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असावारण

EXTRAORDINARY भाग III—खण्ड 4

PART III—Section 4

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

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भारतीय भेषजी परिषद्

अधिसूचना

नई दिल्ली, 18 दिसम्बर, 2014

भेषजी स्नातक (व्यवसाय) विनियम, 2014

सं. 14-117/2014-भा.भे.परि.—भेषजी अधिनियम, 1948 (1948 का 8) की धारा 10 और 18 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए भारतीय भेषजी परिषद्, केन्द्रीय सरकार के अनुमोदन से निम्नलिखित विनियम बनाती है, अर्थात

अध्याय - I

1. संक्षिप्त नाम और प्रारंभ -

- (1) इन विनियमों का संक्षिप्त नाम भेषजी स्नातक (व्यवसाय) विनियम, 2014 है।
- (2) ये राजपत्र में प्रकाशन की तारीख से प्रवृत होंगे।
- भेषजी स्नातक (व्यवसाय) (बी.फार्म. व्यवसाय) को भेषज रजिस्टर में अतिरिक्त अर्हता दर्ज किए जाने के लिए इन विनियमों में यथा विहित पाठ्यक्रम पूरा करने पर और परीक्षा उत्तीर्ण करने पर एक डिग्री प्रमाण-पत्र प्रदान किया जाना।

अध्याय - II

3. पाठुयक्रम की कालावधि -

पाठ्यक्रम की कालावधि दो शैक्षणिक वर्ष होगी जिसमें हर वर्ष कम से कम 180 कार्य दिवसों का होगा।

4. पाठ्यक्रम में प्रवेश के लिए न्यूनतम अर्हता

- भेषजी अधिनियम, 1948 की धारा 12 के अधीन भारतीय भेषजी परिषद् द्वारा अनुमोदित संस्थान से भेषजी में डिप्लोमा पाठ्यक्रम उत्तीर्ण किया हो।
- ii) पंजीकृत भेषजज्ञ हो।
- iii) सामुदायिक या अस्पताल भेषजी में कम से कम चार वर्ष का भेषजी व्यवसाय का अनुभव हो -

- टैक्स्ट बुक ऑफ क्लिनिकल फार्मेसी प्रैक्टिस संपादन जी. पार्थसारथी, केरिन नाइफर्ट हेन्सन और मिलाप सी. नाहटा, ओरियन्ट लोंगमैन पब्लिकेशन्स
- 7. टैक्स्ट बुक ऑफ कम्युनिटी फार्मेसी प्रैक्टिस आर.पी.एस. जी.बी. पब्लिकेशन्स
- 8. कम्युनिटी फार्मेसी हैन्ड बुक जोनाथन वाटरफील्ड
- 9. कम्युनिटी फार्मेसी सिम्टम्स, डाइग्नोसिस एण्ड ट्रीटमेन्ट : पॉल रूटर
- 10. माइनर इलनैस इन मेजर डिसीजेज द क्लिनिकल मेनिफेस्टेशन्स इन द कम्युनिटी : पॉल स्टिलमैन
- 11. सोश्योलॉजी फॉर फार्मेसिस्ट : टेलर, नेटलटन, हार्डिंग
- 12. फार्मेसी प्रैक्टिस : टेलर, हार्डिंग
- 13. सोश्यल फार्मेसी : टेलर ज्योफरी
- 14. स्टॉकलेज़ ड्रग्स इन्टरएक्शन : केरैन बेक्स्टर
- 15. कूपर और गन ः डिस्पेंसिंग फॉर फार्मेसी स्टुडेन्टस
- 16. ए टेक्स्ट बुक प्रोफेशनल फार्मेसी एन.के. जैन और एस.एन. शर्मा
- 17. हावर्ड सी. अन्सेल कृत इन्ट्रोडक्शन टू फार्मास्युटिकल डोज़ेज फॉर्मस
- 18. रेमिंगटन कृत फार्मास्युटिकल सांइसेज
- 19. डी.एम. ब्रह्मांकर और सुनील बी. जायसवाल : टैक्स्ट बुक ऑफ बायोफार्मास्युटिक्स एण्ड फार्माकोकीनेटिक्स - ए ट्रटाइज - वल्लभ प्रकाशन, दिल्ली ।
- 20. स्वर ब्रिक कृत बायोफार्मास्युटिक्स
- 21. मइलो जिबाल्डी कृत बायो फार्मास्युटिक्स एण्ड क्लिनिकल फार्माकोकीनेटिक्स
- 22. मिथल, बी.एम. टैक्स्ट बुक ऑफ फोरेंसिक फार्मेसी, कलकत्ता : नेशनल : 1988
- 23. सिंह, के.के. संपादक, बायोत्राज़ द लाज़ ऑफ ड्रग्स, मेडिसन्स एण्ड कोस्मेटिक्स, इलाहाबाद : लॉ बुक हाऊस, 1984
- 24. जैन, एन.के., ए टैक्स्ट बुक ऑफ फोरेंसिक फार्मेसी, दिल्ली : वल्लभ प्रकाशन, 1995
- 25. रिपोर्ट्स ऑफ द फार्मास्युटिकल इन्क्वायरी कमेटी
- 26. आई.डी.एम.ए. मुम्बई, डी.पी.सी.ओ. 1995
- 27. वेरियस रिपोर्टूस आफ अमेन्उमेंटूस
- 28. देशपांडे, एस.डब्ल्यु : द ड्रग्स एण्ड मेजिक रेमेडीज़ एक्ट 1954 एण्ड रूल्स 1995; मुम्बई सुस्मित पब्लिकिशन्स 1998
- 29. ईस्टर्न बुक कम्पनी, द नारकोटिक्स एण्ड साइकोट्रोपिक सब्सटेन्सेज़ एक्ट 1985 लखनऊ : ईस्टर्न 1987
- 30. ड्रग इन्फार्मेशन एबाउट कॉमनली यूज्ड ड्रग्स : पी.पी. शर्मा, आर सिंह

अर्चना मुदगल, निबन्धक-एवं-सचिव

[विज्ञापन III/4/असा./101/14]

PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 18th December, 2014

Bachelor of Pharmacy (Practice) Regulations, 2014

No. 14-117/ 2014- PCI.—In exercise of the powers conferred by Section 10 and 18 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 **Bachelor of Pharmacy (Practice) Regulations, 2014**
- (2) They shall come into force from the date of their publication in the official Gazette.
- 2. **Bachelor of Pharmacy (Practice)** [B.Pharm. (Practice)] shall consist of a degree certificate of having completed the course of study and passed examination as prescribed in these regulations for the purpose of additional qualification to be entered in the register of pharmacists.

CHAPTER-II

3. Duration of the course. –

The duration of the course shall be of two academic years with each year spread over a period of not less than 180 working days

4. Minimum qualification for admission to the course -

- i. A pass in Diploma course in Pharmacy from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act, 1948.
- ii. A registered pharmacist.
- iii. A minimum of four years of pharmacy practice experience in a community or hospital pharmacy
 - a. A certificate from competent authority stating that the candidate is endorsed as registered pharmacist in the drug license of a pharmacy as proof of practice experience in case of community pharmacist
 - b. A certificate from the Principal/Medical Superintendent/competent person of the Hospital/Health Unit stating that the candidate is working as a pharmacist will be accepted as proof of practice experience in case of hospital pharmacist
- iv. A 'No Objection Certificate' from the employer in prescribed format (Annexure -A)

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.

5. The number of admissions in the programme shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted to 40 students in an academic year

6. Approval of the authority conducting the course of study –

- a. No pharmacy institution shall start Bachelor of Pharmacy (Practice) programme or increase the number of admission without obtaining the prior approval of the Pharmacy Council of India.
- b. Any pharmacy college for the purpose of obtaining permission under sub-section (1) of section 12 of the Pharmacy Act shall submit a scheme as prescribed in Appendix-I by the Pharmacy Council of India.
- c. The scheme referred to in sub-regulation (b) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed.
- d. The institutions approved by the Pharmacy Council of India for running Bachelor of Pharmacy course under section 12 of the Pharmacy Act, 1948 alone shall be eligible for starting Bachelor of Pharmacy (Practice) degree course.

Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, laboratories, equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-II to these regulations.

7. Course of study. –The course of study shall consist of the subjects as given in the Tables below. The course shall consist of class room teaching and assignment works. The assignment works shall be done at the place of work under the supervision and guidance of teaching staff of the academic institution. The number of contact hours in a week devoted to each subject for class room teaching shall not be less than that noted against it in columns (3) below.

TABLE - I

S.No.	Name of Subject	Minimum No.	No. of contact
		of total contact	hours /week
		hours	
(1)	(2)	(3)	(4)
1.1	Pathophysiology and Pharmacotherapeutics I	40	1
1.2	Pathophysiology and Pharmacotherapeutics II	40	1
1.3	Pharmacy Practice I	40	1
1.4	Pharmacy Practice II	40	1
1.5	Applied Pharmaceutics	40	1
1.6	Social Pharmacy I	40	1
1.7	Case presentation, Seminar, Assignments	160	4
	Total	400	10

<u>First Year :</u>

Second Year :

S.No.	Name of Subject	Minimum No. of total contact hours	No. of contact hours /week
(1)	(2)	(3)	(4)
2.1	Pathophysiology and Pharmacotherapeutics III	40	1
2.2	Pathophysiology and Pharmacotherapeutics IV	40	1
2.3	Pharmacy Practice III	40	1
2.4	Pharmacy Practice IV	40	1
2.5	Social Pharmacy II	40	1
2.6	Pharmaceutical Jurisprudence	40	1
2.7	Case presentation, Seminar, Assignments	160	4
	Total	400	10

8. Syllabus. – The detailed syllabus for each subject of study in the said Tables shall be as specified in the guidelines given in Appendix-III. The guidelines may, with the approval of Central Council of the Pharmacy Council of India, be amended and notified from time to time.

9. Examination. –

- 1. There shall be an examination at the end of calendar year. The first examination shall be the annual examination and the second examination shall be supplementary examination.
- 2. The examinations shall be of written nature for theory and for the practicals: The students shall submit the assignments done by them in the form of a report which will be followed by viva-voce carrying maximum marks for each part of a subject as indicated in Tables below :

<u>1st Year examination :</u>

TABLE-II

S.No. Name of Subject		Maximum marks for Theory			Maximum marks for Assignments (including Viva voce 25%)
		University Examination	Sessional marks	Total	
1.1	Pathophysiology and Pharmacotherapeutics I	60	40	100	100
1.2	Pathophysiology and Pharmacotherapeutics II	60	40	100	100
1.3	Pharmacy Practice I	60	40	100	100
1.4	Pharmacy Practice II	60	40	100	100
1.5	Applied Pharmaceutics	60	40	100	100
1.6	Social Pharmacy I	60	40	100	100
	Total			600	600

2nd Year examination :

S.No. Name of Subject		Maximum marks for Theory			Maximum marks for Assignments (including Viva Voce- 25%)
		University Examination	Sessional marks	Total	
1.1	Pathophysiology and Pharmacotherapeutics III	60	40	100	100
1.2	Pathophysiology and Pharmacotherapeutics IV	60	40	100	100
1.3	Pharmacy Practice III	60	40	100	100
1.4	Pharmacy Practice IV	60	40	100	100
1.5	Social Pharmacy - II	60	40	100	100
1.6	Pharmaceutical Jurisprudence	60	40	100	100
	Total			600	600

10. Eligibility for appearing at the examination.— A student who produces a certificate from the Head of the Institution in which he has undergone the course in proof of his having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held in theory and has submitted the assignments/ project report duly approved by the supervising teacher shall be eligible for appearing at the examination.

11. Mode of examinations.—

(1) Theory examination shall be of three hours duration.

(2) A student who fails in theory examination of a subject shall be permitted to re-appear in that subject

(3) Assignment work shall consist of evaluation of report by both internal & external examiners with a seminar and viva –voce (Oral) examination.

12. Award of sessional marks and maintenance of records.-

- (1) A regular record of theory examinations conducted in an institution imparting the Bachelor of Pharmacy (Practice) Course, shall be maintained for each student in the institution and 40 marks for each subject shall be allotted as internal assessment.
- (2) There shall be at least three periodic sessional examinations during each year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.
- 13. Minimum marks for passing examination.— A student shall not be declared to have passed examination unless he secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in assignment work. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the examination shall be declared to have passed in first class. A student 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 passes in all the subjects in a single attempt.

14. Eligibility for promotion to next Class.—

- 1. All students who have appeared for all the subjects and passed the examination are eligible for promotion to the next year.
- 2. The student failing in subjects of 1st year B.Pharm. (Practice) examination shall be permitted to proceed to the 2nd year of B.Pharm. (Practice). However, such students shall have to pass all the subjects of the 1st and 2nd year of B.Pharm. (Practice) course and shall complete the course within 4 academic years from the session in which he was admitted in the course, for the consideration of B.Pharm. (Practice) degree.
- **15. Approval of examinations.** Examinations mentioned in regulations 9 to12 and 14 shall be held by the examining authority approved by the Pharmacy Council of India under sub-section (2) of Section 12 of the Pharmacy Act, 1948.
- **16. Certificate of passing examination**.— every student who has passed the examinations for the Bachelor of Pharmacy (Practice) shall be granted a degree certificate by the examining authority.

CHAPTER-III

17. Assignment work.—

- 1. To allow the student to understand and develop data collection and reporting skills in the area of community, hospital and clinical pharmacy in particular and principles of pharmacy practice in general, the assignment work shall be carried out under the supervision of a teacher of the Academic Institution on the topic approved by the Head of the Academic Institution. The same shall be announced to students within one month of commencement of the classes in each of the subjects for the session. Assignment shall be presented in a written report and as a seminar before the final examination. External and the internal examiners appointed by the examining authority for the said purpose shall do the assessment of the work done.
- 2. Assignment work shall comprise of objectives of the work, methodology, results, discussions and conclusions.
- 18. Objectives of Assignment work.— The main objectives of the work is to—
 - (i) show the evidence of having made accurate description of work and of having recorded the findings in an impartial manner; and
 - (ii) develop the students skills in data collection, analysis and reporting and interpretation skills.

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

- (i) Not more than ten students shall work under an authorized teacher;
- (ii) The topic shall be approved by the Head of the Department or Head of the Institution;

(iii) The work chosen shall be related to the subjects taught in a particular session and due consideration has to be given regarding the suitability for carrying out the work in his workplace.

- **20. Reporting** .— (1) Student working on the assignment shall submit the report after completion of work to the Head of the Department or Head of the Institution. The report should include a certificate issued by the authorized teacher.
 - (2) Submission of the report shall be done at least one month prior to the commencement of annual examination.
- 21. Evaluation.— The following methodology shall be adopted for evaluating assignment work—

Evaluation shall be done on the following items:	Marks
a) Write up of the assignment	(40)
b) Presentation of work	(15)
c) Seminar	(20)
d) Question and answer skills (viva voce)	(25)

Total (100 marks)

CHAPTER-IV

22. The fees for the course shall be prescribed by Pharmacy Council of India from time to time for guidance to the State Government/Course Conducting Authorities.

Annexure-A

{See regulation 4(iv)}

Format for 'No Objection Certificate' from the Employer

This to certify that ------ son/daughter of----- is working in this Institution/Pharmacy- as------ since ------ and the undersigned has no objection if he gets himself admitted in the Bachelor in Pharmacy (Practice) Course for the session-----.

He will be allowed to attend the course and facilities will be provided for carrying out the assignments as part of course in this Institution/Organization.

Signature and seal of the authorized person.