

**Doctor of Philosophy Program in Pharmaceutical Engineering
(International Program/ 2013 Revision)**

Faculty of Pharmacy

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| Name of Program | Doctor of Philosophy Program in Pharmaceutical Engineering (International Program) |
| Name of Degree | Doctor of Philosophy (Pharmaceutical Engineering) Ph.D. (Pharm. Eng.) |
| Location | Faculty of Pharmacy, Silpakorn University, Sanam Chandra Palace Campus, Nakhon Pathom |

Collaboration with other institutes

This curriculum is collaborated with the Graduate School of Pharmaceutical Sciences of Chiba University (Japan) under the Double Doctoral Degree Program. The program provides graduate students the opportunities to study and do research at Chiba University. Student can receive two Doctoral's degrees from Silpakorn University and Chiba University.

Degree Awarded

Student(s) enrolling the Double Doctoral Degree Program will receive a Doctor of Philosophy (Pharmaceutical Engineering) from Silpakorn University and a Doctor of Philosophy (Pharmaceutical Sciences) from the Graduate School of Pharmaceutical Sciences of Chiba University. However, students who do not participate in the program will receive only a Doctor of Philosophy (Pharmaceutical Engineering) from Silpakorn University.

Objectives

1. To produce Ph.D. graduates imbued with responsible leadership in pharmaceutical engineering, to produce qualified professionals who can advance research in pharmaceutical engineering, and bring about self developments in discipline, moral, and code of conduct.

2. To create new knowledge or theory based on interdisciplinary integration that will support sustainable domestic industries, and also international industries

Qualifications of Applicants

1. Holder of a Bachelor's degree with a minimum GPA of 3.50 (or equivalent) in pharmacy, health science, science, or engineering, from a university or institute accredited by the Commission of Higher Education and/or the Office of the Civil Service Commission.

2. Holder of a Master's degree with a minimum GPA of 3.50 (or equivalent) in pharmacy, health science, science, or engineering, from a university or institute accredited by the Commission of Higher Education and/or the Office of the Civil Service Commission.

3. Other qualifications will be considered by Graduate Studies Committee of Faculty of Pharmacy

Curriculum Structure

Doctor of Philosophy Program in Pharmaceutical Engineering offers 4 options for curriculum structure: Type 1.1, Type 1.2, Type 2.1 and Type 2.2

1. Type 1.1

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|------------------------------------|------------|
| Core courses (non-credit) | 7 credits |
| Thesis (equivalent to) | 48 credits |
| Credits earned from entire program | 48 credits |

2. Type 1.2

| | |
|------------------------------------|------------|
| Core courses (non-credit) | 7 credits |
| Thesis (equivalent to) | 72 credits |
| Credits earned from entire program | 72 credits |

3. Type 2.1

| | |
|--|------------|
| Core courses | 7 credits |
| Elective courses (minimum) | 5 credits |
| Thesis (equivalent to) | 36 credits |
| Minimum credits earned from entire program | 48 credits |

4. Type 2.2

| | |
|--|------------|
| Core courses | 13 credits |
| Elective courses (minimum) | 11 credits |
| Thesis (equivalent to) | 48 credits |
| Minimum credits earned from entire program | 72 credits |

Course List

Type 1.1: There are 48 credits for thesis and 7 credits for additional non-credit courses that will be assessed as S/U as follows;

Core Courses (non-credit)

| | | |
|---------|--|----------|
| 551 721 | Research Methodology in Pharmaceutical Engineering | 3(3-0-6) |
| 551 722 | Seminar in Pharmaceutical Engineering I | 1(0-3-0) |
| 551 723 | Seminar in Pharmaceutical Engineering II | 1(0-3-0) |
| 551 724 | Seminar in Pharmaceutical Engineering III | 1(0-3-0) |
| 551 725 | Seminar in Pharmaceutical Engineering IV | 1(0-3-0) |

Thesis 48 credits

| | | |
|---------|--------|--------------------------|
| 550 901 | Thesis | equivalent to 48 credits |
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Type 1.2: There are 72 credits for thesis and 7 credits for additional non-credit courses that will be assessed as S/U as follows;

Core Courses (non-credit)

| | | |
|---------|--|----------|
| 551 721 | Research Methodology in Pharmaceutical Engineering | 3(3-0-6) |
| 551 722 | Seminar in Pharmaceutical Engineering I | 1(0-3-0) |
| 551 723 | Seminar in Pharmaceutical Engineering II | 1(0-3-0) |
| 551 724 | Seminar in Pharmaceutical Engineering III | 1(0-3-0) |
| 551 725 | Seminar in Pharmaceutical Engineering IV | 1(0-3-0) |

Thesis 72 credits

| | | |
|---------|--------|--------------------------|
| 550 903 | Thesis | equivalent to 72 credits |
|---------|--------|--------------------------|

Type 2.1: 12 credits minimum and 36 credits of thesis as follows;

Core Courses 7 credits

| | | |
|---------|--|----------|
| 551 721 | Research Methodology in Pharmaceutical Engineering | 3(3-0-6) |
| 551 722 | Seminar in Pharmaceutical Engineering I | 1(0-3-0) |
| 551 723 | Seminar in Pharmaceutical Engineering II | 1(0-3-0) |
| 551 724 | Seminar in Pharmaceutical Engineering III | 1(0-3-0) |
| 551 725 | Seminar in Pharmaceutical Engineering IV | 1(0-3-0) |

Elective Courses 5 credits minimum

| | | |
|---------|--|----------|
| 551 701 | Theoretical Aspects of Dosage Form Design | 3(3-0-6) |
| 551 702 | Equipment in Pharmaceutical Technology | 3(2-3-4) |
| 551 703 | Current Topics in Pharmaceutical Sciences | 3(3-0-6) |
| 551 704 | Colloidal Sciences and Nanotechnology | 3(3-0-6) |
| 551 706 | Hygiene and Safety in Pharmaceutical Manufacturing | 3(2-3-4) |
| 551 708 | Principles of Pharmaceutical Engineering | 3(3-0-6) |
| 551 716 | Biomaterials in Drug Delivery System | 3(2-3-4) |
| 551 726 | Pharmaceutical Material Science | 2(2-0-4) |
| 551 727 | Advanced Pharmaceutical Engineering | 3(2-3-4) |
| 551 728 | Computational Simulation in Pharmaceutical Engineering | 2(2-0-4) |
| 551 729 | Design and Development of Pharmaceutical Process | 3(2-3-4) |
| 551 730 | Regulatory Affairs in Pharmaceutical Manufacturing | 3(3-0-6) |
| 551 731 | Statistical Modeling and Analysis | 2(2-0-4) |
| 551 735 | Current Topics in Pharmaceutical Engineering | 2(2-0-4) |
| 551 737 | Sterile Pharmaceutical Product and Development | 3(2-3-4) |
| 551 738 | Material Science for Pharmaceutical Industry | 2(2-0-4) |
| 551 739 | Manufacturing Resource Management | 4(3-3-6) |

Thesis 36 credits

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|---------|--------|--------------------------|
| 550 902 | Thesis | equivalent to 36 credits |
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Type 2.2: 24 credits minimum and thesis 48 credits

Core Courses 13 credits

| | | |
|---------|--|----------|
| 551 701 | Theoretical Aspects of Dosage Form Design | 3(3-0-6) |
| 551 708 | Principles of Pharmaceutical Engineering | 3(3-0-6) |
| 551 721 | Research Methodology in Pharmaceutical Engineering | 3(3-0-6) |
| 551 722 | Seminar in Pharmaceutical Engineering I | 1(0-3-0) |
| 551 723 | Seminar in Pharmaceutical Engineering II | 1(0-3-0) |
| 551 724 | Seminar in Pharmaceutical Engineering III | 1(0-3-0) |
| 551 725 | Seminar in Pharmaceutical Engineering IV | 1(0-3-0) |

Elective Courses 11 credits minimum

| | | |
|---------|---|----------|
| 551 702 | Equipment in Pharmaceutical Technology | 3(2-3-4) |
| 551 703 | Current Topics in Pharmaceutical Sciences | 3(3-0-6) |
| 551 704 | Colloidal Sciences and Nanotechnology | 3(3-0-6) |
| 551 706 | Hygiene and Safety in Pharmaceutical Manufacturing | 3(2-3-4) |
| 551 716 | Biomaterials in Drug Delivery System | 3(2-3-4) |
| 551 726 | Pharmaceutical Material Science | 2(2-0-4) |
| 551 727 | Advanced Pharmaceutical Engineering | 3(2-3-4) |
| 551 728 | Computational Simulation in Pharmaceutical Engineering) | 2(2-0-4) |
| 551 729 | Design and Development of Pharmaceutical Process | 3(2-3-4) |

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|---------|--|----------|
| 551 730 | Regulatory Affairs in Pharmaceutical Manufacturing | 3(3-0-6) |
| 551 731 | Statistical Modeling and Analysis | 2(2-0-4) |
| 551 735 | Current Topics in Pharmaceutical Engineering | 2(2-0-4) |
| 551 737 | Sterile Pharmaceutical Product and Development | 3(2-3-4) |
| 551 738 | Material Science for Pharmaceutical Industry | 2(2-0-4) |
| 551 739 | Manufacturing Resource Management | 4(3-3-6) |

Thesis 48 credits

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|---------|--------|--------------------------|
| 550 901 | Thesis | equivalent to 48 credits |
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However, students can take courses in other programs available inside or outside the country if necessary for their specific work or profession with an approval from Graduate Studies Committee of Faculty of Pharmacy, academic advisor, and/or curriculum committee. These courses will be taken a non-creditable remedial courses.

Course Description

550 901 Thesis equivalent to 48 credits
An independent research on pharmaceutical engineering under the supervision of thesis advisors.

550 902 Thesis equivalent to 36 credits
An independent research on pharmaceutical engineering under the supervision of thesis advisors.

550 903 Thesis equivalent to 72 credits
An independent research on pharmaceutical engineering under the supervision of thesis advisors.

551 701 Theoretical Aspects of Dosage Form Design 3(3-0-6)
Theories and principles of designing ideal pharmaceutical dosage forms including drug discovery and development.

551 702 Equipment in Pharmaceutical Technology 3(2-3-4)
Theories, principles, techniques and practices of commonly encountered unit operations in pharmaceutical technology and related areas.

551 703 Current Topics in Pharmaceutical Sciences 3(3-0-6)
Current progresses and future trends in pharmaceutical sciences including research and development, manufacturing, quality control, and quality assurances of pharmaceuticals.

551 704 Colloidal Sciences and Nanotechnology 3(3-0-6)
Theories and principles of colloidal sciences including their applications in nanotechnology.

551 706 Hygiene and Safety in Pharmaceutical Manufacturing 3(2-3-4)
Hygiene of employees in industrial plants including the prevention of physical and chemical hazards to mental and physical health of employees, waste management, environment control, work safety, hygienic services, law and regulation, fringe benefits and recreation.

- 551 708 Principles of Pharmaceutical Engineering 3(3-0-6)
Requirements for design of facilities; equipment and processes in the pharmaceutical and related industries including facility layout and principles of design; planning and construction of critical facilities, emphasizing on water system, ventilation and environmental system; manufacturing process validation.
- 551 716 Biomaterials in Drug Delivery System 3(2-3-4)
Theories, principles, and advanced skills in the applications of biomaterials in pharmaceutical sciences, including research and development of drug delivery systems, desired properties of biomaterial and related mechanisms, and trends in the application of newly developed biomaterials in medicals and pharmaceutical sciences.
- 551 721 Research Methodology in Pharmaceutical Engineering 3(3-0-6)
Systematic approach in conducting a research, including selection of research topic, planning and design of a research project, operational concepts of research populations, samples, parameters and data; research proposal preparation; biostatistics for research; analysis and interpretation of research data; research work dissemination; ethics in pharmaceutical engineering research.
- 551 722 Seminar in Pharmaceutical Engineering I 1(0-3-0)
Searching, retrieving and compiling scientific data in pharmaceutical engineering from various sources; analysis of collected data to present and discuss with rational reason.
- 551 723 Seminar in Pharmaceutical Engineering II 1(0-3-0)
Searching, retrieving and compiling scientific data in pharmaceutical engineering from various sources; analysis of collected data to present and discuss with rational reason. The topic must be different from that in 551 722 Seminar in Pharmaceutical Engineering I.
- 551 724 Seminar in Pharmaceutical Engineering III 1(0-3-0)
Searching, retrieving and compiling scientific data in pharmaceutical engineering from various sources; analysis of collected data to present and discuss with rational reason. The topic must be different from that in 551 722 Seminar in Pharmaceutical Engineering I and 551 723 Seminar in Pharmaceutical Engineering II.
- 551 725 Seminar in Pharmaceutical Engineering IV 1(0-3-0)
Searching, retrieving and compiling scientific data in pharmaceutical engineering from various sources; analysis of collected data to present and discuss with rational reason. The topic must be different from that in 551 722 Seminar in Pharmaceutical Engineering I, 551 723 Seminar in Pharmaceutical Engineering II and 551 724 Seminar in Pharmaceutical Engineering III.
- 551 726 Pharmaceutical Material Science 2(2-0-4)
Development of useful materials for pharmaceutical purposes; theories, principles, and technology in preparing pharmaceutical materials into a desired dosage form; physicochemical and biological properties of pharmaceutical materials and evaluation; technology and trends in the development of pharmaceutical materials.

- 551 727 Advanced Pharmaceutical Engineering 3(2-3-4)
Theories and advanced skills in pharmaceutical engineering processes, emphasizing design, scale-up, trouble-shooting, and optimization of sustainable pharmaceutical processes; pharmaceutical unit operations; design and equipment for packaging; biopharmaceutical product engineering.
- 551 728 Computational Simulation in Pharmaceutical Engineering 2(2-0-4)
Definition and significance of simulation models, computational simulation techniques, defining problem, data collection and analysis, developing simulation models, random number generation, model validation, model experimentation and optimization, implementing simulation results, and evaluation for pharmaceutical engineering.
- 551 729 Design and Development of Pharmaceutical Process 3(2-3-4)
Pharmaceutical process development and design involved in scaling up the formulation from research and laboratory development scale to commercial production scale, including technology related to selection of suitable processes and equipments, process validation, validation master plan, and IQ, OQ and PQ protocol structures.
- 551 730 Regulatory Affairs in Pharmaceutical Manufacturing 3(3-0-6)
Regulations in pharmaceutical manufacturing validation covered in PIC/S, ICH, EU, and FDA cGMPs, including the laws related to industry, such as municipal law, factory act, machinery registration act.
- 551 731 Statistical Modeling and Analysis 2(2-0-4)
Analysis of data collected data to derive a conclusion and generalization about the population including fundamentals of multivariate data analysis and design of experiment (DoE) and their applications in research and development, product development, process analytical technology, quality control and assurance.
- 551 735 Current Topics in Pharmaceutical Engineering 2(2-0-4)
Novel concepts based on current information and trends in technology of research and development of new drugs, emphasizing pharmaceutical technology and engineering process in order to obtain drugs with required specifications.
- 551 737 Sterile Pharmaceutical Product and Development 3(2-3-4)
Theories, principles and skills in practice of formulation, fabrication, manufacturing and property of desirable parenteral dosage forms; including entire processes; criteria and measures of international standard procedure in control and consideration of chemical structure and property of drugs; factors affecting and influencing drug's stability and degradation, problem solving and prevention; concepts and directions of technology in preparation of steril products including evaluation of reliability.
- 551 738 Material Science for Pharmaceutical Industry 2(2-0-4)
Sciences related to the materials used for construction of pharmaceutical plant and equipment; materials and compositions of pharmaceutical packaging; emphasizing properties, characterization, processing and selection of suitable materials.

Effective planning, scheduling, managing, and controlling of manufacturing resources through concepts of engineering design, industrial engineering, management information systems, quality management, production management, inventory management, accounting, productivity improvement, and other novel or up-to-date technology related to resource management.

Graduation Requirement

Criteria for graduation is in accordance with Silpakorn University Regulations on Graduate Studies 2007 and/or later revision; and additional regulations of Faculty of Pharmacy. A graduate of Doctor of Philosophy Program in Pharmaceutical Engineering must have the following qualifications;

1. Thesis or part(s) of a thesis must be published or accepted to be published in an international academic journal or printed media with the following conditions;

1.1 Students with bachelor degree must publish their research work or have their research works accepted for publication at least 2 papers which are parts of their thesis before graduation.

The first article must be published in an international academic journal accredited in an international database as specified by Office of the Higher Education Commission (OHEC).

The second article must be published in an international academic journal accredited in an international database, or a national or international journal in scientific and technology field as specified by Office of the Higher Education Commission (OHEC), or registered for a patent.

1.2 Students with master degree must publish their research work or have their research works accepted for publication at least 1 paper which is a part of their thesis in an international academic journal accredited in an international database as specified by Office of the Higher Education Commission (OHEC), before graduation

1.3 For students who receive the Royal Golden Jubilee Ph.D. Scholarship graduation requirements of the scholarship will be used. At least 2 research works which are parts of their thesis must be published or accepted to be published before graduation with the following conditions specified in current scholarship requirements or later revision.

The first article must be published in an international academic journal in a database approved by Thailand Research Fund, or submitted for registration for a patent.

The second article must be published in a national or international academic journal in a database approved by Thailand Research Fund, or other research work with the equivalent quality approved by Thailand Research Fund.

2. Thesis must be written in English.

3. Students have to attend international academic conferences at least once a year. They are required to communicate with some speakers and other few attendances to improve their English communication skills. After those conferences, the students have to report to the curriculum committee.