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| Code: \* | | **Name: SELECTED TOPIS IN QUALITY CONTROL OF MEDICINES - QUALITY CONTROL OF BORDERLINE MEDICINAL PRODUCTS** | | |
| Level: Integrated study | | Year: The Fifth (V) | Semester: Ninth (VII) | ECTS Credits: 2 (two) |
| Status: Elective course | | Number of hours per week:  Lectures (L)  Practical work (P) | | Total hours: 30  (L: 15; P: 15) |
| Teaching staff: | | Full professor Miroslav Šober, PhD.  tel.+387 33 586 174  [miroslav.sober@ffsa.unsa.ba](about:blank))  Associate Professor Ervina Bečić, PhD  tel. + 387 33 586 179;  [ervina.becic@ffsa.unsa.ba](about:blank)  Associate Professor Belma Imamović, PhD  tel. +387 33 586 179;  [belma.imamovic@ffsa.unsa.ba](about:blank)  Assistant professor Mirza Dedić, PhD  tel. +387 33 586 179;  [mirza.dedic@ffsa.unsa.ba](about:blank) | | |
| 1. Course objectives | | The aim of the quality control of borderline medicinal products course is to provide basic information about the regulations and procedures related to quality control, regulations related to quality assurance and the procedure for registration of borderline medicinal products.  Specificity of the origin and types of active substances and their different content in border products, a large number of different parameters that determine the quality of the starting substances and the finished product will be processed so that a student acquires knowledge about the importance of analytical approach in quality assurance of these products. | | |
| * 1. **Contents of the course**   a) Lectures   * Introduction, borderline medicinal products, definition, division, application * Legislation on quality assurance of borderline medicinal products * Guidelines for testing borderline medicinal products safety * Registration of borderline medicinal products in BiH and EU * Authorized and prohibited substances in borderline medicinal products * Marker substances in analytics of borderline medicinal products * Monographs and specifications of authorized and marker substances in borderline medicinal products, reference samples, analytical methods * Selection and harmonization of analytical methods and procedures for borderline medicinal products quality control with prescribed quality requirements * Identification, evaluation of the purity, potency and composition of borderline medicinal products * Counterfeit borderlinemedicinal products * Analytical methods and procedures for the control of borderline medicinal products with hydrosoluble and liposoluble vitamins * Analytical methods and procedures for the control of borderline medicinal products with active substances of plant origin * Analytical methods and procedures for the control of borderline medicinal products with proteins, growth factors and cytokines * Heavy metals in borderline medicinal products * Evaluation of test results, analytical reports   b) Seminary paper  Seminary paper has to be submitted in writing form, orally presented to the teacher and other students of the course. | | | | |
| * 1. Learning outcomes | After passing the course exam, students will be able to:  1. Apply the knowledge to select the regulations and methods which should be applied in the quality control of borderline medicinal products  2. Select analytical methods when examining active substances in accordance with the legislation  3. Summarize the results of the analysis according to regulatory guidelines, and on that basis to evaluate the analyzed substances and the finished product  4. Compare the obtained results with the quality requirements  5. Critically analyze the results of analytical methods and procedures for borderline medicinal products | | | |
| 1. **ORGANIZATION OF COURSE - Lectures and seminar assay** | | | | |
| Activity description (%) | | | | |
| 2.1. Method | 1. Lectures, all students in the classroom 2. Seminary paper | | | 50 %  50 % |
| Participation in the evaluation (%) | | | | |
| * 1. System of evaluation | Final exam  Seminary paper | | | 50 %  50 % |
| **REQUIRED LITERATURE**   * Presentations from lectures * On line available literature   **OPTIONAL LITERATURE**   1. Handbook of modern pharmaceutical analysis, Satinder Ahuja and Stephen Scypinski, Academic Press, 2001.  Peter Elsner, Howard I. Maibach. Cosmeceuticals and Active Cosmetics: Drugs vs. Cosmetics. CRC Press, 2005.  1. EDQM European Pharmacopoeia, 10th Edition, Council of Europe, Strasbourg, France 2. Guidance document on the demarcation between the cosmetic products Directive 76/768 and the medicinal products directive 2001/83 [http://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products/docs/guidance\_doc\_cosm-medicinal\_en.pdf](about:blank) 3. Manual of the working griop on cosmetic products (sub-group om borderline products) on the scope of application of the cosmetics regulation (EC) NO 1223/2009 ART.2(1)(A)). 4. Law of medicines and medical devices of Bosnia and Herzegovina. 2008. | | | | |