Please fill in all information. After all required signatures are obtained on page two, send to Research and Graduate Studies, Knoles Hall, 2nd Floor. Research and Graduate Studies will then forward to the Academic Affairs Committee, Office of the Provost, Anderson Hall, 2nd Floor.

Date: April 7, 2006
Contact Person: Miki Park
Department: PCSP
Phone: 946-3909
Select below
Addition  □
Revision  √
Deletion  □

School or College: PHS
Department: PMED
Course Number: PCSP 223
Title: Pharmacokinetics and Pharmacodynamics
Units: 3
Minimum Number of Students: 5
Prerequisites: Graduate student standing or with the permission of the instructors.

If replacing a course, old course title and number:

Catalog Description (attach additional paperwork if necessary):
This course teaches critical concepts and basic principles of pharmacokinetics and pharmacodynamics. Such concepts and principles are required for the students to understand the drug behavior in the body.
Please attach a syllabus.

What are the reasons for the new course (e.g., student needs, major, etc.), program changes or deletion of the program?
To teach graduate students more in-depth knowledge of pharmacokinetics and pharmacodynamics

If approved, when will this be implemented? Fall □ Spring  □ Year 2007
What is the anticipated impact on resources (faculty, funds, library, materials, etc.)
One to three instructors from the Department of Pharmaceutics and Medicinal Chemistry, TJL SOPHS
Describe any specific facilities or technology needs.
Need one small multi-media classroom (>25 seats) with internet connection for the lectures and discussion sections and computerized Powerpoint projector and transparency projector

APPROVAL PROCESS

1. Action by department requesting addition/change:
   Approved by: ___________________________ Date: 4/16/06

2. Action by the Curriculum and/or Graduate Studies Committee of the School/College:
   Approved by: ___________________________ Date: 4-11-06

3. Action by the Dean of the School/College:
   Approved by: ___________________________ Date: 4/24/06

4. Action by the Dean of the Library:
   Approved by: ___________________________ Date: 5/29/06

5. Action by the Director of Educational Technology Services (if computer lab, software needed):
   Approved by: ___________________________ Date: __________

6. Action by the Registrar:
   Approved by: ___________________________ Date: 6/7/06

7. Action by the Graduate Studies Committee (as appropriate):
   Approved by: ___________________________ Date: 7/8/06

8. Action by the Academic Affairs Committee:
   Approved by: ___________________________ Date: __________

After approval by the Academic Affairs Committee, information regarding new, revised, or deleted programs and courses is sent to the Registrar for listing in or modifying the catalog.

Form revised 9/4/03
Routing Sheet

Course Name: Pharmacokinetics and Pharmacodynamics

Course Number: PCSP 223

<table>
<thead>
<tr>
<th></th>
<th>Department</th>
<th>CurrComm</th>
<th>Faculty</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Statement of justification of course is acceptable.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Statement of staffing requirements is acceptable.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Statement of estimated class enrollment is acceptable.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Statement of anticipated impact on classroom facilities, equipment, and budgets is acceptable.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Appropriate course number.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Appropriate course title.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Appropriate department.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Appropriate unit value and hours.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Appropriate course description.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Appropriate prerequisites.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Evaluation methodology is appropriate, including honor statement.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Relevant terminal competencies are appropriate (mandatory for required courses, recommended for elective courses, not applicable for graduate courses).</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Course goals are appropriate.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Course objectives are appropriate.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Course outline, including didactic sequence and time allotment, is appropriate. Treatment of the subject material is complete and of appropriate breadth and depth.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Course outline contains no unnecessary duplication of other course content.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Consideration of text (s) is appropriate.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Instructor contact information is indicated on the syllabus.</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
Complete this section for Experimental Courses (149 or 249)

Approval recommended by Department

Xiaoling Li, Chair

Date

Approval by Curriculum Committee

Pat Catania, Chair

Date

Complete this section for Permanent Status Courses

Approval recommended by Department

[Signature]

Xiaoling Li, Chair

4/6/06

Date

Approval by Curriculum Committee

[Signature]

Pat Catania, Chair

4/12/06

Date

Approval by Faculty

Pat Catania, Curriculum Committee Chair

05-05-06

Date

1.) JUSTIFICATION FOR THE COURSE:
   To teach the graduate students critical concepts and basic principles of pharmacokinetics
   and pharmacodynamics. Such concepts and principles are required for the students to
   understand the drug behavior in the body.

2.) STAFFING NEEDS:
   One to three instructors from the Department of Pharmaceutics and Medicinal
   Chemistry, TJL SOPHS.

3.) ESTIMATED CLASS ENROLLMENT:
   10-20 graduate students in pharmaceutics, medicinal chemistry or pharmacology.

4.) ANTICIPATED IMPACT ON CLASSROOM FACILITIES:
   Need one small multi-media classroom (>25 seats) with internet connection for the
   lectures and discussion sections.

5.) ANTICIPATED IMPACT ON ELECTRONIC TECHNOLOGY:
   Need computerized Powerpoint projector and transparency projector.
# COURSE SYLLABUS

Pharmaceutical and Chemical Sciences Graduate Program  

<table>
<thead>
<tr>
<th>Course Number</th>
<th>Course Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCSP 223</td>
<td>Pharmacokinetics and Pharmacodynamics</td>
</tr>
</tbody>
</table>

**Department**  
Pharmaceutics and Med Chem

**Instructor(s)**  
Miki S. Park, Ph.D.

<table>
<thead>
<tr>
<th>Number of Weeks</th>
<th>Maximum Enrollment</th>
<th>Unit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>25</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lecture Hours per Week</th>
<th>Laboratory Hours per Week</th>
<th>Discussion Hours per Week</th>
<th>Number of Labs per Semester</th>
<th>Experiential Hours per Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 or 3</td>
<td>N/A</td>
<td>0 or 1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Course Description**  
To teach the graduate students critical concepts and basic principles of pharmacokinetics and pharmacodynamics. Such concepts and principles are required for the students to understand the drug behavior in the body.

**Prerequisites**  
Graduate student standing or with the permission of the instructors.

**Teaching Methodology**  
Formal lectures, case presentations, discussion sessions, oral and written assignments

**Evaluation Methodology**  
The University Honor Code is an essential element in academic integrity. It is a violation of the Honor Code for a student to give information to or receive information from another student during an examination, to use unauthorized sources during an examination, or to submit all or part of someone else's work or ideas as one's own. If a student violates the Honor Code, the faculty member may refer the matter to the Office of Graduate School. If found guilty, the student may be penalized with failure of the assignment or failure of the course. The student may also be reprimanded or suspended from the University. A complete statement of the Honor Code may be found in the Student Handbook, “TIGER LORE”.

Attendance is expected at all class sessions. Class assignments may be retained by the instructor to assess how the learning objectives of the course are met.

The instructor may be contacted during office hours or by email, phone, or via Blackboard.com.

**Weighting of Assignments:**
- Midterm Examination: 30%
- Final Examination (Comprehensive): 35%
- Critical Thinking Sessions, Quizzes and Written/Homework Assignments: 35%

**Assignment of Grades:**

<table>
<thead>
<tr>
<th>Course Percentage</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 - 89.50</td>
<td>A</td>
</tr>
<tr>
<td>89.49 - 79.50</td>
<td>B</td>
</tr>
<tr>
<td>79.49 - 69.50</td>
<td>C</td>
</tr>
<tr>
<td>69.49 - 60.00</td>
<td>D</td>
</tr>
<tr>
<td>Below 60</td>
<td>F</td>
</tr>
</tbody>
</table>

No make-up exams will be given. The students must have legitimate medical reasons (physician's note) for missing scheduled examinations. Students missing examinations without a legitimate reason will receive a zero grade.

THE USE OF PROGRAMMABLE, ALPHA-NUMERIC, OR GRAPHING CALCULATORS ON EXAMS AND/OR QUIZZES WILL RESULT IN AN “F” IN THE COURSE. NO EXCEPTIONS.
## GOALS

Goals for Pharmacokinetics and Pharmacodynamics.

Upon completion of this course, the student should be able to:

1. Have a comprehensive understanding of the concept of pharmacokinetics and pharmacodynamics.
2. List the basic pharmacokinetic parameters and describe their application to biological systems.
3. Use pharmacokinetic principles to interpret and evaluate drug therapy and data as presented in the literature.
4. Determine the PK parameters following IV and oral dose using compartmental and non-compartmental analysis.
5. Fit plasma concentration profiles to appropriate compartmental models.
6. Define the important rate processes in biological systems in relation to the transport of drugs.
7. Define and evaluate bioavailability and bioequivalence.
8. Describe the concepts and the mechanisms of drug-drug interaction.
9. Identify dose and time dependent kinetics.
10. Scale pharmacokinetic data using in vitro and in vivo animal data.
11. Understand the kinetics of metabolites and macromolecules.
12. Understand the various factors that affect the pharmacokinetics of drugs.
13. Utilize WinNonlin or other software to analyze pharmacokinetic data.
14. Apply the basic concepts in pharmacokinetics and pharmacodynamics to conceptual clinical problems to achieve desired effects, outcomes, or bioresponses.
15. Understand and define the four major processes between the pharmacokinetics and effects.
Upon completion of this course, the students should be able to:

1. Mathematically set up and derive the concentration-time relationship for one compartmental model drugs.
2. Use LaPlace transforms to solve differential equations.
3. Understand basic pharmacokinetic parameters:
   - Plot concentration-time data obtained after IV bolus dose on linear and semilog paper
   - Calculate and define t1/2, V, k and CL from concentration-time data
4. Understand Zero and First order input process
   - Use PK parameters to predict plasma concentration with time during and following a zero order administration
   - Estimate PK parameters from plasma and urine data following a zero order and extravascular administration
   - List factors that govern the rate of absorption of drug
   - Anticipate the effects of altering rate or extent of absorption, CL and V on the plasma concentration and amount of drug in the body with time.
5. Understand Clearance concept
   - Define in both words and equation: CL, blood CL, renal CL, hepatic CL, total CL, unbound CL, intrinsic CL
   - Describe factors that affect the CL of a drug with a high and a drug with a low intrinsic CL
6. Understand Distribution concept
   - Define the factors that determine the fraction unbound of a drug in plasma
   - Derive the expression that relates apparent Vd to the fraction unbound in plasma and tissue
   - List the physiologic factors that determine the apparent Vd
7. Integrate clearance and distribution concept.
8. Perform compartmental modeling.
   - Mathematically set up and derive the concentration-time relationship for various multi-compartment models
   - Calculate macro and micro constants and determine the rate constant, t1/2, CL, Vc, Vss, Vf from concentration-time data
9. Perform System (Non-compartmental) Analysis
   - Determine CL, MRT and Vss using system analysis
   - Define the relationship between AUMC and AUC and the intrinsic drug MRT for IV bolus, IV infusion and oral dose
10. Understand the role of transporters
    - Describe how transporters affect absorption and how transporters are induced and inhibited
11. Understand bioavailability and bioequivalence
    - Describe absolute and relative bioavailability and the essential requirements and means of assessing bioequivalence
12. Identify dose and time dependent kinetics
    - List the possible sources of dose or time dependency
    - Identify the pharmacokinetic parameters affected by dose and time dependent kinetics
    - Predict pharmacokinetic consequences of dose and time dependent changes
13. Recognize various factors that influence pharmacokinetics and drug dosing
14. Understand the kinetics of metabolites and macromolecules
    - Derive plasma metabolite concentration-time relationship following and IV dose of parent drug
    - Distinguish between formation and elimination rate limited kinetics
    - Determine the PK parameters of both parent drug and metabolite from urinary excretion and plasma data
    - Describe the various factors affecting macromolecular absorption, bioavailability and half-life
15. Scale pharmacokinetic data using in vitro and in vivo animal data
    - Describe the physiological basis for allometric scaling
    - Estimate PK parameters using allometric scaling and other methods
16. Utilize WinNonlin or other software to analyze PK parameters
    - Perform compartmental and non-compartmental analysis using WinNonlin or other software
17. Understand direct and empirical pharmacodynamic models
    - Define and explain clockwise hysteresis in the concentration versus effect curve
    - Define and understand linear, Emax, and sigmoidal Emax pharmacodynamic models
18. Define and understand the four major kinetic components of pharmacodynamics
    - Define and understand the difference between effect site, biosensing, biosignaling, and transduction kinetics.
19. Define and understand the behavior of the four major indirect models
**Pharmacokinetics (33)*:**

- LaPlace transforms (1)
- Compartmental modeling (2)
- Non-compartmental analysis (2)
- IV bolus kinetics (3)
- Zero and first order input process (3)
- Clearance and distribution concept (3)
- Kinetics of metabolites and macromolecules (3)
- Bioavailability and bioequivalence (3)
- Transporters (1)
- Multiple dose regimen (3)
- PK variability (3)
- Application of PK in clinical situations (1)
- In vivo predictions using scale up models (2)
- Introduction to WinNonlin or other PK software (3)

**Pharmacodynamics (6)**

- Empirical and direct pharmacodynamic models (2)
- Four major kinetic areas of pharmacodynamics (1)
- Indirect pharmacodynamic models (2)
- Time and state-varying, complex pharmacodynamics: drug tolerance, induction, delayed onset of action, chronopharmacodynamics (1)

*Numbers in parentheses indicate approximate lecture hour equivalence for each topic.*