



09.3.1-11 Planuri tematice și calendaristice; ale cursurilor și lucrărilor practice (seminare)

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Discussed and approved at the meeting of the Department of Pharmaceutical and Toxicological Chemistry Minutes Nr. <u>7</u> of <u>31.01.2025</u> Head of chair PhD, professor

Valica

Calendar Plan of the lectures at the discipline «Drug development and pharmaceutical research», IV year, VIII semester, 2024-2025 academic year

| Nr. | Date | Hours | Theme |
|--------|------------------|-------|---|
| 1-2. | 03-14.02.2025 | 2 | Fundamental notions of research methodology and instruments of pharmaceutical research. |
| 2-3. | 17-28.02.2025 | 2 | Planning and design of a research study. |
| 4-5. | 03-14.03.2025 | 2 | Basic notions in processing and analysis of the experimental results. Dissemination of research results. |
| 6-10. | 17.03-11.04.2025 | 4 | Drug development. Methodology for pharmaceutical research. Stages of drug development. |
| 11-12. | 14.04-02.05.2025 | 2 | Stability studies in drug research. |
| 13-15. | 05-23.05.2025 | 3 | Quality control and validation of experimental results. Validation of drug development stages. Basic notions of a pharmaceutical dossier. Creating of the license thesis. |

Associate professor

Henry

Livia Uncu



Catedra de Chimie farmaceutică și toxicologică

09.3.1-11

Planuri tematice și calendaristice; ale cursurilor și lucrărilor practice (seminare)

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Vladimir Valica

Calendar Plan of the laboratory lessons at the discipline «Drug development and pharmaceutical research», IV year, VIII semester, 2024-2025 academic year

| Nr. | Date | Hours | Theme |
|--------|------------------|-------|--|
| 1-2. | 03-14.02.2025 | 6 | Specialized bibliographical study. Organization, documentation via the Internet (search engines, international scientific databases), drafting of their bibliographic records (classical or electronic system). |
| 3-4. | 17-28.02.2025 | 6 | Critical bibliographical study. Revision of a specialized scientific article. |
| 5-7. | 03–21.03. 2025 | 9 | Experimental data processing. Basic concepts in statistics. Experimental errors. Limits and confidence interval. Statistical significance tests. Regression analysis and calibration. |
| 8. | 24-28.03.2025 | 3 | Control assessment. |
| 9. | 31.03-04.04.2025 | 3 | Stages of drug development. Chemical, pharmaceutical, pharmacological, clinical studies. |
| 10-11. | 07–18.04.2025 | 6 | Stability studies at the drug development stage. Accelerated stability determination studies; calculating the shelf life of drugs. |
| 12. | 29.04–02.05.2025 | 3 | Validation of analytical methods. Principles of validation. Preparation of an analytical protocol. Validation of a method of assay of an active principle in a drug. Preparation of the validation report. |
| 13-14. | 05–16.05.2025 | 6 | Dissemination of research results. Drawing up the plan of a license thesis; drawing up a research report. |
| 15. | 19-23.05.2025 | 3 | Control assessment. |

Associate professor

Henry

Livia Uncu