The School of Pharmacy
University of London

Programme Handbook

MSc Drug Delivery

2012/2013

Disclaimer

Every effort has been made to ensure that the information in this Handbook is correct at the time of going to press (April 2012). The School reserves the right to make amendments to the information contained in this Handbook as a result of unforeseen events or circumstances beyond the School's control or if deemed reasonably necessary by the School.

In the event that amendments are made, the School shall take reasonable steps to notify students as soon as possible.

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Welcome from the Programme Team

Welcome to UCL School of Pharmacy and congratulations on gaining a place to study here on the MSc Drug Delivery.

The MSc in Drug Delivery is a popular course and we have seen around 200 students graduate over the past 10 years. During your time at the School you will become an integral member of the Pharmaceutics Department, learning about the latest developments in drug delivery platforms, devices and strategies and undertaking your research project. You will also develop a range of transferable skills, notably in pharmaceutical analysis, that will help you with career progression, whether you stay in academia or move to industry.

Completing an MSc in 12 months is a challenge, particularly for international students who are studying in a foreign language. Moving to a new country, leaving behind family and friends can be overwhelming. Good time management and practising and improving your English will help you cope with the demands of the course, as will forming friendships with your fellow Delivery students. The relationships you build over the next year, especially that with the School itself, will last a lifetime and we are sure that you will always look back on your time with us with fond memories.

Do read this handbook carefully and keep it for reference throughout the year. Your tutors at the School are here to mentor and to support you, so if you have any problems or queries do come and talk to one of us.

We wish you good luck with your studies and look forward to getting to know you over the coming year.

Dr Simon Gaisford
Course Director, MSc in Drug Delivery

Dr Sudax Murdan
Deputy Course Director, MSc in Drug Delivery

1. General Information

1.1 PROGRAMME HANDBOOK

This Programme Handbook provides an introduction to the programme and contains the key information you need about the programme of study. Amongst other things, this handbook covers the curriculum, teaching and learning, administrative procedures, key personnel and assessment.

This handbook should be read in conjunction with the School Student Handbook, which provides information about School Personnel, Academic Regulations, administrative procedures and School Policies.

The Handbook is relevant to you throughout your studies so please look after it. There will inevitably be some changes during your time with us, particularly in relation to the teaching staff, programme content and assessment patterns and we shall keep you informed of any important changes. However, you should make sure that you keep up to date by reading our communications, checking the notice boards, reading your emails and browsing Moodle and the School Website.

More detailed information on School regulations, examinations, and appeals procedures are available on the School website under *Student Life* at the following link: http://www.pharmacy.ac.uk/studentregulations.html. Students are expected to be fully aware of these procedures but, if in any doubt, please enquire at The Registry for help.

We hope you find this handbook useful. It is revised every year to include new information and to make it easier to use. If you have any comments about the handbook or suggestions for improving the information provided, please forward your comments to Dr Simon Gaisford (s.gaisford@ucl.ac.uk).

1.2 PROGRAMME ADMINISTRATION PERSONNEL

Programme Director
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Postgraduate Programmes Manager
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Programme Team
Most academic members of the Pharmaceutics staff contribute to the MSc in Drug Delivery.

Name	*Role*
Professor Kevin Taylor	Head of the Department of Pharmaceutics and Professor of Clinical Pharmaceutics
Professor Abdul Basit	Professor of Pharmaceutics
Professor Stephen Brocchini	Professor of Chemistry and Drug Delivery
Professor Kostas Kostarelos	Deputy Head of the Centre for Drug Delivery Research
Professor Ijeoma Uchegbu	Professor of Pharmaceutical Nanoscience
Dr Simon Gaisford	Reader in Pharmaceutics
Dr Catherine Tuleu	Reader in Paediatric Drug Delivery
Dr Majella Lane	Senior Lecturer in Pharmaceutics
Dr Sudax Murdan	Senior Lecturer in Pharmaceutics
Dr Soma Somavarapu	Lecturer in Pharmaceutics

Programme Administration
Programme Administration is provided by the Registry and the Teaching Office. Contact details can be found in the Student Handbook.

END OF SECTION 1

2. Programme Information

2.1 PROGRAMME DETAILS

Award:	MSc Drug Delivery
Awarded by:	UCL School of Pharmacy
Department:	Pharmaceutics
Length and Mode:	1 year full-time
Maximum Registration Period:	3 years
Credits:	180 credits at Level 7
ECTS:	90 ECTS
Programme Director:	Dr Simon Gaisford
Deputy Programme Director:	Dr Sudax Murdan

Teaching site
UCL School of Pharmacy
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2.2 THE MSc DRUG DELIVERY PROGRAMME

The MSc in Drug Delivery is a 12-month full-time taught postgraduate programme. The aim of the MSc programme is to enable students to acquire a comprehensive knowledge of the processes involved in the delivery of drugs to therapeutic targets and to equip students with the research skills and practical ability successfully to develop products and processes relevant to the needs of the pharmaceutical industry.

The course has drawn international students, mainly with first degrees in Pharmacy, from a variety of countries including Afghanistan, Bangladesh, China, Cyprus, Denmark, Egypt, Ghana, Greece, India, Iran, Iraq, Jordan, Kenya, Kuwait, Malaysia, Malta, Nepal, Nigeria, Pakistan, Palestine, Peru, Portugal, Romania, Spain, Sri Lanka, Saudi Arabia, Sudan, Thailand, Turkey, the United Arab Emirates and Venezuela.

2.3 MASTER'S LEVEL DESCRIPTORS

Master's level awards are set at Level 7 of the Framework for Higher Education Qualifications in England, Wales and Northern Ireland (FHEQ) published by the Quality Assurance Agency for Higher Education (QAA). Descriptors for the Level 7 qualification are in two parts – (1) what each student must demonstrate in order to gain the award, and (2) the wider abilities that the typical student is expected to develop.

The MSc degree is awarded to students who have demonstrated:

1. Systematic understanding of knowledge and skills required in the application of pharmaceutical care.
2. Critical awareness of current problems and/or new insights in pharmacy practice.
3. Comprehensive understanding of techniques applied to advanced scholarship in pharmaceutics, which include problem solving skills, evaluation, research methods and data analysis.
4. Originality in the application of knowledge, together with a practical understanding of how established techniques of research and enquiry are used to create and interpret knowledge in pharmaceutics.
5. Conceptual understanding that enables the student to:
    - Evaluate critically current research and advanced scholarship in the discipline, and
    - Evaluate methodologies and develop critiques of them and, where appropriate, to propose new hypotheses.

Typically, holders of the MSc degree will be able to:

1. Deal with complex issues both systemically and creatively, make sound judgments in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences;
2. Demonstrate self-direction and originality in tackling and solving problems, and act autonomously in planning and implementing tasks at a professional or equivalent level;
3. Continue to advance their knowledge and understanding through continuing professional development, and
4. Develop new skills to an advanced level in pharmaceutics.

and will have:

5. The qualities and transferable skills necessary for employment requiring:
    - The exercise of initiative and personal responsibility; decision-making in complex and unpredictable situations, and
    - The independent learning ability required for continuing professional development.

2.4 PROGRAMME STRUCTURE

The MSc programme comprises **two** main components:

- Four taught modules (two in semester 1 and two in semester 2)
- A research project

The taught modules are assessed by a combination of coursework and written examination.

2.5 LEARNING AND TEACHING METHODS

Teaching methods are varied and include lectures, seminars, small group work, problem-based learning (PBL) approaches and individual project work. National experts - pharmacists and other health care professionals - contribute to the course. Class size varies from 8-30 students depending on the teaching format.

END OF SECTION 2

3. Modules

3.1 MODULE CHOICE

The list of taught modules may change from year to year to reflect changes in the research areas of the staff and to ensure that the syllabus covers the latest research developments in the pharmaceutical sciences. Every effort is made to inform students of any changes before the programme starts.

Lectures and seminars are, in some cases, shared with fourth year students on the Master of Pharmacy (MPharm) degree, although there is a separate tutorial programme for MSc students which are held weekly throughout the two semesters.

***Semester 1* – Students take 1 core module and 1 module out of 2 core electives:**

Core module

PHAYM022	Overcoming Biological Barriers	30 credits

Core elective modules (choose one of these)

PHAYM003	Clinical Pharmaceutics	30 credits
PHAYM023	Biopharmaceuticals	30 credits

***Semester 2* – Students take one core module and 1 module out of 2 core electives:**

Core module

PHAYM025	Methods of Analysis	30 credits

Core elective modules (choose one of these)

PHAYM024	Intelligent Design of Medicines	30 credits
PHAYM030	Nanomedicines and Targeted Drug Delivery	30 credits

3.2 MODULE OUTLINES

The modules are listed in order by ascending module codes. You will receive more detailed Module outlines at the start of the module and the content may be slightly different to the information published here. This is because staff are constantly updating their teaching in light of developments in current research and new thinking.

PHAYM003 CLINICAL PHARMACEUTICS
Module Leader(s): Professor Kevin Taylor/Dr Catherine Tuleu

This module comprises two elements. Clinical Pharmaceutics deals with the regulatory aspects and manufacture of off-licence formulations in a clinical setting. Invited speakers from the NHS teach a lot of the material and off-site visits to local teaching hospitals is included. Paediatric Medicines considers formulation aspects of medicines for children.

PHAYM022 OVERCOMING BIOLOGICAL BARRIERS
Module Leader(s): Dr Majella Lane

This module focuses on modified release technologies and the barriers encountered to both mucosal and non-mucosal drug delivery. The properties of polymers are discussed in relation to their application in controlled-release systems. An emphasis is placed on microsphere and nanoparticle technologies and the applications of these particulates to drug delivery. The nature of the barriers to achieving delivery by the oral, nasal, pulmonary, ocular, buccal and transdermal routes are studied in detail together with recent developments in devices and formulations to enable drug administration by the above routes.

PHAYM023 BIOPHARMACEUTICALS
Module Leader(s): Professor Ijeoma Uchegbu

Medicines in the new century will encompass a wide variety of actives (low molecular weight heterocyclic compounds, peptides, proteins, nucleotides, cells and even tissues); with these products largely driven by rapidly advancing insight into the molecular basis of both biological function and pathological processes. These actives, especially the biopharmaceuticals or biologics (proteins, peptides, genes, ribonucleic acids, oligonucleotides, cells and tissues) will need comprehensive activity/ toxicology profiling, a new set of analytic descriptors and crucially advanced drug delivery technologies. Current and future drug delivery scientists must be equipped with the skills to formulate and deliver these new actives. The aim of the Biopharmaceuticals lecture series is to present students with knowledge on the specific biological barriers that these new medicines encounter and the state of the art methods that are used to breach these barriers, and thus facilitate pharmacological activity from these new actives.

PHAYM024 INTELLIGENT DESIGN OF MEDICINES
Module Leader(s): Dr Simon Gaisford

Modern medicines contain numerous components (an ibuprofen tablet, for instance, contains around 10 individual ingredients) and each plays a significant role in the performance of the product. It is thus not easy to ensure the stability of such a formulation, because it must be

ensured that each component is stable on its own and also in combination. These processes can be classified as chemical changes. Furthermore, the physical form of a material is often critical to the performance of the final product. An example would be ensuring the correct polymorph (crystal form) of a drug is manufactured. Increasingly, the role of amorphous materials in pharmaceuticals is being understood (and exploited). Again, controlling the physical form of a material through manufacture, quantifying its presence and demonstrating its stability is central to getting a license to produce a new medicine. These processes are classified as physical changes. Once these properties are known they can be exploited to produce products that are easier or cheaper to produce, have a longer shelf life or which have a greater efficacy and/or fewer side-effects. This module concentrates on the assessment of the physical properties of materials, using a range of analytical tools, and considers the implications of these properties at all stages of the formulation, manufacture and distribution of a medicine. At the end of the course consideration is given to the regulatory and licensing aspects of pharmaceutical formulation. Course material is delivered primarily via a lecture series, but a problem-based coursework element runs throughout the module, during which the student deals with the key issues involved in characterising the physical properties of a drug and some excipients and their subsequent formulation. The lecture series is designed to support the student throughout the coursework element. The overall aim is to encourage the student to consider the ways in which physico-chemical information can be obtained and how it can be used to design better products.

PHAYM025 METHODS OF ANALYSIS

Module Leader(s): Dr Hardyal Gill / Dr Simon Gaisford

The method aims to provide an introduction to commonly used methods in pharmaceutical analysis. The main focus is on the principle, use and best practice of HPLC, since this technique is ubiquitous throughout the pharma industry and is the primary technique underpinning most assay development. Other techniques to be discussed include thermal analysis (differential scanning calorimetry, DSC and thermogravimetry, TGA) and dynamic vapour sorption (DVS). Unlike traditional MSc modules, the teaching strategy to be employed splits the course material into theory (lectures) and practical (use of the instruments to assay samples).

PHAYM030 NANOMEDICINES AND TARGETED DRUG DELIVERY

Module Leader(s): Prof Kostas Kostarelos

This module will explain the concept of drug targeting with drug carriers and distinguish between active and passive drug targeting. An appreciation of the strategies adopted in the choice of delivery system for a particular drug and the methods of characterising the key parameters of delivery systems will be developed. Targeting to specific tissues such as brain, liver, spleen and tumours will be discussed. Site-specific delivery and macroparticle uptake in the gastrointestinal tract will be addressed. The scope and limitations of specific examples of

carrier systems such as liposomes, niosomes, nanoparticles and soluble polymer conjugates will be explored. The physiological environment will be emphasised and the latest advances in drug targeting described.

END OF SECTION 3

4. Research Project

4.1 OVERVIEW

PHAYM021 Dissertation – Drug Delivery

The major component of the MSc course is the research project. Projects are assigned in Semester 1 and are supervised by an academic member of staff in the Department of Pharmaceutics. Projects are unique and usually complement the particular research activities of the supervisor. Laboratory work (which can be undertaken either in the supervisor's laboratory or within the dedicated MSc laboratory suite) is undertaken between February and August. Students are expected to develop their own research ideas and experimental series in discussion with their supervisor and complete a comprehensive literature review to supplement their work. Results are written up and submitted as a dissertation and presented in an oral presentation at the end of the year.

Although projects are unique and depend upon the specific research being conducted at the time, examples of research projects undertaken in the past are set out in Section 4.2. It is a reasonable expectation that research work is published; listed below are examples of peer-reviewed research papers involving former MSc students (the MSc student's name is highlighted);

- Al-Jamal, W., **Al-Ahmady, Z.S**., Kostarelos, K. Biomaterials, 33 (2012) 4608-4617.

- Mueannoom, W., **Srisongphan, A**., Taylor, K.M.G., Hauschild, S., Gaisford, S. Eur. J. Pharm. Biopharm., 80 (2012) 149-155.

- **Tian, B**., Al-Jamal, W.T., Al-Jamal, K.T., Kostarelos, K. Int. J. Pharm., 416 (2011) 443-447.

- Freire, A.C., Basit, A.W., **Choudhary, R**., Piong, C.W., Merchant, H.A. Int. J. Pharm., 415 (2011) 15-28.

- Liu, F., Merchant, H.A., **Kulkarni, R.P**., Alkademi, M., Basit, A.W. Eur. J. Pharm. Biopharm., 78 (2011) 151-157.

- Merchant, H.A., McConnell, E.L., Liu, F., Ramaswamy, C., **Kulkarni, R.P**., Basit, A.W., Murdan, S. Eur. J. Pharm. Sci., 42 (2011) 3-10.

- Murdan, S., Milcovich, G., **Goripathi, G.S**. Skin Pharm. Physiol., 24 (2011) 175-181.

- Fadda, H.K., **Khanna, M**., Osman, D., Gaisford, S. and Basit, A. Eur. J. Pharm. Biopharm., 76 (2010) 493-497

- Murdan, S., **Poojary, C**., Patel, D.R., Fernandes, J., Haman, A., **Sheikh, Z**., J. Pharm. Pharmacol., 62 (2010) 1247-1248.

- Gaisford, S., **Buanz, A.B.M**. and Jethwa, N. J. Pharm. Biomed. Anal., 53 (2010) 366-370.

- Gaisford, S., **Dennison, M**., Tawfik, M., Jones, M., Saunders, M. Int. J. Pharm., 393 (2010) 74-78

4.2 SAMPLE PROJECT TITLES AND OUTLINES

The following research projects were offered to students in previous years. The list of research projects changes each year but this list is intended to show the typical range of projects on offer.

Protein nanoparticles for inhalation
This project will examine the process of protein (lysozyme) nanoparticle formation. The nanoparticles will be characterised by photon correlation spectroscopy and electron microscopy. An assay of enzymatic activity will be established to assess the retention of biological activity under processing conditions. The nanoparticles will be formulated in an HFA propellant and the pMDI formulation evaluated by Andersen Cascade Impaction analysis.

Surface modification by surfactants of carrier lactose particles and the effect on drug aerosolisation
Lactose is a commonly used carrier in dry powder inhalation formulations. This project will seek to change the lactose particle surface by adsorption of a range of surfactants. This will provide the opportunity of varying the hydrophobicity and surface charge of the lactose. The influence of these adsorbed films on the aerosolisation of a drug will be examined.

Safe use of the extemporaneous preparation of Sildenafil Citrate for children with Pulmonary Hypertension
The practice of extemporaneous or small volume compounding is widespread even if the quality and applicability of the information on the product is often inconsistent. In order to improve safety of use of sildenafil citrate (Viagra_) used unlicensed in children with pulmonary hypertension, the aims of this work are to provide better quality information on paediatric extemporaneous formulations of Viagra by:

- Comparing the crushed tablets (commonly used on the wards) and the extemporaneous preparation (2mg/ml suspension proposed by Princess Margaret

hospital, Perth, Australia) in terms of uniformity of dose, effect of dilution and in vitro dissolution profiles.

- Establishing the physicochemical and bacteriological stability of the extemporaneous preparation over 6 months and during a simulated treatment course. The extemporaneous preparation, if it is stable enough, could be then prepared in GMP conditions from appropriate suppliers for hospitals.

Cysteamine opthalmic gel in children

In the long-term treatment of cystinosis, compliance is clearly a problem with administration of 1 drop of cysteamine in each eye many times daily. Therefore, a sustained release preparation such as an in situ ophthalmic gel would prove useful. When installed into the cul-de-sac, it shifts from an easy to administer liquid to a transparent or translucent gel that is retained longer in the eye, increasing bioavailability while reducing both systemic absorption and the need of frequent administration. The solgel transition can occur as a result of physicochemical changes such as pH, temperature, ionic strength or a combination of different mechanism depending on polymers used. The aim of the project is the formulation of ophthalmic gels of cysteamine with different polymers and comparison of different formulations in vitro (viscosity measurement, drug release through diffusion studies).

The use of disintegrant in HPMC capsule formulation

In recent years, capsule shells made from the polymer hydroxypropyl methylcellulose (HPMC) have been made available for oral administration of drugs. These capsules, unlike the commonly used gelatine capsules, are non-animal material derived eliminating problems with contamination and religious or dietary restrictions. Unlike gelatine capsules, their disintegration is not temperature dependant but their dissolution was shown to be influenced by the concentration of potassium ions (if over 12.5 mM) and total ions (if over 355 mM) rather than by the pH. Those results were obtained with a formulation containing 10% of disintegrant (Croscarmellose Sodium, Acdisol_). Preliminary results in vitro showed that higher levels of Acdisol_ in HPMC capsule formulations actually retards drug release and lead to more variable results then with gelatine capsules. In vivo, the presence of a low fluid environment such as the fed stomach could further prolong HPMC capsule disintegration, drug release and therefore have serious clinical implications. The aims of this project are to investigate in vitro the mechanisms involved in this retardation phenomenon.

Development and in vitro evaluation of novel delivery systems for colonic targeting

Targeting drugs to the colon has become an increasingly important avenue of research investigation. Traditionally, pH responsive polymers in the form of enteric coatings have been utilised to deliver drugs to the colon; however, the site specificity of such formulations is known to be poor. Systems that are susceptible to degradation by colonic bacteria are believed to offer a more precise approach to targeting. However, drug release from such formulations is generally slow because of the slow rate of fermentation in the colon. This project will seek to develop and assess the in vitro potential of a multi-triggered delivery system for colonic delivery, which is based on the simplicity of the pH responsive approach

and the site specificity of the bacterial approach. Such a system should offer a practical solution to the problem of site specific targeting to the colon via the oral route.

An assessment of the stability of aspirin in solid-state mixtures using isothermal microcalorimetry

Microcalorimetry offers the potential greatly to reduce the time taken to determine product stability because of its inherent sensitivity to changes in heat, but its application to solid-state samples is limited. In this project, the interactions between two commonly used excipients (lactose and magnesium stearate) will be studied; lactose does not interact with aspirin but magnesium stearate is known to cause the drug=s degradation. The data will be used to understand the nature of the interactions occurring and to demonstrate the utility of the method for stability assessment.

The prediction of product stability for multi-component formulations by analysis of microcalorimetric data

Virtually all processes can be followed using microcalorimetry, but this often results in complex data comprising responses from different samples. What is needed is an approach to data analysis that allows deconvolution of the data into their respective individual responses. In this project, real and simulated data for complex pharmaceutical systems will be analysed using a number of recently derived models with the intention of being able to isolate the heat-flow response of a specific process (such as drug degradation).

Development of a formulation for the respiratory delivery of the anti-appetite peptide

A specific peptide appears to have remarkable appetite suppressive effects when administered parenterally immediately before a meal. We suggest that, from a patient=s point of view, it would be easier and more acceptable to simply inhale a mist containing the peptide in an insoluble form prior to a meal. Generally polypeptides have limited physical and chemical stability when dissolved in an aqueous vehicle. By analogy with some investigations on human growth hormone currently being carried out at the University of Illinois at Chicago, we suggest it should be possible to produce insoluble adducts of this peptide with aminoglucosides and deliver these in a number of carriers including chitosan microparticles formulated to be at the optimum size range for respiratory delivery by inhalation from a mist.

Microencapsulation of antigens using supercritical fluid technology and spray drying for pulmonary delivery of vaccines

Supercritical fluid (SCF) technology has been in use for the past 30 years as an environmentally benign, energy- and cost- saving tool in various industries. SCF technology is making progress in many different fields of the pharmaceutical industry especially in operations including crystallization, particle size reduction, and the preparation of drug delivery systems, coating, and product sterilization. The advantages of SCF technology include the use of mild conditions for pharmaceutical processing (which is advantageous for labile proteins and peptides), the use of environmentally benign nontoxic materials (such as CO2), minimization of organic solvent use, and production of particles with controllable

morphology, narrow size distribution. We have recently shown in a pioneering study that by using supercritical fluid technology, liposomes can be produced. We are now aiming at further evaluation of this technology towards a pulmonary drug delivery platform. For this purpose, microparticulate carrier systems will be prepared and loaded with protein based vaccines. The carrier systems will then be characterized with regard to physicochemical parameters and antigen loading and release. Testing will also involve cell culture experiments as well as in vivo studies in animals.

Can piperine enhance the permeation of drug into skin?
The transdermal route is a popular route because of its non-invasiveness, access, low variability between patients, etc. But the skin is a very good barrier. One way to increase drug permeation through the skin is to use enhancers. Piperine, a component of pepper, has been shown to enhance oral drug absorption. The aim of the study is to determine whether piperine can enhance drug permeation into and through the skin. During the conduct of the study, you will formulate drug preparations containing drug and piperine and measure the permeation of drug into and through skin, in the presence and absence of piperine.

Jojoba oil microemulsions
Jojoba oil is used in the cosmetics industry. It is a stable oil, chemically resembles spermaceti (which has been widely used in cosmetic products), resembles the oil secreted on the skin and deeply moisturizes skin. This oil is also non-irritant and hypoallergenic. Hypothesis: Due to the hydrating effect of the oil on skin, microemulsions prepared from jojoba oil may be suitable vehicles for the transdermal delivery of drugs. Last year's MSc project showed that microemulsion of jojoba can be formulated. The aim of this year's project is to characterize the microemulsions for transdermal drug delivery.

The formulation and evaluation of particulate-based proliposomes for pulmonary delivery
The suitability of nebulisers for the delivery of liposomal aerosols is well established. However, conventional liposomes present problems in terms of physical and chemical instability. In this study, particulate-based proliposomes will be prepared that are capable of reconstitution to yield an isotonic formulation of liposomes following hydration within the reservoir of a nebuliser. Work in the laboratory has recently demonstrated that such a system is possible. The proposed study will involve an investigation of strategies to optimise such systems, such that during nebulisation, liposomes of an appropriate size for drug delivery to the lung will be readily formed. The student will prepare proliposome formulations from a range of phospholipids, initially using sucrose as a Acarrier@ material. Additionally, an effervescent proliposome formulation will be developed, as published studies have shown that these hydrate rapidly on addition of water to generate a population of small liposomes. Aerosols will be generated from a range of jet and ultrasonic nebulisers, operated under a range of conditions. Systems will be evaluated in terms of:

- Their ability to generate liposomes
- The size and morphology of the liposomes generated

- The delivery of liposomes into an impinger
- The influence of nebuliser design on the operation of the above

The formulation and evaluation of ethanol-based proliposomes for pulmonary delivery
Whilst the suitability of nebulisers for the delivery of liposomal aerosols is well established, the use of conventional liposome formulations is limited due to their physical and chemical instability. In this study, ethanol-bases proliposomes will be prepared which can be reconstituted to yield an isotonic formulation of liposomes following hydration within the reservoir of a nebuliser. Preliminary work in our laboratory has shown the potential of such a system. The proposed study will involve an investigation of strategies to optimise one such proliposome formulation. In this case, an optimised formulation is one that on hydration will generate drug-containing liposomes of an appropriate size for drug delivery to the lung. The student will prepare proliposome formulations from a range of phospholipids and other excipients, and will encapsulate a model water soluble drug. Aerosols will be generated from a variety of jet nebulisers, and the systems will be evaluated in terms of:

- Their ability to generate liposomes
- The size and morphology of the liposomes generated
- The ability of the liposomes to incorporate a model drug
- The delivery of liposomes and liposome incorporated drug into an impinger
- The influence of formulation variables on the above

Intracellular trafficking of delivery systems using confocal laser scanning microscopy
Delivery systems interact with cells in a variety of ways that commonly lead to uptake and localization at a specific cellular compartment. The interactions and the eventual intracellular fate of a delivery system depends largely on the type of delivery system, its chemical composition, physicochemical characteristics as well as the cell types. In this project, a variety of delivery systems used in transport of drug and gene-encoding molecules will be prepared, fluorescently labelled and allowed to interact with different cell types. Time-dependent intracellular trafficking events will be monitored by confocal laser scanning microscopy. The interaction of delivery systems with cells will be monitored under different conditions to confer different mechanisms of cellular uptake (endocytosis, phagocytosis, etc). Correlation between the physicochemical characteristics of delivery systems and their time-dependent intracellular trafficking profiles will offer valuable information as to their therapeutic capabilities.

Engineering non-viral gene delivery systems: physicochemical and structural characterisation studies
Non-viral gene therapy vectors are predominantly composed of condensates between cationic lipids and other macromolecules (polymeric or biological) with the negatively charged plasmid DNA. This condensation process is governed by complex electrostatic, hydrophobic and other biophysical interactions that usually lead to polydisperse and morphologically non-homogenous soft particles between the condensed DNA and the cationic molecules. Recently, ternary systems between a cationic small molecule (peptide), plasmid DNA and the cationic lipids have been proposed as gene transfer vectors of improved colloidal stability

and pharmaceutical viability. The project will focus on the physicochemical and structural characterization of ternary non-viral gene therapy vectors composed of a small peptide (up to 20 amino acids) as the cationic condensing agent, plasmid DNA and cationic cholesterol- and phospholipid-based lipids. A variety of techniques will be used to characterize the vector systems including photon correlation spectroscopy, laser Doppler electrophoresis, electron microscopy, microcalorimetry, and atomic force microscopy.

Site-specific delivery to the eye

Many conditions of the eye require surgery for treatment. Differentiated healing is often required for a successful outcome. Cytotoxic molecules such as 5FU are administered daily. This collaborative project will examine the release characteristics of 5FU from commercial gels and from excipient-less pellets.

Particulate associated medicines

A library of polymers has been prepared for this collaborative project. They have not shown any in vitro toxicity. This project will examine the processing characteristics of these polymers in the presence of a model protein to determine the potential to stabilise the protein. Release profiles of the protein will also be determined.

Studies of salt formation and the use of salts to improve dissolution and modify physical properties of drugs.

It is well known that changing the salt form of a drug can result in improved solubility and stability. However, the selection of best salts for optimised properties is far from clear. In this project we will explore the selection of salts and assess which ones yield crystalline and which yield amorphous material. We will assess the stability and solubility and attempt to make general plans for the best way to optimise pharmaceutical performance.

Investigation of reasons for adhesion of drug to the container wall of pressurised metered dose inhaler formulations.

Many micronised drugs adhere to container walls and this results in loss of the drug to be delivered to the lung. It is not clear why the drug adheres above the liquid line on the container wall. In this project we will explore reasons for adhesion to the container as well as exploring strategies to prevent adhesion (including the use of coatings for the container and additives to the propellant). As part of the project attempts will be made to stop adhesion above the liquid fill line.

Encapsulation of nanoparticles inside large liposomes and niosomes

The object of this project is to prepare large vesicles and use various techniques to encapsulate nano- and micro-spheres of various diameters and surface properties inside the vesicles. In the study various methods of vesicle preparation will be undertaken to achieve either unilamellar or multilamellar vesicles. The release of the nanoparticles from the vesicle and other characteristic will be studied by micromanipulation techniques which we have developed.

Electronically responsive release of drugs from Room Temperature Ionic Liquids
Room temperature ionic liquids have rarely been used in pharmacy but we have been studying their potential as reservoirs and vehicles for drugs. A phenomenon discovered is that the application of an electric field can increase release of dissolved drugs, giving rise to the possibility of pulsatile delivery prototypes. The project probes this phenomenon in more detail.

END OF SECTION 4

5. Assessment and Regulations

5.1 PROGRAMME REGULATIONS

Students must read these regulations in conjunction with the more detailed General Academic Regulations. The information listed here only summarises the main points of assessment. It is essential that you full understand the regulations prior to taking your assessments.

Coursework
Students must complete a number of formative and summative assessments as detailed in the module outline. Formative assignments give feedback to students on their performance but do not count towards the final mark. The marks for summative assignments count towards the final mark for the degree. The minimum pass mark is 50%.

Examinations
The written examinations are normally three hours in duration and take place in February for term 1 modules, June for terms 2 and 3 modules and September for resit examinations. The minimum pass mark is 50%.

Re-sit Opportunities
The regulations permit students a first opportunity at an assessment and one re-sit opportunity (at the discretion of the Board of Examiners). In exceptional circumstances a second re-sit opportunity may be granted by the Board of Examiners. At a re-sit, the maximum mark that can be achieved is the minimum pass mark for the assessment.

Students who fail the written examination paper may, at the discretion of the Board of Examiners, be permitted to resit the failed examination(s) as a final attempt. The student must have achieved at least 30% in the failed paper and have failed no more than a maximum of two papers. If the student has failed more than two papers it is at the Board of Examiners' discretion as to whether the student takes resit exams in September or is required to repeat the module in the following year.

Final Degree Mark
The overall pass mark for the award of the MSc is 50%. Students who achieve an overall final mark of between 60% and 69.9% will be awarded the degree with merit. Students who achieve an overall final mark of 70% or higher will be awarded the degree with distinction.

Transcript of Marks
Students who do not satisfy all of the requirements for the award of the MSc will be issued with a Transcript of Marks showing the components they have successfully completed.

5.2 COMPENSATION

The following compensation rules apply to the MSc Drug Delivery. These are not automatic and are at the discretion of the Board of Examiners:

- At the discretion of the Board of Examiners, a student who fails one written examination paper may be awarded a compensated pass if the failed mark is at least 35% and the mark for the other written examination paper is at least 45% (aggregate mark of 80%).
- No compensation will be awarded for two failed examination papers.
- No compensation is allowed between the written examinations and the other assessment components.

5.3 MARKING SCHEME

The marking scheme sets out the individual assessment components and their relative weighting. Students will be subject to the marking scheme in effect at the time they start the programme.

The MSc in Drug Delivery comprises the following weighted assessment components:

Module	Marks	Credits	Weighting
Module 1 (Sem 1) PHAYM022	100	30	16.7%
Module 2 (Sem 1) PHAYM003 or PHAYM023	100	30	16.7%
Module 3 (Sem 2) PHAYM025	100	30	16.7%
Module 4 (Sem 2) PHAYM024 or PHAYM030	100	30	16.7%
Dissertation (May to Sept)	100	60	33.2%

The modules are assessed by coursework and written examinations. The relative weighting of coursework to examinations varies between modules and this will be outlined in the Module Specification.

The Dissertation is assessed by coursework alone as follows:

- Assessment of working method 20%
- Written report 60%
- Oral presentation 20%

Appendix 1: Calendar

The MSc is a full-time, twelve-month programme. Students should not plan any activities to interfere with the 9:00am – 5:00pm schedule, Monday – Friday for the entirety of the programme.

Event	Date
Start Date	26 September 2011
Induction Week	26 – 30 September 2011

Semester 1	
Semester 1 classes start	3 October 2011
Last day of classes	9 December 2011
Christmas vacation	*10 December 2011 - 8 January 2012*
Classes Resume	9 January 2012
Lab work for research projects begin	Mid January 2012
Classes End	20 January 2012
Revision period	23 – 27 January 2012
Examination Period	30 January – 3 February 2012
Mid-term break	4 – 12 February 2012

Semester 2	
Semester 2 classes start	13 February 2012
Last day of classes	23 March 2012
Begin Project work	End of March 2012
Easter Vacation	24 March – 15 April 2012
Classes resume	16 April 2012
Bank Holiday	7 May 2012
Classes End	26 May 2012
Revision period	28 May – 1 June 2012
Bank Holidays	4 -5 June 2012
Examination Period	6 -12 June 2012

Finish lab work and research project	End of August 2012
Deadline for Project Submissions	September 2012
Viva Date	September 2012

<u>Important Notes</u>

1. *The School of Pharmacy reserves the right to change these dates if necessary. The School will inform students of any changes.*
2. *Students must ensure that they are available to attend all classes throughout the teaching and examinations periods listed.*