

“KAR BHALA HOGA BHALA”



KADI SARVA VISHWAVIDYALAYA, GANDHINAGAR

(Established vide Gujarat State Government Act 21 of 2007 and approved by UGC (ref F.9-18/2008(cpp-1) March 19, 2009)

ACADEMIC REGULATIONS

PHARM. D (DOCTOR OF PHARMACY)



K. B. INSTITUTE OF PHARMACEUTICAL EDUCATION & RESEARCH

GH-6, SECTOR-23, KADI CAMPUS, GANDHINAGAR-382023.

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भारत का राजपत्र The Gazette of India

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
(Separate paging is given to this Part in order that it may be filed as a separate compilation)

भाग III—खण्ड 4

[PART III—SECTION 4]

[सांविधिक निकायों द्वारा जारी की गई विविध अधिसूचनाएं जिसमें कि आदेश, विज्ञापन और सूचनाएं सम्मिलित हैं]
[Miscellaneous Notifications including Notifications, Orders, Advertisements and Notices issued by
Statutory Bodies]

भारतीय रिज़र्व बैंक

मुंबई-400001, दिनांक 9 अप्रैल 2008

सदर्भ : बैंपविवि. सं. आईबीडी.-14241/23.13.048/2007-08--भारतीय रिज़र्व बैंक अधिनियम, 1934 (1934 का 2) की धारा 42 की उप-धारा (6) के खण्ड (ग) के अनुसरण में भारतीय रिज़र्व बैंक इसके द्वारा निदेश देता है कि उक्त अधिनियम की दूसरी अनुसूची में निम्नलिखित परिवर्तन किये जाएं :--

“अरब बांगलादेश बैंक लिमिटेड” शब्दों के स्थान पर “एबी बैंक लिमिटेड” शब्द होंगे।

आनन्द सिन्हा
कार्यपालक निदेशक

[PUBLISHED IN THE GAZETTE OF INDIA, No.19, PART III, SECTION 4]

Ministry of Health and Family Welfare
(Pharmacy Council of India)

New Delhi, 10th May, 2008.

Pharm.D. Regulations 2008

Regulations framed under section 10 of the Pharmacy Act, 1948 (8 of 1948).

(As approved by the Government of India, Ministry of Health vide, letter No.V.13013/1/2007-PMS, dated the 13th March, 2008 and notified by the Pharmacy Council of India).

No.14-126/2007-PCI.— In exercise of the powers conferred by section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following regulations, namely:-

CHAPTER-I

1. Short title and commencement. – (1) These regulations may be called the Pharm.D. Regulations 2008.
(2) They shall come into force from the date of their publication in the official Gazette.
2. Pharm.D. shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

KADI SARVA VISHWAVIDYALAYA

Pharm. D. REGULATIONS

These regulations shall be called as “The Regulations for the Pharm.D Degree courses of the K. B. Institute of Pharmaceutical Education and Research a constituent college of KADI SARVA VISHWAVIDYALAYA ”. They shall come into force for all the students who have been admitted to this course from its inception. The regulations and syllabi framed are subject to modifications from time to time by the Academic Council.

Minimum Qualification for admission to the course

a) Pharm.D.

A pass in any of the following examinations -

- (1) 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the two subjects: Mathematics or Biology.
- (2) A pass in D.Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.
- (3) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.
- (4) Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.
- (5) Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

Duration of the course

The duration of the course shall be six academic years (five years of study and one year of internship or residency). The period of six years duration is divided into two phases –

Phase I – consisting of First, Second, Third, Fourth and Fifth academic year.

Phase II – consisting of internship or residency training during sixth year involving posting in specialty units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision of a preceptor so that he or she may become capable of functioning independently.

Medium of Instruction and Examinations

Medium of Instruction and Examination shall be English.

Working days in the academic year

Each academic year shall consist of not less than 200 working days.

Attendance and Progress

A candidate is required to put in at least 80% attendance in theory and practical subjects separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

Course of study

The course of study for Pharm.D. shall include the subjects as given in the Tables 1 to 5. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

Table-1 First Year

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology	3	3*	1
	Total hours	16	18	6 = (40)

* For Biology

Table-2 Second Year

S.No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
2.1	Pathophysiology	3	-	1
2.2	Pharmaceutical Microbiology	3	3	1
2.3	Pharmacognosy & Phytopharmaceuticals	3	3	1
2.4	Pharmacology-I	3	-	1
2.5	Community Pharmacy	2	-	1
2.6	Pharmacotherapeutics-I	3	3	1
	Total Hours	17	9	6 = 32

Table-3 Third Year

Sr.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
3.1	Pharmacology-II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Pharmacotherapeutics-II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	-	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	Total hours	16	15	5 = 36

Table-4 Fourth Year

Sr.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total hours	15	12	6 = 33

Table-5 Fifth Year

Sr.No.	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	Total hours	8	20	4 = 32

* Attending ward rounds on daily basis.

Sixth Year:

Internship or residency training including postings in speciality units. Student should provide the clinical pharmacy services to the allotted wards, under the supervision of a preceptor.

- (i) Six months in General Medicine department, and
- (ii) Two months each in three other specialty departments

Academic Work

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective subjects.

Internal Assessment Marks:

Theory: Three sessional examinations evenly spread during the academic year shall be conducted by the constituent colleges. The average marks of the best two examinations shall be computed out of a maximum of 30 marks and shall constitute the sessional award in theory. Provided further the colleges may conduct one special theory sessional examination towards the end of the academic session for those who might have missed any one of the regular sessional examination on genuine grounds.

Practical: Students are expected to perform the experiment listed in the respective syllabus. Marks shall be awarded out of a maximum of 10 to each of the practical exercise and an average of those shall be computed out of maximum of 10 marks. In addition, three practical examinations evenly spread during each academic year shall be conducted. The average marks of the best of two practical examinations shall be computed out of a maximum of 20 marks. A total of 30 marks shall constitute the sessional award in practical. While awarding the sessional marks for practical experiments, the following considerations should be taken into account.

1. Preparation of the candidate.
2. Manipulative skills.
3. Results of the experiment.
4. Knowledge of the experiment
5. Viva voce pertaining to the experiments only.

The college shall maintain the sessional books of the students and the record of sessional award of the students. A regular record of both theory and practical class work and sessional examinations conducted in an institution imparting the course shall be maintained for each student in the institution. Marks shall be awarded as per the schemes given in Tables 6 to 10

University Examinations

- (1) Every year there shall be an examination to examine the students.
- (2) Each examination will be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.
- (3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables 6 to 10.

Table-6 First Year Examination

S.No.	Name of Subject	Maximum marks for Theory			Practicals		
		University	Sessional	Total	University	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/Biology	70	30	100	70*	30*	100*
				600			1100/1200*

* For Biology.

For PCB students: 1100 marks, For PCM students: 1200 marks; For PCMB students: Student can choose either of Maths or Biology

Table-7 Second Year Examination

S.No.	Name of Subject	Maximum marks for Theory			Practicals		
		University	Sessional	Total	University	Sessional	Total
2.1	Pathophysiology	70	30	100	-	-	-
2.2	Pharmaceutical Microbiology	70	30	100	70	30	100
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100
2.4	Pharmacology-I	70	30	100	-	-	-
2.5	Community Pharmacy	70	30	100	-	-	-
2.6	Pharmacotherapeutics-I	70	30	100	70	30	100
				600			300 = 900

Table-8 Third Year Examination

S.No.	Name of Subject	Maximum marks for Theory			Practicals		
		University	Sessional	Total	University	Sessional	Total
3.1	Pharmacology-II	70	30	100	70	30	100
3.2	Pharmaceutical Analysis	70	30	100	70	30	100
3.3	Pharmacotherapeutics-II	70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence	70	30	100	-	-	-
3.5	Medicinal Chemistry	70	30	100	70	30	100
3.6	Pharmaceutical Formulations	70	30	100	70	30	100
				600			500 = 1100

Table-9 Fourth Year Examination

S.No.	Name of Subject	Maximum marks for Theory			Practicals		
		University	Sessional	Total	University	Sessional	Total
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				600			400 = 1000

Table-10 Fifth Year Examination

S.No.	Name of Subject	Maximum marks for Theory			Practicals		
		University	Sessional	Total	University	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

*Clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

** 30 marks – viva-voce (oral), 70 marks – Thesis work

Question Pattern

Long Essay 2/3 = 2 x 15 = 30 marks
 Short Essay 6/8 = 6 x 5 = 30 marks
 Short Answers 5/7 = 5 x 2 = 10 marks

 Total 70 marks

Criteria for pass

- Candidates who have secured a minimum of 50% marks in the Theory (including sessionals) and Practical (including sessional) separately in any subject or subjects shall be declared to have passed in that subject/s and exempted from appearing in that subject/s at subsequent examination.
- If a student fails in theory or practical examination of a subject shall reappear both in theory and practical of the same subject.**
- Those candidates who fail in one or more subjects shall have to appear only in the subject so failed, in the subsequent examinations.

Conditions under which candidates are permitted to proceed to next higher class:

Class	Condition for promotion and term grant
First Year Pharm.D	Minimum 80% attendance in lectures and practicals
Second Year Pharm. D	<p>Condition1: Minimum 80% attendance in lectures and practicals</p> <p>Condition 2: Fulfillment of any one of the criteria mentioned below</p> <p>Criteria no.1. : Pass in all subjects of First Year Pharm.D.</p> <p>Criteria no.2. : Fail in not more than two subjects of Pharm.D first year.</p> <p>NOTE: The student will get one chance of reaching to this criteria by allowing him/her to attempt in supplementary examination to be taken within 6 months but ideally within two months of main examination. During this period the student will be allowed to sit in 2nd year Pharm.D class but if he/she fails even in the supplementary exam in more than two subjects he/she will be considered as detained and will have to rejoin second year only after he/she fulfills at least to above mentioned criteria no.2.</p>
Third Year Pharm.D.	<p>Condition1: Minimum 80% attendance in lectures and practicals</p> <p>Condition 2: Fulfillment of any one of the criteria mentioned below</p> <p>Criteria no.1. : Pass in all subjects of First and Second Year Pharm.D.</p> <p>Criteria no.2. : Fail in not more than two subjects.</p> <p>It can be as two subjects of Pharm.D. First year OR two subjects of Pharm.D. second year OR one subject of each of the two years</p> <p>NOTE: The student will get one chance of reaching to this criteria by allowing him/her to attempt in supplementary examination to be taken within 6 months but ideally within two months of main examination. During this period the student will be allowed to continue teaching in 3rd year Pharm.D class but if he/she fails in more than two subjects he/she will be considered as detained and will have to rejoin third year teaching only after he/she fulfills at least to above mentioned criteria no.2.</p>
Fourth Year Pharm.D.	<p>Condition1: Minimum 80% attendance in lectures and practicals AND</p> <p>Condition 2: Pass in all subjects of Pharm.D. First Year AND</p> <p>Condition 3: Fulfillment of any one of the criteria mentioned below</p> <p>Criteria no.1. : Pass in all subjects of Second and Third Year Pharm.D.</p> <p>Criteria no.2. : Fail in not more than two subjects.</p> <p>It can be as two subjects of Pharm.D. Second year OR two subjects of Pharm.D. Third year OR one subject in each of the two years.</p> <p>NOTE: The student will get one chance of reaching to this criteria by allowing him/her to attempt in supplementary examination to be taken within 6 months but ideally within two months of main examination. During this period the student will be allowed to continue teaching in fourth year Pharm.D class but if he/she fails in more than two subjects he/she will be considered as detained and will have to rejoin fourth year only after he/she fulfills at least to above mentioned criteria no.2.</p>
Fifth Year Pharm.D.	<p>Condition1: Minimum 80% attendance in lectures and practicals AND</p> <p>Condition 2: Pass in all subjects of First and Second Year Pharm.D. AND</p> <p>Condition 3: Fulfillment of any one of the criteria mentioned below</p> <p>Criteria no.1. : Pass in all subjects of Third and Fourth Year Pharm.D.</p> <p>Criteria no.2. : Fail in not more than two subjects.</p> <p>It can be as two subjects of Pharm.D. Third year OR two subjects of Pharm.D. Fourth year OR one subject in each of the two years.</p> <p>NOTE: The student will get one chance of reaching to this criteria by allowing him/her to attempt in supplementary examination to be taken within 6 months but ideally within two months of main examination. During this period the student will be allowed to continue teaching in fifth year Pharm.D class but if he/she fails in more than two subjects he/she will be considered as detained and will have to rejoin fifth year only after he/she fulfills at least to above mentioned criteria no.2.</p>
Sixth Year Pharm.D.	<p>Condition1: Minimum 80% attendance in lectures and practicals AND</p> <p>Condition 2: Pass in all subjects of all five years of Pharm.D.</p> <p>Since the entire year is Internship, the time from which he fulfills above conditions, the one year internship will be initiated.</p>

Declaration of class Pharm. D :

A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt. The class will be awarded to the student every year based on the above criteria. If he/she passes all the subjects of a particular year in parts he will be awarded only pass class irrespective of what aggregate marks he/she achieves. The class obtained as above in the fifth year will be considered for the purpose of final award of class to the student.

Internship

Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and healthcare and acquires skills under the supervision so that he or she may become capable of functioning independently. Every student has to undergo one year internship as per Pharmacy Council of India regulations.

Practical training

- 1. Hospital posting.**— Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course of Pharm.D and in first and second year of Pharm.D. (Post Baccalaureate). Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.
- 2. Project work.**— (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes of Pharm.D and second year of Pharm.D. (Post Baccalaureate). Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.
(2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.
- 3. Objectives of project work.**— The main objectives of the project work is to—
 - (i) Show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and
 - (ii) Develop the students in data collection, analysis and reporting and interpretation skills.

4. Methodology.— To complete the project work following methodology shall be adopted, namely: —

- i. Students shall work in groups of not less than *two* and not more than *four* under an authorized teacher;
- ii. Project topic shall be approved by the Head of the Department or Head of the Institution;
- iii. Project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilization reviews, Pharmacoepidemiology, pharmacovigilance or Pharmacoeconomics;
- iv. Project work shall be approved by the institutional ethics committee;
- v. Student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and
- vi. Two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

5. Reporting.—

- (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorized teacher, Head of the Department as well as by the Head of the Institution
- (2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-titles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.
- (3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

6. Evaluation.— The following methodology shall be adopted for evaluating the project work—

- i. Project work shall be evaluated by internal and external examiners.
- ii. Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).
- iii. Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

iv. Evaluation shall be done on the following items:	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)

v. Final evaluation of project work shall be done on the following items:	Marks
e) Write up of the seminar	(17.5)
f) Presentation of work	(17.5)
g) Communication skills	(17.5)
h) Question and answer skills	(17.5)
Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

Award of degree

Candidates who fulfill the requirements mentioned above will be eligible for award of degree during the ensuing convocation.

Duration for completion of the course of study

The duration for the completion of the course shall be fixed as double the actual duration of the course and the students have to pass within the said period, otherwise they have to get fresh Registration.