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| Code: \* | | **Name of the course: SELECTED TOPICS IN QUALITY CONTROL OF MEDICINES- GOOD CONTROL LABORATORY PRACTICE** | | |
| Level: Integrated study | | Year: The third (III) | Semester: Fifth (V) | ECTS Credits: 2 (two) |
| Status: Elective course | | Number of hours per week: 1+1 (L+S)  Lectures (L): 1 (one) hour  Seminar (S): 1 (one) hour | | Total hours: 30  (L: 15; S: 15) |
| Teaching staff: | | |  | | --- | | Full Professor Miroslav Šober, PhD  Associate Professor Belma Imamović  Associate Professor Ervina Bečić, PhD  Assistant professor Mirza Dedić, PhD  Teaching assistant Armina Gičević, MPh | | | |
| Course objectives | | To enable students to acquire theoretical knowledge in the field of quality assurance in analytical laboratories, with special emphasis on laboratories for testing and quality control of medicines. Students will be introduced to the principles of GMP standards of good control and laboratory practice, but also basic ISO standards, especially ISO 17025. The basic statistical methods used in the validation of analytical methods, documentation related to the control and analytical laboratory will be presented. Student will be familiar with quality assurance system, rulebook on quality and basics of metrology. | | |
| * 1. **Contents of the course**   a) **Lectures**   * Introduction to quality, valency standards and GMP requirements related to good control and laboratory practice. * ISO Standards 9000, 14000. * ISO Standards 17025. * Quality System Organization and Management in GcLP, * Document Control and Records. GcLP staff, space and equipment. * Document management. Quality Manual. * Standard operating procedures, SOP development. * Calibration and standardization. * Samples, reagents, materials, standard reference materials. * Metrology and Traceability of Results. * Measurable insecurity. * Audits and proficiency testing. * Accreditation and certification.   **b) Seminary paper**  Seminary paper has to be submitted in writing form, orally presented to the teacher and the other students of the course | | | | |
| * 1. Learning outcomes | Through the elective classes **SELECTED TOPICS IN QUALITY CONTROL OF MEDICINES- GOOD CONTROL-LABORATORY PRACTICE** the student will be able to:  1. Apply the basic principles of quality assurance in the control and analytical laboratory.  2. Apply the statistical methods used in the validation of analytical methods.  3. Analyse documentation of validated analytical methods  4. Summarises the results of the analyzes according to legal guidelines. | | | |
| 1. **ORGANIZATION OF COURSE - Classes will be performed through lectures and seminary paper** | | | | |
| Activity description (%) | | | | |
| 2.1. Method | 1. Lectures, all students in the classroom 2. Seminary paper | | | 1. 50 % 2. 50 % |
| Participation in the evaluation (%) | | | | |
| * 1. System of evaluation | Final exam  Seminary paper | | | 1. 50 %  2. 50 % |
| 1. **LITERATURE**   Required literature:   * Presentations from lectures     Optional literature:   * Pulok K Mukherjee. Quality Control of Herbal Drugs. Business Horizons, 2012. * Quality control methods for medicinal plant materials. World Health Organisation, Geneva, 1998.   On line:   * EMEA/CPMP Guideline on specifications: Test procedures and acceptance criteria   for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products, (EMEA/CVMP/815/00 Rev 1) , 2006.   * EMEA/ HMPC Guideline on Good Agricultural and Collection Practice (GACP) for Starting Materials of Herbal Origin (EMEA/HMPC/246816/2005), 2006. * EMEA/CPMP Note for guidance on quality of herbal medicinal products, (CPMP/QWP/2819/00), 2006. * http://www.ema.europa.eu/ | | | | |