




University of Belgrade Faculty of Pharmacy	Specialized academic study BIOLOGICAL MEDICINES		
Study programme: Biological Medicines			
Course title: Immunology			
Teachers: Arsenović Ranin M. Nevena, Stojić-Vukanić M. Zorica, Bufan S. Biljana			
Course status: Mandatory			
Semester: I	Year of studies: I		
ECTS points: 9	Course code: 6BMM1IM		
Requirements: No			
Course aims: To provide knowledge on the mechanisms of immune response against infectious and non-infectious antigens, as well as on the pathogenesis of immune mediated disorders.			
Course outcomes: Understanding of mechanisms of immune response against infectious and non-infectious antigens, as well as on the pathogenesis of immune mediated disorders.			
Course contents: <i>Lectures</i> Nomenclature, general properties and components of immune system. Innate immunity: epithelial barriers, phagocytes, NK cells, the complement system (pathways of complement activation, regulation of complement activation, biologic functions of complement, receptors for complement proteins, deficiencies of complement proteins, deficiencies of complement regulatory proteins and complement receptors). The major histocompatibility complex (MHC) - discovery and properties MHC genes, structure and expression of MHC molecules, binding of peptides to MHC molecules. Adaptive immunity. Recognition of antigen in adaptive immunity - the structure of T and B cell receptors for antigen. T cell activation and effector mechanisms of cell-mediated immunity. B cell activation and effector mechanisms of humoral immunity. Cytokines-physiologic role, cytokine receptors and cytokine antagonists. Hypersensitivity reactions. Immunologic tolerance and autoimmunity. Autoimmune disorders. Immune response to tumors. Immunodeficiencies. <i>Practical classes</i> Immunization, the production of polyclonal and monoclonal antibodies. Precipitation reactions. Agglutination reactions. Radioimmunoassays. Enzyme immunoassays. Fluorescently labeled probes - immunofluorescence and flow cytometry. Isolation of immune cells. Assessment of humoral and cell-mediated immunity in vitro and in vivo.			
Recommended literature: 1. Abbas AK, Lichtman AH, Pillai S. Basic immunology – functions and disorders of the immune system. 5th ed. Philadelphia: Elsevier Saunders; 2017. 2. Murphy K, Weaver C. Janeway's Immunobiology, Garland Science, Taylor & Francis Group, LLC, 9th ed., 2017. 3. Abbas AK, Lichtman A, Pillai S. Cellular and molecular immunology. 9th ed. Philadelphia: Elsevier Saunders; 2018.			
The total of active learning classes			
Lectures: 3	Practical classes: 2		
Research work: 1	Other forms of teaching: 1		
Teaching methods: Lectures, interactive classes, practical classes			
Grading system			
Exam prerequisites	Points	Final exam	Points
Active participation in lectures	20	Practical	
Practical classes	20	Written	60
Workshops		Oral	
Colloquia			

Seminars		
Other activities		


University of Belgrade Faculty of Pharmacy	Specialized academic study BIOLOGICAL MEDICINES		
Study programme: Biological Medicines			
Course title: Biotechnological Medicines			
Teachers: Arsenović Ranin M. Nevena, Stojić-Vukanić M. Zorica, Bufan S. Biljana, Živković P. Lada, Savić D. Snežana, Stojanović S. Biljana, Vučićević M. Katarina			
Course status: Mandatory			
Semester: I		Year of studies: I	
ECTS points: 12		Course code: 6BMM1BM	
Requirements: No			
Course aims: To provide knowledge about characteristics, production, mechanisms of action and therapeutic use of different groups of biotechnological medicines.			
Course outcomes: After completing the course the students are expected to know the characteristics, production, mechanisms of action and therapeutic use of different groups of biotechnological medicines.			
Course contents: <i>Lectures</i> Recombinant DNA technology (DNA transfer, DNA sources, DNA and genome sequencing, DNA hybridization, polymerase chain reaction - PCR, cell cultures). Protein production and purification. Analytical techniques (blotting techniques, immunoassays, electrophoresis, chromatography). Manufacturing of biotechnology products. Formulation of biotechnology products. Pharmacokinetics and pharmacodynamics of peptide and protein drugs. List of commercially available recombinant proteins/peptides - therapeutic indications. Cytokines (interferons and hematopoietic growth factors). Recombinant protein hormones (insulin, glucagon, growth hormone, gonadotropins). Recombinant blood products. Monoclonal antibodies. Biosimilars. Regulatory aspects of biotechnological products. Side effects of biotechnological medicines. <i>Practical classes</i>			
Recommended literature: 1. Crommelin DJA, Sindelar RD, Meibohm B. Pharmaceutical Biotechnology: Fundamentals and Applications, 4th ed., Springer-Verlag New York, 2013. 2. Kayser O, Warzecha H. Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications, 2nd ed., Wiley-VCH Verlag GmbH & Co. KGaA, 2012. 3. Groves MJ ed. Pharmaceutical Biotechnology. 2nd ed. CRC Press Taylor&Francis Group Boca raton, 2006. 4. Glazer AN, Nikaido H. Microbial Biotechnology: Fundamentals of Applied Microbiology. 2nd ed. Cambridge University press, 2007. 5. Walsh G. Pharmaceutical Biotechnology - Concepts and Applications. John Wiley & Sons Ltd. 2007. 6. European Pharmacopoeia- 9th edition, 2017.			
The total of active learning classes			
Lectures: 2		Practical classes:	
Research work: 3		Other forms of teaching: 3	
Teaching methods: Lectures, interactive classes, seminars, research work			
Grading system			
Exam prerequisites	Points	Final exam	Points
Active participation in lectures	20	Practical	
Practical classes		Written	60
Workshops		Oral	
Colloquia	20		

Seminars		
Other activities		


University of Belgrade Faculty of Pharmacy	Specialized academic study BIOLOGICAL MEDICINES		
Study programme: Biological Medicines			
Course title: Immunoglobulins and other human plasma-derived medicinal products			
Teachers: Arsenović Ranin M. Nevena, Stojić-Vukanić M. Zorica, Bufan S. Biljana			
Course status: Mandatory			
Semester: I		Year of studies: I	
ECTS points: 6		Course code: 6BMM1IG	
Requirements: No			
Course aims: Acquire professional knowledge in the field of manufacture of immunoglobulin and other plasma-derived medicinal products and their therapeutic application.			
Course outcomes: Application of acquired knowledge in the manufacturing process and application of human immunoglobulin and other human plasma-derived medicinal products.			
Course contents: <i>Lectures</i> Humoral immunity. Effector functions of antibodies. Immunoglobulin preparations for medical use (polyspecific or intravenous immunoglobulin and specific immunoglobulins). The manufacture of immunoglobulins from human plasma. Quality control. Clinical application of immunoglobulins. Dosage and administration. Side effects of immunoglobulin therapy. Passive immunization (xenogeneic and allogeneic sera). Other plasma-derived medicinal products (albumin and coagulation factors). The manufacture and clinical use of albumin and coagulation factors. <i>Practical classes</i> Students will visit the Blood Transfusion Institute of Serbia to familiarize themselves with the manufacture of stable products from human plasma pool. Plasma testing on markers of transfusion transmissible infectious diseases, plasma fractionation, centrifugation, ultrafiltration, lyophilization, finalization. get to know more about			
Recommended literature: 1. Nijkamp FP, Parnham MJ. Principles of Immunopharmacology, 2nd ed. A Birkhäuser book, 2005. 2. Abbas AK, Lichtman AH, Pillai S. Basic immunology – functions and disorders of the immune system. 5th ed. Philadelphia: Elsevier Saunders; 2017. 4. Murphy K, Weaver C. Janeway's Immunobiology, Garland Science, Taylor & Francis Group, LLC, 9th ed., 2017. 5. Abbas AK, Lichtman A, Pillai S. Cellular and molecular immunology. 9th ed. Philadelphia: Elsevier Saunders; 2018.			
The total of active learning classes			
Lectures: 1		Practical classes: 2	
Research work: 1		Other forms of teaching: 2	
Teaching methods: Lectures, interactive classes, practical classes, research work			
Grading system			
Exam prerequisites	Points	Final exam	Points
Active participation in lectures	20	Practical	
Practical classes	20	Written	60
Workshops		Oral	
Colloquia			
Seminars			
Other activities			


University of Belgrade Faculty of Pharmacy	Specialized academic study BIOLOGICAL MEDICINES		
Study programme: Biological Medicines			
Course title: Transplantation			
Teachers: Arsenović Ranin M. Nevena, Stojić-Vukanić M. Zorica, Bufan S. Biljana, Laposavić M. Gordana			
Course status: Mandatory			
Semester: II		Year of studies: I	
ECTS points: 12		Course code: 6BMM2T	
Requirements: none			
Course aims: To provide knowledge about immune mechanisms and clinical manifestations of transplant rejection, measures for the prevention of rejection, as well as the process of obtaining, controlling and preserving the cells for transplantation.			
Course outcomes: After completing the course the students are expected to: - understand the immune mechanisms of transplant rejection. - know methods for the prevention of rejection, and the process of obtaining, controlling and preserving the cells for transplantation.			
Course contents: <i>Lectures</i> Immune response to transplanted tissue. Transplantation antigens - MHC (HLA), minor histocompatible antigens and other antigens important for transplantation. Immune mechanisms of transplant rejection. Methods of prevention and treatment of rejection. Immunosuppression. Transplantation of blood cells (transfusion). Blood groups. Blood and blood components intended for transfusion - preparation, storage, indications for use. Transfusion reactions. Hemovigilance. Transplantation of hematopoietic stem cells. Obtaining and storage of stem cells from peripheral blood, bone marrow and umbilical cord. Graft versus host disease. Application of stem cells in regenerative medicine. Gene therapy - general principles, problems and indications for gene therapy. Gene therapy of hereditary non-malignant diseases. Gene therapy of malignant diseases. Legislation. <i>Practical classes</i> Students will visit the Blood Transfusion Institute of Serbia to familiarize themselves with the processes of preparation of labile blood components for transfusion. Blood typing techniques. Laboratory tests that are performed before transplantation: cross-matching, HLA tissue typing (cytotoxic test, molecular techniques). Visit to the Laboratory for tissue typing within the Blood Transfusion Institute of Serbia and getting familiar with tissue typing methods performed within this institute.			
Recommended literature: 1. Abbas AK, Lichtman A, Pillai S. Cellular and molecular immunology. 9th ed. Philadelphia: Elsevier Saunders; 2018. 2. Murphy MF, Pamphilon DH, Heddle NM. Practical Transfusion Medicine. John Wiley & Sons, Ltd., 2013. 3. Stavropoulos-Giokas C, Charron D, Navarrete C. Steenblock D, Payne A. Cord Blood Stem Cells Medicine, 1st ed., Academic press, 2014. 4. Simon TL, McCullough J, Snyder EL, Solheim BG, Strauss RG. Rosssi's Principles of Transfusion Medicine, 5th ed. Wiley Blackwell 2016. 5. Crommelin DJA, Sindelar RD, Meibohm B. Pharmaceutical Biotechnology: Fundamentals and Applications, 4th ed., Springer-Verlag New York, 2013.			
The total of active learning classes			
Lectures: 2		Practical classes: 3	
Research work: 2		Other forms of teaching: 2	
Teaching methods: Lectures, interactive classes, practical classes, research work			
Grading system			
Exam prerequisites	Points	Final exam	Points

Active participation in lectures	20	Practical	
Practical classes	20	Written	60
Workshops		Oral	
Colloquia			
Seminars			
Other activities			

University of Belgrade Faculty of Pharmacy	Specialized academic study BIOLOGICAL MEDICINES		
Study programme: Biological Medicines			
Course title: Vaccines			
Teachers: Arsenović Ranin M. Nevena, Stojić-Vukanić M. Zorica, Bufan S. Biljana, Leposavić M. Gordana, Milenković T. Marina, Antić Stanković A. Jelena			
Course status: Mandatory			
Semester: II		Year of studies: I	
ECTS points: 6		Course code: 6BMM2VAC	
Requirements: No			
Course aims: To provide knowledge on the immune mechanisms of active immunization, types of vaccines, production and quality control of vaccines.			
Course outcomes: Understanding of immune mechanisms of active immunization, types of vaccines, production and quality control of vaccines.			
Course contents: <i>Lectures</i> Active immunization. Designing vaccines for active immunization. Types of vaccines: live (attenuated) vaccines, dead (inactivated) vaccines, subunit (antigenic) vaccines - toxoids, bacterial capsular polysaccharides, recombinant protein antigens, conjugated vaccines, DNA vaccines, recombinant vector vaccines. Adjuvants. Production, formulation, characterization, storage. Regulatory and clinical aspects. Efficiency and safety - preclinical and clinical studies. Prophylactic vaccines. Therapeutic vaccines. <i>Practical classes</i>			
Recommended literature: 1. European Pharmacopoeia- 9th edition, 2017. 2. Plotkin SA, Orenstein WA, Offit PA. Vaccines, 6th ed., Saunders, 2013. 3. Nijkamp FP, Parnham MJ. Principles of Immunopharmacology, 3rd ed., Birkhäuser Basel, 2011. 4. Abbas AK, Lichtman A, Pillai S. Cellular and molecular immunology. 9th ed. Philadelphia: Elsevier Saunders; 2018. 5. Murphy K, Weaver C. Janeway's Immunobiology, Garland Science, Taylor & Francis Group, LLC, 9th ed., 2017.			
<p style="text-align: center;">The total of active learning classes</p>			
Lectures: 1		Practical classes: 0	
Research work: 2		Other forms of teaching: 2	
Teaching methods: Lectures, interactive classes, seminars, research work			
<p style="text-align: center;">Grading system</p>			
Exam prerequisites	Points	Final exam	Points
Active participation in lectures	20	Practical	
Practical classes		Written	60
Workshops		Oral	
Colloquia	20		
Seminars			
Other activities			

University of Belgrade Faculty of Pharmacy	Specialized academic study BIOLOGICAL MEDICINES		
Study programme: Biological Medicines			
Course title: Immunogenicity of protein drugs			
Teachers: Stojić-Vukanić M. Zorica, Arsenović Ranin M. Nevena, Bufan S. Biljana			
Course status: Elective			
Semester: II	Year of studies: I		
ECTS points: 5	Course code: 6BME2IPD		
Requirements: No			
Course aims: To provide knowledge about types of immune responses to protein drugs, factors influencing immunogenicity of protein drugs, its consequences and technical approaches for their laboratory evaluation.			
Course outcomes: Knowledge about types of immune responses to protein drugs, factors influencing immunogenicity of protein drugs, and its consequences.			
Course contents: <i>Lectures</i> Immune response to protein drugs. Generation of anti-drug-antibodies (ADA) - immune mechanisms. Factors influencing immunogenicity of protein drugs. Factors related to the medicine itself. Factors related to the way of drug application. Patient-related factors. Consequences of ADA formation: reduced efficacy or complete loss of drug efficacy. ADA mediated hypersensitivity reactions. T cell-mediated hypersensitivity reactions to protein drug. Methods for assessment of ADA in serum or in vivo. <i>Practical classes</i>			
Recommended literature: 1. Crommelin DJA, Sindelar RD, Meibohm B. Pharmaceutical Biotechnology: Fundamentals and Applications, 4th ed., Springer-Verlag New York, 2013. 2. Review papers published in prominent international journals.			
The total of active learning classes			
Lectures: 1	Practical classes:		
Research work: 1	Other forms of teaching: 3		
Teaching methods: Lectures, interactive classes, seminars, research work			
Grading system			
Exam prerequisites	Points	Final exam	Points
Active participation in lectures	20	Practical	
Practical classes		Written	60
Workshops		Oral	
Colloquia	20		
Seminars			
Other activities			

University of Belgrade Faculty of Pharmacy	Specialized academic study BIOLOGICAL MEDICINES		
Study programme: Biological Medicines			
Course title: Biological medicines for the treatment of immune-mediated diseases			
Teachers: Bufan S. Biljana, Stojic-Vukanic M. Zorica, Arsenovic Ranin M. Nevena			
Course status: Elective			
Semester: II		Year of studies: I	
ECTS points: 5		Course code: 6BME2TID	
Requirements: none			
Course aims: To provide knowledge about biological medicines used for the treatment of autoimmune and allergic diseases, their mechanisms of action, adverse effects and clinical use.			
Course outcomes: After completing the course the students are expected to know about the biological medicines used for the treatment of autoimmune and allergic diseases, their mechanisms of action, adverse effects and clinical applications.			
Course contents: <i>Lectures</i> Patogenesis of autoimmune diseases. Pathogenesis of allergic diseases. Targeted therapies based on understanding the mechanisms underlying these diseases. Biological therapy directed at B cells and humoral immune response. Biological therapy aimed at inhibiting the activation and differentiation of T cells. Biological therapy aimed at blocking harmful effector inflammatory pathways: drugs aimed at blocking the effects of cytokines, drugs blocking adhesive molecules, chemokine and complement effects. Anti-IgE antibodies in asthma therapy. Approved biological drugs and biological therapy in development. <i>Practical classes</i>			
Recommended literature: 1. Crommelin DJA, Sindelar RD, Meibohm B. Pharmaceutical Biotechnology: Fundamentals and Applications, 4th ed., Springer-Verlag New York, 2013, 2. Chapel H, Haeney M, Misbah S, Snowden N. Essentials of Clinical Immunology, 6th ed., John Wiley & Sons, 2014 3. Murphy K and Weaver C. Janeways Immunobiology, Garland Science, Taylor & Francis Group, LLC, 9th ed., 2017.			
The total of active learning classes			
Lectures: 1		Practical classes:	
Research work: 1		Other forms of teaching: 3	
Teaching methods: Lectures, interactive classes, seminars, research work			
Grading system			
Exam prerequisites	Points	Final exam	Points
Active participation in lectures	20	Practical	
Practical classes		Written	60
Workshops		Oral	
Colloquia	20		
Seminars			
Other activities			

University of Belgrade Faculty of Pharmacy	Specialized academic study BIOLOGICAL MEDICINES		
Study programme: Biological medicines			
Course title: Biological medicines in cancer immunotherapy			
Teachers: Stojić-Vukanić M. Zorica, Arsenović Ranin M. Nevena, Bufan S. Biljana, Filipić V. Brankica			
Course status: Elective			
Semester: 2		Year of studies: I	
ECTS points: 5		Course code: 6BME2CI	
Requirements: No			
Course aims: To provide knowledge about immune responses to tumors, categories of tumor antigens, and biotechnological medicines and strategies used in immunotherapy.			
Course outcomes: Knowledge of immune responses to tumors, categories of tumor antigens, and biotechnological medicines and strategies used in immunotherapy.			
Course contents: <i>Lectures</i> The role of immune system in eliminating and controlling malignant cells. Categories of tumor antigens. Cancer immunotherapy. Enhancing the immune response to tumors by vaccination with tumor cells, tumor antigens or antigen-loaded dendritic cells. Checkpoint blockade strategies for augmenting immune response to existing tumors. Non-specific immunotherapy with immunostimulatory cytokines. Adoptive cell therapy with in vitro expanded tumor-specific T cells or using T-cells that have been engineered in vitro (technique known as chimeric antigen receptor T-cell (CAR T-cell) therapy). Immunotherapy with monoclonal antibodies against tumor antigens, alone or linked to toxins, chemotherapeutic drugs or radioisotopes. <i>Practical classes</i>			
Recommended literature: 1. Crommelin DJA, Sindelar RD, Meibohm B. Pharmaceutical Biotechnology: Fundamentals and Applications, 4th ed., Springer-Verlag New York, 2013. 2. Abbas AK, Lichtman AH, Pillai S. Basic immunology – functions and disorders of the immune system. 5th ed. Philadelphia: Elsevier Saunders; 2017. 3. Murphy K, Weaver C. Janeway's Immunobiology, Garland Science, Taylor & Francis Group, LLC, 9th ed., 2017. 4. Abbas AK, Lichtman AH, Pillai S. Cellular and molecular immunology. Elsevier Saunders, Philadelphia, PA, USA, 9th ed. 2018. 5. Review papers published in prominent international journals.			
The total of active learning classes			
Lectures: 1		Practical classes:	
Research work: 1		Other forms of teaching: 3	
Teaching methods: Lectures, interactive classes, seminars, research work			
Grading system			
Exam prerequisites	Points	Final exam	Points
Active participation in lectures	20	Practical	
Practical classes		Written	60
Workshops		Oral	
Colloquia	20		
Seminars			
Other activities			

