**DESCRIPTION OF THE COURSE OF STUDY**

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| **Course Code:** |  | 0916.4.FAR.B/C.TPL |
| **Course Name:** | Polish : | **Technologia Postaci Leku** |
| English:  | ***Drug Form Technology*** |

**1. USYTUOWANIE PRZEDMIOTU W SYSTEMIE STUDIÓW**

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| **1.1. Field of study** | **PHARMACY** |
| **1.2. Mode of study** | **Full-time** |
| **1.3. Level of study:** | **Integrated Master’s Degree** |
| **1.4. Profile of study** | Practical |
| **1.5. Person/s preparing the course description** | mgr farm. Olga Spałek |
| **1.6. Contact** | olga.spalek@ujk,edu,pl |

# 2. GENERAL COURSE CHARACTERISTICS

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| **2.1. Language of instruction** | Polish |
| **2.2. Prerequisites** | Information on general and inorganic chemistry, analytical chemistry, medicinal chemistry, organic chemistry, pharmacognosy, Latin, botany. |

**3. DETAILED COURSE CHARACTERISTICS**

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| **3.1. Form of classes** | Lectures, Laboratory Sessions |
| **3.2. Place of classes** | Teaching facilities at UJK,  |
| **3.3. Form of assessment** | ExaminationGraded credit |
| **3.4. Teaching methods** | Lectures – informative lecture with multimedia presentationExercises – demonstration exercises, practical exercises in specialist laboratories with full equipment (formulation laboratory, galenic technology laboratory, galenic preparation laboratory, aseptics laboratory) |
| **3.5. Bibliography** | **Primary:** | 1. Sznitowska M. Farmacja stosowana. Technologia postaci leku, PZWL, Warszawa 2017.
2. Gajewska M., Sznitowska M. Podstawy receptury aptecznej. Materiały do ćwiczeń dla studentów farmacji., Wydawca: Fundacja ProPharmacia
3. Futura, wydanie VI uaktualnione, Warszawa 2022.
 |
| **Supplementary:** | 1. Jachowicz R. (red.): Receptura apteczna. Sporządzanie leków jałowych i niejałowych PZWL, Warszawa 2021 r. 2. Jachowicz R. (red.): Postać leku. Optymalizacja leków doustnych i do oczu w nowoczesnej technologii farmaceutycznej, PZWL, Warszawa 2013 r. 3.Farmakopea Polska XII, Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Warszawa 2020 r. |

1. **OBJECTIVES, CONTENT, AND LEARNING OUTCOMES**

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| **4.1. Course Objectives****Lectures:** C01. Providing knowledge on the principles of issuing and fulfilling prescriptions. C02. Familiarizing students with the international, Polish, Latin nomenclature of chemical substances and synonyms used in the formulation. C03. Providing students with knowledge on substances used in pharmaceutical technology, technological processes and methods of preparing and controlling various forms of the drug. C04. Familiarizing students with the principles of proper preparation of prescription drugs, including the selection of appropriate packaging, determining storage conditions, and quality assessment tests for prescription drugs. C05. Providing students with knowledge on prescription inconsistencies and dose control. C06. Familiarizing students with modern drug forms.**Laboratories:** C01. Teaching students how to independently make prescription forms of drugs (including drugs produced under aseptic conditions). C02. Learning basic technological processes and the ability to use devices in the technology of manufacturing all forms of prescription drugs. C03. Teaching students how to use appropriate control and measurement equipment. C04. Acquiring knowledge and skills related to methods of assessing the quality of various drug forms. C05. Teaching students how to use pharmacopoeias, formularies and technological regulations, guidelines and literature related to the technology and quality of drug forms. |
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| 4.2. Course Content**Lectures:** Basic information on the technology of drug forms. Sources of information on drugs. Polish Pharmacopoeia XII. Solvents used in the preparation of drugs. Types of water for pharmaceutical purposes. Unit processes in the preparation of drugs. Characteristics of selected excipients used in the formulation. Principles of manufacturing liquid drug forms. Principles of manufacturing solid drug forms. Principles of manufacturing semi-solid drug forms. Aseptic formulation - sterilization methods, requirements for sterile drugs, preparation of eye drugs. Incompatibilities in prescription drugs and methods of solving. Dose control. Methods of quality control of individual drug forms. Drug form stability, storage conditions. Pharmaceutical packaging, types, selection depending on the drug form. Technology of manufacturing pediatric and geriatric drugs. Veterinary and homeopathic formulation. Radiopharmaceuticals. Biological drugs - characteristics, application. Parenteral drugs – injection preparations, infusion fluids, parenteral forms of prolonged-release drugs. Enteral and parenteral nutrition. Cytostatic preparations formula. Control of parenteral drugs. Contrast agents used in medical diagnostics. Dressing materials - types, application Digestion and herbal medicines (tinctures, extracts, intracts and others). Drying and lyophilization processes. Polymers in drug form technology. Good Manufacturing Practice principles. Principles of marketing authorization of medicinal products and medical devices. Risk analysis and process analysis in pharmaceutical production. Methods of testing the quality of drug forms and the method of analyzing the production series. Documentation of technological processes. Modern drug forms. Modified release drug forms. Therapeutic systems. Medicinal aerosols. Pediatric preparations. Blood derivatives and blood substitutes. Microparticles, nanoparticles, microemulsions, submicron emulsions, liposomes - modern methods of obtaining, application. Application of nanotechnology in pharmacy. Counterfeit medicines.e-learning: Polymers in drug form technology. Microparticles, nanoparticles, microemulsions, submicron emulsions,liposomes - modern methods of obtaining, application in diagnostics and therapy. Application of nanotechnologyin pharmacy.**Laboratories:** Liquid, semi-solid, solid forms of prescription drugs (solutions, drops, mixtures, emulsions, suspensions, potions, decoctions, infusions, maceration, powders, suspensions, emulsions, ointments, creams, pastes, suppositories, rods, globules) - practical execution, preparation of protocols of activities carried out during the preparation of the drug, description of the prescription, selection of packaging, determination of appropriate storage conditions. Galenic formulation. Rheology of systems - practical application. Aseptic formulation (eye drops and ointments, forms of drugs with antibiotics) - practical execution, sterilization methods, preparation of protocols of activities carried out during the preparation of the drug, description of the prescription, selection of packaging, determination of appropriate storage conditions.. Prescription inconsistencies and their resolution. Calculations for ethanol dilutions and performing dilutions. Different ways of expressing solution concentrations and their conversion. Cytostatics formulation, parenteral nutrition. Infusion fluid technology. Principles of preparing homeopathic medicines, herbal medicines. Cosmetic agents technology. Methods of testing the quality of manufactured drug forms using appropriate control and measurement equipment. Assessment of the quality of selected drug forms in relation to pharmacopoeial requirements. |

## 4.3. Subject learning outcomes

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| **Code**  | **A student, who passed the course** | **Relation to learning****outcomes** |
|  | within the scope of KNOWLEDGE: |  |
| W01  | the structure of the pharmacopoeia and its importance for the quality of medicinal substances and products; | C.W.5 |
| W02  | the issue of counterfeit medicines; | C.W.9 |
| W03  | metody poszukiwania nowych substancji leczniczych | C.W.13 |
| W04 | physicochemical and functional properties of basic excipients used in the technology of drug forms | C.W.15 |
| W05 | forms of biopharmaceuticals and problems related to their stability; | C.W.20 |
| W06 | basic blood products and blood substitutes and the method of obtaining them; | C.W.22 |
| W07 | pharmacopoeial requirements that biological drugs should meet and the rules for introducing them to the market | C.W.23 |
| W08 | nomenclature, composition, structure and properties of individual drug forms; | C.W.25 |
| W09 | requirements for different forms of a drug and principles for selecting a form of a drug depending on the properties of the drug substance and the intended use of the medicinal product; | C.W.26 |
| W10 | principles of preparation and control of prescription drugs and their storage conditions; | C.W.27 |
| W11 | types of physicochemical incompatibilities between components of pharmaceutical preparations; | C.W.28 |
| W12 | basic technological processes and devices used in drug formulation technology; | C.W.29 |
| W13 | methods of preparing liquid, semi-solid and solid forms of a drug on a laboratory and industrial scale and the influence of technological process parameters on the properties of the drug form; | C.W.30 |
| W14 | methods of aseptic procedure and obtaining sterility of medicinal products, substances and materials; | C.W.31 |
| W15 | types of packaging and dosing systems; | C.W.32 |
| W16 | principles of Good Manufacturing Practice specified in the regulations issued pursuant to Article 39, paragraph 5, point 1 of the Act of 6 September 2001 - Pharmaceutical Law (Journal of Laws of 2019, item 499, as amended), including the principles of documenting technological processes | C.W.33 |
| W17 | methods of testing the quality of drug forms and the method of analyzing the production batch; | C.W.34 |
| W18 | factors influencing the stability of drug forms and methods of testing their stability; | C.W.35 |
| W19 | principles of preparation of homeopathic medicines; | C.W.38 |
| W20 | methods of ex tempore preparation of radiopharmaceutical products; | C.W.39 |
| W21 | possibilities of using nanotechnology in pharmacy | C.W.40 |
| W22 | methods of testing plant substances and products and methods of isolating components from plant material; | C.W.45 |
| W23 | nanoparticles and their use in diagnostics and therapy. |  C.W46.  |
|  | within the scope of **ABILITIES:** |  |
| U01  | explain the use of radiopharmaceuticals in the diagnosis and treatment of diseases; | C.U.2 |
| U02 | use pharmacopoeias, guidelines and literature relating to the assessment of the quality of substances for pharmaceutical use and medicinal products; | C.U.4 |
| U03 | detect, on the basis of observation of a medicinal product, its defects that qualify for reporting to the body competent for matters of supervision over the safety of the use of medicinal products; | C.U.8 |
| U04 | use pharmacopoeias, formularies and technological regulations, guidelines and literature on the technology of drug forms, in particular with regard to prescription drugs; | C.U.14 |
| U05 | propose the appropriate form of the drug depending on the properties of the drug substance and its intended use; | C.U.15 |
| U06 | prepare prescription drugs, select packaging and determine the shelf life of the drug and how it should be stored; | C.U.16 |
| U07 | recognize and solve problems resulting from the composition of a prescription drug,control the doses of this drug and verify its composition; | C.U.17 |
| U08 | prepare herbal products in laboratory conditions and assess their quality using pharmacopoeial methods; | C.U.18 |
| U09 | evaluate the functional properties of excipients for pharmaceutical use; | C.U.19 |
| U10 | prepare preparations under aseptic conditions and choose the sterilization method; | C.U.20 |
| U11 | make parenteral nutrition mixtures | C.U.21 |
| U12 | prepare cytostatic drugs in a form ready for administration to patients; | C.U.22 |
| U13 | prepare operating procedures and prepare protocols of activities carried out during the preparation of prescription and pharmacy medicines; | C.U.23 |
| U14 | plan the stages of manufacturing a drug form in industrial conditions, select equipment and select inter-process control methods; | C.U.24 |
| U15 | perform tests to assess the quality of the drug form, operate appropriate control and measurement equipment and interpret test results; | C.U.25 |
| U16 | assess the risk of poor quality of the medicinal product and medical device and the clinical consequences; | C.U.26 |
| U17 | propose specifications for the medicinal product and plan stability studies of the medicinal substance and the medicinal product; | C.U.27 |
| U18 | determine factors influencing the durability of the medicinal product and select storage conditions. | C.U.28 |
|  | within the scope of SOCIAL COMPETENCE: |  |
| K01  | formulating conclusions from your own measurements or observations; | FAR\_K.08.  |
| K02  | using objective sources of information. | FAR\_K.07.  |
| **4.4. Methods of assessment of the intended learning outcomes** |  |  |
| **Teaching****outcomes****(code)** | **Method of assessment (+/-)** |  |  |
| **Exam oral/written****\***  | **Colloquium\* written or oral** | **Project\***  | **Effort****in class\*** | **Self-study\*** | **Group****work\*** | **Others\* e.g.****standardized test****used in elearning** |
| Form of classes | Form of classes | Form of classes | Form of classes | Form of classes | Form of classes | Form of classes |
| *L*  | *E*  | *Lab*  | *L*  | *E*  | *Lab*  | *L*  | *E*  | *Lab*  | *L*  | *E*  | *Lab*  | *L*  | *E*  | *Lab*  | *L*  | *E*  | *Lab*  | *L*  | *E*  | *Lab* |
| W01 -W 23 | **+** |  |  |  |  | **+** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| U01 | **+** |  |  |  |  | **+** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| U02-U18 | **+** |  |  |  |  | **+** |  |  |  |  |  | **+** |  |  | **+** |  |  |  |  |  |  |
| K01-K02 | **+** |  |  |  |  | **+** |  |  |  |  |  | **+** |  |  | **+** |  |  |  |  |  | **+** |

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| **4.5. Criteria of assessment of the intended learning outcomes** |
| **Form of****classes** | **Grade**  | **Assessment criterion** |
|  **(lecture (L) \*** | **3**  | Obtaining 61-68% correct answers in the final written exam in semesters VI and VII and the written exam in semester VIII |
| **3,5**  | Obtaining 69-76% correct answers in the final written exam in semesters VI and VII and the written exam in semester VIII |
| **4**  | Obtaining 77-84% correct answers in the final written exam in semesters VI and VII and the written exam in semester VIII |
| **4,5**  | Obtaining 85-92% correct answers in the final written exam in semesters VI and VII and the written exam in semester VIII |
| **5**  | Obtaining 93-100% correct answers in the final written exam in semesters VI and VII and the written exam in semester VIII |
| **laboratory** **(L)** | **3**  | Obtaining 61-68% correct answers in the oral and written partial tests after each semester of studies and the correct preparation of 2 pharmaceutical preparations + obtaining 1 point from the preparation protocol. |
| **3,5**  | Obtaining 69-76% correct answers in the oral and written partial tests after each semester of studies and the correct preparation of 2 pharmaceutical preparations + obtaining 2 points from the preparation protocol |
| **4**  | Obtaining 77-84% correct answers in the oral and written partial tests after each semester of studies and the correct preparation of 2 pharmaceutical preparations + obtaining 3 points from the preparation protocol |
| **4,5**  | Obtaining 85-92% correct answers in partial oral and written tests after each semester of studies and correct preparation of 2 pharmaceutical preparations + obtaining 5 points from the preparation protocol |
| **5**  | Obtaining 93-100% correct answers in the oral and written partial tests after each semester of studies and the correct preparation of 2 pharmaceutical preparations + obtaining 6 points from theperformance protocol |

# 5. BALANCE OF ECTS CREDITS – STUDENT’S WORK INPUT

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| **Kategoria**  | **Student's workload** |
| **Full-time****studies** | **Extramural studies** |
| *NUMBER OF HOURS WITH THE DIRECT PARTICIPATION OF THE TEACHER**/CONTACT HOURS/* | ***340*** |  |
| *Participation in lectures* | 60 |   |
| *Participation in laboratories* | 265 |   |
| *Other:e-learning* | 15 |  |
| *SAMODZIELNA PRACA STUDENTA /GODZINY NIEKONTAKTOWE/*  | 110 |  |
| *Preparation for exercises, laboratory* | 55 |   |
| *Preparation for the exam/colloquium* | 55 |   |
| ***TOTAL NUMBER OF HOURS*** | 450 |  |
| **ECTS credits for the course of study** | 18 |  |

***I accept for implementation (date and legible signatures of persons teaching the subject in a given academic year)*** ............................................................................................................................