APPENDIX I CONTINUED

Ph.D. in Pharmaceutical Sciences (Division of Pharmaceutics and Pharmacology)

A minimum of 80 semester hour credits is required for the Ph.D. degree. These credits will be obtained through successful completion of required courses, electives and research credit. Flexibility in the program allows students to prepare for a variety of careers in the pharmaceutical sciences. This is achieved by having only a few required courses in the Program and allowing the remainder of the courses to be electives determined by the student and her/his advisor to better tailor the coursework to match the student's research project and interests relative to her/his career goals.

Background and Prerequisites

While there are no specific required course prerequisites for admission to the Program, admitted applicants must have completed a Bachelor's degree program, and typically this will have been within a scientific discipline (e.g. pharmacy, pharmaceutics, pharmacology, biology, biochemistry, chemistry, engineering, etc.). A majority of admitted applicants also have Master's degrees in a scientific discipline.

Coursework within the Program

<u>Required of all students</u>:

A. Fundamentals of Drug Disposition (PHR 8005, 3 credit hours)

B. Biostatistics (e.g. STAT 5301, MOLGEN 5650 or equivalent, 2 credit hours minimum).

C. Pharmaceutical Sciences Research and Communication (Pharmacy 8008, 1 credit hour).

D. Research Ethics (PHR 8520; 1 credit hour).

E. Journal Club (Pharmacy 8730, 1 credit hour) is required for pre-candidacy students. Post-candidacy students may enroll as an elective. Journal club will be offered one semester per academic year.

F. Pharmaceutics and Pharmacology Seminar (either Pharmacy 8882.01 (presentation) or 8882.02 (participation), 0.5 credit hour). Enrollment in Pharmacy 8882.01 (student presentation) is required twice in years 3-5; enrollment in Pharmacy 8882.02 (student participation) is required for all other semesters except Summer.

G. Individual Study in the Pharmaceutical Sciences (pre-candidacy: Pharmacy 8993) or Research in the Pharmaceutical Sciences (post-candidacy: Pharmacy 8999) is required every semester.

<u>Elective Courses</u>

A minimum of 3 graduate level courses are required as electives for each student. Any graduate level course relevant to the student's research focus area may be acceptable as an elective. However, the

student must obtain the advisor's approval for all elective courses that are taken to ensure both the student and advisor are in agreement about the coursework relevant to the student's training. Students should confer with their advisors to evaluate prior coursework relative to the student's focus area of research and determine if there are any gaps in basic knowledge that could be filled with courses inside or outside the College of Pharmacy. Some suggestions are listed below.

Electives within the College of Pharmacy

Pharmaceutics and Pharmacology Courses	**Course**
Pharmacometrics	PHR 8025
Advanced Drug Delivery Systems	PHR 8070
Drug Discovery and Drug Design	PHR 7350
Principles of Safety Pharmacology (online)	PHR 5780
Organ System Toxicology (online)	PHR 7582
Chemotherapy of Infectious Diseases	PHR 8370
CNS Drug Discovery	PHR 7180
Introduction to Bioinformatics: Introduction to the structure, analyses and interpretation of genomic data studies	PHR 8194

Elective Courses outside the College of Pharmacy

The Ohio State University has a large number of graduate courses that may be appropriate for students in Pharmaceutics to take as electives. Examples of subject areas and some specific courses are listed below:

Biochemistry (e.g. BIOCHEM 5613/5614, 5721/5722)
Biostatistics/statistics (e.g. STAT 5301/5302, MOLGEN 5650, STAT 6201, STAT 6450, STAT 6730)
Cell Biology (e.g., MOLGEN 5623)
Bioinformatics (e.g., BMI 5730)
Biomedical Engineering (e.g. BIOMEDE 4610)
Fundamentals of Oncology (e.g. PATHOL 6640)
Grant Writing (e.g. BSGP 7070 and 7080)
Introduction to General Pharmacology (online) (BIOPHARM 5600)
Molecular Biology (e.g. CHEM 6230)
Molecular Genetics (e.g. MOLGEN 5623).
Physical Chemistry (e.g. CHEM 4300/4310)
Physics (Physics 5740)
Signal Transduction (MOLGEN 5796)

Minimum Enrollment Requirements

Prior to passing the candidacy exam, full-time students supported as Graduate Teaching Associates and Graduate Research Associates are required by the college to enroll for a minimum of 8 and no more than 18 credits per semester; Graduate Fellows are required to enroll for a minimum of 12 and no more than 18 credits per semester. Prior to passing the candidacy exam, students typically enroll for 12 to 18 credit hours per autumn and spring semesters using the variable unit Pre-Candidacy Research credit (PHR 8993) to make up the difference between credit hours obtained for required/elective courses and

the remainder of the course credits. After passing the candidacy exam, all full-time students should enroll in 3 credits per semester, and this will typically be done using the Post-candidacy Research credit (PHR 8999).

Example Course Schedule

Course	Credit Hours		Credit Hours		Credit Hours
Autumn, Year 1		**Spring, Year 1**		**Summer, Year 1**	
Fundamentals of Drug Disposition, PHR 8005	3	Biostatistics, STAT 5301	4	Research Ethics, PHR 8520	1
Pharmaceutical Sciences Research and Communication, PHR 8008	1	Elective (research area focused)	~3		
		Journal Club, PHR 8730	1		
Seminar, PHR 8882.02	0.5	Seminar, PHR 8882.02	0.5		
Pre-candidacy Individual Research Studies, PHR 8993	~11.5	Pre-candidacy Individual Research Studies, PHR 8993	~7.5	Pre-candidacy Individual Research Studies, PHR 8993	3
Total	16		16		4
Autumn, Year 2		**Spring, Year 2**		**Summer, Year 2**	
Elective (research area focused)	~3	Elective (research area focused)	~3	Milestone: Successful completion of candidacy exam	
		Journal Club, PHR 8730	1		
Seminar, PHR 8882.02	0.5	Seminar, PHR 8882.02	0.5		
Pre-candidacy Individual Research Studies, PHR 8993	~12.5	Pre-candidacy Individual Research Studies, PHR 8993	~11.5	Pre-candidacy Individual Research Studies, PHR 8993	3
Total	16	Total	16	Total	3
Autumn, Years 3-5		**Spring, Years 3-5**		**Summer, Years 3-5**	
Seminar, PHR 8882.02 (or 8882.01 presentation)	0.5	Seminar, PHR 8882.02 (or 8882.01 presentation)	0.5		
Post-candidacy Research in the Pharmaceutical Sciences, PHR 8999	~2.5	Post-candidacy Research in the Pharmaceutical Sciences, PHR 8999	~2.5	Post-candidacy Research in the Pharmaceutical Sciences, PHR 8999	~3
Total	~3		~3		~3

Committees

For first year students the Pharmaceutics & Pharmacology Graduate Program Committee (PGPC) will advise on coursework, rotations and advisor selection until a permanent advisor is identified. First year students are required to complete at least 2 rotations and identify a permanent advisor by the end of the Spring semester. Any exceptions to this requirement must be approved in advance by the PGPC. Laboratory rotations generally range between 4-7 weeks depending on the laboratory requirement and/or project involved but cannot be less than 4 weeks or more than 7 weeks. Once an advisor is identified, it is helpful for students to have their first dissertation committee meeting held by at least the beginning of the Autumn semester of second year.

Committees involved in each student's doctoral program are the Dissertation Committee, the Candidacy Examination Committee and the Final Oral Examination Committee. Procedures for the oral examination can be found at https://gradsch.osu.edu/handbook/7-9-doctoral-final-examination. See Section 7 of the University Graduate School Handbook for information on the composition and responsibilities of these committees. All of the committees are composed of the advisor, who must be a Category P graduate faculty member, and at least three authorized graduate faculty members who must be either Category M or Category P. The advisor must be a member of the graduate faculty of the Division of Pharmaceutics & Pharmacology and, for the two examination committees, at least one member other than the advisor must be a faculty member in the Division of Pharmaceutics & Pharmacology. The student's advisor will chair the committee and committee members will be selected by the student in consultation with the advisor. The composition of the examination committees must be approved by the PGPC; names of proposed committee members must be submitted to the College of Pharmacy Research and Graduate Studies Program Manager at least two weeks before submission of the "Doctoral Notification of Candidacy Examination" form or the "Application to Graduate" form to the graduate school.

Candidacy Examination

The first candidacy committee meeting must be held before the end of the Spring semester of the second year in the program. Students failing to complete the candidacy exam by the end of their second year will receive an unsatisfactory ("U") grade for their research credit in the last semester of their second year (typically this will be the Summer semester). Note that two "U" grades will lead to dismissal from the program.

If for any reason the candidacy examination cannot be completed on time, students should petition the reason(s) for their delay with an anticipated examination date to the Division of Pharmaceutics & Pharmacology Graduate Program Committee (PGPC) for approval. This petition must be received by the PGPC before the end of the Spring semester of the second year. The graduate committee will evaluate the petition and may offer an extension time of one, or under extreme circumstances, two semesters to complete the candidacy examination. On any account, students must complete their candidacy exam before the end of the Spring semester of 3rd year. Failure to complete the candidacy exam by the end of the third year Spring semester may result in denial of further registration in the program.

The purpose of the candidacy examination is to determine whether graduate students have achieved the competency level and capacity to carry out pharmaceutical sciences research at the doctoral level. The exam tests for a broad knowledge base in the area of pharmaceutical sciences and the capability

for critical thinking. This includes the ability of the student to critically review the pharmaceutical sciences literature, analyze experimental data, and to form hypotheses and design experiments to test them. The candidacy exam generally does not test recall of specific information presented in course work, although students are presumed to have mastered knowledge and concepts presented in courses.

The candidacy examination is composed of a written part and an oral part. The written part must be passed before the oral part can be taken. Both parts of the Candidacy Examination will be conducted by the student's Candidacy Examination Committee.

A. Written Part

To be eligible to take the examination, students must have a cumulative grade point average of 3.00 or higher and generally should have completed one and a half years of course work. The written examination requires the student to prepare an original research proposal in the area of pharmaceutical sciences. The proposal may, but does not have to, be in the dissertation research area.

Approval of the Proposal: The student will provide the candidacy committee with the tentative summary, hypothesis and specific aims of the proposal (one page). The committee will determine within one week whether the ideas are acceptable to develop into a full proposal. Within thirty days from the date of approval, the student will submit an original research proposal in the form outlined below.

Instructions for preparation of the proposal.

Include sufficient information to permit an effective review without reviewers having to refer to the literature. Brevity and clarity are considered indicative of an applicant's approach and ability.

1) Margins are 1"; Font is 11; Arial typeface, black font; Single Spaced
2) Color can be used in figures, but all text must be black.
3) Specific Aims = 1 Page
   a) State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives (Specific Aims) of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.
4) Research Strategy = 6 pages

   a) Organize the Research Strategy in the specified order and using the instructions provided below.

      Start each section with the appropriate section heading—Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Reference section.

   b) Format
      i) Significance (approximately one half to one page)
         (1) Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
         (2) Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

(3) Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

ii) Innovation (approximately one half to one page)
   (1) Explain how the proposal challenges and seeks to shift current research or clinical practice paradigms.
   (2) Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
   (3) Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

iii) Approach (approximately 4-5 pages)
   (1) Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted.
      (a) Extensive experimental detail (e.g., buffer components, sources of equipment and chemicals, injection volumes) should not be included. Emphasis on rationale for the chosen model(s), experimental groups, positive and negative controls, data analysis, and possible outcomes are essential.
      (b) Statistical procedures by which the data will be analyzed should be included
   (2) Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
      (a) Potential experimental difficulties should be discussed together with alternative approaches that could achieve the desired aims.
      (b) An estimated timeline and budget for the project should be included.

c) The applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.
d) Background and Preliminary data should be incorporated into the Significance, Innovation or Approach section. Be sure to summarize your progress, if any, to date.
e) References should be cited by number in the text and listed at the end in the order of appearance in the text. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature; it is important to be concise and to select only those literature references pertinent to the proposed research. References are not counted in the 6 page limit.

While the proposal must be entirely the work of the student, she or he is encouraged to seek feedback from the advisor to facilitate learning during preparation of the proposal and to insure it is of high quality prior to submitting to the full Committee. The completed proposal will be evaluated by the members of the Candidacy Examination Committee; the Committee must unanimously agree that the proposal meets their expectations. If the written proposal is not unanimously approved, the Candidacy Examination Committee will meet with the student individually or as a group to discuss improvements that should be made to the document. A second and final proposal will be prepared by the student and evaluated by the original Committee. The second proposal may be a new proposal or a revision of the first proposal. Failure of the second proposal to gain the approval of the Committee disqualifies a student from advancement to doctoral candidacy status.

Proposal Evaluation Criteria

Significance: Does this study address a scientifically important problem? If the aims of the proposal are achieved, how will scientific knowledge be advanced?

Innovation: How would the proposed studies add to the existing concepts or methods in the field? Does the proposal employ novel concepts, approaches or methods?

Approach: Are the conceptual framework, design (including composition of study population), methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Are problem areas acknowledged and alternative tactics considered?

B. Oral Part

The oral part of the examination must occur within one month of approval of the written proposal. The purpose of the oral exam is to further evaluate the student's knowledge and capacity for critical thinking about the pharmaceutical sciences problem proposed in the written proposal? The student's oral presentation could consist of up to 12 PowerPoint Slides based on the advisor's recommendation. The committee members can ask questions throughout the presentation as well as require explanation of concepts and experimental strategy on a blackboard or drywall board. While the written proposal may function as a starting point for the examination, questions from examiners will not be constrained to the proposal. Questioning of the student should occupy the entire period of the examination. Upon recommendation by the Candidacy Examination Committee, a student failing the oral exam may be permitted to retake the oral exam, which must be taken during the subsequent semester; a maximum of two examinations will be allowed. A second failure of the oral examination disqualifies a student from advancing to doctoral candidacy status.

Graduate School Policy

See Section 7 of the university Graduate School Handbook, for important information about the candidacy examination.

Dissertation Committee Meetings

After the candidacy exam, dissertation committee meetings must be held no more than one year apart until completion of the graduate program. The final dissertation committee meeting must be held within three to four months of the anticipated defense date. Students that are overdue for a meeting will be considered not in compliance with this policy and may receive an Unsatisfactory (U) grade in PHR 8999 and/or may not be considered for awards that require nomination by the program.

The structure of each dissertation meeting should be decided in advance by the student and the advisor. Typically, the student prepares a presentation of about 30 minutes that describes the overall goal of the dissertation project, progress made in the previous year(s), and goals for the upcoming year(s) including plans for graduation if is nearing the fifth year. It might be also helpful for the student to prepare a brief document or slide deck outlining their progress and goals, to be distributed to the committee before the meeting.

Each committee meeting must be documented through completion of a Dissertation Committee Meeting Report Form and submitted to the College of Pharmacy Research and Graduate Studies

Program. During the course of the program, students typically completes about three to four dissertation committee meetings (not including candidacy examination meeting(s)) before they graduate from the program.

Dissertation and Final Oral Examination

Please see the University Graduate School Handbook sections 7.8 and 7.9 regarding the Dissertation and Final Oral Examination procedures.

In accordance with section 7.9.8 of the University Graduate Handbook, the final oral examination lasts no longer than 2 hours. At least one hour of the two-hour examination period must be allotted to discussion of the research and to questions of the committee and answers by the doctoral candidate. This one hour closed examination period will be preceded by a public presentation lasting approximately 45 minutes. It is recommended that committee members hold substantial questions for the oral examination in the closed questioning after the public presentation. This public presentation is considered to be the program's required exit seminar.

Normal Progress for Graduate Students in Doctoral Program

1. Students holding half-time associateship appointments are expected to complete an average of eight (8) credits of course work (excluding S/U graded courses) per semester during the first two years of enrollment (i.e. until the candidacy exam is completed). Grades of B or better are expected in required courses. Information on graduate standing and academic standards can be found at https://gradsch.osu.edu/handbook/5-academic-and-professional-standards for academic standards.
2. Students are expected to complete the candidacy examination according to the schedule outlined in the 'Candidacy Examination' section of this handbook.
3. Students are expected to make progress on their dissertation research. Evidence of such progress includes publication of papers and abstracts, written research reports, and presentations at local, regional and national scientific meetings. Students are required to publish at least one first-author research (non-review) publication prior to graduation.
4. Students are expected to complete all requirements for the Ph.D. degree within 15 semesters.
5. Students not making normal progress will be considered by Division faculty for reassessment of status in the graduate program. Possible changes in status include enrollment in the M.S. degree program and conclusion of graduate studies with a M.S. with or without Thesis Curriculum and/or discontinuation of enrollment. If the student is supported by division funds (GTA or Fellowship), determination will be made of whether support will be continued.