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| **UNIVERSITY OF NIŠ** | | | | | | |
| **Course Unit Descriptor** | | **Faculty** | | | Faculty of Technology | |
| **GENERAL INFORMATION** | | | | | | |
| Study program | | | | Chemical Technologies | | |
| Study Module (if applicable) | | | | Pharmaceutical and cosmetic engineering | | |
| Course title | | | | Laboratory standards and validation | | |
| Level of study | | | | ☐Bachelor ☒ Master’s ☐ Doctoral | | |
| Type of course | | | | ☐ Obligatory☒ Elective | | |
| Semester | | | | ☒ Autumn ☐Spring | | |
| Year of study | | | | I year | | |
| Number of ECTS allocated | | | | 6 | | |
| Name of lecturer/lecturers | | | | Goran Nikolić | | |
| Teaching mode | | | | ☒Lectures ☐Group tutorials ☒ Individual tutorials  ☐Laboratory work ☐ Project work ☒ Seminar  ☐Distance learning ☐ Blended learning ☐ Other | | |
| **PURPOSE AND OVERVIEW (max. 5 sentences)** | | | | | | |
| Acquiring knowledge of quality systems, norms and standards of laboratory work. Getting to know with the characteristics and validation mode of laboratory methods and equipment. | | | | | | |
| **SYLLABUS (brief outline and summary of topics, max. 10 sentences)** | | | | | | |
| Students learn to work independently in an accredited control, research and development laboratories, through next main subjects:  Standards and systems of quality assurance of laboratory work. The principles and goals of Good Laboratory Practice (GLP). Laboratory competence and accreditation. Handling substances and standards. Maintenance and calibration of equipment. Standard procedures (SOP). Reports. Storing and searching of records and data. Validation. Analytical validation parameters. The process of validation. Internal validation. | | | | | | |
| **LANGUAGE OF INSTRUCTION** | | | | | | |
| ☒Serbian (complete course) ☐ English (complete course) ☐ Other \_\_\_\_\_\_\_\_\_\_\_\_\_ (complete course)  ☐Serbian with English mentoring ☐Serbian with other mentoring \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| **ASSESSMENT METHODS AND CRITERIA** | | | | | | |
| **Pre exam duties** | **Points** | | **Final exam** | | | **points** |
| **Activity during lectures** | **20** | | **Written examination** | | |  |
| **Practical teaching** | **20** | | **Oral examination** | | | **60** |
| **Teaching colloquia** | **/** | | **OVERALL SUM** | | | **100** |
| **\*Final examination mark is formed in accordance with the Institutional documents** | | | | | | |