

**The University of Jordan**

**Accreditation & Quality Assurance Centre**

**Selected Topics in Pharmaceutical Technology**

**Course Syllabus**

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| **1** | Course title | Selected Topics in Pharmaceutical Technology |
| **2** | Course number | 1202538 |
| **3** | Credit hours (theory, practical) | 2 Theoretical |
| Contact hours (theory, practical) | 2 hours per week, theoretical |
| **4** | Prerequisites/corequisites | 1202333 Pharmaceutical Technology 2 |
| **5** | Program title | Bachelor of Science in Pharmacy |
| **6** | Program code | - |
| **7** | Awarding institution | The University of Jordan |
| **8** | School | Pharmacy |
| **9** | Department | Department of Pharmaceutics and Pharmaceutical Technology |
| **10** | Level of course | Undergraduate |
| **11** | Year of study and semester (s) | Fifth year |
| **12** | Final Qualification | Bachelor of Science in Pharmacy |
| **13** | Other department (s) involved in teaching the course | None |
| **14** | Language of Instruction | English |
| **15** | Teaching methodology | Blended Online |
| **16** | Electronic platform(s) | Moodle Microsoft Teams Skype Zoom  Others………… |
| **17** | Date of production/revision | 04 October 2020 |

16. Course Coordinator:

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| *Office numbers, office hours, phone numbers, and email addresses should be listed.*  Name: Hatim S. AlKhatib  Office Number: 221  Phone Number: 23335  E mail: h.khatib@ju.edu.jo |

17. Course instructors:

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| *Office numbers, office hours, phone numbers, and email addresses should be listed.*  Name: Hatim S. AlKhatib  Office Number: 221  Phone Number: 23335  E mail: h.khatib@ju.edu.jo  Faculty members of the department of Pharmaceutics and Pharmaceutical Technology. |

**18. Course Description:**

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| The course builds on the knowledge and skills of students in the area of pharmaceutics to solve bioavailability and satisfy therapeutic objectives through dosage form design. The course will cover the design and manufacturing of solid solution/dispersion systems, prodrugs, nanocrystal suspensions, self-emulsifying drug delivery systems and gastroretentive systems. |

19. Course aims and outcomes:

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| A- Aims:   1. To recognize challenges encountered when attempting oral delivery of drugs 2. To understand the effect of solubility and dissolution enhancement on optimizing drug delivery 3. To understand the mechanisms through which different delivery systems ensure and optimize bioavailability 4. To know the different methods of manufacturing solid solutions / dispersions 5. To know the different types of lipid based formulations 6. To know the different technologies involved in gastroretention of a dosage form 7. To be able to suggest suitable delivery technology based on physical and biopharmaceutical properties of a drug   B- Intended Learning Outcomes (ILOs):  Upon successful completion of this course students will be able to: |
| * **Develop, integrate, and apply knowledge from the foundational sciences (learner)**  1. Define solubility, dissolution rate, intrinsic solubility and the effect of a drug's physicochemical properties on them. 2. Suggest methods for the evaluation of solubility of a drug 3. Understand the energetics of solubility and the relationship between the enthalpies of sublimation, melting and hydration to the free energy of solubility. 4. Understand the effects of chemical modification of the structure of a drug on its biopharmaceutical properties and formulation choices. 5. Understand the concept of biorelevant dissolution and solubility. 6. Know the different physical molecular arrangements in a solid solution / dispersion type formulation 7. Know the different methods of manufacturing of solid solution/dispersion 8. Know the methods used in characterizing the internal structure and performance of a solid solution/dispersion type formulation. 9. Suggest a suitable materials and method for manufacturing a solid solution/dispersion based on API properties 10. Interpret the results of different characterization methods for solid solution/dispersion 11. Know the different classes of lipid based formulations 12. Know the excipients used in lipid based formulations 13. Understand the differences in physical properties between different classes of excipients used in lipid based formulations 14. Suggest suitable lipid based formulation based on API properties 15. Know the different methods of assessing the performance of lipid based formulations in terms of drug release and stability 16. Know the applications of a gastroretentive dosage form 17. Know the different types of technology used in manufacturing of a gastroretentive dosage form 18. Know the methods of evaluation of gastro retention. 19. Analyze and critically evaluate case studies in pharmaceutical formulation presented in the course  * **Exhibit behaviors and values that are consistent with the trust given to the profession by patients, other healthcare providers, and society (*Professional*)**  1. Communicate effectively and respectfully with professors and classmates 2. Show responsibility, accountability and commitment by complying with tutor’s instructions and relevant university regulations 3. Demonstrate integrity by not cheating and not committing plagiarism  * **Dispense, compound, distribute, and manage so as to operate a successful pharmacy outlet/store; (*Pharmacy System Manager*).**  1. Develop and provide accurate and usable dosage forms information regarding dosing and use instructions.  * **Carry out compounding procedures to produce an effective and safe medicine (*Compounder*), and implement quality control measures and tests (*Quality Manager*); Pharmaceutical Product Expert *Manufacturer*).**  1. Develop formulations and manufacturing procedure for solid solution/dispersion systems, prodrugs, nanocrystal suspensions, self-emulsifying drug delivery systems and gastroretentive systems.  * **Identify problems; explore and prioritize potential strategies; and design, implement, and evaluate a viable solution; Problem Solving and critical thinking (*Problem Solver*).**  1. Identify key elements of problems and choose appropriate methods for their resolution in a systematic manner. 2. Outline and solve the problems encountered during formulation and manufacturing processes of pharmaceutical dosage forms in pharmaceutical firms.  * **Demonstrate self-directed learning through ongoing reflection and analysis to identify areas and methods necessary to expand professional knowledge and competence in a changing practice environment; *(Self-learner)*.**  1. Seek actively new knowledge related to solid solution/dispersion systems, prodrugs, nanocrystal suspensions, self-emulsifying drug delivery systems and gastroretentive systems, their composition, manufacturing, critical quality attributes, testing procedures, storage, dispensing and administration.  * **Communicate effectively with patients, caregivers, pharmacy personnel, other health care professionals, community members, policy makers and administrators; *(Communicator)*.**  1. Communicate effectively and respectfully with professors and classmates 2. Show responsibility, accountability and commitment by complying with tutor’s instructions and relevant university regulations 3. Develop skills and confidence required for assertive, persuasive, and clear communications.  * **Exhibit behaviors and values consistent with the trust given to the profession by patients, other healthcare providers, and society; *(Professional)*.**  1. Demonstrate integrity by not cheating and not committing plagiarism. 2. Demonstrate respect to professors and classmates by observing active listening inside the classroom   C. Program Competencies Achieved:   * ***Learner***: Develop, integrate, and apply knowledge from the foundational sciences (Biomedical sciences, Pharmaceutical sciences, Clinical sciences, Social/behavioral/administrative). * ***Pharmacy System Manager***: Dispense, compound, distribute, and manage so as to operate a successful pharmacy outlet/store. * ***Pharmaceutical Product Expert (Manufacturer)***: Carry out compounding procedures to produce an effective and safe medicine (Compounder), and implement quality control measures and tests (Quality Manager). * ***Problem Solving and critical thinking (Problem Solver)***: Identify problems; explore and prioritize potential strategies; and design, implement, and evaluate a viable solution. * ***Self-learner***: Demonstrate self-directed learning through ongoing reflection and analysis to identify areas and methods necessary to expand professional knowledge and competence in a changing practice environment. * ***Communicator***: Communicate effectively with patients, caregivers, pharmacy personnel, other health care professionals, community members, policy makers and administrators. * ***Professional***: Exhibit behaviors and values that are consistent with the trust given to the profession by patients, other healthcare providers, and society. |

20. Topic Outline and Schedule:

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| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Week** | **Lecture** | **Topic (Achieved ILOs)** | **Teaching Methods/ platform** | **Evaluation Methods\*\*** | **References** | | Week 1  4-8 /10 | 1.1 | Barriers to effective (oral) drug delivery: Stability, Solubility and Permeation (1, 2, 3, 5, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam/Quiz | Textbook, handouts. | | 1.2 | Solubility, intrinsic solubility, dissolution rate, intrinsic dissolution rate (1, 2, 3, 5, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam/Quiz | Textbook, handouts. | | Week 2  11-15/10 | 2.1 | BCS, dose number, biowaiver, technologies for solubility / dissolution enhancement, technology selection criteria (1, 2, 3, 5, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam/Quiz | Textbook, handouts. | | 2.2 | Energetics of solubility and dissolution (1, 2, 3, 5, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam/Quiz | Textbook, handouts. | | Week 3  18-22/10 | 3.1 | Brick dust and grease ball molecules (1, 2, 3, 5, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam/Quiz | Textbook, handouts. | | 3.2 | Prodrug definition, examples, addition of polar functionalities and hydrophilic prodrugs (4, 5, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam/Quiz | Textbook, handouts. | | Week 4  25-29/10 | 4.1 | Prodrugs with reduced crystal packing (4, 5, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | 4.2 | Case study: Acyloxymethyl phenytoin prodrugs (4, 5, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | Week 5  1-5/11 | 5.1 | Solid Solutions / Dispersions definition, general methods of preparation (6-10, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | 5.2 | Types of solid solutions dispersions: eutectic mixtures, crystalline solid solutions (cocrystals), glass solutions (6-10, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | Week 6  8-12/11 | 6.1 | Types of solid solutions dispersions: glass and crystalline suspensions and complexes (6-10, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | 6.2 | Mechanisms of increased dissolution rate in solid dispersions (6-10, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | Week 7  15-19/11 | 7.1 | Selection of a carrier in solid dispersions (6-10, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | 7.2 | Characterization of Solid Solutions / Dispersions: dissolution, internal structure (IR, XRPD, DSC, HSM) (6-10, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | Week 8  22-26/11 | 8.1 | Case study: spray dried solid dispersions of probucol and PVP-K30 (6-10, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | 8.2 | Lipid-based delivery systems for oral administration, Self-Emulsifying and Self-Miceroemulsifying drug delivery systems (11-14, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | Week 9  29/11 - 3/12 | 9.1 | Lipid Formulation Classification System (LFCS) (11-14, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | 9.2 | Excipients for lipid formulations: Triglycerides, partial glycerides, polar oils (11-14, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | Week 10  6-10/12 | 10.1 | Excipients for lipid formulations: Water insoluble surfactants, water soluble surfactants, cosolvents, additives (11-14, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | 10.2 | Factors affecting choice of lipid-based formulations: Regulatory issues (safety and experience), solvent capacity, mutual miscibility, morphology at room temperature (11-14, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | Week 11  13-17/12 | 11.1 | Factors affecting choice of lipid-based formulations: Self dispersibility, digestibility, capsule compatibility, chemical composition (quantitative vs qualitative similarity) and effect on robustness of formulation, cost-effectiveness (11-14, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | 11.2 | Solid self-emulsifying drug delivery system: spray cooling and spray drying (11-14, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | Week 12  20-24/12 | 12.1 | Solid self-emulsifying drug delivery system: Adsorption onto solid carriers, melt granulation, melt extrusion (11-14, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | 12.2 | In vitro evaluation of self-emulsified, lipid-based drug delivery systems: digestion and dispersion testing vs drug release (11-14, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | Week 13  27-31/12 | 13.1 | Case Study: Enhanced oral bioavailability of silybin by a supersaturable self-emulsifying drug delivery system (11-14, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | 13.2 | Case Study: Development of solid SEDDS by adsorbing lipid-based formulations onto Neusilin® US2 (11-14, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | Week 14  3-7/01 | 14.1 | Gastroretentive dosage forms: definition, PK aspects, PD aspects (15-18, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | 14.2 | Gastroretentive dosage forms: Formulation technologies: bioadhesion, floating systems (15-18, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | Week 15  10-17/1 | 15.1 | Gastroretentive dosage forms: Formulation technologies: Size-increasing dosage forms and high-density dosage forms (15-18, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | | 15.2 | Case study: Evaluation of novel CR-GRDF formulation of levodopa in dogs (15-18, 19, 20-32). | MS Teams, JU E learning, Synchronous. | Exam | Textbook, handouts. | |

21. Teaching Methods and Assignments:

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| Development of ILOs is promoted through the following teaching and learning methods:   1. Teaching Methods:  * Lectures * Self-Reading * Multimedia demonstrations * Assignments * E-learning  1. Learning Skills:  * Critical thinking * Scientific reasoning * Digital literacy * Communication skills * Problem-solving skills * Self-directed learning |

22. Evaluation Methods and Course Requirements:

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| Opportunities to demonstrate achievement of the ILOs are provided through the following assessment methods and requirements:   * Exams: Midterm and final exams are scheduled by the school. * Quizzes  |  |  |  | | --- | --- | --- | | Thursday November 5th at 10:30 am | Material covered up to lecture 3.2 | First Quiz – 10 points |  * Assignment: Discussion of an assigned paper including submitting written answers. |

23. Course Policies:

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| A- Attendance policies:   * As per the applicable university regulations   B- Absences from exams and handing in assignments on time:   * As per the applicable university regulations   C- Health and safety procedures:   * N/A   D- Honesty policy regarding cheating, plagiarism, misbehavior:   * As per the applicable university regulations   E- Grading policy:   * Semester work (20 %) * Mid exam (30 %) * Final exam (50 %)   F- Available university services that support achievement in the course:   * University libraries * Student computer labs * University website (including E-Learning and faculty member websites) |

24. Required equipment:

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| * Computer, internet connection and data show projector * Whiteboard and associated equipment * Access to e-learning website |

**25. References:**

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| 1. Required book (s), assigned reading and audio-visuals:  * Water-Insoluble Drug Formulation. [Rong Liu](http://www.amazon.com/exec/obidos/search-handle-url/ref=ntt_athr_dp_sr_1?%5Fencoding=UTF8&sort=relevancerank&search-type=ss&index=books&field-author=Rong%20Liu). CRC; 2nd edition, 2008. * Pharmaceutical Dissolution Testing. Jennifer J. Dressman and Johannes Kramer. Informa HealthCare; 2005.  1. Recommended books, material, and media:  * Physiological Pharmaceutics: Barriers to Drug Absorption, Neena Washington, Clive Washington, and Clive Wilson, Taylor & Francis Series in Pharmaceutical Sciences, 2000. * Modern Pharmaceutics, Volume 1: Basic Principles and Systems. Informa Health Care Series: Drugs and the Pharmaceutical Sciences. Alexander T. Florence and Juergen Siepmann, Fifth Edition, 2009. |

26. Additional information:

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Name of Course Coordinator: -------------------Signature: ------------------------- Date: ------------------------- Head of curriculum committee/Department: ------------------------- Signature: ---------------------------------

Head of Department: ------------------------- Signature: ---------------------------------

Head of curriculum committee/Faculty: ------------------------- Signature: ---------------------------------

Dean: ------------------------------------------- -Signature: ---------------------------------

Copy to:

Head of Department

Assistant Dean for Quality Assurance

Course File