabilis • Gwerslyfrau Radiofferylliaeth • Ffynonellau cyfair SPC
LO2	<p>AC 2.2</p> <p>Mae fformwleiddiadau yn cynnwys:</p> <ul style="list-style-type: none"> • Emylsiynau • Daliannau • Coloidau • Systemau hydoddadwy • Systemau powdr • Systemau wedi'u rhewi-sychu <p>Gallai llwybrau gweinyddu gynnwys:</p> <ul style="list-style-type: none"> • Chwistrelladwy • Argroenol • Diferion llygaid <p>AC 2.3</p> <p>Mae mathau o lenwyddion yn cynnwys:</p> <ul style="list-style-type: none"> • Dŵr ar gyfer pigiadau • Addaswyr pH • Addaswyr tonigrwydd • Cadwolion • Cyd-doddyddion • Emylsydd • Cyfryngau arwyneb-weithredol – micelles • Lipsomau • Cyfryngau cymhlethu cylchol • Sefydlogyddion protein <p>AC 2.5</p> <p>Priodweddau Ffisegol:</p> <ul style="list-style-type: none"> • Hydoddedd, hydoddyn, hydoddydd • Dirlawn, uwch-ddirlawn • Isotonigrwydd • Ffactorau sy'n effeithio ar gyfradd hydoddi <p>AC 2.6</p> <p>Dylai mathau o ddŵr gynnwys:</p> <ul style="list-style-type: none"> • Dŵr ar gyfer pigiad • Dŵr ar gyfer dyfrhau • Dŵr yfed <p>AC 2.7</p> <p>Swyddogaethau dŵr fel a:</p> <ul style="list-style-type: none"> • Hydoddydd • Cyfrwng • Clustogwr tymheredd
LO3	<p>AC 3.1</p> <p>Mae mathau o ymbelydredd yn cynnwys:</p> <ul style="list-style-type: none"> • Alfa • Beta • Gama
LO4	<p>AC 4.1</p> <p>Mae deunyddiau yn cynnwys:</p> <ul style="list-style-type: none"> • Plastigau

	<ul style="list-style-type: none"> • Rwberi clinigol (e.e. syr byngiau) • Gwydr • Ireidau silicôn • Metalau <p>AC 4.3 Dylai gynnwys arsguniad ac amsugnad</p> <p>AC 4.4 Mae hidlyddion yn cynnwys:</p> <ul style="list-style-type: none"> • HEPA • Pilen (hydroffilig a hydroffobig)
LO5	<p>AC 5.1</p> <p>a) Mae carbohydradau yn cynnwys:</p> <ul style="list-style-type: none"> • Ffurfiâu cylch syml a chadwyn syth o fonosacaridau • Discaridau • Polysacaridau <p>b) Mae swyddogaeth protein yn cynnwys:</p> <ul style="list-style-type: none"> • Ensymau • Proteinau cludo • Proteinau cyfangol • Gwrthgyrff/ imiwno-broteinau • Proteinau pilen • Proteinau strwythurol • Hormonau • Cyfeiriwch hefyd at Polypeptidau <p>Mae Strwythur Protein yn cynnwys cyfeiriad at:</p> <ul style="list-style-type: none"> • Asidau amino • Strwythur sylfaenol, eilaidd, trydyddol a chwarterol • Proteinau metelaidd <p>c) Mae lipidau yn cynnwys:</p> <ul style="list-style-type: none"> • Glyserol • Asidau braster dirlawn ac annirlawn • Triglyseridau • Ffosfolipidau <p>AC 5.4 Mae asidau niwclëig yn cynnwys:</p> <ul style="list-style-type: none"> • niwcleotidau • Asid Deocsriboniwcleig (DNA) • Asid riboniwcleig (RNA)
LO6	<p>AC 6.2 Mae meinweoedd yn cynnwys:</p> <ul style="list-style-type: none"> • Meinwe epithelial • Meinwe cysylltiol • Meinwe cyhyr • Meinwe nerf <p>AC 6.3 Mae homeostasis yn cynnwys:</p> <ul style="list-style-type: none"> • Pwysigrwydd angen y corff i gynnal yr amgylchedd mewnol gorau posibl ar gyfer swyddogaeth cell • Rôl mecanweithiau adborth negyddol a chadarnhaol • Swyddogaeth y system dreulio mewn cynnal homeostasis

	<ul style="list-style-type: none"> • Achosion ac effeithiau anhwylderau homeostatig <p>AC 6.4</p> <p>Systemau ac organau:</p> <ul style="list-style-type: none"> • System gardiofasgwlaidd • System cylchrediad y Gwaed • Llygad • System anadlol • System lymffatig • System dreulio • System wrinol • System ysgerbydol • System cyhyrau • Croen
LO7	<p>AC 7.1</p> <p>Mae'r dosbarthiadau mawr o gyffuriau yn cynnwys:</p> <ul style="list-style-type: none"> • Cyffuriau a reolir • Gwrthfotigau • MABs (gwrthgyrff monoclonaid) • Cemotherapi • Radiofferylliaeth <p>AC 7.2</p> <p>Maeth Parenterol:</p> <ul style="list-style-type: none"> • Hylifau'r Corff • Risgiau • Electrolytau <p>AC 7.3</p> <p>Mae cyfrifiadau yn cynnwys:</p> <ul style="list-style-type: none"> • BMI • Dos fesul kg • Cyfrifiadau seiliedig ar gliriad
LO8	<p>AC 8.1</p> <p>Mae micro-organebau yn cynnwys:</p> <ul style="list-style-type: none"> • Bacteria • Ffwng • Protosa • Firysau • Celloedd Procaryotig • Celloedd Ewcaryotig <p>Mae mecanweithiau amddiffyn yn cynnwys:</p> <ul style="list-style-type: none"> • Ffuriant sbôr • Ymwrthedd • Trosglwyddiad capsid • Ffuriant biofilm <p>AC 8.4</p> <p>Mae gofynion ar gyfer twf yn cynnwys:</p> <ul style="list-style-type: none"> • Haen ganol y cyhyr • Ocsigen • Tymheredd • Pathogenau • Mirco-organebau amgylcheddol

AC 8.7

Mae prosesau yn cynnwys:

- Trin samplau
- Deoriad
- Adnabod yn ôl dulliau morffolegol, cemegol ac awtomataidd

AC 8.8

Dylai dadansoddi ac adrodd gynnwys:

- Dadansoddiad Ystadegol
- Terfynau Rheoli
- Cyflwyno ac Adrodd