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| Code: FFS33 | | **Name of the course: QUALITY CONTROL OF MEDICINES 1** | | |
| Level: Integrated study | | Year: The third (III) | Semester: Fifth (V) | ECTS Credits: 8 (eight) |
| Status: Compulsory | | Number of hours per week:  Lectures (L): 3 (three) hours  Laboratory excersies (LE): 4 (four) hours | | Total hours: 105  (T: 45; P: 60) |
| 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 objective | | Accepting the concept of drug quality and recognizing the role played by the state and the manufacturer of the drug in achieving this concept, and recognizing the importance and role of quality control in the overall auxiliary substances and packaging materials, but also play the role of detectors in coupled chromatographic systems. Practical training aims at acquiring skills and competences in the application of spectroscopic methods in solving problems of quality control of medicines, starting materials and packaging materials, as well as determination of impurities and degradation products in the starting material and finished product. | | |
| * 1. **Contents of the course**   a) **Lectures**   * Law of Medicines and Procedure for Registration of Medicines in BiH; * Quality assurance, good manufacturing practice, basics of validation of analytical methods; * Visible and UV spectroscopy; * Infrared and Raman spectroscopy, * Nuclear magnetic resonance imaging, * Mass spectrometry: principles, spectra characteristics, instrument construction and imaging techniques, spectra interpretation and applications in the identification of organic molecules as well as in quantitative analysis; * Atomic absorption and optical emission spectroscopy, flame photometry: application in drug analysis, instrument design, sample preparation and modes; * Polarimetry and refractometry; * Test methods for radiopharmaceuticals.   **b) Laboratory excersies**   * Documents in CTD format that the applicant submits to the Medicines Agency, Module 3, which documents are submitted to the Medicines Commission; * Determination of average tablet weight and PhEur mass variation, mean, standard deviation, relative standard deviation; * Quantitative analysis using spectrophotometry in the visible area, construction of the calibration curve, calculation of the equation of the least squares method, calculation of the parameters of the validation of the method (linearity, limit of detection, limit of quantification); * Determination of paracetamol in tablets by UV spectrophotometry, qualitative analysis (spectrum recording), quantitative analysis by calibration curve; * Determination of sulfacetamide sodium in eye drops by UV spectrophotometry; * Determination of digoxin content in tablets, color develop, quantitative analysis by visible spectrophotometry by comparison solution method; * Determination of the content of diazepam in tablets by UV spectrophotometry, calculating the content by the method of specific extinction coefficient; * Determination of nitrate and nitrite content of the mixture by equi-absorbance method; * Spectrofluorimetric determination of quinine in tonic water, identification and quantitative analysis, basis for method validation; I * IR spectrophotometry, preparation of solid samples, interpretation of recorded spectra; * Interpretation of IR spectra of alkanes, alkenes, alkynes and aromatics, and compounds with OH and carbonyl groups, amines and amides; * Interpretation of 1H-NMR spectra; * Interpretation of the combination of IR, 1H-NMR and mass spectra. | | | | |
| * 1. Learning outcomes | Student will be familiar of the requirements related to the pharmaceutical-chemical quality of the medicinal product set by the regulatory authorities in the country and the Good Manufacturing Practice system, and how to apply spectroscopic methods in the examination of this quality. | | | |
| 1. **ORGANIZATION OF COURSE** | | | | |
| Activity description (%) | | | | |
| 2.1. Method | 1. Lectures, all students in the classroom 2. Practical work are performed in groups of students | | | 1. 37,5 % 2. 62,5 % |
| Participation in the evaluation (%) | | | | |
| * 1. System of evaluation | 1. Class attendance  2. Laboratory attendance  3. Active participation in practical work  4. Test  5. Final test | | | 1. 0- 2,5 %  2. 0- 2,5 %  3. 0-7 %  4. 0-8 %  5. 0-80 % |
| **LITERATURE**  Required literature:   * Nikolin, B., Šober, M. Analitika lijekova, Sarajevo publishing, 2001. * Praktikum iz kontrole lijekova. Interna skripta, Faculty of Pharmacy in Sarajevo.     Optional literature:  Ohanessian, L., Streeter, A.J. eds. Handbook of Pharmaceutical Analysis, Marcel Dekker 2002  Gauglitz, G. and Vo-Dinh, T. eds. Handbook of Spectroscopy, Wiley 2003  On line:   * The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use http://www.ich.org/ * The Agency for Medicinal Products and Medical Devices: http://www.alims.gov.ba/ | | | | |
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