UNIVERSITY SCHOOL OF PHARMACEUTICAL SCIENCES
V.P.O. Sahauran, Tehsil Kharar, Distt. Mohali PIN – 140104 Punjab INDIA

From Dean Desk

Dear students,

Congratulations for being promoted in the next semester and to be '*Proud Student*' of University School of Pharmaceutical Sciences

It gives me immense pleasure to extend my warm welcome to University School of Pharmaceutical Sciences for the even semester of academic session 2015-16. USPS is one of the front runner in developing pharmaceutical education and technology with skills, attitudes and knowledge through four years Bachelor of Pharmacy (B. Pharm) program and two years of Masters of Pharmacy (M. Pharmacy) program. . The academic environment is aesthetic and oriented toward knowledge acquisition.

You owe a responsibility towards nation, your career and pharmaceutical profession. The hard work, sincerity, dedication and reading - writing composure shall make your learning with us enjoyable and rewarding in every sense. I assure that the accumulation of pharmaceutical based knowledge shall stand by you throughout your career and also for your personality and a better citizen of our nation.

We have a team of exceptionally brilliant and qualified faculty. Each member of the team is expert in his/her discipline and full of a enthusiasm to share knowledge with you. Their positive, dynamic, focused, cooperative and result oriented attitude is our main asset. The more you demand the more they shall deliver. We in the Institute contribute to the idea that learning is an unending process. While we teach we also learn, and many a times from our own students. Every increment in our knowledge / learning is matter of pride and joy for us.

In our institute, 100% attendance is compulsory and 25% can be relaxed in case of medical emergency or other reasons. Evaluation plan includes two mid term examination (30 marks each), end term examination (80 marks) and continuous assessment by teacher (60 marks). Teacher's continuous Assessment is calculated on the basis of 8 assignments/subject (20 marks), 2quizzies or class-tests/subject (10 marks), 1 extempore/subject (10 marks), 1 project/subject (10 marks) and 1 seminar/syndicate/subject (10 marks).

I expect you a role model for all students of the campus in discipline, behavior, personal conduct, dress habits, attendance etc. They should look at you with awe and inspiration to emulate you. This should be your first planned and organized step towards long and strenuous journey to effective leader in the field of Pharmaceutical profession.

I shall be regularly interacting with you and look forward to mutually beneficial intellectual discourse, may be bouts!

I once again, welcome you back to the Institute and wish you highly rewarding and enjoyable stay with us.

Prof. S. L. Harikumar

Dean, USPS, RBU

UNIVERSITY SCHOOL OF PHARMACEUTICAL SCIENCES

STUDY SCHEME

M.PHARM 2nd SEMESTER

S. No	Subject code	Subject Name	L	T	P	Credits	Teacher Name
1	PS6201	Core-II: Pharmaceutical Formulation & Development	4	0	0	4	Dr. Geeta Aggarwal
2	PS6202	Core-III: Quality Control & Quality Assurance of Pharmaceuticals	4	0	0	4	Ms. Nirmala
3	PS6203	Research Methodology & Biostatistics	4	0	0	4	Dr. Shoaib Ahmad
4	PS6204	Elective **–II** **Safety Pharmacology**	4	0	0	4	Ms. Ashish Kumari
5	PS6205	Pharmaceutics Lab-II	0	0	6	3	
6	PS6206	Seminar-II	0	0	0	2	
Total			**16**	**0**	**6**	**21**	

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EVALUATION PROCESS

- Each subject has Theory and Practical exam of 200 marks and 100 marks respectively
- Out of this 200, Sixty Marks (60) have been assigned to mid term examination (30 each), end term examination (80 marks) and continuous assessment by teacher (60 marks).
- The practical assessment includes continuous assessment by teacher of 50 marks and end term examination of 50 marks. Continuous evaluation includes viva, practical record and daily performance during practicals.

Examination Pattern for Theory

Component	**Frequency**	**Marks***
1st Term	1 time	30
2nd Term	1 time	30
End Term	1 time	80
Continuous Assessment*	Throughout the Semester	60
Total		200

Scheme for evaluation of Continuous Evaluation for theory

Component	**Frequency***	**Marks***
Assignments	8 Nos.	30
Student Seminar (syndicate)	1/student	10
Extempore/Presentation	1/student	10
Quiz/surprise test	2 times	10
Total		60

Important:

- Every student has to submit 8 assignments per subject i.e. 4 subjectsX8=32 assignment at the end of semester
- Every student has to present 10 min extempore per subject i.e. 4 subjectsX10min =40 mint extempore during the whole semester
- For the seminars, every syndicate has to give one seminar per subject i.e. 4 seminars during the semester (approximately one/student).
- All students have to give 2 quizzies or class test per subject i.e. 12 quizzies or class tests per semester

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Rayat Bahra University (RBU), Mohali
(Academic Calendar (2016) (Even Semester Jan-Jun 2016)

S. No.	Description	Period
1.	Registration – B.Pharm 2nd & 4th Sem, M Pharm 2nd Sem	Jan 27, 2016
2.	Late Registration with fine of Rs.1000/-	Feb 3, 2016
3.	Orientation - B.Pharm 2nd & 4th Sem, M Pharm 2nd Sem	Jan 28-29, 2016
4.	**Commencement of Classes** - B.Pharm, M Pharm 2nd Sem	Feb 1, 2016
5.	Guest Lecture- Industry	Feb 15-Feb 19, 2016
6.	1st Assignment Submission	Feb16, 2016
7.	Group Discussion	Feb18, 2016
8.	Competition (Fun with colors)	Feb 19, 2016
9.	**Holiday (Ravidas Jayanthi)**	Feb 22, 2016
10.	**NSS/Club Activity/ Community Service**	Feb 01-Mar 31, 2016
11.	Guest Lecture –Institute (B.Pharm, MPharm)	Feb 22-26, 2016
12.	2nd Assignment Submission	Feb 29, 2016
13.	Competition (Taste & Tell)	Mar 01, 2016
14.	Annual Day celebrations	Mar 04, 2016
15.	**1st MST**	**March 07-11, 2016**
16.	Guest Lecture- Industry (B.Pharm, MPharm)	Mar 14-Mar 18, 2016
17.	Evaluation of books and to be shown to students	March 15, 2016
18.	3rd Assignment Submission	March 21, 2016
19.	Guest Lecture –Institute (B.Pharm, M Pharm)	March 21-25, 2016
20.	Industrial Trip (B.Pharm, M Pharm 2nd Sem)	Feb 01-Mar 31, 2016
21.	Evaluation Meeting for Academic Activities (Attendance, Syllabus Covered, Test	March 16 – March 17, 2016
22.	4th Assignment Submission	March31, 2016
23.	**Sports Meet**	**March18, 2016**
24.	Poster making competition	Mar 21, 2016
25.	**Holiday (Holi)**	Mar 23, 2016
26.	Best out of waste competition	Mar 26, 2016
27.	5th Assignment Submission	April 11, 2016
28.	**Holiday (Ambedkar Jayanti)**	April 14, 2016
29.	**2nd MST**	**April 18-22, 2016**
30.	Competition (Taste & Tell)	April 21, 2016
31.	Evaluation of books and to be shown to students	April 25, 2016
32.	Guest Lecture- Industry (B.Pharm, MPharm)	April 25-29, 2016
33.	Guest Lecture-Institute (B.Pharm, MPharm)	April 26-29, 2016
34.	6th Assignment Submission	April 25, 2016
35.	Evaluation Meeting for Academic Activities (Attendance, Syllabus Covered, Test	April 27-29, 2016
36.	Guest Lecture-Institute (B.Pharm, MPharm)	April 28, 2016
37.	7th Assignment Submission	May 2, 2016
38.	8th Assignment Submission	May16, 2016
39.	Last Day of Teaching	May 31, 2016
40.	End term. Practical Exams	June 6-8, 2016
41.	End term. Exams	June 13-24, 2016
42.	Evaluation of books and to be shown to students	June 28,2016
43.	Finalizing of Grades Meeting	June 30, 2016
44.	Declaration of Results	July 5, 2016
45.	Institutional/ Industrial Training	June 25-July24, 2016
46.	Summer Break	June 25-July 24, 2016

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TEACHING LEARNING EVALUATION PLAN

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TEACHING LEARNING EVALUATION PLAN

Course	Sub Code	Sub Name	L	T	P	C
M. Pharmacy (Pharmaceutics) (2nd Sem)	PS6201	Core-II: Pharmaceutical Formulation & Development	**4**	**0**	**0**	**4**
Name of Subject Teacher	**Dr. Geeta Aggarwal**					

Course Objectives:
Complete understanding of manufacturing equipment for various pharmaceutical dosage forms, material handling procedure in industry, Quality assurance procedures and packaging procedure and regulatory aspects.

Course Learning Outcome:

- Student able to demonstrate processes, procedures and manufacturing equipment for various pharmaceutical dosage forms.
- They will be able to apply knowledge of Pharmaceutical Formulation & development in industry
- Students aware of improved production technology procedures and regulatory aspects of production.

A. Teaching Learning Plan:

Note: **A**- Assignment, **E**-Extempore, **Q**- Quiz**, S**- Student Seminar, **T-Test**

S. No	Topic/Module/Unit	No. of Class	Pedagogy	Unit Objectives	Unit Learning Outcome	No. of				
						A	E	Q	S	T
1	Formulation and development of tablets	12	Interactive lecture, demo, presentation	To understand tablet manufacturing and coating technique along with improvement of tablet for betterment of industry.	Students able to demonstarte tablets manufacturing, equipment, material handling procedure followed in industry, Quality assurance procedure for improved tablet production, film coating and their problems, different layout followed in industry.	8	3	1	2	1
2	Formulation and development of capsules	10	lecture, Discussion	Various principles and general consideration regarding capsules manufacturing and their evaluation parameters	Complete understanding of capsule manufacturing, equipments used in industry,	6	2	1	2	2
3	Spheronization	6	Interactive lecture, demo, presentation,project	To understand extrusion spheronization processing, equipment used for the process and evaluation technique and recent packaging development	Complete understanding of pellets manufacturing, by spheronization equipment, material handling procedure in industry and Quality control procedures.	4	2	0	1	1
4	Formulation and development of liquids	10	Interactive lecture, demo, presentation,project	To understand liquid (solution, suspension, emulsion) manufacturing and fluid flow technique along with improvement of liquid manufacturing for betterment of industry.	Students able to participate in liquid manufacturing, by various methods and understanding of working of equipments and problems of liquid dosage forms.	6	2	1	2	2
5	Formulation and	4	Interactive	To understand	Complete understanding of	4	1	0	2	2

	development of semisolids		lecture, demo, presentation,project	semisolid preparation manufacturing and various base used for their formulation technique along with improvement in their manufacturing procedures.	semisolid manufacturing by various methods and usage of equipments and material handling procedure during production.					
6	Quality Assuarance	8	Interactive lecture, presentation,project	To understand quality assurance procedure for manufacturing and validation methods for Quality audits.	Students will be aware about various quality assurance procedures for manufacturing of various formulations and validation procedures.	2	1	0	1	2
7	Packaging developments	10	Interactive lecture, demo, presentation, project	To know about FDA regulation for packaging, child resistant packaging and child resistant packaging.	Students will be able to demonstrate packaging procedures and various packaging materials used for packaging of Pharmaceuticals.	2	1	0	2	2

References:

1. **Reference Books:**

a. Pharmaceutical dosage forms Lachman et al.,: Tablets, volume I,II,III

b. Pharmaceutical dosage forms Lachman et al. : Parenterals, volume I,II

c. Remington, Science and practice of Pharmacy, Vol.1, 2000, Lippincot williams and wilkins.

d. J.T. Carstensen, Drug Stability: Principles and Practices, Marcel Dekker, N.Y.

2. Text Books:

a. N.K. Jain , Pharmaceutical product development. CBS publication and distributors, New Delhi.

b. G.S. Banker and C.T.Rhodes, Modern Pharmaceutics, IInd edition , Marcel Dekker, INC, NewYork.

c. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.

RAYAT-BAHRA UNIVERSITY

UNIVERSITY SCHOOL OF PHARMACEUTICAL SCIENCES

TEACHING LEARNING EVALUATION PLAN

Course	Sub Code	Sub Name	L	T	P	C
M. Pharmacy (Pharmaceutics) (2nd Sem)	PS6202	Quality Control & Assurance of Pharmaceuticals	**4**	**0**	**0**	**4**
Name of Subject Teacher	**Ms. Nirmala**					

Course Objectives:

- To understand the importance of QA and QC in order to supplies better quality goods and renders service to-the consumers.
- To understand that quality control has become major consideration before establishing an industrial undertaking. Proper quality control ensures most effective utilization of available resources and reduction in cost of production.

Course Learning Outcome: ●The QA/QC process make students enable in a reassessment of inventory.
● Students can rectify the situation, If data quality is found to be lower than previously thought.

A. Teaching Learning Plan:

Note: **A**- Assignment, **S**- Student Seminar, **P**- Presentation

S.No	Topic/Module/Unit	No. of Class	Pedagogy	Unit Objectives	Unit Learning Outcome			
						A	S	P
1	Quality control and Assurance technique: Basis concepts of Quality: - Developing quality culture.	2	Blackboard,chalk, Seminar, Interactive lecture	To contributes the objectives of good practice guidance, namely to improve transparency, consistency, comparability, completeness, and confidence.	Students able to understand the importance of quality evaluation throughout the process „	1	2	
2	Quality Assurance General Concepts: Definition of quality assurance concept and components of Q. A., Good Manufacturing Practices	5	Blackboard,chalk, Interactive lecture	To understand the importance of GMP in preparation of pharmaceutical products	Students able to followed GMP practice and assure that the drug product has been manufactured following GMP, and it contains necessary ingredients in correct proportion	1	2	
3	Personnel, Premises and Equipments: Qualification, experience, training responsibilities and hygiene of personnel. Drainage system, Sewage, Sanitation,	6	Seminar, Interactive lecture	To understand the need of qualify person and training To understand the need of well equipped building and its maintenance.	Students know various ways of training and promotion in pharmaceutical industry Students able	1	2	

	Lighting, maintenance of building and premises; Design, size, location, construction, cleaning and maintenance of equipments. Documents and formats related to personnel, premises and equipment.				to establish a well equipped pharmaceutical industry.			
4	Material Management: Purchasing, Raw material, packaging materials, Intermediate and Bulks products, Finished products, Rejected and recovered materials, recalled products, returned gods, Reagents and culture media, Waste materials, reference standards, Miscellaneous material. Documents and formats.	6	Blackboard,chalk, Seminar, Interactive lecture	To understand the various steps involved in production of pharmaceutical. To understand how documents of different steps are prepared.	Students able to play important role in **enhancement of firm's goodwill by** producing quality material	2	2	
5	Manufacturing operations and control: Revised schedule M, sanitation of manufacturing premises, Mix –ups and cross contamination, processing of intermediates and Bulk product, Packaging operations, I.P.Q.C., Release of finished products process deviations, Drug product inspection, expiration dating, Document and formats.	5	Blackboard,chalk, Seminar, Interactive lecture	To aware the students about schedule M and chances of contamination	Students able to follow the guidelines of schedule M and release finished product of required qulity	2	2	
6	Documents and Records: Specification, Master production and control record, Batch production and control record, Significance of SOPs and record, change control, Drug	4	Seminar, Interactive lecture	To understand the method to prepare documents and record of all activities involved in production of pharmaceutical product	Able to prepare record of master production , batch production and drug master file	1	1	

	Master file, Documents and formats.							
7	Quality control of Biological products: International Biological standards, safety testing of pharmaceutical Quality control of antibiotics.	5	Seminar, Interactive lecture	To understand the need of quality control in biological products	Able to prepare biological product of good quality by following international biological standards	1	1	
8	Pharmaceutical Plant Audit: Department wise documents and audit questionnaire.	4	Blackboard,chalk, Seminar, Interactive lecture	To understand the need of audit	Able to do plant audit and preparation of document	1	1	
9	Sterile Pharmaceutical Products: GMP aspects related to sterile products- General guidelines, personnel, building and premises, equipment, sanitation, processing, sterilization, Quality control and validation, Documentation	5	Seminar, Interactive lecture	To understand the need of GMP in sterile pharmaceutical product	Able to prepare sterile pharmaceutical product by following guidelines of GMP and establishing a well equipped building	2	1	

Reference books:

1. Pharmaceutical Quality Assurance, MA Potdar, Nirali Prakashan, Pune
2. Validation of Pharmaceutical process, F. J. Carleton and J. Agalloco, Marcel Dekker Inc.
3. Pharmaceutical Process Validation, Second Ed., Ira R. Ferry & Robert Nash, Marcel Dekker Inc.
4. Quality Planning & Analysis by J. M. Juran and F. M. Gryna, Tata Mcgraw Hill, India.
5. Improving Quality through Planned experimentation by Moen, Tata Mcgraw Hill.

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TEACHING LEARNING EVALUATION PLAN

Course	Sub Code	Sub Name	L	T	P	C
M. Pharmacy (Pharmaceutics) (2nd Sem)	PS6203	**Research Methodology & Biostatistics**	**4**	**0**	**0**	**4**
Name of Subject Teacher	**Dr. Shoaib Ahmad**					

* Research methodology

Sub code	Subject Name	L	T	P	C
PS6203	Research Methodology	2	0	0	2

* Biostatistics by

Sub code	Subject Name	L	T	P	C
PS6203	Biostatistics	2	0	0	2

Course Objectives:

1. To understand meaning and objective of research.
2. To have knowledge of literature survey process.
3. To explore abstracting services.
4. To explore scientific documentation services.
5. To be able to prepare an article for journal publication.
6. To improve presentation skills.
7. To learn project management techniques.
8. To create awareness of funding sources.

Course Learning Outcome:

1. Ability to prepare a research proposal.
2. Ability to identify abstracting services.
3. Ability to access offline and online literature sources.
4. Ability to retrieve and compile meaningful information
5. Ability to write a journal paper.
6. Ability to give a presentation.
7. Ability to manage economy in project planning and execution.
8. Ability to seek funding from identified agencies under various schemes.

A. Teaching Learning Plan: Research Methodology

Note: **A**- Assignment, **E**-Extempore, **Q**- Quiz**, S**- Student Seminar, **P**- Project

S.No	Topic/Module/Unit	No. of Class	Pedagogy	Unit Objectives	Unit Learning Outcome	No. of				
						A	E	Q	S	P *
1.	Research	3	Lecture, Discussion	To understand meaning and objective of research.	Ability to prepare a research proposal.		1			
2.	Literature survey and documentation	4	Lecture, Discussion, Demo	To have knowledge of literature survey process. To explore abstracting services. To explore scientific documentation services.	Ability to identify abstracting services. Ability to access offline and online literature sources. Ability to retrieve and compile meaningful information	1	2		1	
3.	Technical writing	5	Lecture,	To be able to prepare an article for journal	Ability to write a journal paper.	1	1		1	

			Discussion, Writing Assignment	publication.						
4.	Presentation	4	Lecture, Discussion, Presentation	To improve presentation skills.	Ability to give a presentation.	1	1		1	
5.	Project [cost] management	4	Lecture & Discussion	To learn project management techniques.	Ability to manage economy in project planning and execution.		1			
6.	Research organizations and procurement of research grants	8	Discussion	To create awareness of funding sources.	Ability to seek funding from identified agencies under various schemes.	1	1	1	1	

* Two manuscripts will be prepared for journal submission as project.

Reference:

1. Text Books:
    1. Research methodology: Methods and Techniques by C. R. Kothari, second edition.
2. Reference books:
    1. Research In Education- John V. Best, John V. Kahn 10thedition
    2. Presentation skills - Michael Hallon- Indian Society for Institute education
    3. Thesis projects in Science & Engineering – Richard M. Davis.
    4. Thesis & Assignment – Jonathan Anderson
    5. Writing a technical paper- Donald Menzel
    6. Protection of industrial Property rights- P. Das & Gokul Das
    7. Preparation for publication – King Edward Hospital Fund for London
    8. Manual for evaluation of industrial projects-United Nations
    9. Manual for the preparation of industrial feasibility studies
    10. Pharmaceutical Statistics: Practical and Clinical Applications by Sanford Bolton and Charles Bon, fourth edition.
    11. Research methodology: Methods and Techniques by C. R. Kothari, second edition
    12. Research in Education by john W. Best and James V. Kahn, 11th edition
    13. Instruction to Authors of journals.

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TEACHING LEARNING EVALUATION PLAN

Course	Sub Code	Sub Name	L	T	P	C
M. Pharmacy (Pharmaceutics) (2nd Sem)	PS6204	Elective II- Safety Pharmacology	**4**	**0**	**0**	**4**
Name of Subject Teacher	**Ms. Ashish Kumari**					

Course Objectives:

- To make students well verse with subject matter related to Safety Pharmacology.
- To make students learn about broad range of drugs safety from early preclinical testing, risk/benefit assessment and clinical adverse event signal detection.

Course Learning Outcome:

- Students will have ability to understand the role of drug safety in the successful development and usage of a medicine to the benefit of patients.
- Student should be able to gain the knowledge about techniques and methodologies used in drug safety evaluation and even the withdrawal of drugs from market after launch.
- Students can interprets the literature relating to drug research and usage.

A. Teaching Learning Plan:

Note: **A**- Assignment, **E**-Extempore, **Q**- Quiz**, S**- Student Seminar, **P**- Project

S NO:	Unit (Topic)	No.of Class	Pedagogy	Unit Objectives	Unit wise Expected learning Outcome	Number of				
						A	E	Q	S	P
1	Definition and scope of safety pharmacology and basic principles of toxicology	6	Lectures(4) Discussion(1) Seminar (1)	To impart knowledge of expected and unexpected pharmacological effects of the test material on the parameters associated with desired clinical activity.	Students will have ability to understood the concept of safety pharmacology and general principles and recommendations for its evaluation.	1	-	1	1	1
2	Principals and study design of safety evaluation: Repeated dose studies (sub-acute and chronic), Analysis of safety pharmacological data	4	Lecture (3) Discussion (1)	To make students well verse with the determination of toxicity after repeated administration of the test material. To impart knowledge to establish doses for sub-acute and chronic studies.	Students will be able to understand the selection of doses for repeated dose toxicity tests. Students will be able to determine the median lethal dose (LD50) and maximum tolerated dose after single administration through one or more routes.	1	-	1	-	1
3	Preclinical safety	7	Lecture (4)	To give	Student should	1	1	1	1	-

	pharmacology: In vitro and in vivo studies including genotoxicity, mutagenicity, carcinogenicity, reproductive and ocular toxicity, Safety testing for dermatological product		Seminar (1) Discussion (1) Presentations(1)	exposure to students about the various tests involved in studying Preclinical safety pharmacology. To make students well verse with molecular and cellular basis of toxic reactions.	be able to describe the integration of preclinical testing into the overall drug development plan.					
4	Clinical Safety pharmacology: Definition, data collection, reporting methods and assessment and analysis of adverse event (AE) monitoring during clinical trials	5	Lecture(3) Presentation (1) Quiz (1)	To acustomize students about the knowledge of adverse events during clinical trials.	The students will be able to discuss the collection, evaluation and reporting adverse event data in clinical trials.	1	-	1	1	1
5	Clinical Evaluation: Clinical evaluation of antihypertensive agents, antianginal agents, antiepileptics, antidepressants, antipsychotics, antiparkinsonian agents, drugs used in Alzheimer's disease, antiulcer agents, and antidiabetics.	14	Lecture (9) Seminar (2) Disscusion (1) Presentation (2)	For students to have better understanding of different methods used in clinical evaluation and drug therapy of antihypertensive agents, antianginal agents, antiepileptics, antidepressants, antipsychotics, antiparkinsonian agents.	Student should be able to gain the knowledge of diagnosis of different disorders and the drug therapy for that.	1	1	1	1	1
6	Pharmacovigilance: Definition, scope and aims of pharmacovigilance, Adverse drug reactions-Classification, mechanism, predisposing factors and causality assessment, Role of clinical pharmacist in reporting, evaluation, monitoring, prevention and management of ADRs.	8	Lecture (6) Seminar (1) Guest lecture (1)	To impart the knowledge of Pharmacovigilance aspects of medicines regulation throughout the life cycle of medicines.	The students should be able to describe safety reporting requirement (according to the type of adverse event/reaction) pre- and post-approval. Explain the role of pharmacovigilance in monitoring of drugs in non-clinical research and in market place	1	-	1	1	1
7	Risk-benefit assessment:	6	Lecture (4) Seminar (1)	To a customize students about	The students should be able	1	-	1	1	1

	Definition, collection of data, reporting, assessment of Post marketing surveillance, periodic safety update reports, Risk-benefit assessment		Quiz (1)	the knowledge of Post marketing surveillance and Risk-benefit assessment.	to demonstrate the sources of safety data: methods for collection, analysis, interpretation and reporting drug safety data including the choice of the most appropriate study design.					
8	Regulatory requirements for the new drug safety assessment: Important guidelines such as ICH, OECD, USFDA, EMEA, Japan MHW	6	Lecture (3) Seminar(1) Discussion (1) Guest lecture (1)	To introduce about the impact of medicines legislative requirements on regulatory activities. And explain the role of international bodies in medicines regulation.	Student will be able to understand the general principles of medicines regulations.	1	1	1	1	1

References:

Recommended Books:

1. Sogliero-Gilbert, G., Drug safety assessment in clinical trials. Statistics, textbooks and monographs, New York: Dekker.
2. Marx, U. and V. Sandig, Drug testing in vitro : breakthroughs and trends in cell culture technology, Weinheim: Wiley-VCH.
3. Turner, J.R., New drug development : design, methodology, and analysis, Hoboken, N.J.: Wiley-Interscience.
4. Dmitrienko, A., C. Chuang-Stein, and R.B. D'Agostino, Pharmaceutical statistics using SAS : a practical guide, Cary, N.C.: SAS Institute.
5. Smith, C.G. and J. O'Donnell, The process of new drug discovery and Development., New York: Informa Healthcare.
6. Bénichou, C., Adverse drug reactions : a practical guide to diagnosis and management, Chichester, West Sussex, England; New York: Wiley.
7. Mann, R.D. and E.B. Andrews, Pharmacovigilance, Chichester, England ; Hoboken, NJ: John Wiley & Sons.
8. Cobert, B.L., Manual of drug safety and pharmacovigilance, Sudbury, Mass.:Jones and Bartlett Publishers.