



ARISTOTLE UNIVERSITY OF THESSALONIKI

INTERNAL OPERATING REGULATIONS

MSc TITLE: INDUSTRIAL PHARMACY



REGULATIONS FOR POSTGRADUATE STUDIES

(according to the provisions of Law 4485/2017 and Law 4957/2022)

THESSALONIKI OCTOBER 2023



**REGULATIONS FOR POSTGRADUATE STUDIES
OF THE DEPARTMENT OF PHARMACY
SCHOOL OF HEALTH SCIENCES
TITLE: INDUSTRIAL PHARMACY
OF THE ARISTOTLE UNIVERSITY OF THESSALONIKI**

GENERAL PROVISIONS

The second cycle of studies consists of the attendance of a Postgraduate Studies Program and is completed with the award of the Diploma of Postgraduate Studies (D.P.S.).

The second cycle concerns the organization of Postgraduate Study Programs (M.Sc.) with a minimum number of sixty (60) credit units (ECTS) and a minimum duration of two (2) academic semesters, the successful completion of which leads to level seven (7) of the National and European Qualifications Framework, according to article 47 of Law No. 4763/2020.

Postgraduate Study Programs are organized and operated:

- 1) in autonomous Departments providing first cycle studies,
- 2) by several Departments of the same or another higher education institution and the Research Centers and Institutes referred to in Article 13 A of Law 4310/2014, including the research centers of the Academy of Athens. A prerequisite is that at least one of the collaborating Departments must be independent and
- 3) by autonomous departments of higher education institutions of Greece in cooperation with departments of recognized peer institutions or research centers and institutes abroad. In the case of interdepartmental or interdisciplinary MSc programs,

a Special Cooperation Protocol (S.C.P.) is drawn up and approved by the respective Senates and the collective governing bodies of the Research Centers.

The present Postgraduate Studies Regulation complements the provisions of Chapter F [Second and Third Cycle of Studies] of Law 4485/4-8-2017 (Government Gazette 114/A/4-8-2017): 'Organization and operation of higher education, regulations for research and other provisions' as well as the updated provisions of Law 4957/21-7-2022 (FEK A'141/21-07-2022) 'New Horizons in Higher Education Institutions: Strengthening the quality, functionality and connection of higher education institutions with society and other provisions'.

Article 1

Purpose of the Postgraduate Studies Programs

The purpose of the Postgraduate Studies Program is to promote scientific knowledge and to satisfy the educational, research and development needs of the country in the field of Pharmaceutical Sciences. At the same time, it aims to link the research effort with the production process and to meet specific needs related to the operational design and development of pharmaceutical products.

The evolution of events over the last decade has changed the professional rehabilitation situation for many university graduates. The direction of Industrial Pharmacy can offer the holder of the diploma all the know-how of applied modern knowledge in matters related to Pharmacy and prepare him/her for a job in the industry. At the same time, the learning of specialized techniques will provide him/her with the necessary qualifications to be employed in the field of New Product Development (Research & Development) which is considered a growing and promising sector. Thus, an important disadvantage that graduates of higher education institutions sometimes present, the lack of practical training and specialization of analytical knowledge, can now become a prerequisite for their absorption in corresponding jobs both in Greece and abroad.

Article 2

Bodies of the Postgraduate Studies Programs

(Articles 31, 44 and 45 of Law 4485/2017 and 81 and 82 of Law 4957/2022)

Subject to the articles of Law 4485/2017 and the updated articles of Law 4957/2022, the competent bodies for the administration, organization and operation of postgraduate programs are:

- I. **The Senate of the Institution** is the competent body for the academic, administrative, organizational and financial issues of the master's degree programs, and exercises those responsibilities related to the master's degree programs that are not specifically assigned by law to other bodies.
- II. **The Assembly of the relevant Department**, which has the powers defined in article 31 par. 3 of Law 4485/2017 and articles 29 and 30 of Law 4957/2022.
- III. **The Coordinating Committee (C.C.)** of the MSc, composed of five (5) faculty members of the Department, who have undertaken postgraduate work. According to Article 81 par. 2 of Law 4957/2022., it consists of the Director of the MSc and four (4) members of the Department's Teaching and Research Staff, who have a related subject with that of the MSc and undertake teaching work in the MSc. Its competences are defined in Article 82 par. 3 of Law 4957/2022.

The C.C. is responsible for monitoring and coordinating the operation of the program and in particular:

- i. prepare the initial annual budget of the MSc and its amendments and recommend its approval to the Research Committee of the Special Account for Research Funds (SACR),
 - ii. prepare the program report and recommend its approval to the Departmental Assembly,
 - iii. approve the expenditure of the MSc,
 - iv. approve the granting of scholarships, contributory or not, as defined in the decision establishing the MSc and the Regulations for postgraduate and doctoral studies.
 - v. recommends to the Assembly of the Department the allocation of teaching work, as well as the assignment of teaching work to the teaching categories of article 83 of Law 4957/2022,
 - vi. recommends to the Assembly of the Department the invitation of Visiting Professors to cover the teaching needs of the MSc,
 - vii. draw up a plan for the modification of the curriculum, which is submitted to the Department Assembly,
 - viii. recommend to the Departmental Assembly the reallocation of courses between academic semesters, as well as issues related to the qualitative improvement of the curriculum.
- IV. **The responsibilities of the Postgraduate Studies Committee** are defined in accordance with Article 81 par. 3 of Law 4957/2022. In particular for interdepartmental, interdisciplinary and joint MSc programs, the responsibilities

of the Departmental Assembly are exercised by the Program of Studies Committee, the number of members and the composition of which are defined in the Cooperation Protocol of the MSc program. The committee shall be composed of members of the Teaching and Research Staff of the collaborating Departments in accordance with the provisions of the Cooperation Protocol of the MSc and shall have the competences provided for in the same article. By decision of the Curriculum Committee, a Board may be established, with a two-year term of office, in which the Director of the MSc and four (4) of the members of the Curriculum Committee must participate.

- V. The Director of the MSc** has the responsibilities provided for in article 31 par. 8 of Law 4485/2017 and as amended in accordance with Law 4957/2022. The Director of the MSc, according to par. 4 of Article 81, is drawn from the members of the Department's teaching staff, preferably of the rank of Professor or Associate Professor, and is appointed by decision of the Department's Assembly for a two-year term of office, renewable without limitation.

According to par. 7 of the same article, the Director of the MSc, as well as the members of the Board and the Curriculum Committee are not entitled to remuneration or any kind of compensation for the execution of the responsibilities assigned to them and related to the execution of their duties. The Director shall have the powers provided for in Article 82 par. 4 of Law 4957/2022 and in particular:

- i. presides over the Board, as well as the Curriculum Committee, in case of interdepartmental or interdisciplinary or joint MSc, prepares the agenda and convenes its meetings,
- ii. recommend issues concerning the organization and operation of the MSc to the Departmental Assembly, in the case of a single-disciplinary MSc,
- iii. recommends to the Board and other bodies of the MSc and the UAS issues related to the effective operation of the MSc,
- iv. be the Scientific Director of the program in accordance with Article 234 and exercise the corresponding responsibilities.
- v. monitor the implementation of the decisions of the bodies of the MSc and of the Internal Regulations for postgraduate and doctoral programs, as well as the monitoring of the implementation of the MSc budget,
- vi. exercise any other responsibilities specified in the decision establishing the MSc.

- VI. The six-member Scientific Advisory Committee**, responsible for the external academic evaluation of the MSc programs (article 44 par. 3 of Law 4485/2017).

- VII. The Tripartite Scientific Committee**, responsible for the selection and evaluation of Postgraduate Diploma Theses.

- VIII. The four-member External Advisory Committee.** The MSc 'Industrial Pharmacy' provides education and specialization aiming at the absorption of its students in the labor market. In the context of a more thorough communication between the postgraduate program and the industry, the definition of an 'external advisory committee' is established. The committee consists of four (4) with a two-year

term of office and are appointed by the 5-member Steering Committee. The role of the committee is coordinating and aims at broadening the knowledge provided, linking professional needs and teaching, introducing students to research and ensuring their future employment in the Pharmaceutical Industry.

Article 3

Categories of candidates for admission to postgraduate programmes

(article 34 par. 1, 7 and 8 of Law 4485/2017)

Categories of candidates who can be admitted attending Postgraduate Studies Programs are:

1. holders of first cycle qualifications of higher education institutions of the domestic territory. In more detail, graduates of the Departments of Pharmacy, Chemistry, Biology, Medicine, Dentistry, Veterinary Medicine, Agriculture, Chemical Engineering or related Departments from Universities of the domestic territory as well as graduates of TEI of related cognitive subject are accepted for the preparation of MSc. For graduates of other Departments than the Departments of Pharmacy, the General Assembly of the Department decides, after the recommendation of the Committee of the MSc, whether the candidates have the required basic knowledge.

2. Holders of first cycle degrees from similar institutions abroad. **A Master's Degree is not awarded to a student whose first cycle degree from a foreign institution has not been recognized by the Interdisciplinary Organization for the Recognition of Academic and Information Degrees (D.O.A.T.A.P.), in accordance with Law No. 3328/2005 (A' 80).**

3. Members of the categories E.E.Π., E.Δ.Ι.Π. and E.T.E.Π., if they meet the requirements of the first subparagraph of par. 1 of Article 34, may be registered as supernumerary and only one per year per MSc, organized in departments of the institution they serve, which is relevant to the degree and the work they carry out in the institution concerned.

Article 4

Number of applicants, criteria and procedure for the selection of applicants

(Articles 34 and 45 of Law 4485/2017)

The maximum number of admissions per year is set at 34 postgraduate students, of which 24 attend all courses and laboratories in person during the academic year, while 10 of them constitute a special group of postgraduate students. The special group includes executives or staff of companies of a related or identical subject to that of Industrial Pharmacy, which will be confirmed by the submission (together with the other supporting documents) of a signed statement-confirmation from their employer or employees working at a distance of more than 50 km from the university site. In addition, in cases of serious impediment to attend lectures and workshops (e.g. serious health reasons), students already admitted to the special group are given the opportunity to participate in the special group, following a decision of the Coordinating Committee and when there are available places. This group will attend all lectures online and one week per academic semester is invited to participate with physical presence at the Department of Pharmacy AUTH to complete all laboratory obligations. The exact date of the workshops will be determined by a decision of the five-member Steering Committee every February.

The total number of tuition-free students may not exceed the number corresponding to 30% of the total number of registered students per academic year according to article 86 of Law 4957/2022. The total number of enrolled students shall include scholarship or sponsorship holders.

Those admitted without tuition fees will be required to submit a statement each semester proving that they have no income and are still eligible for the scholarship. In addition, they must assist in labs, if needed, and be generally available. Finally, employment in various industries is optional and they will be nominated on a merit basis based on their performance.

In order to ensure the quality of all study cycles (article 45 par. 1b of Law 4485/2017), the maximum number of postgraduate students should be 4 per lecturer and the maximum number of lecturers in the MSc in relation to the number of undergraduate students should be 1 lecturer per 10 undergraduates.

The number of posts will be announced by the Department in April and May in national newspapers or on its website (Internet). Applications will be accepted by the Secretariat of the Department of Pharmacy from 1 July to the end of the first week of September. The selection process for candidates will follow the following timetable:

- 2nd week of September interview of the candidates
- 3 working days after the end of the interviews, a meeting of the selection board takes place.
- ratification of the decision of the selection committee at the next General Assembly of the Department
- Beginning of October: reception of students and start of courses

Applications together with the necessary documents are submitted to the Secretariat of the relevant Department, with notification to the Secretariat of the MSc, either in paper or electronic form. The necessary supporting documents that candidates must submit with their application are:

- I. A certified certificate of analytical grades (in case of graduates of foreign universities, the recognition or the application for recognition and matching grades from the ΔOATAP must be presented),
- II. A brief curriculum vitae and
- III. A certificate of proficiency in a foreign language (preferably English). The level of proficiency in a foreign language is proved by the candidates in the following ways. State Certificate of Language Proficiency (Candidate of National Language Proficiency Certificate No. 2740/1999 as replaced by par. Article 19 of Article 13 of Law 2740/2003, as amended by Article 13 of Law 2740.19). 3149/2003, b) A bachelor's degree in foreign Language and Literature or a Degree in Foreign Languages Translation and Interpreting of the domestic language or equivalent and equivalent of foreign language schools, c) A Diploma, undergraduate or postgraduate diploma or doctoral degree of any recognized higher education institution abroad, d) With a diploma equivalent to the Greek Secondary Education Schools, if obtained after at least six years of regular study abroad.
- IV. Certificates confirming professional experience, publications, scientific papers, letters of recommendation (up to 2)
- V. Candidates whose admission is based on financial criteria will be required to provide the relevant documents relating to their family situation (tax information, personal and family income, etc.)

The selection process of the candidates by decision of the Department's Board of Directors is carried out by a competent Tripartite Selection and Examination Committee composed of faculty members who have undertaken postgraduate work. The Committee shall draw up a complete list of all candidates and, after the relevant screening, shall reject from the outset those who do not meet the basic criteria established by the Department concerned. It will then invite the shortlisted candidates who have met the prerequisites to an interview, as provided for. On completion the procedure (on the basis of the application file, supporting documents and interview), the final list of successful candidates is drawn up.

| TABLE Selection criteria and weighting factors | |
|---|-------------------|
| Selection criteria | weighting factors |
| 1. Degree relevance | |

| | | |
|--|-------------------------|-----------------------------|
| Pharmacy | | 1 |
| Chemistry, Chemical Engineering | | 0,95 |
| Biology, Physics, Medicine, Dentistry | | 0,9 |
| Veterinary Medicine, Agriculture, Forestry | | 0,5 |
| Other departments | | 0,5 |
| 2. General degree | | |
| Excellent (8,5 - 10) | | 1 |
| Very Good (6,5 - 8,4 [⌈]) | | 0,75 |
| Good (5 - 6,4) | | 0,5 |
| 3. GPA in relevant undergraduate courses (for Pharmacists only) | | |
| Pharmaceutical Technology, Formulation, Pharmaceutical Analysis | | |
| Excellent (8,5 - 10) | | 0,7 |
| Very Good (6,5 - 8,4 [⌈]) | | 0,5 |
| Good (5 - 6,4) | | 0,1 |
| 4. Undergraduate Thesis Grade | | |
| | Excellent (8,5 – 10) | Very Good (6,5 – 8,4) |
| Same subject | 0,75 | 0,5 |
| Related | 0,5 | 0,25 |
| Related | 0,25 | 0 |
| 5. Existing related research or professional activity | | |
| i. Publications in journals (relevant to the courses of the Master's degree) | Y No | 0,5 0 |
| ii. Other postgraduate qualifications (relevant to the subjects of the Master's degree) | Y No | 0,5 0 |
| iii. Work experience in a pharmaceutical industry (relevant to the subjects of the master's degree) | Y No | 0,3 0 |
| iv. Conference presentations (speech or poster) | Y No | 0,2 0 |
| 6. Knowledge of English or other foreign language | | |
| i. English | Proficiency Lower | 0,75 0,5 |
| ii. Other language (German or French at the highest level) | | 0,25 |
| 7. Overall personality (interview) | | |
| 1. Motivation - personal interest | | 0,25 |
| 2. Personal constitution | | 0,2 |
| 3. Duration of undergraduate studies (5 years) | | 0,15 |
| 8. Participation in competitive research projects | | |
| | Y | 0,25 |
| | No | 0 |

The selection criteria for the candidates and the corresponding weighting factors are detailed in the following table:

In the event of a tie: According to the regulation, if there are more candidates with the same total number of points and from the same department, the candidate with the highest degree will be given priority. If they come from different departments, the

relevance of the degree will be taken into account, as will the degree, the grade and the degree itself. and finally the relevant professional experience and research activity.

The final list of successful candidates and any runners-up, once confirmed by the Departmental Assembly, will be posted on the Secretariat's notice board and on the Department's and the MSc's website. Postgraduate students are enrolled and participate in postgraduate programs under the terms and conditions provided for in the relevant Regulation for Postgraduate Studies. The registration of admitted postgraduate students begins after an announcement by the Secretariat of the relevant Department, in which the duration of the registration and the documents required for registration are specified. Postgraduate students have all the rights, benefits and facilities provided for first cycle students except for the right to free textbooks. The department concerned must ensure that facilities are provided for postgraduate students with disabilities and/or special educational needs.

Article 5

Duration and conditions of study

(Articles 33, 34 and 35 of Law 4485/2017)

The duration of study in the MSc leading to the award of the Diploma of Postgraduate Studies is defined as three (3) semesters, which includes the time for the preparation and assessment of the postgraduate thesis.

The maximum time allowed for the completion of studies is set at a total of six (6) semesters including three semesters of regular study and those of part-time, suspended or extended study. In any case, the extension of studies will be validated individually and by name for each postgraduate student (following a proposal by the AC) at the General Assembly of the Department. Postgraduate students are provided in accordance with para. 2 of article 33 of Law 4485/2017 (114 A) provides for the possibility of part-time study for working students, the duration of which cannot exceed twice the duration of the regular course of study. At the same time, the student must submit the relevant documents, signed by his/her employer, proving his/her employment for at least 20 hours per week. Part-time attendance is also provided for non-employed postgraduate students who are unable to meet the minimum requirements of the "full-time" program in special and extremely serious cases, which are decided by the Assembly of the Department and are included in the relevant Regulations for Postgraduate Studies.

Postgraduate students may also be granted, upon application, a temporary suspension of studies, which may not exceed two (2) consecutive semesters. During the period of

suspension, the postgraduate student shall lose his/her student status. The period of suspension shall not count towards the maximum period of regular study.

Only in exceptional cases (workload, serious family reasons, military service, reasons of force majeure) may an extension of studies be granted for up to one year, following a reasoned decision of the Departmental Assembly.

The Departmental Assembly decides on issues of revision of courses in due courses or on the removal of students from the course after a proposal from the Board, which decides on the conditions of revision and the reasons for removal. Reasons for deletion are: a) the insufficient progress of the postgraduate student (which is documented by non-participation in the educational process: attendance, examinations), b) inadequate fulfilment of other obligations that may be defined by the relevant Regulations, c) behavior that offends academic ethics such as plagiarism, and d) the request of the postgraduate student himself/herself. If the graduate student fails the examination of a course or courses for two (2) consecutive times and is deemed by the relevant Postgraduate Studies Regulations not to have successfully completed the program, he/she shall be examined, at his/her request, by a three-member committee of faculty members of the Faculty, who have the same or related subject matter as the course being examined and who are appointed by the Departmental Assembly. The lecturer in charge of the examination shall be excluded from the committee.

Tuition fees: The tuition fees to be paid by the postgraduate student per semester amount to 1500 euros. The fees are payable at the beginning of each semester and are payable to the Secretariat of the postgraduate program.

FREE OF CHARGE: In accordance with Article 86 par. 1 of Law 4957. /2022, the prerequisite for the granting of the right to free education on the basis of economic or social criteria is the fulfilment of excellence requirements during the first cycle of studies, which corresponds at least to the possession of a grade equal to or higher than seven and a half with an excellent grade out of ten (7,5/10), if the evaluation in the basic degree presented for admission to the P. M.Sc. has been awarded in accordance with the ten-point scale of a higher education institution (HEI) in the country, otherwise this criterion is applied proportionally in accordance with the respective evaluation scale, if the degree has been awarded by a foreign institution.

In accordance with paragraph 2 of the same article, up to 30% of the total number of applicants admitted will be admitted free of charge and on the basis of financial/family criteria (upon submission of the relevant supporting documents).

According to paragraph 4 of the same article, the student of the MSc who fulfils the condition of par. 1, provided that the following criteria apply:

i. the average of the sum of the taxable incomes of the last two (2) financial years of all family members of the applicant for exemption from tuition fees, i.e. the applicant himself, his parents, regardless of whether they file a joint or separate tax return, and his siblings up to twenty-six (26) years of age, if they are unmarried and have the same taxable income within the meaning of article 7 of Law No. 4172/2013 (A' 167), does not exceed seventy percent (70%) of the national median disposable equivalent income, according to the most recently published data of the Hellenic Statistical Authority (EL.STAT.), if the applicant has not reached the twenty-sixth (26th) year of age and is unmarried or has not entered into a cohabitation agreement,

ii. the average of the applicant's personal taxable income of the last two (2) financial years does not exceed one hundred percent (100%) of the national median disposable equivalent income, according to the most recently published data of the National Statistical Office, if the applicant has reached the age of 26,

iii. the average of the sum of the taxable income of the last two (2) financial years of the applicant for exemption from tuition fees and his or her spouse or partner, if married or in a civil partnership, regardless of whether they file a joint or separate tax return, does not exceed one hundred percent (100%) of the national median disposable equivalent income, according to the most recently published data of the National Statistical Office.

Finally, according to par. 5 of the same article, if the applicant for exemption has not reached the age of 26 and is a child of a family with three or more children or a child of an unmarried parent or an orphan of at least one (1) parent or a person with a disability or a member of a household with a person with a disability, he/she may apply for exemption from half (50%) of the obligation to pay tuition fees, provided that the average in paragraph i) of par. 4 exceeds seventy percent (70%) and does not exceed one hundred percent (100%) of the national median disposable equivalent income. The application for waiver of tuition fees shall be submitted by the person concerned to the Department after the completion of the admission process of students to the master. In no case shall financial inability be a reason for non-election to a MSc.

AWARD OF EXCELLENCE: A decision of the five-member Steering Committee shall establish the institution of the annual award of the Award of Excellence. The award is monetary and is given in a one-off payment to the graduate of the year with the best academic performance (completion of studies in 4 semesters with the highest degree). The amount is determined by the C.C, taking into account the finances of the postgraduate course.

Article 6
Curriculum - Knowledge check
(Articles 34 and 45 of Law 4485/2017)

To obtain the Master's degree:

- i) A minimum of three (3) semesters of study.
- ii) Completion of at least 90 ECTS credits.
- iii) Completion of the postgraduate thesis which is supervised by a member of the teaching staff, appointed by the Coordinating Committee and examined by a committee of three appointed by the Departmental Assembly on the recommendation of the Coordinating Committee.

| Master "Industrial Pharmacy" | | | |
|-------------------------------------|-------------|-----------------------|-------------|
| A' semester | | | |
| COURSE TITLE | TYPE | HOURS (WEEKLY) | ECTS |
| | | | |

| | | | |
|--|---|---|-----------|
| M1. Design, development and pharmacological evaluation of pharmacomolecule action - preformulation studies | Y | 5 | 8 |
| M2. Introduction to Industrial Pharmaceutical Analysis | Y | 5 | 8 |
| M3. Preclinical and clinical drug evaluation | Y | 5 | 8 |
| M8. Drug Promotion (marketing) and sales strategies | Y | 4 | 6 |
| Total ECTS for the semester | | | 30 |
| B' semester | | | |
| M4. Design and development of pharmaceutical forms. New approaches | Y | 5 | 8 |
| M5. Applied Pharmaceutical Analysis-Quality Assurance | Y | 5 | 8 |
| M6. Cosmetics - Natural products | Y | 5 | 8 |
| 1st stage of thesis preparation | Y | | 6 |
| Total ECTS for the semester | | | 30 |
| C' semester | | | |
| M7. Regulatory framework for the approval of medicinal products and clinical studies | Y | 4 | 6 |
| 2nd stage of thesis preparation | Y | | 24 |
| Total ECTS for the semester | | | 30 |
| general sum of ECTS units | | | 90 |

M1. Design, development and pharmacological evaluation of pharmacomolecule action - preformulation studies

In the context of the course, the following topics are developed: Study of preformulation-formulation in modern pharmaceutical forms. Quantitative Structure Activity Relationships (QSAR), Physicochemical Properties, Chemometrics, Simulation, Fundamentals and Examples of 2D and 3D-QSAR relationships for various molecular targets. ADMET models. Simulation models. Solid phase selection – Polymorphism control.

Physico-mechanical properties of powders (size, shape, flow, compressibility). Computational simulation of the solid state (prediction, crystal polymorphism, mechanical properties estimation, crystal morphology prediction). Design and development of products: Selection of excipients and factors that determine them in the production of solid pharmaceutical products (Tablets). Evidence of anticancer drug development. Pharmacological and

pharmacogenomic approach. Design, Production and Quality Control of Radiopharmaceutical (pre) Formulations. Development of production methods and quality control of radiopharmaceutical preparations and preparations.

M2. Introduction to Industrial Pharmaceutical Analysis

In the context of the course, the following topics are developed: Introduction to analytical concepts. Quality control of analytical methods. Evaluation and statistical processing of analytical results, estimation, measurement uncertainty, confidence limits. Pharmacopoeias and their usefulness as appropriate tools for the application of analytical methods. General principles of atomic emission and absorption spectrometry. Control of heavy metal impurities in raw materials by ICP-AES inductively coupled plasma atomic emission spectrometry. Infrared spectrophotometry. General principles of X-ray (X Ray); 'In process' methods of drug screening. Ultraviolet spectrophotometry on pharmaceuticals. Stability study of active substances in UV. Quantification of active ingredient in tablets, with UV detector.

M3. Preclinical and clinical drug evaluation

The following thematic units are developed in the course: Pharmacological evaluation and applications. Drug delivery and pharmacogenomics approach. Introduction to Biopharmaceutics. Biopharmaceutical Classification System, Determination of biopharmaceutical properties, Active ingredient release profile from tablets/capsules. Dissolution rate control. Bioavailability and basic pharmacokinetics. Design, - Biowaiver Justification. Bioequivalence and IVIVC studies. Ethical evaluation, preparation, organization, implementation and monitoring of experimental protocols. Good Clinical Practice (GCP).

M4. Design and development of pharmaceutical forms. New approaches

The following thematic units are developed in the course: Introduction to dosage forms for drug administration. Modern formulation techniques to increase bioavailability. Characterization of pharmaceutical substances and excipients. Characterization of drug substances and their properties. Granulation, extrusion, production of microspheres (pellets). Pharmaceutical nanotechnology - prosthetics. Preparation of nanoparticles, liposomes, microspheres. Controlled release injectables. Innovative drug systems for transdermal, ocular, parietal, nasal, pulmonary and oral delivery. Permeability studies with innovative pharmacoforms.

M5. Applied Pharmaceutical Analysis-Quality Assurance

The following thematic units are developed in the course:

Theory of chromatography. Retention mechanisms and chromatographic columns. Learning how to operate HPLC, (system suitability). Quantification of two active substances in a colloidal solution by HPLC. Quantification by HPLC of an active substance with an internal standard. Theory of mass spectrometry. Mass spectrometry of natural products (ESI-MS APCI-MS on flavonoids and their glycosidic derivatives, tannins, procyanidins, iridoids, saponins, alkaloids). Gas chromatography coupled with mass spectrometry in the analysis of essential oils, fatty acids, and alkaloids. Determination of active substance by ESI-LC/MS

(positive/negative mode). Sample purification methods, Solid Phase Extraction (SPE) on biological fluid sample/active substance (cortisol) recovery, use of internal substance template. Validation of analytical methods, objectives of method validation.

M6. Cosmetics - Natural products

Within the framework of the course, the following thematic modules are developed: Introductory concepts. Structure of skin, hair, nails. Nanotechnology and cosmetology preparations. Project Management of innovation projects in the field of cosmetology. Cellular techniques for proving the safety and effectiveness of ingredients and cosmetic products. Industrial production of essential oils and extracts. Applications of natural products in cosmetics I. Laboratory I (creams, shampoos, sunscreens, powders, face masks). Laboratory II (diffusion experiments with human skin). Biophysical studies of skin. Laboratory V (biophysical studies of the stratum corneum). Laboratory VI (Development of cosmetological preparations by the students).

M7. Regulatory framework for the approval of medicinal products and clinical studies

Within the framework of the course, the following thematic modules are developed: The drug as a product and social good from its discovery until it reaches the user - patient. Legal parameters. Existing regulatory framework (Laws, Community Medicines Code, other Regulations and Union Directives, International Conventions). Drug market and its specificities, mainly from the point of view of free competition. E-commerce of medicines. European Pharmaceutical Regulatory Environment, European Pharmaceutical Legislation. Regulatory framework for drug approval, general dossier requirements, specific requirements per category. Biosimilars and Orphan drugs. Regulatory framework for clinical trials of medicinal products intended for humans. Pharmacies. GMP Good Manufacturing Practices. Pharmacovigilance: regulatory framework and drug development. Liability issues related to the production and circulation of medicines. Patents and drugs. The function of the pharmacist in the EU and Greece, based on legislation and jurisprudence. Drug distinctions and their significance for the law (generic and reference drugs, prescription drugs, orphan drugs). Health Technology Assessment. The European and Greek Reality for Galenic preparations. Regulatory framework for nutritional supplements, cosmetics and medical technology products.

M8. Drug Promotion (marketing) and sales strategies

The following thematic units are developed in the course: Basic Principles of Pharmaceutical Marketing. Business Development in the Pharmaceutical Industry - Value Creation and Portfolio Management. Evolution of Business Models in the Pharmaceutical Industry Business Models in the Post-Covid Era. The role of the Medical Visitor in the modern pharmaceutical market. The role of cross-functional collaboration in communication between healthcare workers. Marketing tools in the new pharmaceutical environment.

The semester courses are distributed in the 1st, 2nd and 3rd semester respectively and start in October. They are specialization courses and are taught according to the timetable in Greek.

Postgraduate students are required to be engaged in the postgraduate programme (courses, tutorials, laboratory exercises and postgraduate research work) with compulsory presentation and are allowed to be absent up to 2 times in each course. Failure to comply with the above obligations will result in the withdrawal of the postgraduate student from the MSc programme after a reasoned proposal by the Board and a decision by the Departmental Assembly. In special cases of absence of the student for reasons of illness, serious family reasons, the person concerned may submit a request to the AC which in turn decides according to the data.

The examination in the individual courses is done by written or oral examinations, assignments or a combination of the above. Examination marks will not be rounded off but will be shown exactly, including the decimal point.

There will be only one examination in each academic year and only one in the November-December period, following a decision by the Board of Governors, for the spring semester courses only. The participation of students is subject to the following conditions:

1. The student has already taken the course at least once and has achieved a grade above 2.
2. The student has completed the obligations of his/her thesis (with a certificate from a supervising professor).

Any other embolic examination is possible upon request of the student and decision of the CC. In this case, the student bears the costs of conducting the CC for each course (payment of faculty members and external collaborators for the topic and the correction of writing).

The Postgraduate Diploma Thesis will start exploratory in the 2nd semester (1st stage of the Diploma Thesis) with the writing of the research design, literature review, subject and purpose and will be completed in the 3rd semester (2nd stage of the Diploma Thesis).

Teaching and assessment, for specific categories of students with particular problems, is carried out using flexible learning methods in order to treat them with respect and leniency, following a decision of the Board of Governors.

The MSc Industrial Pharmacy supports education and offers specialization to people with specific health problems related to movement or vision. Postgraduate students are trained in the laboratories with the assistance of teaching and specialist or technical staff and safely complete, under their guidance, the preparation of their experimental thesis, thereby gaining the equivalent of a Master of Sciences degree. The MSc Industrial Pharmacy gives the opportunity to Erasmus students from foreign or domestic institutions to attend and recognize courses of the postgraduate course of study, according to the law in force and to prepare an experimental thesis, according to the agreements in force.

Article 7

Rules for the Execution of a Diploma Thesis

For the preparation of a Postgraduate Diploma Thesis (article 34, paragraph 4 of Law 4485/2017), the Coordinating Committee, following the candidate's application (which includes the proposed title of the thesis, the proposed supervisor and a summary of the proposed thesis), appoints the supervisor and sets up a three-member Examination

Committee (including the supervisor). The members of the Tripartite Examination Committee must have the same or related scientific specialization as the subject of the MSc. Supervision assignments for theses will be distributed equally among the faculty members of the 1st and 2nd and 3rd semester courses. More specifically, at the end of the first semester, faculty members will inform the number of graduate students they can employ and determine the topics of the theses. The maximum number of places per lecturer is 3 (exceptions excepted). According to the procedure, the postgraduate student who has passed the courses of the first semester and has the highest marks will be the first to choose the supervisor he/she wishes, and the others will follow with priority criterion of the best marks. The process of assigning a supervisor must be completed by the end of the second semester. A prerequisite for the appointment of the supervisor is that the student must accept the choice of the supervisor.

For the group of special postgraduate students, they should have secured the possibility of working on their thesis in their professional field at the time of registration. More specifically, these students will carry out their thesis at their place of work, under the supervision of a faculty member (from the MSc lecturers) and a supervisor (holder of a master's or PhD degree) from their place of work. The two other members of the three-member committee are appointed as required by the law on postgraduate studies. During the course of the Postgraduate Diploma Thesis and in exceptional cases, the supervisor or member of the Examination Committee may be replaced (following a decision of the Assembly of the relevant Department) if there is an objective impossibility or an important reason (e.g. resignation, illness, etc.). Part or even the whole thesis may be prepared by the students in the context of their internship in a pharmaceutical company, a relevant laboratory or a public institution (article 8). In this case, the first stage of the thesis, which refers to the collection of bibliographic data, is carried out at the premises of the MSc, while the second stage may be carried out, as an internship, at the host institution after its consent. The duration of the internship varies from 3 to 6 months and depends on the hours and days of work of the intern.

In order to achieve the intended learning outcomes, the appointment of a faculty member, a lecturer of the MSc, as a supervisor who will be responsible for the guidance of the student throughout the internship at the host institution and a supervisor from the host institution who has academic qualifications (at least a master's degree) is a prerequisite. The successful completion of the internship as a thesis entails the award of 24 credits (European Credit Transfer and Accumulation System ECTS) corresponding to the second stage of the thesis (Catalogue of courses of the MSc). The master's Thesis is written in at least five (5) copies and one of them is deposited in the library of the department for archiving. It includes the Preface, Introduction, Object and Purpose, Instruments and Materials used, Experimental part, Results, Discussion, Conclusions and Bibliography. It also includes an abstract in Greek and English. The text is written in Times New Roman Gr font, size 12 and 1.5 font size. Details and drafting templates for the master's Thesis are provided in the "Guide to the Drafting of the Thesis" of the Library and the Information Centre of the Aristotle University of Thessaloniki, which is available on the website of the master's Program. The presentation of the Postgraduate Diploma Thesis is supported before the Tripartite Examination Committee at a date and place determined by the Board. After its approval by the Committee, it is obligatory posted on the website of the relevant School. The master's Thesis is graded in whole points from 0 to 10 with a minimum grade of 6. If a grade of less than 6 is obtained, the presentation of the corrected thesis will be repeated after two months. In case of disagreement between the graders, both in the courses and in the thesis, the Board will appoint a re-evaluator who will give a final grade after an examination (written or oral) of the candidate. The grade of the

Diploma of Postgraduate Studies is obtained from the weighted average of the courses of the MSc and the Postgraduate Diploma Thesis (weighted by the credits of the courses) and is calculated, to the second decimal place, in the following way:

The grade of each course and of the Postgraduate Diploma Thesis (where applicable) is multiplied by the corresponding number of credit points (ECTS) and the sum of the products is divided by the minimum number of credit points required for the award of the MSc.

$$\text{Grade} = \frac{\text{sum of the product of (grade of each course x ECTS of each course) + (grade of postgraduate thesis x ECTS)}}{\text{(total ECTS)}}$$

The grading scale for the evaluation of graduate student performance is defined from zero (0) to ten (10), as follows:

- Excellent (8.5 to 10)
- Very Good (6.5 to 8.5 not including)
- Good (6 to 6.5 not including).

Grading of the Master's thesis shall be in integer units on a scale of 0 to 10 with a minimum grade of six (6).

Article 8

Rules governing internships.

(Article 69 of Law 4957/2022)

The internship is provided as an optional educational activity of the MSc as long as it does not replace the procedure of preparing a thesis. In this case, it takes place on an optional basis, after the completion of the teaching and laboratory duties of the postgraduate student and before the completion of studies and the awarding of the degree (organization). It aims at the practical application of the theoretical scientific knowledge acquired through the successful completion of the study program and the familiarization of students with possible workplaces. It may be carried out in public services, legal persons under public law, first and second-degree local authorities, legal persons under private law and enterprises, hereinafter referred to as 'host organizations', under the supervision of a lecturer of the study program. The internship may also be carried out in foreign institutions, provided that the supervision of the educational process is feasible. For student internships, an internship contract is concluded between the higher education institution (HEI), the student and the host institution.

In case of limited available internship places, which are not sufficient to cover all the applications of the interested postgraduate students of the program, the steering committee will decide on a first-come, first-served basis according to the following criteria:

1. grade point average of semester courses (provided that the student has passed all courses).

2. Depending on the specialty requested by the institution and the intern's specialization.

In case of a tie, the final decision is made by the CC. Students who carry out an internship are subject to the compulsory insurance of the National Health Care Services Agency through the Electronic National Social Insurance Agency (formerly the Social Insurance Foundation, the Single Fund for Employee Insurance, I.K.A. E.T.A.M.), in accordance with par. 10 of article 15 of Law No. 3232/2004 (A' 48) only for the accident branch, the cost of which is borne exclusively by the host institution. The amount of the monthly allowance for carrying out an internship in private sector institutions is eighty percent (80%) of the statutory minimum basic wage, provided that the internship concerns an educational activity corresponding to full-time employment of forty (40) hours per week. If the traineeship involves a smaller number of hours per week, the amount of the monthly allowance shall be pro-rated according to the total hours per week. The allowance may be paid either on a monthly basis or on completion of the training process of the traineeship. The cost of compensation and insurance for students for the conduct of the internship is borne primarily by the host institutions. By way of exception, the costs of compensation and insurance may be borne, in part or in full, by the budget of co-financed programs or projects financed from own or private resources managed by the Special Research Funding Accounts (SRAs) of the higher education institutions. The granting of an allowance for the carrying out of an internship shall not constitute grounds for the interruption of other financial benefits granted or special allowances or pensions received or to which students of the higher education institution are entitled for other reasons.

Article 9

Student Mobility Regulations

Students who are enrolled in the MSc, have not exceeded the minimum attendance limit and have completed their obligations regarding their courses, may apply for participation in mobility programs in domestic (internal mobility) or foreign (international mobility) university institutions. Mobility is carried out to similar or related programs of University Institutions in the country or abroad with which the Department of Pharmacy of the Aristotle University of Thessaloniki collaborates. The Coordinating Committee decides the student's participation in the mobility program, upon his/her request where specified:

- the host institution or department
- the expected duration of the student's stay in the host institution or department
- in the case of a thesis carried out on the premises of the University institution, the student must submit to the C.C. a "learning agreement" between the responsible professor(s) of the institution and the supervisor of the MSc. The C.C. must have a written agreement with the supervisor of the student's thesis (Article 7 of the Regulations), which ensures that the student will carry out part or all his/her thesis at the host institution, which must be peer-reviewed and with research activity related to the MSc.

After the arrival of the student, a "certification of attendance" signed by the responsible professor(s) of the host institution and by the supervisor of the MSc must be presented to the C.C., which will specify exactly all the work completed by the student in the context of the

preparation of the MSc. The role of the supervisor(s) of the host institution during the preparation of the thesis is advisory and has nothing to do with the evaluation of the thesis. The language of writing the thesis should be in Greek and optionally in English. The right of mobility may be exercised once (1) until the completion of the MSc.

Article 10

Teaching staff

(articles 36, 45 of Law 4485/2017 and article 83 of Law 4957/2022)

The teaching work of the MSc is assigned, following a decision of the C.C of the MSc, to the following categories of lecturers:

1. of the Department or other Departments of the same or another Higher Educational Institution (HEI) or Higher Military Educational Institution (HEMI), with additional employment beyond their legal obligations, if the MSc has tuition fees,
2. professors emeritus or retired members of the Department or other Departments of the same or other higher education institutions,
3. cooperating teachers,
4. appointed lecturers,
5. visiting professors or visiting researchers,
6. researchers and special functional scientists of research and technological institutions of article 13A of Law No. 4310/2014 (A' 258) or other research centers and institutes of the country or abroad,
7. scientists of recognized prestige, who have specialized knowledge and relevant experience in the subject matter of the MSc.

In any case, the assignment of the teaching work of the MSc is carried out by the Assembly of the Department following the recommendation of the Board.

The obligations of the lecturers include, inter alia, the description of the course or lectures, the citation of relevant bibliography, the way of examining the course, the communication with the postgraduate students.

Article 11

Labor Regulations and Contracts of Employment, Obligations of Teaching Staff

(Articles 126 and 127 of Law 4957/2022)

According to the regulation of remuneration for the provision of teaching work of the Rector's Council of the Aristotle University of Thessaloniki (protocol no. 26993/24-11-2022), which was formed on the basis of articles 126 and 127 of Law 4957/2022, the maximum limit of remuneration per teaching hour/teaching work in second cycle programs (M.Sc.) for the mentioned categories of teaching staff, depending on their qualifications, is determined.

The exact salaries of teaching staff are determined after the decision of the C.C., taking into account the maximum limit of remuneration per teaching hour/teaching work of the master as defined by the remuneration regulation for the provision of teaching work of the Rector's Council of the Aristotle University of Thessaloniki (protocol no. 26993/24-11-2022). According to article 5 of the Rector's salary regulation, the right to additional employment for the provision of teaching work in the educational/training programs of the second cycle (MSc) is granted provided that this teaching work is in addition to the minimum regular obligations of the lecturer according to the category to which he/she belongs and that he/she has fulfilled the minimum obligations to the Department to which he/she belongs. For this purpose, the teaching staff of the MSc shall submit to the E.L.C.E. a declaration of compliance with all the terms and conditions of additional employment in addition to the minimum obligations assigned to them under the contract they have concluded.

The submission of a false declaration on behalf of the lecturer constitutes disciplinary misconduct. In addition to the lecturer's remuneration (hourly teaching allowance), the lecturer may be financed by a one-off amount determined annually by the C.C., with a maximum limit set by Law 4957/2022, for the supervision of the student's thesis.

According to the internal regulations of the MSc, Industrial Pharmacy, each lecturer has the possibility to spend part or all of the corresponding amount of money on the operating costs of his/her laboratory.

Article 12

Program revenue - Financial management procedure

(Article 37 of Law 4485/2017, Article 84 of Law 4957/2022)

The resources of the Postgraduate Studies Program (MSc) may come from:

- I. tuition fees,
- II. donations, sponsorships and financial aid of any kind,
- III. bequests
- IV. resources from research projects or programs
- V. own resources of the higher education institution (HEI)
- VI. the State budget or the public investment program.

According to Article 84 par. 3 and Law 4957/2022, the resources of the MSc are distributed as follows:

- (a) an amount corresponding to thirty percent (30%) of the total revenue derived from tuition fees is retained by the E.L.K.E. This amount includes the percentage of retention in favor of the E.L.K.E. for the financial management of the P.M.S. The decision of the Administrative Council, taken by the end of March each year, decides whether the remaining amount after deduction of the retention in favor of E.L.K.E. is to be used for the financial management of the P.M.S. By decision of the Administrative Council, taken by the end of March each year, it is decided whether the remaining amount after deduction of the retention in favor of E.L.K.E. is to be used for the financial management of the Master, or is allocated for the creation of projects/programs through the E.L.K.E. in order to cover, on a priority basis, the needs of the postgraduate program operating without tuition fees and to cover research, educational and operational needs of the higher educational institution. The revenue

of the postgraduate program shall be subject to the same deduction for the benefit of the E.L.C.E. as the revenue from the corresponding funding sources.

- (b) The remaining amount of the total income of the MSc is allocated to cover the operating costs of the MSc.

Finally, each year the Board shall approve the income and expenditure statement, indicating the distribution of expenditure by category and in particular the amount of tuition fees, the fees of teaching and other staff of the MSc and the number of lecturers who have received them.

Article 13

Administrative support - Technical and logistical infrastructure

The logistical infrastructure of the Department is sufficient to meet the needs of the MSc. The Department of Pharmacy is housed on floors 2, 3 and 4 of the Biological Sciences/Pharmacy building of the Aristotle University of Thessaloniki. The Department of Pharmacy has 5 statutory laboratories: Pharmaceutical Chemistry, Technology and Drug Control, Pharmaceutical Analysis, Pharmacognosy and Pharmacology.

The laboratories have libraries which contain many series of scientific journals and books and some of them contain computers connected via the internet to the main library of the U.T.H. and to other databases and electronic libraries. It is equipped with modern machines, such as state-of-the-art DSC, TGA, Nanosizer, Dissolution apparatus USPI, II, III and IV, Franz cells, automatic disc machines, inhaler control devices, porosity and specific surface area measuring devices, pehameters, 5 decimal and 3 decimal analytical balances, laminar flow hoods, automatic autoclaves, a large number of UV spectroscopy, Fluorimetry, ATR-FTIR, Raman, high pressure liquid chromatography and LC-MS, ELSD.

Administrative support will be provided by the Departmental Secretariat in collaboration with the MSc secretariat which will be staffed after the start of the MSc.

Article 14

Graduation Ritual

(article 223 par. 1 subparagraph a of Law 4957/2022)

The graduation/graduation ritual of Postgraduate Studies graduates is held in parallel (in the same room, on the same day and time) with the corresponding one of the Undergraduate Studies graduates. According to the ritual, the graduate student with the best (among those present) score will read the oath while the rest of the students watch by raising their hands. This is followed by speeches by the Vice Rector, the Department Chair and the outstanding graduate student.

Article 15

Type of Postgraduate Diploma

(article 45 par. 1 sub-paragraph o of Law 4485/2017)

The Diploma of Postgraduate Studies is issued by the Secretariat of the Department of Pharmacy. The Diploma includes the Department of Pharmacy, the emblem of the institution, the date of completion of studies, the date of issue of the Diploma, the graduation protocol number, the title of the MSc, the details of the postgraduate student and the evaluation classification Good, Very Good, Excellent. The graduate of the Diploma of Postgraduate Studies may be issued, prior to the award, with a certificate of successful completion of the program.

In addition to the Diploma of Postgraduate Studies, a Diploma Supplement [article 15 of Law 3374/2005 and Y.A. Φ5/89656/BE/13-8-2007 (Government Gazette 1466 Vol.B)] is issued, which provides information on the nature, level, general educational framework, content and status of the studies that have been successfully completed and does not replace the official degree or the detailed course grades awarded by the institutions.

The type of Postgraduate Diploma Certificate will be in the following format:



Greek Republic
PHARMACEUTICAL DEPARTMENT
postgraduate PROGRAMME

No. of Certificate:

COPY OF DEGREE

IT IS CERTIFIED THAT:

The {First Name Last Name} of {Last Name}

Place of birth: {.....}

having passed the required courses, the Postgraduate Diploma Thesis and accumulated the required number of credits, was deemed worthy of the

Postgraduate Diploma
of the Dept. of Pharmacy
with the title: 'INDUSTRIAL PHARMACY'.

with grade _____
on _____ {date} _____

This certificate is granted for any legal use.

Thessaloniki,200....
Department Secretariat

Article 16

Research Ethics Regulation

When submitting any postgraduate thesis, the postgraduate student must indicate whether he/she has used the work and opinions of others.

Copying is considered serious academic misconduct. Plagiarism is considered copying someone else's work, as well as using someone else's work - published or unpublished - without proper attribution. The citation of any documentary material, even from the candidate's own studies, without reference, may constitute grounds for a decision by the Assembly of the Department concerned to expel the candidate. In the above cases -and after a reasoned recommendation of the supervisor- the Assembly of the relevant Department may decide to delete the student.

Any misconduct or violation of academic ethics is referred to the Coordinating Committee of the MSc for judgment and recommendation for addressing the problem to the Department Assembly. The offences of copying or plagiarism and in general any violation of the provisions on intellectual property by a postgraduate student during the writing of papers in the context of the courses or the preparation of a postgraduate thesis (provisions of Law 5343/1932 (articles 120 to 123), PD 160/2008 -23 to 25) are considered as offences.

Article 17

Complaints & Objections Regulation

In case a student wants to express his/her difficulty or objection on any issue, a special request is given to the five-member Graduate School Board, which in turn decides and responds to the student's request.

According to the procedure, the request is submitted to the MSc Secretariat by the student. In the request, the problem is recorded briefly, clearly and objectively. The MSc Secretariat forwards the request to the Director and he in turn forwards it to the five-member. The C.C. decides or forwards the request to the competent administrative bodies and informs the applicant of the actions taken and the general handling of the case, as well as the decisions of the competent administrative body.

Article 18

Transitional arrangements

Any issue that arises in the future that is not covered by the relevant legislation, or the relevant Postgraduate Studies Regulations will be dealt with by its re-drafting or amendment by the Board and its approval by the relevant Departmental Assembly. The Senate of the Aristotle University of Thessaloniki is informed and ratifies the amendment of the Regulation upon its publication in the Government Gazette.