

POST-GRADUATE DIPLOMA IN CLINICAL RESEARCH AND REGULATORY AFFAIRS

Eligibility: Students are eligible B.Sc./M.Sc. (All streams of Life Science), B.E/B.Tech. (Chemical/Biotech/Computer Science) MCA, B.Pharma, M.BB.S./M.D/B.D.S/M.D.S. / Nursing/BHMS/BVSc/BPT

Duration : Two Semesters(One Year) with 16 weeks per Semester & 40 lectures per Semester

Time: Saturday (1.00 pm to 5 pm)

Tuition fees: Rs. 75,000/-

Course structure:

FIRST SEMESTER (12 CREDITS/400 MARKS)

Theoretical Papers	Subject Code	Contact hours/week	Credits	Marks
Fundamentals of Clinical Research	PGD/CRRA/T/111A	3	3	100
Regulatory Affairs & Regulations in Clinical Research	PGD/ CRRA /T/112A	3	3	100
Pharmacology & Pharmacy in Clinical Research	PGD/ CRRA /T/113A	3	3	100
Biostatistics & Clinical Data Management	PGD/ CRRA /T/114A	3	3	100

SECOND SEMESTER (18 CREDITS/600 MARKS)

Theoretical Papers	Subject Code	Contact hours/week	Credits	Marks
Ethical Issues & Clinical Trial Documentation	PGD/CRRA/T/121A	3	3	100
Preclinical Studies and Toxicity & Toxic -kinetics	PGD/ CRRA /T/122A	3	3	100
Bioavailability , Bioequivalence & Pharmacokinetics	PGD/ CRRA /T/123A	3	3	100
Practice and Case Studies—Project Work	PGD/ CRRA /S/121A	3	3	100
Seminar	PGD/ CRRA /S/122A	3	3	100
Viva-Voce	PGD/ CRRA /S/123A	3	3	100

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(Examination Rule)

1. The PG Diploma Course will be of 2-Semesters duration and semester examination system.
2. A student will have to pass each theoretical subjects, sessionals and dissertation including vive-voce within 3(Three) consecutive academic sessions from his/her admission to the course. A student will be promoted to the next semester irrespective of his/her performance in theoretical subjects provided

he/she passes the sessionals in that semester. However, a student is required to pass all theoretical subjects before submission of dissertation. A student will be ineligible to appear in the semester examination, if he/she fails to pass the sessionals in that semester. In such cases he/she will have to take readmission in that particular semester paying full fees for the semester.

- a) Pass marks will be 50% in each theoretical subjects and sessionals
 - b) courses except theoretical papers, will be treated as sessional papers. Each student must satisfactorily complete the sessional work and must obtain at least 50% marks in each of the sessional subjects in respective semester.
3. A student will have to appear in all the theoretical papers taken by him at a semester at regular semester examination to be held at the end of the semester.
 4. The PG Diploma will be awarded to the candidate in the department on successful completion of all semester examinations (theoretical) and the Sessionals.
 5. A student who have appeared and passed in all the semester papers in the regular semester examination and has passed all the sessional papers within the scheduled date (he/she must have not appeared at any examination for clearing back paper(s) in any semester) shall be placed in the appropriate class and shall hold such position in their respective class list in order of merit as the percentage of total marks secured by them.
 6. A student who has appeared at any examination(s) for clearing back paper(s) in any semester subject(s) in the next year and passed in all papers will be placed in the appropriate class in order of merit. but shall be placed below the list of candidates as determined under clause (vii) irrespective of the fact they might have secured higher aggregate marks than the candidates whose merit list has been determined according to the same provision.
 7. Candidates securing 65% or more of the aggregate marks in the total number of papers including the thesis will be declared to have passed in First Class and other successful candidates securing 50% or less than 65% of the aggregate marks will be placed in the Second Class.
 8. All students will have to appear in written examinations for theoretical subjects in each semester conducted by Controller of Examinations, Jadavpur University and the venue of the theoretical and sessional examinations will be decided by the Controller of Examinations, Jadavpur University
 9. Controller of Examination on the recommendation from the Director of concerned School will appoint the paper setters as well as examinations of answer scripts. The paper setters and examiners may be internal or external members.
 10. The students' performance in both theory and sessional will be indicated as Grade points and Credit hours and CGPA in the both the Semester Grade Card and the total percentage of marks and Class will be additionally mentioned in the second semester's Grade card.

11. . Classifications of Grades

<u>% of Marks Obtained</u>	<u>Performance</u>	<u>Grade</u>	<u>Grade Points</u>
90 and above	Outstanding	S	10
80 to 89	Excellent	A	9
70 to 79	Very Good	B	8
60 to 69	Good	C	7
50 to 59	Fair	D	6
Less than 50	Unsatisfactory / Fail	X	0

12. The following Examination fees be fixed :

- i) Semester Examination fee – Rs. 1000/-
- ii) Grade Card – Rs. 500/-
- iii) Repeat Exam. fee – Rs. 500/- per paper
- iv) Certificate fee – Rs. 200/-