Lista zagadnień do egzaminu magisterskiego (dyplomowego)
w roku akademickim 2019/2020
KIERUNEK: DRUG DISCOVERY AND DEVELOPMENT

NAZWA PRZEDMIOTU	ZAGADNIENIA
OGÓLNE **(2 pytania)**	1. Present a Drug Discovery and Development process. Name each stage and give the approximate duration and cost of it. 2. Define a term and show differences between: i) validated hit ii) lead structure iii) candidate (pre-clinical candidate/development candidate). 3. Name and shortly describe three main patentability requirements. How long does patent protection last? Is there any special prolongation designed for pharmaceuticals? What is data exclusivity and market exclusivity? 4. Describe potential funding sources (public, private) that could be used to support a drug discovery or early development program. What are the advantages and disadvantages of them? 5. Give examples of "hard law" and "soft law" which are in force regulating the drug approval process. 6. Explain the term "drug-likeness" and discuss how drug-like property optimization during drug discovery process may enhance the probability of becoming successful drug product for a compound. What are the main parameters used to describe "drug-likeness"? 7. Name and describe the chemical interactions that are important for drug binding to a target and influence its physicochemical properties. 8. Explain how the solubility, ionization state and lipophilicity influence membrane permeability. 9. Describe the aims, design, data analysis and results of TQT studies. 10. Describe the clearance concept. 11. What liver models do you know? Compare them in brief. 12. Discuss factors that may have an influence on permeation during in vitro assessment. 13. Explain how the compound safety and toxicity can be assessed in in vitro conditions. 14. Explain how the compound safety and toxicity can be screened in silico. 15. What are the main differences between Physiologically-based Pharmacokinetic (PBPK) modelling approach and Classical Compartment analysis? 16. Describe phase I of clinical trials: number of subjects, scope, major objectives and impact on the next stages of drug development 17. What are the differences between generic and biosimilar drugs? 18. Name primary and secondary parameters of bioequivalence and explain their meaning. 19. Define term "controlled release" and demonstrate this feature on the examples of different dosage forms. 20. Describe quality control assays for tablets. 21. Explain differences between critical quality attributes (CQA) and critical process parameters (CPP). What is the system that these parameters belong to? 22. What is PAT (process analytical technology) and where is it applicable? 23. Name major types and provide examples of excipients used for manufacturing of oral solid dosage forms. 24. Describe stability assays for selected dosage forms. What are the physical principles in the background of these assays? 25. Name and describe compendial dissolution testing methods used for solid dosage forms. 26. What are the differences between pellets and granulates? Describe their manufacturing methods.

	27. Provide brief characteristics of drugs used in the treatment of the central nervous system diseases (division, examples,selected recent achievements) 28. Provide brief characteristics of drugs used in the treatment of the cardiovascular system diseases (division, examples,selected recent achievements) 29. Provide brief characteristics of drugs used in the treatment of infective diseases (division, examples,selected recent achievements) 30. Provide brief characteristics of drugs used in the treatment of oncological diseases (division, examples,selected recent achievements)
MODEL INFORMED DRUG DEVELOPMENT (1 pytanie)	1. Define QSP and give a few examples of its potential implementation to the drug development process. 2. Discuss causes and consequences of nonlinear pharmacokinetics. 3. What is allometry and how can it be used in pharmacokinetic studies? 4. Discuss the advantages and limitations of pharmacodynamic models that you know. 5. Discuss the concept of physiologically-based pharmacokinetic modeling. 6. What is hepatic intrinsic clearance and how can it be determined? 7. Discuss and assumptions and usage of perfusion-limited and permeability-limited PBPK models. 8. What is a reason to describe an organ as a permeability-limited tissue in a PBPK approach? Give examples of such situations. 9. Describe briefly the human GI tract anatomical structure and microstructure and how it influences the small molecules absorption after oral dosing. 10. Drug transporters are proteins involved in active transport of small molecule drugs. Define their role in the drug disposition using examples from various tissues. 11. Discuss factors (different than formulation) that can influence the effectiveness of inhalational therapy. 12. Discuss formulation parameters influencing therapeutic effectiveness in pulmonary drug delivery. 13. Discuss the reasons for the importance of the size of particle or droplet in the process of pulmonary drug delivery. 14. Describe briefly the human skin anatomical structure and microstructure and how it influences the small molecules absorption after topical administration. 15. Discuss factors that can influence skin permeability in vivo. 16. Define solid particles solubility and discuss how solubility as a complex physical process occurs in the GI tract 17. Explain the basic concepts and physiological parameters influencing supersaturation and precipitation of drugs in the GI tract and discuss how do these processes influence drug absorption 18. Explain what is a flip-flop kinetics and how it can be examined. 19. Define renal clearance and describe how it can be estimated in practice. 20. Discuss the differences and the use of whole-body (full) PBPK model and minimum-PBPK models. 21. Describe statistical procedure used for establishing bioequivalence. Explain differences between average, population and individual bioequivalence measures. 22. What are the data necessary to establish Level A IVIVC (in vitro in vivo correlation)? Explain differences between convolution and deconvolution approach to establish Level A IVIVC according to the relevant FDA guideline(s).

	23. Explain major benefits of continuous vs. batch manufacturing processes 24. Describe BCS system, its applications and extensions. 25. Explain differences between model dependent and model independent methods for dissolution profiles comparisons. Provide at least one example for each category.