Odessa National Medical University
Faculty of Pharmacy
Department of Drug Technology

Syllabus course

PHARMACEUTICAL BIOTECHNOLOGY

Amount	Total number of hours - 90; number of ECTS credits - 3
Semester, year	IX semester, V year of study
Days, time, place	According to the approved schedule
Teacher	Candidate of Biological sciences, senior teacher Zamkovaya A. V.
Contact phone	0507425467
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Work place	Odessa, Malinovsky Street, 37, Department of Drug Technology, office.122
Consultations	*Online consultations*: remotely on the Microsoft Teams platform

COMMUNICATION

Communication in the audience on schedule. Other types of communication: consultation on a schedule on the principle of "Face to face", remotely on the MicrosoftTeams platform and with the help of an e-mail lecturer. The solution of "working issues" is possible by the specified phone number.

COURSE ANNOTATION

One of the newest branches of the rapidly developing pharmaceutical industry is pharmaceutical biotechnology, which is based on the use of biological processes and objects, the scientific potential of which determines the level of innovative development of the state economy as a whole. Most developed countries consider pharmaceutical biotechnology as one of the most important strategic directions of its development in the pharmaceutical industry, ie the use of fundamental biological knowledge in practical activities aimed at the production of drugs, enzymes, antibodies, vaccines, proteins, dyes, vitamins, growth peptides. , and other biologically active compounds, genetic construction of organisms, etc. is prerogative.
In pharmaceutical biotechnology, the objects of use can be divided into sections: general biotechnology, pharmaceutical plant biotechnology, pharmaceutical animal biotechnology and pharmaceutical biotechnology of microorganisms.

In this regard, the main task of the course is to master the basic concepts, chemical bases and technological principles of biotechnological industries based on the involvement of theoretical and practical knowledge of related (basic) sciences.

The discipline is based on the study of physics, general and inorganic chemistry, physical and colloid chemistry, biology with the basics of genetics; The discipline is the basis for the study of medical and pharmaceutical commodity science, good practices in pharmacy, pharmaceutical chemistry, management and marketing in pharmacy, biopharmacy, standardization of medicines, technology of medicinal cosmetics, pharmaceutical technology, which integrates teaching with the above disciplines. in the process of further training and in professional activities;
the discipline lays the foundations of professional training, promotes the formation of technical and pharmaceutical thinking necessary for the pharmaceutical specialty;
together with other pharmaceutical disciplines and social sciences, pharmaceutical biotechnology plays an important role in providing special technological training for professional activities.:

The purpose of teaching the discipline "Pharmaceutical Biotechnology" is acquaintance of students of pharmacists with a subject of biotechnology of medicines, with new achievements of a science in the field of genetic engineering, cellular engineering, culture of isolated fabrics and cells, manufacture of antibiotics and vaccines, enzyme biotechnology, biotechnological processes in pharmaceutical and power industry. and ecology, and cloning of animals and humans.

The main tasks of studying the discipline "Pharmaceutical Biotechnology" are:

Theoretical:

- - to form students' ideas about the chemical unity of the environment;
- - plant biotechnology, cloning of plant organisms, production of virus-free plants, production of transgenic plants for the production of drugs
- - biotechnology of microorganisms, genetic engineering, gene cloning, construction of recombinant DNA, vectors
- - the possibility of cloning animal organisms, individual organs and tissues, the production of antibiotics and vaccines, hormones, monoclonal antibodies, vitamins
- - the possibility of using viruses, bacteria, plant and animal cells to obtain drugs
- - general methodology for obtaining drugs
- - features of application of existing genetic vectors in molecular cloning - methods of screening and selection of cells containing recombinant DNA
- - features of selection and purification of the target product
- - methods of obtaining recombinant drugs: interferon, somatotropin, monoclonal antibodies, vaccines, antibiotics

Practical:

- - to choose the most suitable object for research and production in the field of biotechnology

- - navigate in molecular genetic methods that can be used to study the properties of producer organisms
- - calculate the production capacity of bioreactors with different cultivation conditions on different substrates;
- - prepare nutrient media, disinfect the workplace and sterilize nutrient media for plant cloning;
- - clone plants, obtain sterile explants and grow plants from them
- - be able to distinguish between natural and artificially created chemicals
- - to study the impact of new materials on the environment and the possibility of their utilization
- - master the theoretical foundations of the course.

COURSE DESCRIPTION

Forms and methods of teaching

The course will be presented in the form of practical (30 hours), organization of independent work of students (60 hours).

Teaching methods: explanatory-illustrated (multimedia lectures with elements of discussion communication with applicants for higher education), reproductive, research, part-search (independent search work, work with literature). The following teaching methods are used: verbal - story, explanation, conversation, instruction, lecture, discussion; visual - demonstration of films, visual equipment (small mechanization), illustrations, materials, demonstration of operations and processes of drug production in pharmacies and industrial enterprises; practical methods - laboratory and practical work; inductive methods (generalization of the results of observations and experiments). Preference is given to active and interactive methods and multimedia learning (multimedia lectures, educational films).

The content of the discipline

TOPIC 1. General issues of biotechnology of drug production.

TOPIC 2. Bioobjects as a means of production of drugs, prophylactics and diagnostics.

TOPIC 3. Pharmaceutical biotechnology of plants.

TOPIC 4. Pharmaceutical biotechnology of phospholipids

TOPIC 5. Pharmaceutical biotechnology of protein drugs.

TOPIC 6 Pharmaceutical biotechnology of amino acids.

TOPIC 7 Pharmaceutical biotechnology of vitamins and coenzymes.

TOPIC 8. Pharmaceutical biotechnology for the production of steroid hormones.

TOPIC 9. Pharmaceutical biotechnology of antibiotics

TOPIC 10. Pharmaceutical biotechnology of immunobiotechnological drugs.

TOPIC 11. Biotechnology of manufacturing yeast pharmaceuticals.

TOPIC 12. Pharmaceutical biotechnology of nanodrug preparation.

TOPIC 13. Requirements for the production and quality control of biotechnological drugs.

Recommended Books:

Basic:

1. S. Spada. G. Walsh Directory of Approved Biopharmaceutical Products 1st Edition . – CRC Press, 2019. – 336 p.
2. C. Kokare PHARMACEUTICAL BIOTECHNOLOGY 1st Edition. – Nirali Prakashan, 2017. – 274.
3. Лихач А. В. Промислова біотехнологія / А. В. Лихач. – МНАУ. – 2016. – 116 с.
4. Determination of Candida albicans proteins concentration by enzyme-linked immunosorbent assay method at subcutaneous introduction in candidiasis therapy / Mykola Rybalkin, Natalia Khokhlenkova, Julia Azarenko ,Tetiana Diadiun // PHARMACIA (Bulgaria), 2020, 67 (4), P. 393-396. DOI 10.3897/pharmacia.67.e52568
5. Kaliuzhnaia O.S. Investigation of the use of fluoroplastic filter elements in the production of a promising antibiotic substance Pyocyanin / Kaliuzhnaia O.S., Kaliuzhnyi O.B., Soloviova A.V. Технічний сервіс агропромислового, лісового та транспортного комплексів. № 18, 2020. *ISBN 978-1-9993071-4-1*
6. Калюжная О.С. Використання фторопластових фільтруючих елементів у біотехнологічному виробництві антибіотичних речовин. Технічний сервіс агропромислового, лісового та транспортного комплексів. № 19, 2020. *ISBN 978-1-9993071-4-1*
7. Біотехнологічні дослідження при розробці льодяників з пробіотиками / Старущенко У.А., Ярова Л.О., Калюжная О.С., Хохленкова Н.В., Калюжний О.Б. *Вісник фармації.* № 1 (101), 2021. –С. 38-43. *ISSN 2415-8844*
8. Стрілець О.П. *Paramecium caudatum* як тест-обєкт у біотестуванні / О.П. Стрілець, Л.С. Стрельников. Новітні досягнення біотехнології: Матеріали IV Мжнародної науково-практичної конференції, присвяченої 15-річчю кафедри біотехнології Національного авіаційного університету (23 вересня 2020 р., Київ). – К.:НАУ, 2020. – – С.53-54.
9. Стрілець О.П. Биотехнологічне тестування за допомогою найпростіших / О.П.Стрілець, Л.С. Стрельников. Science, engineering and technology: globaltrends, problems and solutions: International scientific and practical conference, September 25-26, 2020, Prague, 2020. P.2. – P. 52-54.
10. Зима Е.П. Перспективність розробки пігментів на основі технологій мікробного синтезу / Зима Е.П., Калюжная О.С. // Topical issues of new medicines development: Матеріали XXVIII Міжнародної науково-практичної

конф. молодих учених та студентів присвяченої 150-річчю з дня народження М.О.Валяшка (18-19 березня 2021 р., м. Харків). – Харків: НФаУ, 2021. – С. 226-228.
11. Kushka R.O., Dvinskykh N.V. Bacteriophages – as an essential alternative to antibiotics // Topical issues of new medicines development: матеріали XXVIII Міжнародної науково-практичної конференції молодих учених та студентів присвяченої 150-річчю з дня народження М.О. Валяшка (18-19 березня 2021 р., м. Харків). – Харків: НФаУ, 2021. – С. 212-213.
12. Fesenko L. O., Dvinskykh N.V. Prospect of production biologically of active additives of probiotics // Topical issues of new medicines development: матеріали XXVIII Міжнародної науково-практичної конференції молодих учених та студентів присвяченої 150-річчю з дня народження М.О. Валяшка (18-19 березня 2021 р., м. Харків). – Харків: НФаУ, 2021. – С. 210-211.

EVALUATION

Methods of current control:

Current control of the discipline carried out in each classroom through various forms of questionnaires on theoretical issues and assessment of practical skills - at the end of each topic.

Means of current control of students' knowledge.

- checking the completion of written homework;
- test control of initial and final level of students' knowledge;
- oral examination of the main issues of educational material;
- solving situational problems;
- protection of laboratory work protocols;
- test of practical skills.

Evaluation of the success of the study of each topic of the discipline is performed on a traditional 4-point scale.

At least 50% of students should be interviewed in a practical (laboratory) lesson, and at least 30% in a seminar. At the end of the semester (cycle), the number of grades for students in the group should be the same on average.

At the end of the course, the current performance is calculated as the average current score, ie the arithmetic mean of all grades obtained by the student on a traditional scale, rounded to 2 (two) decimal places, for example 4.75.

At the last practical lesson, the teacher is obliged to announce to students the results of their current academic performance, academic debt (if any).

Only those students who do not have academic debts and have an average score of at least 3.00 for current academic activities are allowed to take the final attestation.

The university uses various forms of control of classes in a particular discipline (oral, written, combined, testing, practical skills, etc.). The results of academic success of students are presented in the form of assessment on a national scale, 200-

point and ECTS scale and have standardized generalized criteria for assessing knowledge: national scale:

- **grade "excellent"**exhibited to a student who worked systematically during the semester, showed during the exam versatile and deep knowledge of the program material, is able to successfully perform the tasks provided by the program, mastered the content of basic and additional literature, realized the relationship of individual sections of the discipline, their importance for future profession. showed creative abilities in understanding and using educational material, showed the ability to independently update and replenish knowledge; level of competence - high (creative);
- **grade "good"** exhibited to a student who has shown full knowledge of the curriculum, successfully performs the tasks provided by the program, mastered the basic literature recommended by the program, showed a sufficient level of knowledge of the discipline and is able to update and update them during further study and professional activities;

level of competence - sufficient (constructive-variable);

- **assessment "satisfactory"** exhibited to a student who has shown knowledge of the basic curriculum in the amount necessary for further study and further work in the profession, copes with the tasks provided by the program, made some mistakes in answering the exam and when performing exam tasks, but has the necessary knowledge to overcoming mistakes under the guidance of a research and teaching staff, the level of competence - average (reproductive);
- **assessment "unsatisfactory"**exhibited to a student who did not show sufficient knowledge of the basic curriculum, made fundamental mistakes in performing the tasks provided by the program, can not without the help of the teacher to use the knowledge in further study, failed to master the skills of independent work; level of competence - low (receptive-productive).

A form of final control knowledge of the discipline in the third year is a test.

The final control in the form of tests is evaluated on a two-point scale:

- **grade "credited"** exhibited to a student who has completed the curriculum of the discipline, has no academic debt, the level of competence - high (creative);
- **grade "not credited"**exhibited to a student who has not completed the curriculum of the discipline, has an academic debt (average score below 3.0 and / or absences); level of competence - low (receptive-productive).

The multi-point scale characterizes the actual success of each student in mastering the discipline. Conversion of the traditional grade from the discipline to 200-point is performed by the information and computer center of the university program "Contingent" according to the formula:

Average grade point average (current / discipline) x 40

національна оцінка	бали
«5»	185-200
«4»	151-184
«3»	120-150

The ECTS rating scale evaluates the achievements of students in the discipline who study in one course of one specialty, in accordance with the scores obtained by them, by ranking, namely

Оцінка ECTS	Статистичний показник
«A»	найкращі 10 % студентів
«B»	наступні 25 % студентів
«C»	наступні 30 % студентів
«D»	наступні 25 % студентів
«E»	останні 10 % студентів

The ECTS scale establishes the student's belonging to the group of the best or worst among the reference group of classmates (faculty, specialty), ie his rating. When converting from a multi-point scale, as a rule, the limits of grades "A", "B", "C", "D", "E" do not coincide with the limits of grades "5", "4", "3" on the traditional scale. Grade "A" on the ECTS scale cannot be equal to grade "excellent", and grade "B" - grade "good" and so on. Students who receive grades "Fx" and "F" ("2") are not included in the list of ranked students. Such students automatically receive a score of "E" after re-assembly. The grade "Fx" is given to students who scored the minimum number of points for the current educational activity, but who did not pass the final control. Grade "F" is given to students who attended all classes in the discipline, but did not score an average (3, 00) for current educational activities and not admitted to the final control. Criteria for assessing the current performance of students should be reflected by the departments in the work programs of the discipline, indicating a clear structure of student receipt in the assessment class.

The procedure for assessing student learning activities Current performance.

Evaluation of the success of studying the topics of the discipline is performed on a traditional 4-point scale. At the practical (laboratory) lesson students must be interviewed at least once for 2-3 practical (laboratory) lessons (not more than 75% of students), and at the seminar - at least once for 3-4 lessons (not more than 50) % of students). At the end of the semester (cycle) the number of grades for students in the group should be the same on average. At the end of each lesson, the teacher must announce the students' grades, make an appropriate entry in the Journal of attendance and student performance and Information on the performance and attendance of students. At the end of the discipline, the current performance is calculated - the average current score (arithmetic mean of all current grades on a traditional scale, rounded to two decimal places). At the last practical lesson, the teacher is obliged to provide information to students about the results of their current academic performance and academic debt (if any), as well as when completing the curriculum in the discipline to fill in the student's record book. To increase the average score in the discipline, the current grades "3" or "4" are not rearranged.

Semester test.

Assessment of students' performance in the discipline, the study of which is provided for two or more semesters, is based on the results of their current performance. Semester credit is given to students who have attended all types of classes in the discipline in the current semester (there are no omissions of lectures and practical seminars, laboratory classes). The average score is not calculated during the semester test. For such students, the teacher is obliged to put "enrolled" in the student's record book in the last lesson of the discipline in the semester.

Final credit.

Students who have fully completed the curriculum in the discipline have no academic debt, their average score of current performance is 3.00 or more, in the last class receive a credit, which is set as "passed" / "not credited". Conversion of a traditional national assessment into a multi-point one (maximum 200 points) is mandatory.

If a student receives a minimum grade point average of 3.00 for current performance, even if there are unsatisfactory grades, he receives a credit for the discipline. At the end of the discipline, which ends with the exam, only those students who have completed all types of work provided for in the curriculum (do not have passes) are admitted to the final certification, their average score for the current academic activity is 3.00 and more. For disciplines included in the integrated test exams Step-1 and Step-2, a mandatory component of the curriculum is the final test control of the discipline, which includes 50 test questions (30 minutes) as an indicator of students' acquisition of knowledge. Compilation of the final test control takes place at the last practical lesson on the discipline in CIAVKYAO according to the schedule of the educational department, approved by the rector of the university. The student must provide the correct answers by at least 90% (45 questions). A paper copy of the results of test control in the discipline signed by the head of the Center is sent to the department. The teacher files a statement in the Journal of attendance and student performance and puts assessments of current performance for the last lesson in the discipline, converting the results on the following scale:

- grade "excellent" - 50 correct answers;
- score "good" - 47-49 correct answers;
- assessment of "satisfactory" - 45-46 correct answers;
- score "unsatisfactory" - 44 correct answers and less

A student who has not passed the final test control in the discipline is considered to have not completed the program in the discipline. At the last lesson of the discipline in the semester, the teacher is obliged to put "enrolled" in the student's record book. Differential credit is set at the last lesson of the discipline based on the results of the final interview with the mandatory performance by the student of all types of work provided for in the working curriculum and evaluated for current learning activities on average not less than 3.00. The grade obtained for the answer on the differential test and the score of the average current performance during the study of the discipline are used to calculate the arithmetic mean, which is the overall grade for the discipline. In the student's record book the teacher enters the grade in the discipline on the traditional and 200-point scales.

Possibility and conditions for obtaining additional (bonus) points.

- ***Writing abstracts***- these are individual tasks that contribute to the deepening and expansion of students' theoretical knowledge on certain topics of the discipline, develop skills of independent work with educational and scientific literature.
- Availability of scientific report and abstracts (maximum score - 5 points).
- Speech at the student scientific conference (maximum score - 5 points).
- Participation in a student research group (maximum score - 5 points).

Independent work of students.

Indicate forms of independent work, methods of control, evaluation criteria and deadlines.

Student's independent work (STS) is the main means of mastering educational material in free time from classroom activities.

Independent work of the student includes: processing of educational material, performance of individual tasks, research work.

Study time allotted for independent work is regulated by the curriculum.

The content of the student's independent work on a particular discipline is determined by the working curriculum, teaching materials, tasks and instructions of the teacher.

The student's independent work is provided by the system of educational and methodical maintenance provided by the working curriculum of discipline: educational and methodical manuals, lecture notes, collections of tasks, sets of individual semester tasks, methodical recommendations on the organization of independent work and performance of separate tasks, electronic and other educational and methodical materials. .

Appropriate scientific and periodical literature is also recommended for the student's independent work.

The educational material of the discipline, provided for mastering by the student in the process of independent work, is submitted for the final control together with the educational material, which was studied during the classroom classes.

Independent work of students contributes to the formation of independence, initiative, discipline, accuracy, sense of responsibility, necessary for the future specialist in education and professional activities.

Evaluation criteria:

Availability of bibliographic review of scientific literature on the relevant topic of VTS (maximum score - 5 points).

Availability of scientific report and abstracts (maximum score - 5 points).

Speech at the student scientific conference (maximum score - 5 points).

The absence of one or another component reduces the score by the appropriate number of points.

The results of the current control of knowledge and competencies obtained by students as a result of independent work are entered into the statement of current and final performance and are taken into account when setting the final score.

COURSE POLICY:

Deadline and recompilation policy. The final control is carried out in the audience in the penultimate week. In case of absence or low result, the final written control is rescheduled once in the last week on the day of the scheduled consultation (Thursday 15.00-16.00). In case of non-compliance with the policy on deadlines and rescheduling, control measures are considered not passed.

Academic Integrity Policy: the course involves the writing of abstracts (SRS) that will be tested for academic integrity (according to the Regulations on the Commission on Academic Integrity of Odessa National Medical University).

Attendance and lateness policy: attendance practical classes is mandatory, lateness is not desirable. Points for attending classes are not accrued. An important reason for absence from classes is an illness, which is confirmed by a certificate from a doctor (hospital).

Mobile devices: with the permission of the teacher it is allowed to use a smartphone, tablet or other device for storing and processing information.

Behavior in the audience or remotely on the Microsoft Teams platform: active, business and creative atmosphere.

Audience behavior:

1. When working in the classrooms of the Department of Drug Technology it is necessary to maintain cleanliness, silence, order.
2. Students are not allowed to be in classrooms without a robe and medical cap. The hair must be collected.
3. Everyone should know where the fire protection and first aid kit are.
4. Smoking, eating, drinking water or other beverages are prohibited in the laboratory.
5. Experiments should be performed only in clean containers. At the end of the experiments, the dishes should be washed immediately.
6. During work, you should be very careful and tidy, make sure that the substances do not get on clothes, skin and eyes.
7. It is inadmissible to check substances or solutions for taste. It is necessary to sniff substances, carefully directing on itself steam or gas with easy movement of a hand.
8. The container in which the substances or solutions are stored must have a label with the name of the substance or with the composition of the solution.
9. When heating liquids and solids in test tubes and flasks, do not direct the hole at yourself or a neighbor. It is forbidden to look into the hole of the test tube from above.
10. At the end of the work it is necessary to turn off gas, water, electricity.

11. It is forbidden to pour concentrated solutions of acids, alkalis, salts of heavy metals into a sink.
12. When working with toxic substances, concentrated acids and alkalis, phenol, organic solvents, etc., it is necessary to use goggles, gas masks, respirators, etc.
13. Experiments with flammable substances (ether, gasoline, acetone, alcohol, etc.) are performed away from fire and switched on electrical appliances.
14. In the event of a fire, immediately turn off the gas, turn off electrical appliances in the laboratory. Quickly remove all flammable substances away from the fire, and extinguish the flame with a fire extinguisher, sand or use a fire blanket. Do not fill the fire with water.
15. If someone's clothes catch fire, it is necessary to knock the victim to the floor and quickly cover him with a woolen blanket, while running around the laboratory is prohibited, as the flame will increase.
16. In case of thermal burns, make lotions immediately with an alcoholic solution of tannin, ethanol or a solution of potassium permanganate.
17. At burns by acids it is necessary to wash out at once the struck place with running water, then with 5% solution of sodium bicarbonate
18. At burns by alkalis it is necessary to wash out at once the struck place with running water, then 3% solution of boric or acetic acid.
19. If acid or alkali gets into the eyes, rinse quickly with a small stream of tap water for 3-5 minutes, then rinse the eyes with sodium bicarbonate solution (in the case of acid) or boric acid solution (in the case of alkali). After that, you need to see a doctor.
20. Skin affected by an organic substance (eg phenol) should be washed with plenty of alcohol or a second neutral solvent. The injured student must be sent to the emergency room.