NANYANG TECHNOLOGICAL UNIVERSITY SINGAPORE

COURSE CONTENT

Academic Year	2024/2025	**Semester**	1
Course Coordinator	Assoc Prof. Zaher Judeh		
Course Code	CH4106		
Course Title	Formulation of Active Pharmaceutical Ingredients dosage forms		
Pre-requisites	Nil		
No of AUs	3		
Contact Hours	39		
Proposal Date	4 Apr 2023		

Course Aims

The objective of the course is to give an insight in drug formulation and the setting of quality specifications. Thus, the course is devoted to the objectives involved in bringing an active pharmaceutical ingredient into an effective and safe dosage form.

Intended Learning Outcomes (ILO)

By the end of this course, you (as a student) would be able to:

1. Explain the process of drug development and approval
2. Explain the pre-formulation considerations applicable to the design of specific dosage forms
3. Explain the biological and physicochemical properties of drugs that must be considered in the design of pharmaceutical dosage forms
4. Apply the concepts of chemical kinetics, drug stability and explain the factors that impact dosage forms stability
5. Identify different dosage forms and outline their advantages and shortcomings
6. Explain the formulation of a dosage form with respect to:
   - Types and functions of the additives/excipients used
   - Problems encountered during the formulation of a specific dosage form
   - Techniques used in the production of different dosage forms

Course Content

1. Principles of Dosage form Design and Development
2. Solid Dosage Forms and Modified-Release Drug Delivery Systems
3. Semi-Solid and Transdermal Systems
4. Pharmaceutical Inserts
5. Liquid Dosage Forms
6. Sterile Dosage Forms and Delivery Systems

Assessment (includes both continuous and summative assessment)

Component	Course LO Tested	Related Programme LO or Graduate Attributes	Weightage		Remarks
			Individual Assessment	Team Assessment	
1. (CA1): Quiz	1, 2	EAB SLO* a, b, c, d, f, g, i, j	4%	6%	All assessments are in form of MCQs. Some questions are answered individually for
2. CA2: Quiz	2, 3	EAB SLO* a, b, c, d, h, k, i, j	4%	6%	

3. CA3: Quiz	3	EAB SLO* a, b, c, d, k, i, j	4%	6%	Individual Assessment and some questions are answered collectively in a group for Team Assessment. Evaluation Rubric can be found in Appendix 1a.
4. CA4: Quiz	2, 4	EAB SLO* a, b, c, d, g, i, j	4%	6%	
5. CA5: Quiz	1, 4	EAB SLO* a, b, c, d, f, g, i, j	4%	6%	
6. CA6: Quiz	3, 4, 5	EAB SLO* a, b, c, d, g, h, k, i, j	4%	6%	
7. CA7: Quiz	5, 6	EAB SLO* a, b, c, d, g, h, i, j	4%	6%	
8. CA8: Quiz	1, 2, 3, 4, 5, 6	EAB SLO* a, b, c, d, g, h, i, j	25%	0%	
9. Peer evaluation	1, 2, 3, 4, 5, 6	EAB SLO* i	5%	0%	See Appendix 1b
Total			100%		

Mapping of Course ILOs to EAB Graduate Attributes

Course Intended Learning Outcomes	**EAB's 12 Graduate Attributes***											
	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)
	◐	◐	●	◐	●	●	š	š	●	●	◐	
Explain the process of drug development and approval	a, b, c, d, f, g											
Explain the pre-formulation considerations applicable to the design of specific dosage forms	a, b, c, d, h, i											
Explain the biological and physicochemical properties of drugs that must be considered in the design of pharmaceutical dosage forms	a, b, c, d, k,											
Apply the concepts of chemical kinetics, drug stability and explain the factors that impact dosage forms stability	a, b, c, d, g, h											
Identify different dosage forms and outline their advantages and shortcomings	a, b, c, d, g, j, i											
Explain the formulation of a dosage form with respect to: -Types and functions of the additives/excipients used -Problems encountered during the formulation of a specific dosage form -Techniques used in the production of different dosage forms	a, b, c, d, h, j											

Legend:

● Fully consistent (contributes to more than 75% of Intended Learning Outcomes)
◐ Partially consistent (contributes to about 50% of Intended Learning Outcomes)
š Weakly consistent (contributes to about 25% of Intended Learning Outcomes)
Blank Not related to Student Learning Outcomes

Formative feedback

During class, the instructor will communicate the expected learning outcomes in detail. Team-based learning is designed to give instant feedback when students do quizzes as the correct/incorrect answers will be displayed using LAMS. You will be discussing the answers among yourselves and with the instructor. All answers will be discussed in class among students and moderated by the instructor.

Learning and Teaching approach

Approach	How does this approach support students in achieving the learning outcomes?
Team based Learning	Team-based learning enforced collaborative work and deep discussions among you.

Reading and References

1. H. C. Ansel, L. V. Allen Jr., N. G. Popovich, Pharmaceutical Dosage forms and Drug delivery systems, 8th Edition, Lippincott Williams & Wilkins, 2005. ISBN 0-683-305727.
2. Michael E. Aulton and Kevin M.G. Taylor The Design and Manufacture of Medicines, 4th Edition, Elsevier.

Course Policies and Student Responsibilities

(1) General

You are expected to complete all assigned pre-class readings and activities, attend all seminar classes punctually and take all scheduled assignments and tests by due dates. You are expected to take responsibility to follow up with course notes, assignments and course related announcements for seminar sessions they have missed. Students are expected to participate in all seminar discussions and activities.

(2) Absenteeism

TBL requires you to be in class to contribute to team work. In-class activities make up a significant portion of your course grade. Absence from class without a valid reason will affect your overall course grade. Valid reasons include falling sick supported by a medical certificate and participation in NTU's approved activities supported by an excuse letter from the relevant bodies. There will be no make-up opportunities for in-class activities.

If you miss a seminar session, you must inform your team leader and me via email (Zaher@ntu.edu.sg) prior to the start of the class. Students who miss T-RATs and team in-class activity with valid reasons will earn the team score. Students who miss I-RAT or T-RAT without a valid reason will earn nothing for that session of absence.

For I-RAT scores, we will consider the best of seven I-RATs out of nine I-RATs. This method will take care of students who miss classes with valid reasons. Students, who miss I-RATs more than twice with valid reasons, may be asked to take a separate test.

Academic Integrity

Good academic work depends on honesty and ethical behaviour. The quality of your work as a student relies on adhering to the principles of academic integrity and to the NTU Honour Code, a set of values shared by the whole university community. Truth, Trust and Justice are at the core of NTU's shared values.

As a student, it is important that you recognize your responsibilities in understanding and applying the principles of academic integrity in all the work you do at NTU. Not knowing what is involved in maintaining academic integrity does not excuse academic dishonesty. You need to actively equip yourself with strategies to avoid all forms of academic dishonesty, including plagiarism, academic fraud, collusion and cheating. If you are uncertain of the definitions of any of these terms, you should go to the academic integrity website for more information. Consult your instructor(s) if you need any clarification about the requirements of academic integrity in the course.

Course Instructors

Instructor	Office Location	Phone	Email
Zaher Judeh	N1.2-B1-14	67906738	Zaher@ntu.edu.sg

Planned Weekly Schedule

Week	Topic	Course LO	Readings/ Activities
1	Principles of Dosage form Design and Development - Introduction to Drugs and Pharmacy -New Drug Development and Approval Process - Dosage Form Design: Pharmaceutic and Formulation Considerations Dosage	1-6	Students are to read the prescribed textbooks, lecture notes, mind maps, and videos. They are to pay attention to the case studies discussed in classes.
2	Solid Dosage Forms and Modified-Release Drug Delivery Systems -Powders and Granules	1, 2, 4, 6	
3	Solid Dosage Forms and Modified-Release Drug Delivery Systems -Tablets -Modified-Release Dosage Forms and Drug Delivery Systems -CA1	1, 2, 4, 6	
4	Solid Dosage Forms and Modified-Release Drug Delivery Systems -Capsules -CA2	1, 3, 4, 6	
5	Semi-Solid and Transdermal Systems - Ointments and creams -CA3	1, 2, 3, 4, 6	
6	Semi-Solid and Transdermal Systems -Transdermal Drug Delivery Systems -CA4	1, 2, 3, 4, 6	

7	Pharmaceutical Inserts -Suppositories and Inserts -CA5	1, 3, 4, 6	
8	Liquid Dosage Forms -Solutions	1-6	
9	Liquid Dosage Forms Disperse Systems (Suspensions) -CA6	1-6	
10	Liquid Dosage Forms Disperse Systems (Emulsions and aerosols) -CA7	1-6	
11	Sterile Dosage Forms and Delivery Systems -Parenterals	1-6	
12	Sterile Dosage Forms and Delivery Systems - Ophthalmic Solutions and Suspensions	1-6	
13	Revision CA8	1-6	

Appendix 1a: Evaluation Rubric

Criteria	Unsatisfactory: 1	Borderline: 2	Satisfactory: 3	Very good: 4	Exemplary: 5	Score
1. Understanding of drug development process and approval ***(Learning and Comprehension)***	Unable to understand how drugs are developed and approved	Some understanding of how drugs are developed and approved but no linkage among them	Understands how drugs are developed and approved and the importance of developing drugs that are approvable	Understands how drugs are developed and approved very well and most likely can predict problems in the approval and development process	A thorough understanding of how drugs are developed and approved and can accurately predict problems in the approval and development process and can fix them	
2. Applying the principles of preformulation and formulation to produce dosage forms ***(Evaluation)***	Given a number of excipients and an API, unable to apply the principles of preformulation and formulation to produce dosage forms	Given a number of excipients and an API, able to apply the principles of preformulation and formulation to produce dosage forms, but not clear about the mechanism involved	Given a number of excipients and an API, able to apply the principles of preformulation and formulation to produce dosage forms, clear about the mechanism involved, but not clear on the reason causing problems in the formulations	Given a number of excipients and an API, clearly applies the principles of preformulation and formulation to produce dosage forms with clear understanding of the mechanism and reasons for why formulations become unstable	Given a number of excipients and an API, clearly applies the principles of preformulation and formulation to produce dosage forms with clear understanding of the mechanism and reasons for why formulations become unstable. Predict possible problems and take precautions to avoid them	
3. Different excipients in dosage forms and their application and impact on routs of administration	Understands the role of excipients in dosage forms and their application and impact on routs of administration but	Understands the role of excipients in dosage forms and their application and impact on routs of administration and	Understands the role of excipients in dosage forms and their application and impact on routs of administration and	Understands the role of excipients in dosage forms, their application, impact on routs of administration, their interactions and predict stability over time	Understands the role of excipients in dosage forms, their application, impact on routs of administration, and their interactions and predict stability over time. Chose the most suitable	

Criteria	Unsatisfactory: 1	Borderline: 2	Satisfactory: 3	Very good: 4	Exemplary: 5	Score
(Analysis)	unable to use them to make a dosage form	able to use them to make a dosage form	able to use them to make a dosage form As well as the interactions/reactions between themselves and also with the API		excipients with optimum manufacturing process and economic factors into consideration	
4. Apply the concepts of chemical kinetics, drug stability and **explain the factors that impact dosage forms stability** ***(Application)***	Lack knowledge of chemical kinetics, drug stability and factors that impact dosage forms stability	Knows chemical kinetics, drug stability and factors that impact dosage forms stability but not able to link between them	Can successfully link different types of stabilities to factors that impact dosage forms stability	Can successfully link different types of stabilities to factors that impact dosage forms stability and able to predict the impact over storage time	Can successfully link different types of stabilities to factors that influence dosage forms stability and able to predict the impact over storage time. Able to propose remedies to prevent degradation of the dosage times as a result of different types of instabilities	

Appendix 1b: Assessment for Peer Evaluation

Team exercises involve Peer Evaluation. Please evaluate each team member's contribution during the course. Rank your group members from 1-5. Use the scale below for assessing each team member.

1	**2**	**3**	**4**	**5**
Always late or absent from classes. Made no effort to contribute during discussions. Shows no little interest.	Did not attend classes few times. Made below average contribution to the discussion.	Always attended classes. Made some contributions but greater effort could have been exhibited during discussions.	Always attended class. Demonstrated appropriate effort in contributions during discussions.	Always attended class. Showed outstanding contributions and efforts during discussions. Ensured everyone contributes to discussions

Appendix 2: The EAB (Engineering Accreditation Board) Accreditation SLOs (Student Learning Outcomes)

a) **Engineering knowledge:** Apply the knowledge of mathematics, natural science, engineering fundamentals, and an engineering specialisation to the solution of complex engineering problems
b) **Problem Analysis:** Identify, formulate, research literature, and analyse complex engineering problems reaching substantiated conclusions using first principles of mathematics, natural sciences, and engineering sciences.
c) **Design/development of Solutions:** Design solutions for complex engineering problems and design system components or processes that meet the specified needs with appropriate consideration for public health and safety, cultural, societal, and environmental considerations.
d) **Investigation:** Conduct investigations of complex problems using research-based knowledge and research methods including design of experiments, analysis and interpretation of data, and synthesis of the information to provide valid conclusions.
e) **Modern Tool Usage:** Create, select, and apply appropriate techniques, resources, and modern engineering and IT tools including prediction and modelling to complex engineering activities with an understanding of the limitations
f) **The engineer and Society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety, legal, and cultural issues and the consequent responsibilities relevant to the professional engineering practice.
g) **Environment and Sustainability:** Understand the impact of the professional engineering solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for the sustainable development.
h) **Ethics:** Apply ethical principles and commit to professional ethics and responsibilities and norms of the engineering practice.
i) **Individual and Team Work:** Function effectively as an individual, and as a member or leader in diverse teams and in multidisciplinary settings.
j) **Communication:** Communicate effectively on complex engineering activities with the engineering community and with society at large, such as, being able to comprehend and write effective reports and design documentation, make effective presentations, and give and receive clear instructions.
k) **Project Management and Finance:** Demonstrate knowledge and understanding of the engineering and management principles and economic decision-making, and apply these to one's own work, as a member and leader in a team, to manage projects and in multidisciplinary environments.
l) **Life-long Learning:** Recognise the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change