

## **ORDINANCE**

## For

# **Diploma in Pharmacy**



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w.e.f. session 2021-2022

[The Education Regulations, 2020 For Diploma Course in Pharmacy]

**1** of 13 Faculty of Pharmacy Integral University

## PHARMACY COUNCIL OF INDIA NOTIFICATION

New Delhi, the 9th October, 2020

#### The Education Regulations, 2020 for Diploma Course in Pharmacy

Regulations made under section 10 of the Pharmacy Act, 1948.

(As approved by the Government of India, Ministry of Health & Family Welfare vide letter No. Z-28020/59/2019-AHS/FTS-8012809 dated 7.10.2020 and notified by the Pharmacy Council of India.)

**No.14-55/2020-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 1

- **1. Short title and commencement-** (1) These regulations may be called the Education Regulations, 2020 for Diploma course in Pharmacy.
- (2) They shall come into force on the date of their publication in the official Gazette.
- **2. Qualification for Pharmacist-** The minimum qualification required for registration as a pharmacist shall be a pass in Diploma in Pharmacy (Part-II) and satisfactory completion of Diploma in Pharmacy (Part-III).

Or

Any other qualification approved by the Pharmacy Council of India as equivalent to the above.

**3. Diploma in Pharmacy (Part-I, Part-II and Part-III)** shall consist of a certificate of having completed the course of study and passed the examination after satisfactory completing the practical training as prescribed in Chapter-2 and Chapter-3 of these regulations.

#### **CHAPTER 2**

#### 4. Diploma in Pharmacy (Part-I and Part-II)-

Minimum qualification for admission to Diploma in Pharmacy-A pass in 10+2 examination (science academic stream) with Physics, Chemistry and Biology or Mathematics.

or

Any other qualification approved by the Pharmacy Council of India as equivalent to the above examination.

Provided that there shall be reservation of seats for the Scheduled Castes and the Scheduled Tribes candidates in accordance with the instructions issued by the Central Government /State Governments /Union territory administrations as the case may be from time to time.

#### 5. Duration of the course-

- (1) The duration of the course shall be for two academic years. Each academic year shall be spread over a period of not less than one hundred and eighty working days.
- (2) In addition there shall be a five hundred hours of practical training spread over a period of not less than three months.
- **6.** Course of study- The course of study for Diploma in Pharmacy Part-I and Diploma in Pharmacy Part-II shall include the subjects as given in the Tables I & II below. The number of hours devoted to each subject for its teaching in Theory and Practical, shall not be less than that noted against it in columns 2 and 3 of the Tables below. **However, the course of study and practical training may be modified by the Pharmacy Council of India from time to time.**

Table – I Diploma in Pharmacy (Part - I)			
	Nun		
Subject	Theory	Practical	Tutorial
Pharmaceutics	75	75	25
Pharmaceutical Chemistry	75	75	25
Pharmacognosy	75	75	25
Human Anatomy & Physiology	75	75	25
Social Pharmacy	75	75	25
Total	375	375	125

Table – II Diploma in Pharmacy (Part II)			
	Nur	mber of hours	
Subject	Theory	Practical	Tutorial
Pharmacology	75	50	25
Community Pharmacy & Management	75	75	25
Biochemistry & Clinical Pathology	75	50	25
Pharmacotherapeutics	75	25	25
Hospital & Clinical Pharmacy	75	25	25
Pharmacy Law & Ethics	75		25
Total	450	225	150

# TABLE III Diploma in Pharmacy (Part III) Practical Training – 500 hours

#### **Activities**

- 1) Stocking of Drugs and Medical Devices
- 2) Inventory Control Procedures
- 3) Handling of prescriptions
- 4) Dispensing (250 hours)
- 5) Patient counseling
- **7. Syllabus-** The syllabus for each subject of study shall be as prescribed by the Pharmacy Council of India from time to time.
- 8. Approval of the authority conducting the course of study-
  - (1) No authority in a State shall start or conduct Diploma in Pharmacy course of study without the prior approval of the Pharmacy Council of India.
  - (2) The course of regular academic study prescribed under regulation 6 shall be conducted in an institution, approved by the Pharmacy Council of India under sub-section (1) of Section 12 of the Pharmacy Act, 1948.

Provided that the Pharmacy Council of India shall not approve any institution under this regulation unless it provides adequate arrangements for teaching in regard to building, accommodation, equipments and teaching staff etc. as specified in Appendix-A to these regulations which may be amended by the Pharmacy Council of India from time to time.

#### 9. Examinations-

- 1) There shall be an annual examination at the end of the academic year.
- 2) If necessary, there shall be a supplementary examination for the students who are not able to pass Diploma in Pharmacy Part-I or Part-II, as the case may be, as per the criteria specified by the examining authority.
- 3) The examinations shall be of written and practical (including viva voce) nature, carrying maximum marks for each part of a subject, as indicated in Table IV and V below.

		ximum marks for Theory		Maximum marks for Practicals			
Subject	Examination	*Sessional	Total	Examination *Sessional		Total	
Pharmaceutics	80	20	100	80	20	100	
Pharmaceutical Chemistry	80	20	100	80	20	100	
Pharmacognosy	80	20	100	80	20	100	
Human Anatomy & Physiology	80	20	100	80	20	100	
Social Pharmacy	80	20	100	80	20	100	

\*Internal assessment

Table – V  DIPLOMA IN PHARMACY (PART-II) EXAMINATION						
Maximum marks for Theory for Practicals						
Subject	Examination	*Sessional	Total	Examination	*Sessional	Total
Pharmacology	80	20	100	80	20	100
Community Pharmacy & Management	80	20	100	80	20	100
Biochemistry & Clinical Pathology	80	20	100	80	20	100
Pharmacotherap eutics	80	20	100	80	20	100

Hospital and Clinical Pharmacy	80	20	100	80	20	100
Pharmacy law & Ethics	80	20	100	-	-	-
			600	+400 +100	= 1100	

\*Internal assessment

#### 10. Eligibility for appearing at the Diploma in Pharmacy Part-I and Part II examination-

Only such candidates who produce certificate from the Head of the academic institution in which he/she has undergone the Diploma in Pharmacy Part-I and Part-II course in proof of his/her having regularly and satisfactorily undergone the course of study by attending not less than 75% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at the Diploma in Pharmacy (Part-I) or (Part II) examination, as the case may be.

#### 11. Mode of examinations-

- (1) Theory and Practical examination in the subjects mentioned in Tables IV & V shall be of three hours duration. Both Theory and Practical are considered as two separate papers.
- (2) A candidate who fails in theory or practical examination of a subject shall re-appear for the failed subject. Theory and Practical of a particular subject are considered as individual subjects for the purpose of pass criteria.
- (3) Practical examination shall also consist of a viva-voce examination.

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

- (1) A regular record of both theory and practical class work and examinations held in an institution imparting training for diploma in Pharmacy Part-I and diploma in Pharmacy Part-II courses, shall be maintained for each student in the institution and 20 marks for each theory and 20 marks for each practical subject shall be allotted as sessional marks.
- (2) There shall be two or more periodic sessional (internal assessment) examinations during each academic year. The highest aggregate of any two performances shall form the basis of calculating sessional marks.
- (3) The sessional marks in practicals shall be allotted on the following basis:-
  - (i) Actual performance in the sessional / spacing examination = 10 marks.
  - (ii) Day to day assessment in the practical class/spacing work =10 marks.
- 13. Minimum marks for passing the examination A student shall not be declared to have passed Diploma in Pharmacy examination unless he/she secures at least 40% marks in each of the subjects separately in the theory as well as the practical examinations, including sessional marks. The candidates securing 60% marks or above in aggregate in all subjects shall be declared to have passed in first class. The candidates securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in that subject or those subjects. The grant of first class and distinction shall be subject to the condition that the candidate shall pass all the subjects in a single attempt.

#### 14. Eligibility for promotion to Diploma in Pharmacy (Part-II)-

All candidates who have appeared for all the subjects and passed the Diploma in Pharmacy Part-I examination are eligible for promotion to the Diploma in Pharmacy Part-II class. However failure in more than two subjects shall debar him/her from promotion to Diploma in Pharmacy Part II class.

#### 15. Improvement of sessional marks-

The candidates who wish to improve sessional marks can do so, by appearing in two additional sessional examinations during the next academic year. The average score of the two examinations shall be the basis for improved sessional marks in theory as well as in practical. Marks awarded to a candidate for day to day assessment in the practical class cannot be improved unless he/she attends a regular course of study again.

- **16. Approval of examinations-** The examinations mentioned in regulations 9 to 15 shall be held by an authority (hereinafter referred to as the Examining Authority) in a State, which shall be approved by the Pharmacy Council of India under sub-section (2) of section 12 of the Pharmacy Act, 1948. Such approval shall be granted only if the Examining Authority concerned fulfills the conditions as specified in Appendix-B to these regulations.
- 17. Certificate of passing examination for Diploma in Pharmacy (Part-II)- Certificate of having passed the examination for the Diploma in Pharmacy Part-II shall be granted by the examining authority to a successful student.

#### **CHAPTER-3**

#### Diploma in Pharmacy (Part-III)

#### (Practical Training)

#### 18. Period and other conditions for practical training-

- (1) After having appeared in Part-II examination for the Diploma in Pharmacy held by an approved Examining Authority a candidate shall be eligible to undergo practical training in one or more of the following institutions namely:
  - (i) Hospitals/Dispensaries run by Central /State Governments.
  - (ii) A pharmacy licensed for retail sale of drugs under the Drugs and Cosmetics Rules, 1945 having the services of registered pharmacists.
  - (iii) Hospital and Dispensary other than those specified in sub-regulation (i) above for the purpose of giving practical training shall have to be recognized by Pharmacy Council of India on fulfilling the conditions specified in Appendix-C to these regulations.
- (2) The institutions referred in sub-regulation (1) shall be eligible to impart training subject to the condition that number of student pharmacists that may be taken in any hospital, dispensary or pharmacy licensed under the Drugs and Cosmetics Rules, 1945 made under the Drugs and Cosmetics Act, 1940, shall not exceed four where there is one registered pharmacist engaged in the work in which the student pharmacist is undergoing practical training, where there is more than one registered pharmacist similarly engaged, the number shall not exceed two for each additional such registered pharmacist.
- (3) In the course of practical training, the trainee shall have exposure to -
  - (i) Working knowledge of keeping of records required by various Legislative Acts concerning the profession of pharmacy; and
  - (ii) Practical experience in activities mentioned in Table III under regulation 6 of these regulations.
- (4) The practical training shall be not less than five hundred hours spread over a period of not less than three months provided that not less than two hundred and fifty hours are devoted to actual dispensing of prescriptions.

#### 19. Procedure to be followed prior to commencement of the training-.

- (1) The head of institution imparting practical training, on application, shall supply in triplicate 'Practical Training Contract Form for Pharmacist' (hereinafter referred to as the Contract Form) to the candidate eligible to undertake the said practical training. The Contract Form shall be as specified in Appendix-D to these regulations.
- (2) The head of institution imparting practical training shall fill Section I of the Contract Form. The trainee shall fill Section II of the said Contract Form and the head of the institution agreeing to impart the training (hereinafter referred to as the Apprentice Master) shall fill Section III of the said Contract form.
- (3) It shall be the responsibility of the trainee to ensure that one copy (hereinafter referred to as the first copy of the Contract Form) so filled is submitted to the head of institution imparting practical training and the other two copies (hereinafter referred to as the second copy and the third copy) shall be filed with the Apprentice Master (if he so desires) or with the trainee till completion of the training.

#### 20. Certificate of passing Diploma in Pharmacy Part-III-

On satisfactory completion of the practical training period the Apprentice Master shall fill Section IV of the second copy and third copy of the Contract Form and forward it to the head of institution imparting practical training who shall suitably enter in the first copy of the entries from the second copy and the third copy and shall fill Section V of the three copies of Contract Form and thereafter hand over both the second copy and the third copy to the trainee.

This Contract Form, completed in all respects, shall be regarded as a certificate of having successfully completed the course of Diploma in Pharmacy (Part- III).

#### **CHAPTER-4**

**21. Certificate of Diploma in Pharmacy-** A certificate of Diploma in Pharmacy shall be granted by the examining authority to a successful candidate on producing certificates of having passed the Diploma in Pharmacy Part I and Part II and satisfactory completion of practical training for Diploma in Pharmacy (Part-III).

#### 22. Repeal and Savings-

- (1) The Education Regulations, 1991 (hereinafter referred to as the said regulations) published by the Pharmacy Council of India vide No. 14-55/87(Part)-PCI/2484-2887 dt.11.7.1992 and all amendments thereto are hereby repealed.
- (2) Notwithstanding such repeal,
  - (a) Anything done or any action taken under the said regulations shall be deemed to have been done or taken under the corresponding provision of these regulations.
  - (b) A person who was admitted as a student under the said regulations to the course of training for Diploma in Pharmacy and who had not passed the examination at the commencement of these regulations shall be required to pass the examination in accordance with the provisions of the said regulations as if these regulations had not come into force:

Provided however, the Examining Authority in a particular State may fix a date after which the examinations under the said Regulations shall not be conducted.

#### Appendix-A

#### (See regulation 8)

#### Conditions to be fulfilled by the academic institution

Any authority in India applying to the Pharmacy Council of India for approval of courses of study for Pharmacists under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall provide.

#### (A) ACCOMMODATION

Suitable and sufficient accommodation with adequate ventilation lighting and other hygienic conditions should be provided to the rooms for Principal /Head of the department, office, class room, library, staff, staff common room, students common room, museum, stores etc.

At least four laboratories specified below should be provided for:-

- 1. Pharmaceutics Lab.
- 2. Pharm. Chemistry Lab.
- 3. Physiology, Pharmacology and Pharmacognosy Lab.
- 4. Biochemistry, Clinical Pathology, Hospital and Clinical Pharmacy Lab.

In addition to the laboratories, balance room, aseptic room or cabinet, a machine room are also to be provided for.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 500 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fume cupboards be provided wherever necessary.

The institutions shall provide "Model Pharmacy" as per following details –

Model Pharmacy	No.	Area
Essential:	01	80 Sq. Mts.
Running Model Community Pharmacy		(Including 10 Sq. mt for Drug Information Centre & 10 Sq. mt. for Patient Counseling)
<u>Desirable</u> :		
Drug Model Store		

Wherever animal experimentations are prescribed in the curriculum, the required knowledge and skill should be imparted by using computer assisted modules. Animal hold area shall be as per the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines.

#### (B) STAFF

Principal/Director/Professor/Head of Institution /Head of the Department may be engaged in teaching upto eight hours a week, and the work load of other teaching staff should not be more than sixteen hours per week.

Staff student ratio should not exceed 1:60 in theory classes and 1:20 in practical classes. There should be two teachers for a batch of 30 students in practicals. According to the above norms, the following staff is required for an intake of 60 students:

1.	Principal/Director/Professor/Head of Institution/Head of the Department	- One
2.	Lecturer:	
	• M.Pharm/Pharm.D	- Three
	• B.Pharm with 3 years of	- Four
	professional experience	

In addition to regular faculty, the institution can have Bachelor of Medicine and Bachelor of Surgery (M.B.B.S) faculty as visiting faculty for teaching Anatomy & Physiology and Biochemistry and Clinical Pathology.

The minimum qualification and experience of the teaching faculty including the Principal/ Director/ Professor/ Head of Institution/ Head of Department and their payscales shall be as prescribed in the Minimum Qualification for Teachers in Pharmacy Institutions Regulations, 2014.

The pay scale of teaching staff shall not be less than the scale of pay prescribed by the State Government/ University Grants Commission/ All India Council for Technical Education for similar category of posts.

Provided that the above qualifications shall not apply to the incumbents appointed under the repealed Education Regulations.

#### Non-Teaching Staff

List of Non-Teaching staff for the D.Pharm course:

1.	Laboratory Technician	2
	(Qualification-Diploma in Pharmacy)	
2.	Laboratory Attendent	4
3.	Office Superintendent	1
4.	Clerk-cum-Accountant	1
5.	Store-Keeper	1
6.	Typist	1
7.	Asstt. Librarian	1
8.	Peons	2
9.	Cleaners/Sweepers	4
10.	Gardener	1

#### Museum

Every institution shall maintain a museum of crude drugs, herbarium sheets, botanical specimens of the drugs and plants mentioned in the course. In addition, the following are recommended:-

- 1. Coloured slides of medicinal plants:
- 2. Display of popular patent medicines; and
- 3. Containers of common usage in medicines.

#### Library

Every institution shall maintain a library which should contain books mentioned in the syllabus and also the current pharmaceutical journals. There should be adequate place in the library for students and staff to refer books.

NOTE: The above requirements are the minimum requirements and the Institution is free to provide more-physical and teaching facility.

#### **Equipments**

The list of equipments & apparatus shall be as may be decided by the Pharmacy Council of India from time to time.

#### Appendix-B

#### (See regulation 16)

#### Conditions to be fulfilled by the Examining Authority

- 1. The Examining Authority shall be either a statutory Indian University or a body constituted by the Central or State Government. It shall ensure that discipline and decorum of the examinations are strictly observed at the examination centers.
- 2. It shall permit the Inspector or Inspectors of the Pharmacy Council of India to visit and inspect the examinations.
- 3. It shall provide:-
  - (a) adequate rooms with necessary furniture for holding written examinations;
  - (b) well-equipped laboratories for holding practical examinations;
  - (c) an adequate number of qualified and responsible examiners and staff to conduct and invigilate the examination; and
  - (d) such other facilities as may be necessary for efficient and proper conduct of examinations.
- 4. It shall, if so required by a candidate, furnish the statement of marks secured by a candidate in the examinations after payment of prescribed fee, if any, to the Examining Authority.
- 5. It shall appoint examiners whose qualifications should be similar to those of the teachers in the respective subjects as shown in Appendix-A.
- 6. In pursuance of sub-section (3) of section 12 of the Pharmacy Act, 1948, the Examining Authority shall communicate to the Secretary, Pharmacy Council of India not less than six weeks in advance the dates fixed for examinations, the time-table for such examinations, so as to enable the Council to arrange for inspection of the examinations.
- 7. The Chairman and at least one expert member of Examining Committee of the Examining Authority concerned with appointment of examiners and conduct of pharmacy examinations should be persons possessing pharmacy qualifications.

#### Appendix-C

[See regulations 18 (1)(iii)]

#### Conditions to be fulfilled by the institution to be recognised for giving practical training

- 1. The Institution, where practical training is given to student pharmacists, shall from time to time, if required, furnish such information as may be needed by the Pharmacy Council of India about the staff, accommodation and equipment of the Institution concerned and its working.
- 2. The Institution shall permit the Inspectors of the Pharmacy Council of India to inspect the premises at any reasonable time while the work is proceeding therein.
- 3. The Institution shall entrust some member or members of its staff, who shall be registered pharmacist (s), to look after the student pharmacists. Such members of the staff shall be responsible in this behalf to the Head of the Institution concerned.
- 4. The Institution shall provide such opportunity, accommodation, apparatus, materials and books of reference as may be required to enable the student pharmacists to undergo the practical training properly.

- 5. The number of student pharmacists that may be taken in any hospital, pharmacy and chemist and druggist licensed under the Drugs and Cosmetics Rules, 1945 made under the Drug and Cosmetics Act, 1940 shall not exceed four where there is one registered pharmacist engaged in the work in which the student pharmacist is undergoing practical training; where there is more than one registered pharmacist similarly engaged, the number shall not exceed two for each additional such registered pharmacist.
- 6. The Institution wishing to be recognised under regulation 18 shall apply in writing to the Secretary, Pharmacy Council of India stating its desire, to be so recognised.
- 7. Having satisfied that the institution shall follow the conditions laid down in these rules, the Pharmacy Council of India shall grant such recognition.
- 8. In the event of any question arising as to the interpretation or observance of these conditions the decision of the Pharmacy Council of India shall be final.

#### Appendix-D

[See regulations 19(1)]

Pract	ical training contract form for phari	macists
	SECTION I	
This form has been issued to		
(Name	of student pharmacist)	
son of /daughter of r that he/she is entitled to receive the I section 10 of the Pharmacy Act, 1948.	residing atPractical Training as set out in the Ed	who has produced evidence before meducation Regulations, 2020 made under
Date:	The Head of	Institution imparting
		practical training
	SECTION II	
I	:	accept
(Name of the Stud	lent Pharmacist)	
	of	
(Name of the Apprentice Master)	(Name of the Institution)	
	(Hospital or Pharmacy)	

as my Apprentice Master for the above training and agree to obey and respect him /her during the entire period of my training.

(Student Pharmacist)

	SECTI	ON III
Ι,		accept
	(Name of th	e Apprentice Master)
		as a
	(Name of th	e student pharmacist)
trainee and I agree to acquire:	give him /her training facilities in m	y organisation so that during his /her training he /she may
1. Working knowled	dge of keeping of records required by	the various Acts affecting the profession of pharmacy; and
Practical experies	nce in -	
1) Stocking of	Drugs and Medical Devices	
2) Inventory c	ontrol procedures	
3) Handling of	f prescriptions	
4) Dispensing		
5) Patient cour	nseling	
I also agree that a Reg	gistered Pharmacist shall be assigned to	For his /her guidance.
		(Apprentice Master)
		(Name & address of the Institution)
	SECTI	
I certify that	(Name of student pharmacists)	had
has undergone	hours training spread over	months in
accordance with the d	etails enumerated in SECTION III.	
		(The Head of Institution imparting practical training)

[ADVT.-III/4/Exty./298/2020-21]

	SECTION V
I certify that	has (Name of student pharmacists)
completed in a	all respect his practical training under regulation 18 of the Education Regulations, 2020 made under
section 10 of t Council of Indi	the Pharmacy Act, 1948. He had his practical training in an Institution approved by the Pharmacy ia.
Date:	
	(Head of the Academic Institution)
	ARCHNA MUDGAL, Registrar-cum-Secy.