

Kingdom of Saudi Arabia

**The National Commission for Academic Accreditation &
Assessment**

COURSE SPECIFICATION

PHT 436

Pharmaceutical Quality Control and GMP

Revised March 2007

Course Specification

*For Guidance on the completion of this template, please refer to of Handbook 2
Internal Quality Assurance Arrangements*

Institution	King Saud University
College/Department :	Pharmacy/ Pharmaceuticals

A Course Identification and General Information

1. Course title and code:	(Pharmaceutical quality control and GMP) PHT 436
2. Credit hours (2 + 1)	
3. Program(s) in which the course is offered. (If general elective available in many programs indicate this rather than list programs)	B. Pharmacy
4. Name of faculty member responsible for the course;	Prof. Mohammad Al-Mishaal, Dr. Ibrahim Al-Juffali, Samar Afifi and Kadria Khoudri
5. Level/year at which this course is offered	10 / Second
6. Pre-requisites for this course (if any)	PHT 414
7. Co-requisites for this course (if any)	NA.....
8. Location if not on main campus	Malaz and Derreiyah
9. Course Language :	English

B Objectives

1. Summary of the main learning outcomes for students enrolled in the course.

The students will learn more about definition of good quality drug products, GMP regulations regarding product manufacturing, processing, packaging and holding. The student will also learn the various methods for evaluation of pharmaceutical dosage forms according to BP or USP.

2. Briefly describe any plans for developing and improving the course that are being implemented. (eg increased use of IT or web based reference material, changes in content as a result of new research in the field)

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C. Course Description (Note: General description in the form to be used for the Bulletin or Handbook should be attached)

LECTURES' OUTLINE :

Week	Lecture number	Topic
1	1	Introduction to drug product quality.
	2	Quality control of raw materials. In process control .
2	3	Cont.
	4	Application of statistics to analysis of data.
3	5	Cont.
	6	Stability and expiration dating.
4	7	QC of parenteral products.
	8	QC of ointments and creams.
5	9	QC of Suppositories.
	10	QC of suspensions and emulsions.
6	11	Concept of GMP
	12	Building facilities.
7	13	Cont.
	14	Personnel and equipment.
8	15	Packing and labeling control
	16	Storage and distribution
9	17	Validation .
	18	Complaint and recall.
		2 Exams

LABORATORY PROJECTS' OUTLINE :

Week	Topic	Description
1	Quality control of uncoated and enteric coated tablets.	QC according to B.P. and USP : Hardness- Friability- Uniformity of dosage units.
2	Cont.	QC of uncoated tablets according to BP and USP : Disintegration and dissolution tests.
3	Capsules	QC of capsules according to BP and USP
4	Suppositories	QC of suppositories according to BP
5	Parenterals	QC of containers
6	Cont.	Sterility testing- Pyrogen test- microbial examination of water- Particulate matter test.
7	Cont.	QC test for NaCl and Ascorbic acid injections.
8	Topical preparations.	QC of topical preparations according to BP and USP
9-10	Final exam.	

3. Additional private study/learning hours expected for students per week. (This should be an average :for the semester not a specific requirement in each week)

Part-4. Development of Learning Outcomes in Domains of Learning.

For each of the domains of learning shown below indicate:

- A brief summary of the knowledge or skill the course is intended to develop;
- A description of the teaching strategies to be used in the course to develop that knowledge or skill;
- The methods of student assessment to be used in the course to evaluate learning outcomes in the domain concerned.

LO	Teaching methods	Assessment methods
Knowledge skills <ul style="list-style-type: none"> • Knowledge about regulation behind product manufacturing, processing and packing of pharmaceuticals. • Knowledge how to conduct stability studies for pharmaceuticals. • Knowledge of how to evaluate the dosage forms according the BP or USP standards. • Knowledge of how to analyse and interpret the obtained results in the lab. • Knowledge of the necessary statistics to analyse the results. 	<ul style="list-style-type: none"> • Via theoretical” lectures” and practical approaches. • Reports, homework and use of IT e.g. power point for presentation. 	<ul style="list-style-type: none"> • Written mid-terms, final exams, and practical exams. • Verbal discussions, and power point presentation. • Evaluation of home assignments. • Solve problems
Cognitive skills <ul style="list-style-type: none"> • Critical thinking. • Interpretation of results. • Problem solving. 	<ul style="list-style-type: none"> • Conducting group discussion. • Asking question in lectures and expecting an answer in return. • Discussion of student's reports. 	<ul style="list-style-type: none"> • Student way of thinking and analysing of results in lab will be monitored. • Reports will be presented and will be evaluated accordingly. • Presentation of selective topics using power point.

<p>Interpersonal skills and responsibilities</p> <ul style="list-style-type: none"> • Communication with instructors, tutors, staff. • Communication with different personalities and attitudes. • The student should be engaged in higher responsibilities 	<ul style="list-style-type: none"> • Students will be trained on simulating situations. • Oral exams will be made. • Group discussion will be needed. • Group projects will be carried out 	<ul style="list-style-type: none"> • Monitoring of students' attitudes in lectures and labs. • Participation of students in the community activities. • Assessment of home assignments and reports. • Evaluation of the group projects. • Monitoring the action/ reaction of students when entitled to higher responsibilities.
<p>Communication, Information Technology and Numerical Skills.</p> <ul style="list-style-type: none"> • 1. Search utilizing internet to cope with course demand. • 2. Follow the update knowledge concerning the course demand. • 3. Presentation using power point. • 4. Self learning. 	<ul style="list-style-type: none"> • Training on different software and special programs related to the course e.g. Excel, Word. • Students will be asked to present a research project utilizing the I.T. showing the latest information about certain topics. 	<ul style="list-style-type: none"> • Evaluation of the extent of comprehension of students in problem solvation. • Assessment of home assignments. • The positive role of the student in group projects. <p>The effective participation of the student in the activities of his society.</p>
<p>Psychomotor Skills (if applicable)</p> <ul style="list-style-type: none"> • Alertness of the student during presence in labs. • Good management of the students in labs. • Performance of proper treatment under stressful circumstances. • Level of performance required should meet the international standards 	<ul style="list-style-type: none"> • The student should perform a practical demonstration • In front of others "colleagues and staff". • Motivation and encouragement from the staff. • Audio visual demonstration of different pharmaceutical situations. <p>4. Punctuality</p>	<ul style="list-style-type: none"> • Practical exams. • Oral exams. • Close supervision of the student during labs. • Evaluation of students for different assignments.

5. Schedule of Assessment Tasks for Students During the Semester			
Assessment	Assessment task (eg. essay, test, group project, examination etc.)	Week due	Proportion of Final Assessment
1	Home work	3	3
2	Midterm I	6	17
3			
4	Midterm II	12	20
5	Practical exam	14	20
6	Final exam	15	40
Total			100

D. Student Support

1. Arrangements for availability of faculty for individual student consultations and academic advice. (include amount of time faculty are available each week)

The staff members who teach the course, provide the students with 10 specific academic hours per week. In addition to availability of the web site.

E Learning Resources

1. Required Text(s)
2. Essential References
3- Recommended Books and Reference Material (Journals, Reports, etc) (Attach List)
1. Good manufacturing practices regulations.
2. The theory and practice of industrial pharmacy.

<p>3. Pharmacy practice .</p> <p>4. BP / USP.</p>
<p>4. Electronic Materials, Web Sites etc</p> <p>www.sciencedirect.com</p> <p>www.pubmed.com</p>
<p>5- Other learning material such as computer-based programs/CD, professional standards/regulations</p> <p>CD for British Pharmacopeia (B.P.), and United States Pharmacopeia (U.S.P). British Pharmaceutical Codex (B.P.C). Martindale(extra pharmacopeia).</p>

F. Facilities Required

<p>Indicate requirements for the course including size of classrooms and laboratories (ie number of seats in classrooms and laboratories, extent of computer access etc.)</p>
<p>1. Accommodation (Lecture rooms, laboratories, etc.)</p> <p>The classrooms can accommodate up to 60 students. Labs can accommodate up to 40 students.</p>
<p>2. Computing resources</p> <p>The students have an access to computer room available at the campus.</p>
<p>3. Other resources (specify --eg. If specific laboratory equipment is required, list requirements or attach list)</p> <p>Balances, Hardness tester, Disintegration tester, Dissolution apparatus, Viscometer, UV spectrophotometer.</p>

G Course Evaluation and Improvement Processes

<p>1 Strategies for Obtaining Student Feedback on Effectiveness of Teaching</p> <p>Questionnaire is given to students to be filled about course content and teaching Procedures.</p> <ul style="list-style-type: none"> -Evaluation of standards of the students in the quizzes, midterms, final exams, and home assignments, reports, and presentations.
<p>2 Other Strategies for Evaluation of Teaching by the Instructor or by the Department</p> <ul style="list-style-type: none"> - Discussion of the model answer of the written exams- quizzes& midterms- with the students to review their answers. - listening to students' complaints
<p>3 Processes for Improvement of Teaching</p> <ul style="list-style-type: none"> -
<p>4. Processes for Verifying Standards of Student Achievement (eg. check marking by an independent faculty member of a sample of student work, periodic exchange and remarking of a sample of assignments with a faculty member in another institution)</p> <p>Check marking of a sample of student work by the demonstrators and lecturers working in the same course.</p>
<p>5 Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.</p> <ul style="list-style-type: none"> -