रजिस्ट्री सं. डीएल (एन)-04/0007/2003--05 REGISTERED No. DL(N)—04/0007/2003—05

सत्यमेव जयते

भारत का राजपत्र
The Gazette of India

साप्ताहिक/WEEKLY

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं॰ 19] नई दिल्ली, शनिवार, मई 10—मई 16, 2008 (वैशाख 20, 1930)

No. 19] NEW DELHI, SATURDAY, MAY 10—MAY 16, 2008 (VAISAKHA 20, 1930)

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.

CHAPTER-II

3. Duration of the course. –

a) Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. 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 speciality 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 so that he or she may become capable of functioning independently.

b) Pharm.D. (Post Baccalaureate): The duration of the course shall be for three academic years (two years of study and one year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –

Phase I – consisting of First and Second academic year.
Phase II – consisting of Internship or residency training during third year involving posting in speciality 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 so that he or she may become capable of functioning independently.

4. Minimum qualification for admission to. –

a) Pharm.D. Part-I Course – A pass in any of the following examinations -

(1) 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the following 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.

Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.

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.

b) Pharm.D. (Post Baccalaureate) Course -

A pass in B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:

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. Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –
   i) Pharm.D. Programme – 30 students.
   ii) Pharm.D. (Post Baccalaureate) Programme – 10 students.

6. Institutions running B.Pharm programme approved under section 12 of the Pharmacy Act, will only be permitted to run Pharm.D. programme. Pharm.D. (Post Baccalaureate) programme will be permitted only in those institutions which are permitted to run Pharm.D. programme.

7. Course of study. – The course of study for Pharm.D. shall include the subjects as given in the Tables below. 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.

T A B L E S

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

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**

Third 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)**
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**

Fourth Year:

S.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**

Fifth Year:

S.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 Pharmacoeconomics	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 independently provide the clinical pharmacy services to the allotted wards.

(i) Six months in General Medicine department, and

(ii) Two months each in three other speciality departments

8. Syllabus. – The syllabus for each subject of study in the said Tables shall be as specified in Appendix -A to these regulations.

9. Approval of the authority conducting the course of study. – (1) No person, institution, society or university shall start and conduct Pharm.D or Pharm.D. (Post Baccalaureate) programme without the prior approval of the Pharmacy Council of India.

(2) Any person or 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 by the Pharmacy Council of India.

(3) The scheme referred to in sub-regulation (2) 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:

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, labs., equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.

10. Examination. – (1) Every year there shall be an examination to examine the students.

(2) Each examination may 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 below :

T A B L E S

First Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	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			600 = 1200

* for Biology.

Second Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	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

Third Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	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

Fourth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	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

Fifth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	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

***** Attending ward rounds on daily basis.

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

11. Eligibility for appearing Examination.— Only such students who produce certificate from the Head of the Institution in which he or she has undergone the Pharm.D. or as the case may be, the Pharm.D. (Post Baccalaureate) course, in proof of his or her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at examination.

12. Mode of examinations.— (1) Theory examination shall be of three hours and practical examination shall be of four hours duration.

    (2) A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.

    (3) Practical examination shall also consist of a viva –voce (Oral) examination.

    (4) Clerkship examination – Oral examination shall be conducted after the completion of 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.

13. Award of sessional marks and maintenance of records.— (1) A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm.D. or as the case may be, Pharm.D. (Post Baccalaureate) course, shall be maintained for each student in the institution and 30 marks for each theory and 30 marks for each practical subject shall be allotted as sessional.

    (2) There shall be at least two periodic sessional examinations during each academic year and 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 examination (20 marks);
        (ii) Day to day assessment in the practical class work, promptness, viva-voce record maintenance, etc. (10 marks).

14. Minimum marks for passing examination.— 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.

15. Eligibility for promotion to next year.— All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.

16. Internship.— (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.

    (2) Every student has to undergo one year internship as per Appendix-C to these regulations.

17. Approval of examinations.— Examinations mentioned in regulations 10 to12 and 14 shall be held by the examining authority hereinafter referred to as the university, 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–D to these regulations.

18. Certificate of passing examination.— Every student who has passed the examinations for the Pharm.D. (Doctor of Pharmacy) or Pharm.D. (Post Baccalaureate) (Doctor of Pharmacy) as the case may be, shall be granted a certificate by the examining authority.

CHAPTER-III
Practical training

19. 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. 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.

20. 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. 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.

21. 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.

22. 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 authorised 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 utilisation 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.

23. 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 authorised 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-tiles 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.

24. 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
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) 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.

Website: www.jntuk.edu.in
Email: dap@jntuk.edu.in

Phone : 7032894555

Directorate of Academics & Planning

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA
KAKINADA-533003, Andhra Pradesh, INDIA
(Established by AP Government Act No. 30 of 2008)

Lr. No. JNTUK/DAP/AC/ II,III,IV & V Years/Pharm D/2022 *Date: 28-07-2022*

Dr. KVSG Murali Krishna,
M.E, Ph.D.,
Director, Academics & Planning
JNTUK, Kakinada

To
All the Principals of Affiliated Colleges.
JNTUK, Kakinada.

Academic Calendar of II, III, IV and V Year Pharm D
Academic year 2022-23

Description	From	To	Weeks
Commencement of Class Work	**01.08.2022**		
Community Service Project	01.08.2022	13.08.2022	2W
I Unit of Instruction	15.08.2022	29.10.2022	11W
I Mid Examinations	31.10.2022	05.11.2022	1W
II Unit of Instructions	07.11.2021	21.01.2023	11W
II Mid Examinations	23.01.2023	28.01.2023	1W
III Unit of Instructions	30.01.2023	15.04.2023	11W
III Mid Examinations	17.04.2023	22.04.2023	1W
Preparation & Practical Exams	24.04.2023	29.04.2023	1W
End Examinations	01.05.2023	13.05.2023	2W
Commencement of next Year Class Work	**05.06.2023**		

*** As per the APSCHE Guidelines Out of the Total 180 hours of Community Service Project leading to 4 Credits, two weeks will be offline and remaining project work can be done during the III-I semester weekends and holidays.**
All the B. Tech, B. Pharmacy & Pharm D students admitted from 2020-21 onwards are supposed to do CSP (Community Service Project)

28/7/22
Director Academic Planning

Director
Academic Planning
JNTUK, Kakinada

Copy to the Secretary to Hon'ble Vice Chancellor, JNTUK.
Copy to the Rector, JNTUK.
Copy to the Registrar, JNTUK.
Copy to Director, Academic Audit, JNTUK.
Copy to Director, Evaluation, JNTUK.

PRINCIPAL
VIJAYA INSTITUTE OF
PHARMACEUTICAL SCIENCES FOR WOMEN
NIKEPADU, VIJAYAWADA 521 108

INSTITUTIONAL EXAMINATION COMMITTEE

VIJAYA INSTITUTE OFPHARMACEUTICAL SCIENCES FOR WOMEN
Enikepadu, Vijayawada – 521108

Date: 26-07-2021

OFFICE ORDER

INSTITUTIONAL EXAMINATION COMMITTEE

The Institutional Examination Committee for the academic year 2021 – 2022 is constituted as follows and it is effective for a period of 06-09-2021 to 06-08-2022. Following staff members are appointed as Institutional Examination Committee.

S.NO	NAME	DESIGNATION	POSITION	SIGNATURE
1	Dr. K. Padmalatha	Principal	Chairman	
2	Mr. S. Venkateswara Rao	Assoc. Professor	College Examination Officer	
3	Mr. A. Jayarami Reddy	Assoc. Professor	Member	
4	Mrs. A.V.S. Hima bindu	Asst. Professor	Member	
5	Dr. N. Prathibha	Asst. Professor	Member	
6	Dr. S. Sundar	Professor	Member	

Functions and Responsibilities:

1. Ensure proper dissemination of information with regard to examination among all the stakeholders' viz. students / faculty / non – teaching staff / university authorities etc.
2. Receive and submission of exam notification / schedule from JNTUK web portal.
3. To ensure proper organization of in semester assessments / sessional / end semester examinations in the college.
4. Ensure proper communication with JNTUK with regards to examination and fulfillment of university circulars.
5. Appoint alternative external senior supervisor / chairman / internal examiners / external examiners for conduct of end semester theory / practical examination with permission of university authorities.
6. Record and issue the answer books and other exam related stationary to the invigilators / internal examiners 30 minutes before start the exam
7. Download and print the appropriate number of question papers at least 20 minutes before the commencement of the exam and maintaining absolute confidentiality
8. Resolve students / faculty / university grievances with regards to examinations.
9. Uploading internal theory / practical examination marks on JNTUK web portal.
10. Maintain records with regards to conduct of examination and results.

Copy to: 1. Establishment File
2. Concerned Faculty member

Dr. K. Padmalatha
PRINCIPAL
VIJAYA INSTITUTE OF
PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU, VIJAYAWADA - 521 108

Vijaya Institute of Pharmaceutical Sciences for Women
ENIKEPADU
VIJAYAWADA

VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU, VIJAYAWADA – 521108

Date: 15.04.2023

V & VI Pharm. D / III Mid Exam Time Table

Date	Subject Name	Staff Name	Staff Signature
17.04.2023 (Monday)	Clinical Research (T5101)	Dr. K. Pavani	Pavani K
18.04.2023 (Tuesday)	Pharmacoepidemiology and Pharmacoeconomics (T5102)	Dr. I. Reshma Naidu	Reshma Naidu
19.04.2023 Wednesday)	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring (T5103)	Dr. B. Dhanush	B. Dhanush

NOTE:

3. Timings: **10.00 AM – 12.00 PM**
4. Send the Question Papers to Exam Section Mail. Id: vipwexams@gmail.com

Exams in charge
(Dr. S. Venkateswara Rao)
EXAMS-INCHARGE
VIJAYA INSTITUTE
PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU VIJAYAWADA 521 108

Vijaya Institute of Pharmaceutical Sciences for Women
ENIKEPADU
VIJAYAWADA

Principal
(Dr. K. Padmalatha)
VIJAYA INSTITUTE OF
PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU, VIJAYAWADA
PIN - 521 108

VIJAYA INSTITUTE OF PHARMCEUTICAL SCIENCES FOR WOMEN
ENIKEPADU, VIJAYAWADA – 521108.

V Pharm.D III Mid Exams Invigilation Duties, April-2023

Morning : 02:00 PM TO 04:00 PM

Exam Dates	Staff Name	Staff Signature
17.04.2023 (Monday)	Mrs. K. Raja Rajeswari	
18.04.2023 (Tuesday)	Dr. Mallesh	
19.04.2023 (Wednesday)	Dr. M. Tabitha Sharon	

Exams Incharge
(Dr. S. Venkateswara Rao)
EXAMS INCHARGE
VIJAYA INSTITUTE
PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU VIJAYAWADA 521 108

Principal
(Dr. K. Padmalatha)
VIJAYA INSTITUTE OF
PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU,VIJAYAWADA
PIN - 521 108

Vijaya Institute of Pharmaceutical Sciences for Women
ENIKEPADU
VIJAYAWADA

INTERNAL SQUAD COMMITTEE

VIJAYA INSTITUTE OFPHARMACEUTICAL SCIENCES FOR WOMEN
Enikepadu, Vijayawada – 521108

Date: 26-07-2021

OFFICE ORDER

INTERNAL SQUAD COMMITTEE

The Internal Squad Committee has been constructed for smooth conduct of sessional / end semester examinations for the academic year 2021 – 2022 for the period of 06-09-2021 to 06-08-2022. Following staff members are appointed as Internal Squad Committee.

S.NO	NAME	DESIGNATION	POSITION	SIGNATURE
1	Dr. K. Padmalatha	Principal	President	
2	Mr. S. Venkateswara Rao	Assoc. Professor	Chairman	
3	Mr. A. Jayarami Reddy	Asst. Professor	Member	
4	Mrs. A.V.S. Hima bindu	Asst. Professor	Member	
5	Mrs. Ch. Anupama Swathi	Asst. Professor	Member	

Responsibilities:

1. Strict checking of unfair means is sole responsibility of members of committee.
2. Before the start of examination, the committee members should check every student.
3. Care should be taken by committee members, that the students should not carry mobile phones, calculator or any sort of electronic material inside the examination hall.
4. Check weather students are carrying hall tickets by committee members to maintain environment of examination. Any issue related to the unfair means should immediately report to the principal or college examination officer.

Copy to: 1. Establishment File
2. Concerned Faculty member

Dr. K. Padmalatha
PRINCIPAL

Vijaya Institute of Pharmaceutical Sciences for Women
ENIKEPADU VIJAYAWADA

PRINCIPAL
VIJAYA INSTITUTE OF
PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU, VIJAYAWADA - 521

VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN

ENIKAPDU,VIJAYAWADA-521108.

V PHARM. D / MID EXAMS
ATTENDANCE DIARY

SUBJECT NAME: Clinical Research (T5101)

S.NO	ROLL.NO	STUDENT SIGNATURE		
		I MID	II MID	III MID
1	187N1T0001	Aliya	Aliya	Aliya
2	187N1T0002	ABSENT	A.Mamatha	A.Mamatha
3	187N1T0003	D.Amrutha valli	D.Amrutha Valli	ABSENT
4	187N1T0004	A.Bhagya lakshmi	A.Bhagya Lakshmi	A.Bhagya lakshmi
5	187N1T0005	B.Karishma.	B.Karishma.	B.Karishma.
6	187N1T0006	B.Priyankasri	B.Priyankasri.	B.Priyankasri.
7	187N1T0007	CH.M.N.Mallika	CH.M.N.Mallika	CH.M.N.Mallika
8	187N1T0008	ABSENT	E.Sri.Lakshmi	E.Sri.Lakshmi
9	187N1T0009	G.Komali	G.Komali	G.Komali
10	187N1T0010	G.Supriya.	G.Supriya	G.Supriya.
11	187N1T0011	J.Amrutha	J.Amrutha	J.Amrutha
12	187N1T0012	Thahmayee	Thahmayee	ABSENT
13	187N1T0013	K.Naga Sivanadi	K.Naga Sivanadi	K.Naga Sivanadi
14	187N1T0014	K.Sravani	K.Sravani	ABSENT
15	187N1T0015	K.Sirivalli	K.Sirivalli	K.Sirivalli
16	187N1T0016	K.L.Vaidhani	K.L.Vaidhani	K.L.Vaidhani
17	187N1T0017	L.N.Sai Priya.K	L.N.Sai Priya.K	L.N.Sai Priya.K
18	187N1T0018	M.Pavallika	M.Pravallika	M.Pavallika
19	187N1T0019	M.Prasanthi	M.Prasanthi	M.Prasanthi
20	187N1T0021			
21	187N1T0022	Rahmedunnisa	Rahmedunnisa	ABSENT
22	187N1T0023			ABSENT
23	187N1T0024			ABSENT
24	187N1T0025	T.DeviPriya	T.Devi Priya.	T.DeviPriya
25	187N1T0026	Sharani.U	Sharani.U	Sharani.U
26	187N1T0028	V.Anjana	V.Anjana	V.Anjana
27	187N1T0029	P.Supriya devi	P.Supriya devi	P.Supriya devi
28	187N1T0030	K.Vedha Sri	K.Vedha Sri	K.Vedha Sri
Total Number of Students		26	28	22
Signature of Invigilator		Dr.Ravi.K	K.V.Rajeswari	K.V.Rajeswari
Exams Incharge		S.Venkateswarlu	S.Venkateswarlu	S.Venkateswarlu
Signature of Head of the Institution				

177N1T0021 P.Jyaswi P.Jyaswi ABSENT

Model of Evaluated Mid Exam

Answer Script

187N1R0001

SRK FOUNDATION'S

VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN

ENIKEPADU, VIJAYAWADA

KNOWLEDGE IS POWER

SRK FOUNDATION

VIJAYAWADA

2022 - 2023

SESSIONAL BOOK

Name : Aliya

Class : V- Pharm.D

Roll No. : 187N1T0001

Subject : Clinical Research

Internal	Objective	Subjective	Assignment	Total	Staff Sign	Student Sign
I		22		22	Dr Pavani B	Aliya
II		29		29	Dr. Pavani B	Aliya
III		30		30	Pavani B	Aliya

Final Average : 30

Dr Pavani B

Staff Sign

HOD Sign

I-Mid

2A:- Pharmacological Action studies and Toxicological studies in the drug development process.

1. Pharmacological Action studies

The drug development process under the pharmacological studies. It is important to study the pharmacological actions of the compound.

Components of pharmacological studies:

1. Selectivity of the Compound
2. Pharmacological profiling
3. Testing on Animal models
4. Safety profiling.

22/30

Dr Pawan K

1. Selectivity of compound:-

(i) Screening of selectivity:

— The screening of selected compound will determine the Potency of the compound, to its target site.

— The selected screening compound bind to the choosen molecular target or may not bind therefore unwanted effects of drug occurs.

(ii) Binding of Assays:-

— The main aim of binding of Assays is to determine the dissociation constant of test compound.

as measure of affinity towards receptor.

— It determines the affinity of test compound inhibit the binding to receptor site by radioligand which is high potent of affinity. They done by membrane Preparations.

2. Pharmacological profiling:-

— The aim of pharmacological profiling is to determine the pharmacodynamic properties of the drug.

— Either done by:-

1. In vitro :- Intact tissues, cell lines & receptor

2. In vivo :- on small animals, animals of disease.

In vitro :-

— In vitro studies involves the intact tissues or cell lines of receptors.

— They are generally collected by fresh tissues or anasthesited animals. which were preserved in biological fluids. (maintaining physiological property)

— In vitro studies they assess for the pharmaco-dynamic changes in the tissues.

Eg:- Fall in BP, Fall in Blood glucose etc.

In vivo studies:-

- In vivo studies involves the animals to perform the pharmacological profiling.
- They perform to determine the PK, bioavailability, affinity of the compound.

Eg:- Agonists or antagonists.

Genetic Models.

3. Animal Models:-

i) Acute physiological and pharmacological Model
ii) Chronic physiological and pharmacological Model
iii) Genetic Models.

Acute physiological and pharmacological Models

- Short term study.
- In this the 10-15 animals involved and studied for acute change.
- In Acute Models they mimic the changes of clinical condition.

Eg:- Hot plate for analgesic drugs for pain

Chronic Models:-

Eg:- Alloxan inhibiting insulin secretion in diabetes Mellitus (DM).

— In this models they shows same as clinical condition of disease.

Genetic Models:-

— These are performed on Transgenic animals which are produced by or overexpression of the deletion of gene.

Selection of Species:-

— It is very important to select the species

— A small animals in lab such as rats, mouse are involved in studies

— Transgenic animals also used.

— The Animal Models which are prepared in lab doesnot exactly carry the same clinical condition as humans do.

— So, that set up of validity criteria is done.

Validity Criteria in Animal Models

Face Validity.

Predictive Validity.

Screening Validity.

Safety profiling:-

- Safety profiling is done to prevent unwanted adverse effects that are previously unnoticed.
- To determine the safety, efficacy and minimal adverse effects of the drug.
- Purpose:- To avoid adverse effects
  To minimize drug interactions.

---

2. Toxicological Studies :-

- Once the substance or compound attain to lead status than its toxicity study should be studied for its safety and efficacy.
- After the approval also the toxicity studies should be conducted for the life time of the drug.
- The toxicologists in pharmaceutical industry identify the toxicity of the drug and they Report.

Various components of Toxicological studies

1. Acute toxicity [short-term] studies
2. Sub-Acute or sub chronic toxicity studies
3. Chronic toxicity studies
4. Carcinogenicity studies
5. Reproductive toxicity studies
6. Genetoxicity studies
7. Perinatal toxicity studies
8. Teratogenicity studies

1. Acute toxicity [short term] studies :-

- In this study a small group of 3 subjects administered with single drug with various dose level and observed for 24 weeks
- If there is any high toxicity than other three fresh subjects with same strength of drug is administred and observed for reactions.

2. Sub-Acute Toxicity Studies:-

- A group of subjects with daily administring a

drug with various dose levels

- Duration of above tweeks.
- The abnormal functions and biological, clinical evidence arise means than register the dose.

3. Chronic Toxicity studies:-

- A group of subjects with 2 different species with the multiple drug with different dose levels administered.
- Determine the long time adverse effects.
- Mainly done for chronic disease condition.

4. Carcinogenicity study:-

- Done on wee, rat or mouse and same dose is carried out in these individuals. And the changes arised were noted.
- Asseved for other changes than the Carcinogenicity

5. Reproductive toxicity studies:-

- In mammalian species the reproductive character and mating behaviour is observed.
- The foetus changes observed.

- Mammals bering of age that child bearing than the should continue in those animals also.

6. Genotoxicity Studies:-

- Alteration in Inherent Genes is analyzed and Observed.
- Drugs that has property to alter the Gene function is under observation.

7. Teratogenicity Studies:-

- The study continued along the maternal time and conduct study on foetal development
- If the drug use in maternal along pregnancy duration than, it is under Observation upto the delivery and after that also Infant study should conduct for all normal physiological functions.
- If not mentioned normal values than the Reporting of effects should be continued.

1Ans- 1a. Post-Marketing Surveliance.

- It is also called as Phase IV clinical trails
- It involves safety pharmacovigilance

Need:-

- No indication
- minimize rare ADR
- Patient
- No duation.

Methods:-

1. Passive Surveliance
   i) Screening Method
   ii) Case series / reports
   iii) Spontaneous method
2. Active Surveliance.
   i) Sentinel Method
   ii) Registers method
   iii) Drug Monitoring Method.
3. Comparitive Observational Studies
4. Toxicity studies

1. Passive Surveillance:-

(i) Screening Method

— Passive Surveillance often begins with the screening of biochemical reactions involved in the disease.

— It is also called as direct individual Pharmacovigilance

— In this method physician self notice the ADR and reports.

— or the patient self can notice the ADR complaints.

(ii) Case Series/reports:-

— It may be grouped of individual components Pooled of potential components.

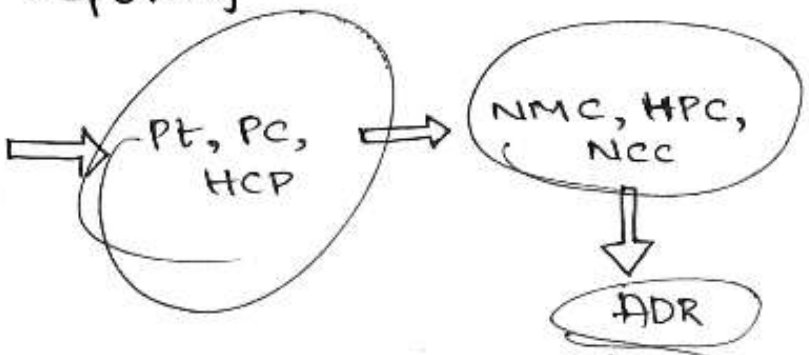
— A group is considered depending upon the same characteristic that group contain.

— All the individual characters have been studied.

— Case reports may collect from physician or by patients

directly by the questionnaire format.

(iii) Spontaneous Reporting



— Spontaneous Reporting done by the patient complaints.

— Sources of it is Literature,

Patient | Subject Review

Patient | Subject complaints.

Media.

Objectives:-

— To minimize ADRs

— No indication

— maintain safety and efficacy.

2. Active Surveillance:-

(i) Sentinel Method.

— Sentinel means disease. Incidence of

— The subjects consists of same characters of the disease are grouped and analyzed.

— The aim objective of this method to minimize unidentified previous adverse effects.

— It not only identify adverse effects but also identifies the drug-drug and drug-Food interactions.

(ii) Drug event Monitoring Method :-

a. Medicine event Monitoring method

b. Disease cohort event monitoring Method.

— The Drug used for the following Treatment should be under observation.

— Analyze of all the drug related problems.

— Assess for drug utilization studies.

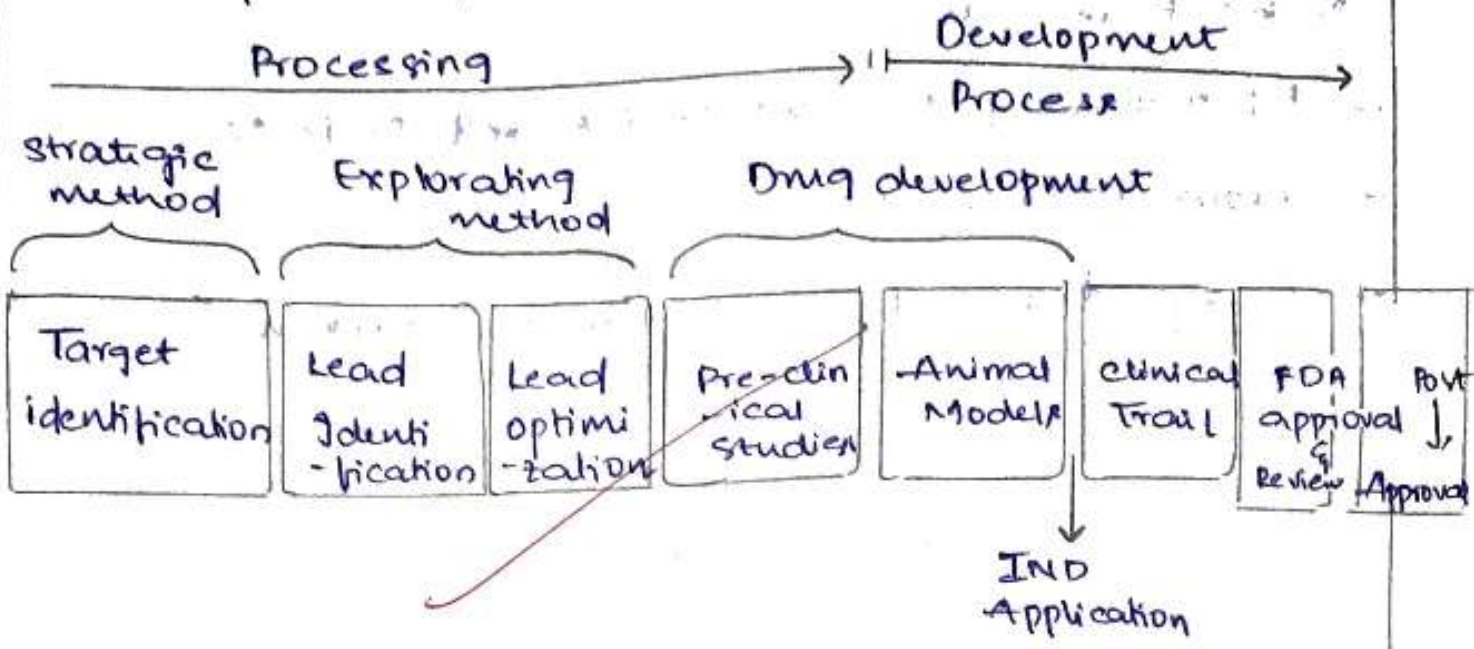
(iii) Register :— Types?

— Register consists of group of patients with same identical characters.

— one type of Register consists of all patients with same disease.

— and another with the same exposure of the drug

1b. (1b). Schematic Representation, Integrated drug development process.



- Schematic Representation of Integrated drug development process.

Steps:-

1. Basic Research
2. New drug discovery
3. Screening
4. Preclinical trails
5. Formulation development
6. Pre-clinical studies
7. IND Application
8. Clinical studies
9. Official / Marketing Approval.

1: Basic Research:-

- Before conducting any trail often begin with Basic Research
- By reviewing previous trails and projects
- from literature etc.
- Basic knowledge should be build upon.

2. New drug development

i) Target Identification and validation

ii) Lead Identification

iii) ~~Lead~~ Optimization

(a) Target Identification and validation:-

- The Target should be Identify. where the compound should bind.
- The substance or drug should bind to target site it is very important to Identify
- Once the relation b/n compound and target is identify than the validation of it will starts.

(b). Lead Identification:-

— Lead is the substance which possess the all quality a drug that should get treated called "lead identification."

— After the ideal lead identify the lead optimization process continues

— Ideal Charactrs of lead:-

Should possess good therapeutic effect

Should not alter biological functions

good bioavailability.

No / minimal ADRs.

(c) Lead optimization:-

— Among all the various lead components validation is conducted.

— By pharmacological Approach the lead optimization is done to help the pharmaceutical and biotechnological companies to find out best safest & efficacy drug molecule.

— Lead validation is also conducted among invivo and invitro studies.

3. Screening:-

— Screening of disease means screening of each component of disease (pathophysiology)

— what are / is the symptoms?

— what is the cause?

— what is the mechanism of Action?

4. Preclinical trails.

— Pharmacological Studies

— Toxicological studies

5. IND Application:-

— It is the permission to continue the next step of clinical trails

— It is not application for marketing approval.

6. Clinical Trails

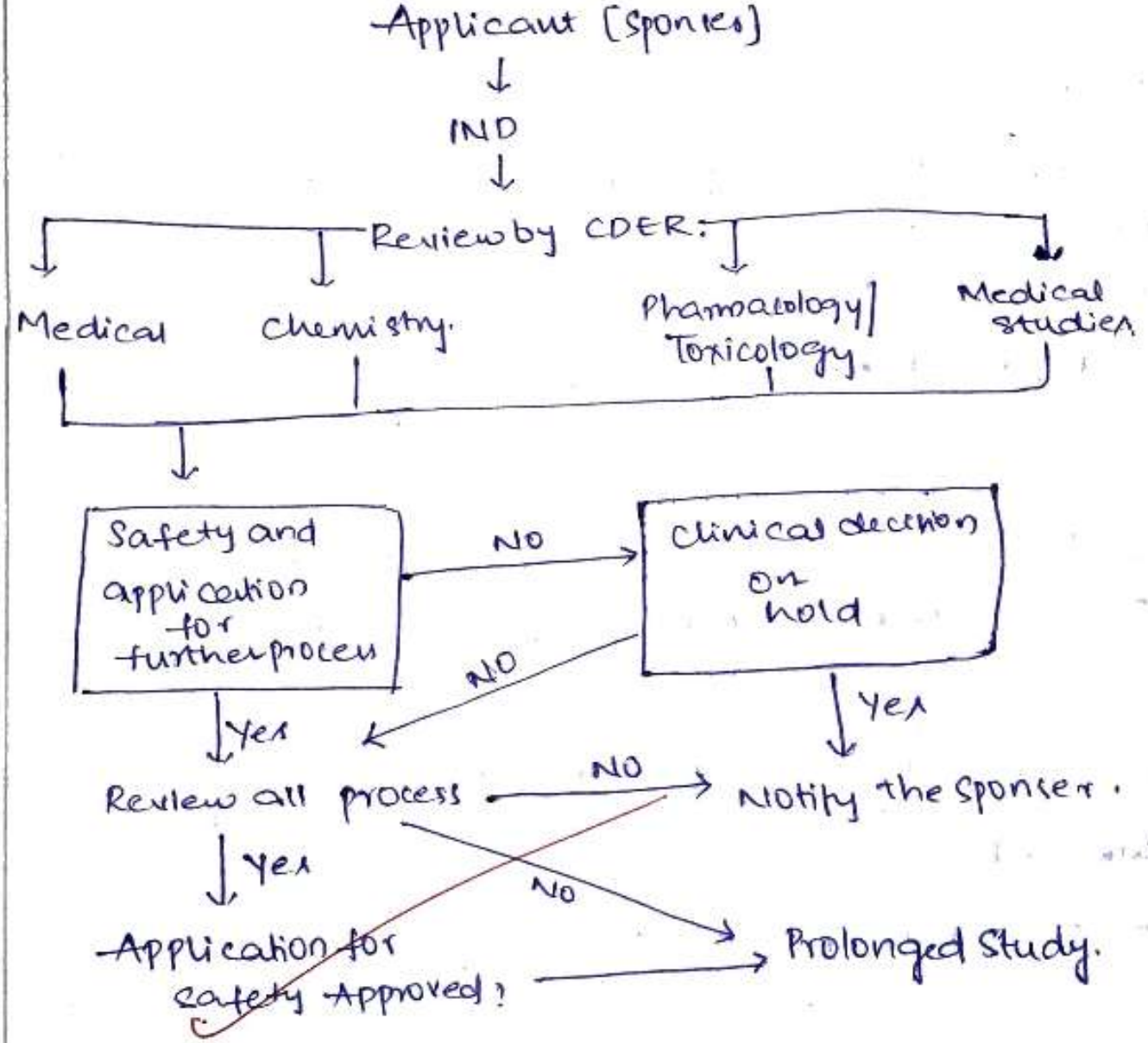
— any experiments done on human participants to analyze the change in clinical condition or in disease condition do.

— Phase 0, phase I, phase II, phase III, phase IV

Official Marketing Approvals

- NDA for the drug to use among the general Public.
- Contains all the ethical committee authorization.

IND Application :-



3Ans:- Clinical Trials:-

Introduction:

Definition:-

Clinical Trials is defined as any experimental study on living organisms with comparision of clinical conditions as same contain in disease patients.

Phases of clinical Trials:-

Phase 0 (Microdosing)

Phase I [Pharmacology and safety)

Phase II.

Phase III [Therapeutical activity]

Phase IV [Post Marketing surveliance].

Phase 0:-

- It is the first step of clinical trails
- Aim of this trials to identify what drug does to the body.
- Pharmacodynamic properties of the drug is determined
- 10-15 volunteers

Phase I:-

- first in human clinical trials
- 20-250 volunteers

- It is also called as pharmacology and safety method of clinical trial
- The aim objective is to find out the safety of the drug.

Phase II :-

- Among 25-100 volunteers
- The aim objective is to find out the safety and efficacy of the medicine
- Chronic disease conditions, like trials conducted
- longer duration Adverse effects analyzed.

Phase III :-

- Among 100's of volunteers
- The safest dose of drug from the phase II is used in phase III
- Give constant dose of drug for therapeutic effect.
- On this the safety, efficacy of the drug is analyzed.

Phase IV :-

- It is also called as post Marketing Surveliance
- On this NDA [New drug Application] is taken.
- for the post marketing process approval should be taken.

— Post Marketing Surveillance - sponcer asks for safety, efficacy and stability of drug in documented form.

— even though the drug approved in market the observation should be carried out.

* Phase II :-

Phase IIa and Phase IIb.

Phase IIa — about drug dosing.

Phase IIb - About affect of the drug

— In phase IIa - no placebo

In phase IIb - Sometimes placebo acts.

* Phase III :-

Phase IIIa and phase IIIb

— Placebo

— blinded.

Dr Pavan K

II - Mid Examination

28½/30

Dr Pawan

1Ans:- ANDA Submission:-

- ANDA is abbrevatid as abbrevatid new drug Application.
- It contains data which when submitted to FDA, center for Drug evaluation and Research, Office of Drugs, provides information related to Review and ultimate Approval of Generic drug product
- General drug Applications also called as abbrevated because there is no including preclinical and clinical data.
- The Generic drug product should be bioequivalenc with the innovator drug product.
- The bioavailability of the Generic drug should demonstrate bioequivalenc with innovator drug
- The same amount of Active ingredient should re deliver into blood stream as innovator drug
- Using bioequivalence as the basis for approval of Generic product is established by "Drug Price competition and Patent Term Restoration Act"

1989 also called as Hatch Waxman Act.

- Innovator drug product can additionaly apply more five years patent for the New medicine

Resources of ANDA:-

1. ANDA Application
2. Consultative sign by "CDER" which help you meet the requirements for safety, efficacy and quality of pharmaceutical products
3. Summary tables, Application form and other submissions of ANDA are the many resources of ANDA submissions.

Guidelines of ANDA:-

1) Guidelines describe content and format of following:-

1. Application of ANDA
2. Chemistry, Manufacturing and control section
3. Non-clinical pharmacology and Toxicology section.

4. Human biopharmacokinetics and biologics
5. clinical and bioavailability section.
6. Microbiology section.

Guidelines functions of ANDA :-

1. Organization of ANDA
2. Granting license for drugs and cosmetics
3. Implementing Amendments of drugs and cosmetic Act
4. Banning of exporting drugs and cosmetics
5. Information on impurities of drug substance
6. Submitting supporting documentation of the Manufacture of drug substance
7. Submitting supporting documentation of the Manufacture of finished dosage form
8. Submitting supporting documentation of scientific studies related to humans and biologics

9. Post Marketing Reporting of ADRs.

Code of federal Regulations:

- The daily proposed rules, policies, meeting notices all are collected in the Code of federal Register (CFR).
- section 21 of CFR contains information regarding drug and cosmetic Act.
- 21 CFR FORM 314 Approval from FDA to market the New drug

21 CFR FORM 320 Bioavailability and Bioequivalence.

ANDA Requirements:-

- Signed ANDA form
- Index
- Information on the basis on which ANDA is submitting
- Information on conducting use of Drug.
- Bioavailability, dosage strength and indication.

- Bioequivalence
- Labelling
- Analysis
- Chemistry, Manufacturing and standards of drugs.
- Pharmacokinetics.
- Applicant.

1. Signed ANDA form:- Contains all the information about name of the applicant, address, name of drug product, dosage strength etc
2. Index:- should include each volume and Page number of each detailed item
3. Information of basis on which ANDA is submitting:-
   - Reference drug name, dosage strength
   - information on exclusively listed drugs
4. Bioavailability, dosage strength and standards of drugs.

Route of administration, dosage strength & bioavailability of Generic drug should be same as branded drug.

5. Bioequivalence :-

Applicant should demonstrate the bioequivalence between Generic drug and reference drug.

6. Labelling :-

Labelling of newly listed drug and previous listed drugs should compare side by side

7. ~~Analysis~~ :-

Method of Analysis

Validation Methods

~~Analysis~~ methods

Quality checker.

8. Chemistry, Manufacturing and Standards

It includes composition, procedure and standards of drug product

9. Pharmacokinetics :-

It includes i) The design

ii) dosing strength.

iii) Number and frequency of blood and urine sample collection.

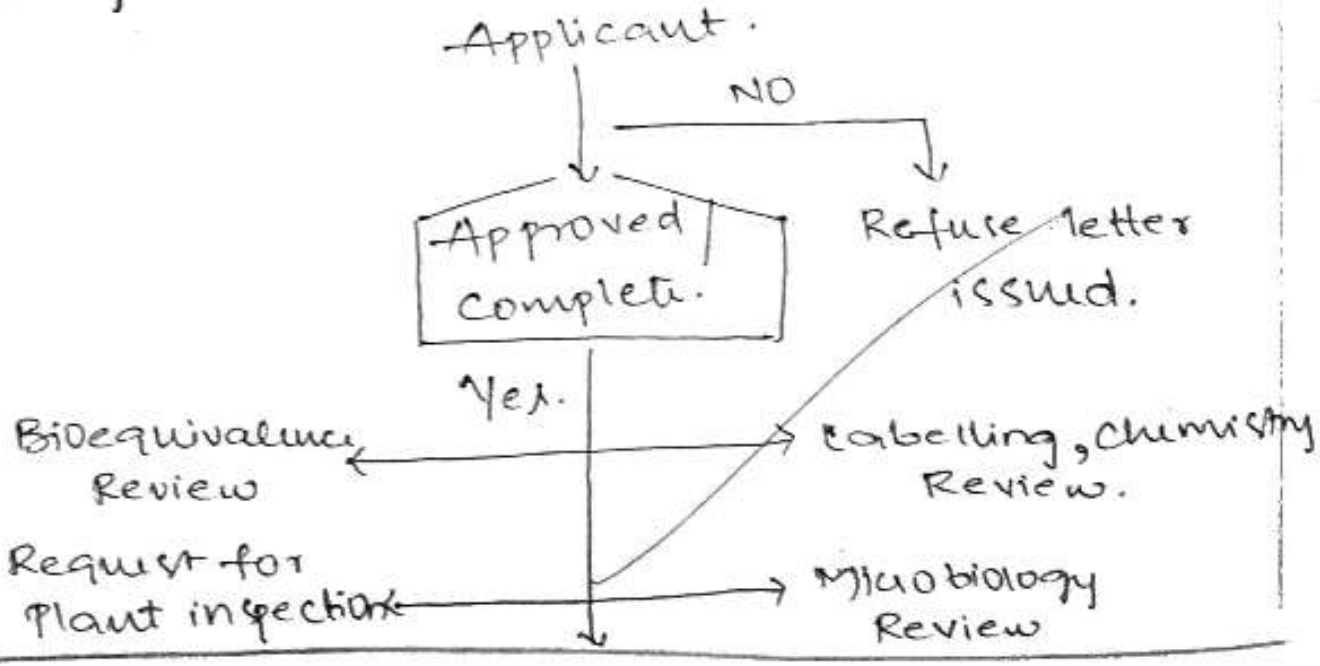
Applicant:-

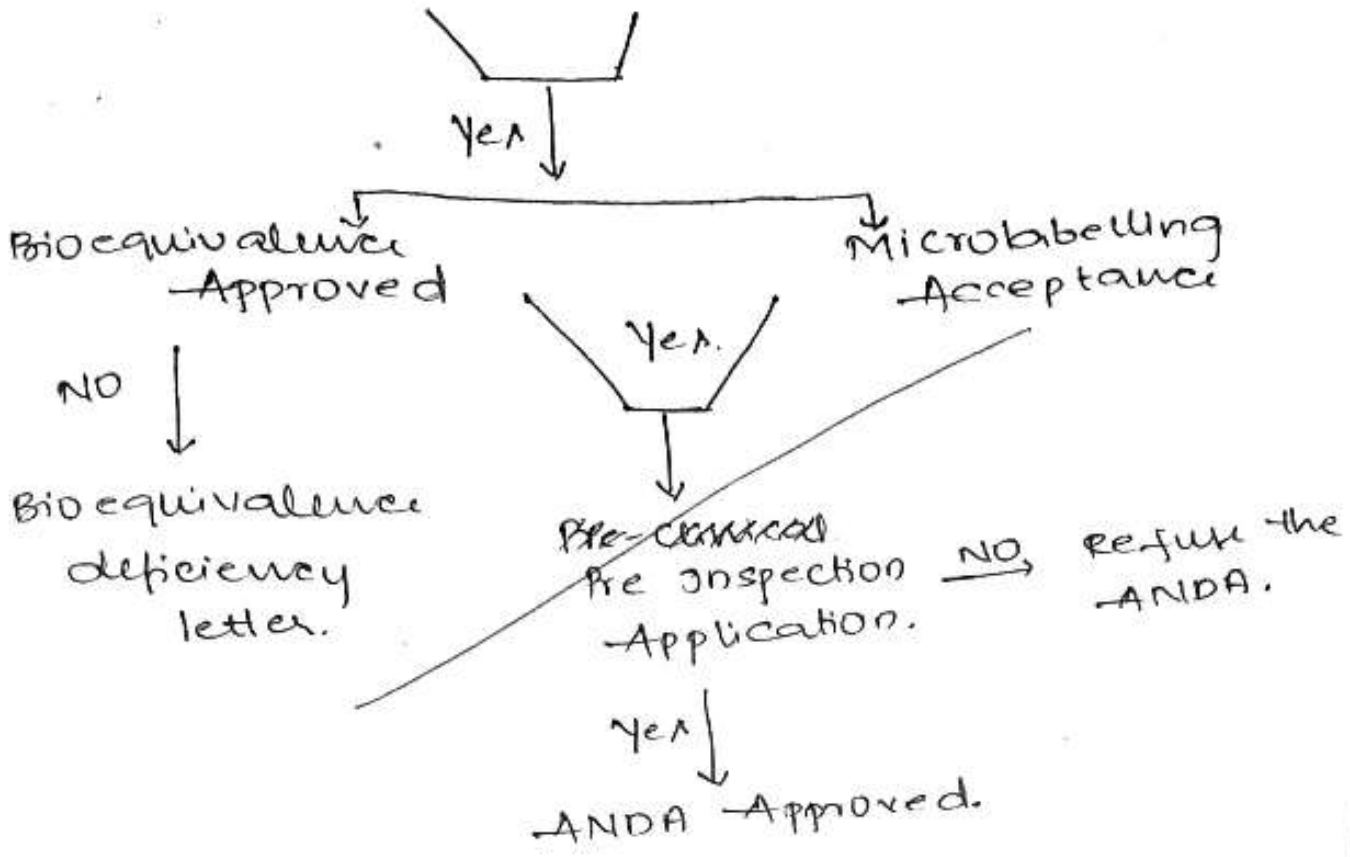
— Applicant is defined as one who willing to get an approval for generic drug Manufacturing and Marketing in country.

Goals of ANDA:-

1. To reduce the price of drug
2. To reduce time of development
3. To increase the bio availability than the reference drug.
4. Maintaining less Risk than benefits.

Filing of ANDA:-





Classification of Certificates:-

PARA- I classification certification.

PARA- II "

PARA- III "

PARA- IV "

1. PARA I ~~classification~~ Certification:

Required more information for filling patent

↓

One or more Applicant can Apply.

FDA may approve immediately the Generics.

PARA-II Certification:-

Patent was expired

↓

FDA may approve Generic immediately one or more Applicants can Apply.

PARA - III Certification:-

Patent was not expired will expire on specific date.

↓

FDA approve only on the date of expiry. one or more Applicants can Apply.

PARA - IV Certification:-

Invalid Patent or non infringed by Generic Applicant.

↓

Generic Application notice to Patent holder.

PARA IV certification.

After 45 days patent holder doesn't sue Applicant FDA will approve the ANDA.

ANDA Application Approved.

After 45 days patent holder sue Applicant 30 months in favour of patent holder.

30 months stay expired

30 months stay not expired.

For the first applicant EMRQ 180 days added

subsequently addition of EMR 180 days after the expiry of 1st applicant EMR.

If Judgement favourable to Patent holder, FDA will not approve the ANDA

Judgement not favourable to Patent holder.

will not enter until FDA approves

For 1st Applicant EMR of 180 days

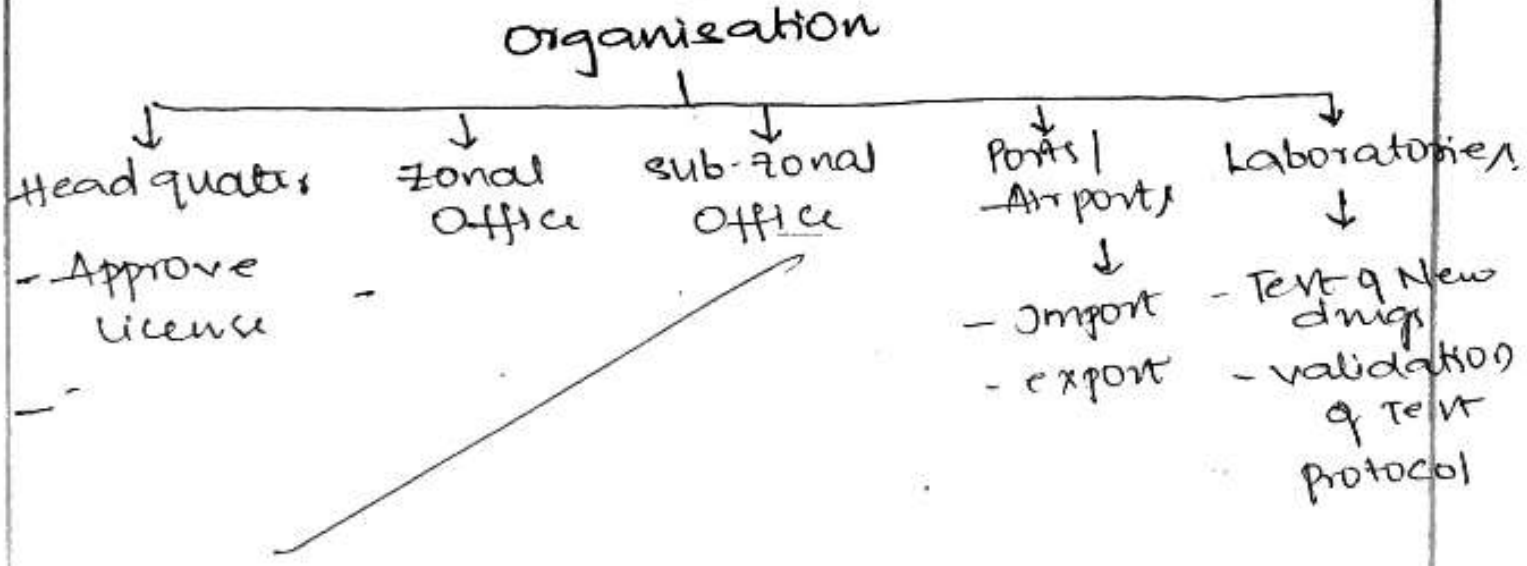
subsequent addition of EMR 180 days after expiry of first EMR of Applicant.

- ANDA Clause

↓ Paragraph I ↓ paragraph II ↓ paragraph III ↓ paragraph IV

2Ans:- CDSCO

- Central Drug standards control Organitation [CDSCO)
- CDSCO is the main regulatory to the regulation of Technical Requirements for pharmaceutical products of human use.
- Main head Office of CDSCO is located in New delhi functioning under directorate General of health service, Human welfare Committee, etc.
- Drug controller General of India [DCGI] appointed by Government of India. and State drug control organisation.
- DCGI advised by Drugs Technical Advisory Board [DTAB] and Drugs consequtive Committee.



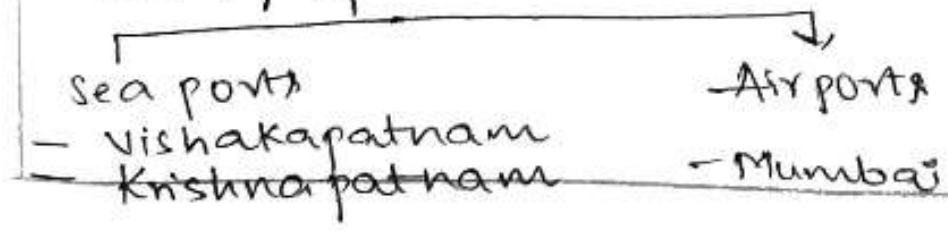
(6) Zonal Officers :-

Chennai
Mumbai
Kolkata
hyderabad
Ahmedabad
Ghaziabad

(3) Sub zonal Officers :-

Bangalore
Jammu
chattisgarh

Ports / Airports :-

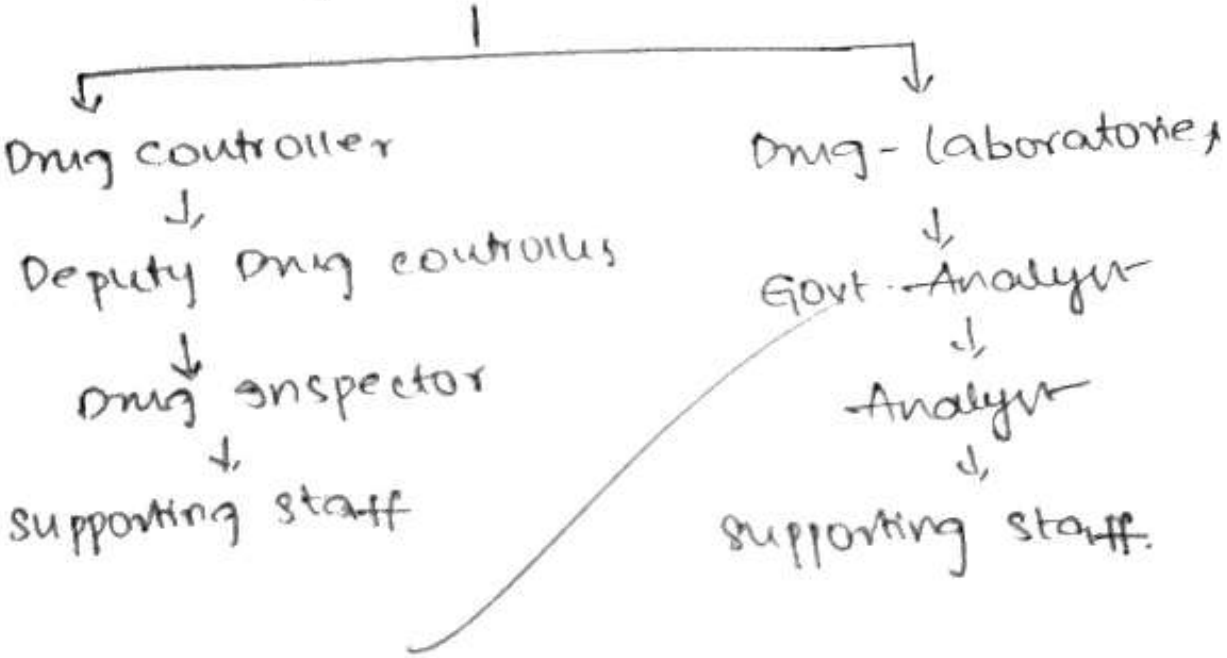


- Chennai
- Kolkata
- Hyderabad
- Cochin
- Gndore.

Functions of Central Authority:-

- Testing of drugs from central labs
- Monitoring of ADRs.
- Registration of drugs in CDSCO.
- Examine the drugs before Approved by DCGI.

State drug control organisation.



Functions :-

- Investigations and prosecution for the Guidelines adopted for legal provisions
- pre-port inspection Advices.
- Information on substandard drugs.

New drug Approval :-

- The Applicant should apply to CDSCO to Approve.
- Examined by DCGI and finished only when the CDSCO satisfy with scientific technical data of Application.

Approval of Drugs.

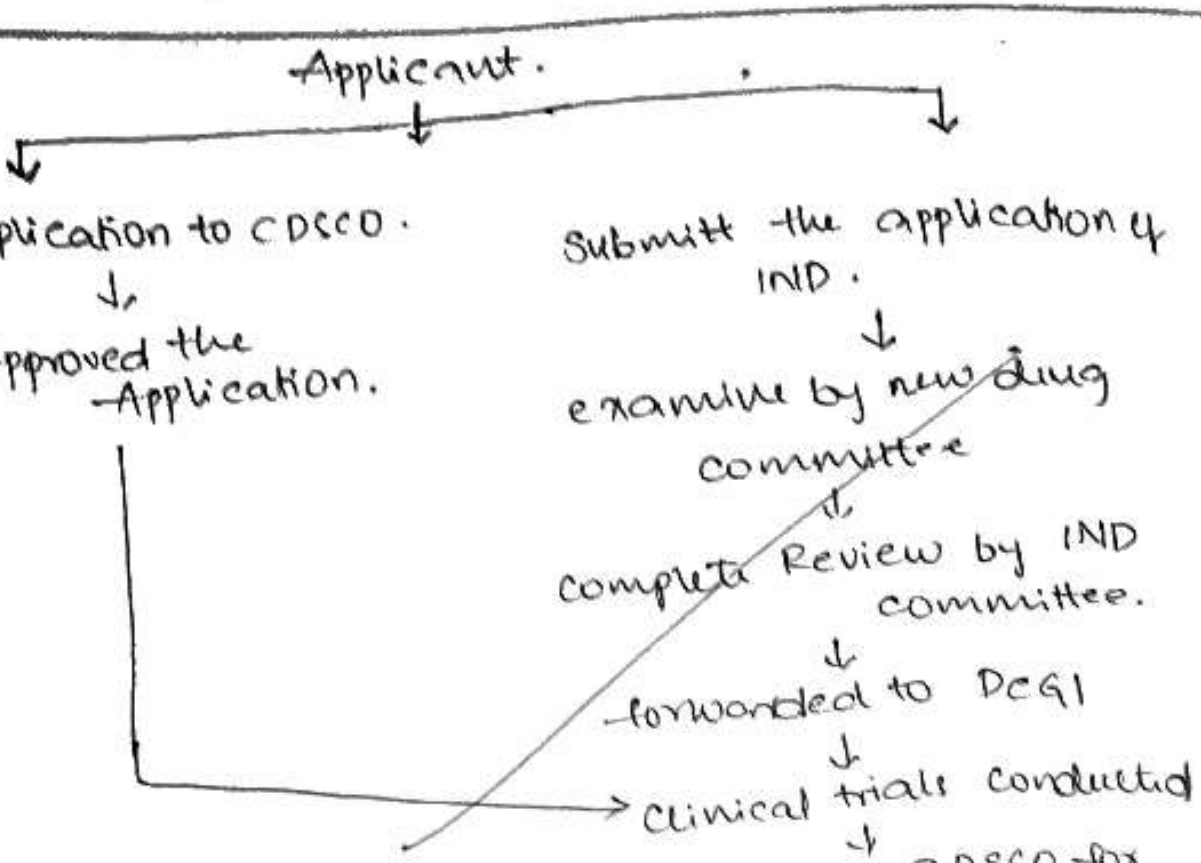
Many drafts are prepared and Revised & Circulated for the harmonication of draft to complete.

↓

final harmonication draft signed by EWR and forwarded to CDSCO.

↓

3 regulatory sponsers conduct normal contravention of regulatory from 3 regions. for new comments.



3 Ans 1- ICH :-

(a) Definition -

ICH is the International Conference or council for harmonisation of Technical requirements for the medical products, clinical trails in India.

Organization of ICH :-

1. Steering Committee
2. Secretariat
3. co-ordinators

4. Working groups.

organisation

- steering committee
  - Approve ICH.
  - maintain the discussion of groups records.
- secretariat
  - Prepare policy and procedures for ICH and
  - inspection of pharmaceutical products.
- co-ordinator
  - maintain the reports and result of group discussion.
  - Act as link between ICH and non ICH members
- working groups
  - expert working groups
  - Information working groups
  - Regulatory working groups.

6 parties of ICH.

2 from Japan.

1) Minister of welfare of health and humanare (sewice)

2) Japan pharmaceutical and Research Association

2 from Europe

1) Europeon union

2) Europeon union of federation pharmaceutical and Research Association

2 from US

1. Pharmaceutical and Research Associates from America.

2) FDA

Operating process:-

Many drafts are prepared and circulated through revision for selected harmonisation of draft.

↓

final draft is signed by EWR and forwarded to CDSCO.

↓

3 Regulatory sponsers will conduct normal contravention to recieve comments.

↓

It only recieves when the Guidelines adopted for legal provisions.

↓

The endorsement of representatives from Japan, europe and US must assign.

↓

Approval of ICH

Q7 (b)

GCP:-

Good clinical practice is the set of International standards and scientific ethical rules for requirement of safety, efficacy and multi - disciplinary products.

Nuremberg code:-

- voluntary human subjects participation is necessary.
- conduct the experiments to promote good to society.
- This human participants can stop the experiments whenever they needed.
- There should be no mental and physical injuries.
- Risk must be low and overweigh by the benefits.
- Experiment can stop by the technician when there is continuous result of risk observed.
- Human subjects can also stop the experiment when there mental and physical status not supported.

29½/30

III - Mid Examination

2 Ans:- Clinical Data Management in Clinical Trials:-
[2a]

Clinical Data Management is an important area in which needs a good data management to conduct Clinical Researchs to the earliest.

Clinical Data Management helps in high quality, sound scientific validity, effective Clinical trials.

Components of Clinical Data Management:-

1. Protocol Management Component
   - Protocol submission
   - Protocol Approval
   - Protocol Monitoring
   - Protocol Reviewed

2. Data Informatics:- It contains all the details of the patient including in Clinical trials.
   - Recruitment of subject
   - enroll

- Data collection
- Data entry
- Medical coding
- Validation etc.

3. Integrated Data Management.

- Information of the data collected from the warehouse. And also collected from different data from different sources, including external data sources.

Clinical Data Management in Clinical Research:

- CDM plays an important role in clinical Research
- Helpful in Data collection
- Reduce the time from data processing to marketing.
- Provide high quality, effective and scientifically sound clinical Researches

Clinical Data Management Plan:-

- CDM plan is an document which outlines the needs from starting of the

Study to complete end of the study.

Clinical Data Management Plan Tools:-

— CDM Plan Tools are web based which contains documents and spread sheets which is useful for data entry.

— Examples:-

Public Data Management Plan [PDMP]

NIH from simple social plan.

ICPSR

Clinical Data Management Tools:-

— There are 2 types of CDM software Tools

i) Commercial DM Tool

ii) Open source DM Tool

i) commercial clinical Data Management Tool:-

- It is non significant from one source to another
- It is expensive
- It contains pharmaceutical giants in which these is specified tools relating to different areas of pharmaceuticals
- Examples:-
  - CLINITICAL CLINITIS
  - ORNICA CLINICAL
  - REVA
  - E-CLINICAL SUITS

ii) Open source clinical Data management tools.

- It is freely available
- It contains various websites which shows free access for the CDM.
- Example:-
  - Open CLINICA
  - Open CLINICAL Data Management Tool
  - Pho.SCo

Clinical Data Management provides

High quality Data:-

- CDM provides highly effective and sound scientific validity.

Elements of Clinical Data Management Plan

1. Types of data.

Data collection and creati

- Source of data
- format of data
- Data may be fixed or change or not
- Additional of data through clinical trial, if chance.

2. Contixtual Informatics.

Data Documentation

- How the data of the study documented and where ?

3. Storage, Backup and Security.

- Storage, manage, data safety and data security
- How the data is stored & security.

4. Provisions for protection and privacy.

- data safety, data security, privacy.
- How the data maintained privately?

5. Policy and Reuse.

- data security, privacy, Reuting
- How the data maintain policy?

6. Access and sharing.

- How the data can be utilized by the different resources.

7. Archival Data Management

- The final Data Management is Archived.

8. Roles and Responsibilities

- The clinical Data Management plan maintain all the compliance with the regulatory authorities.

Procedure of Clinical Data Management.

1. Case Report Form [CRF] designing.
2. CRF annotation
3. Database designing
4. Data collection
5. CRF Tracking
6. Data validation
7. Discrepancies Management
8. Medical coding
9. Data Extraction
10. Data Base locking.

1. Data base designing:-

— It is an Clinical data Management software.

— On which the data base designing taken place.

- Scientific validation is done to prevent the errors in database designing.

2. Data Collection:-

- Data collection is done by paper or electrical data collection.
- Traditional method is to collect through paper.
- But the data collection through paper form is error prone.
- Electrical data collection is useful for minimization of error
- It is also called as REMOTE DATA ENTRY.

3. Data Tracking:-

- The data tracking is done through case Report form.
- while monitoring of retrieved CRFs was done.

4. Data Validation:-

— The data from the retrieved CRF's validation process is conducted from which the errors must be noted

— The data which is failed in validation called as discrepancies.

— This discrepancies are further Managed.

5. Discrepancies Management:-

— The issue is resolved then it is called as CLOSED discrepancies

— Some of the issues may not be resolved called as IRREVERSIBLE discrepancies.

— They may be further undergone investigations to resolve the errors.

6. Medical coding:-

- Medical coding Needs medical terminology.
- A basic knowledge about the drug, disease or basic pathological conditions.
- common Medical coding for :-

(i) ADR :- Medical Dictionary of relative activities

(ii) Drugs :- Medical Drug Dictionary

7. Data Base Locking:-

- Generally once the retrieved CRFs undergone the validation and finish the final process than Data Base locking implemented.
- Data Base locking appointed by the stakeholders.
- Once the data is locked it can't be changed., followed by Archival.

Q Ans:- Retrospective studies:-

2[b)

- It is a type of cohort study
- on which subjects are collected from past.
- The treatment or disease stage already noted.
- It is done to evaluate difference between group of a variables.
- By this result of past subjects get to know.

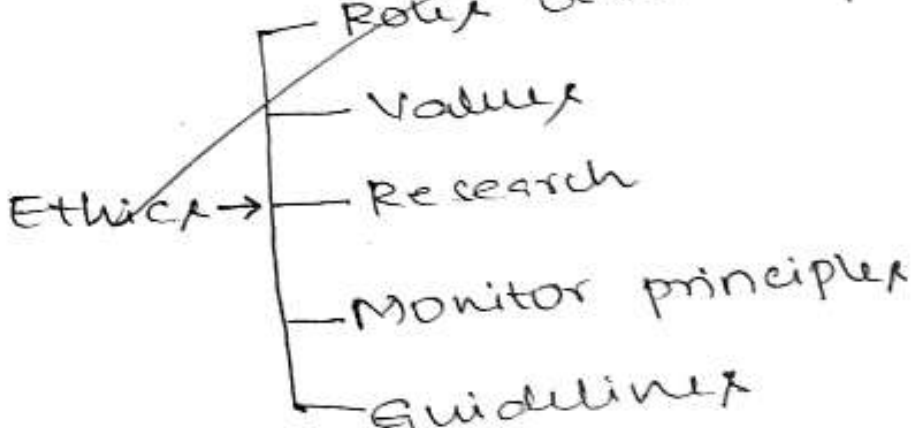
Prospective studies:-

- It is a type of cohort study.
- on which subjects are collected from the present situations.
- May the subjects not prone to that diseases or treatment.
- to know the or to find out the condition to prevent future issues of there particular disease or treatment.

1 Ans:- (1a) Ethical Guidelines in Clinical Research

ETHICS:-

- It is a group of standards or principles.
- This standards are universal.



Ethical Guidelines in Clinical Research:

Nowadays ethical guidelines in clinical trials followed as

1. Social and clinical values
2. Scientific validity
3. Fair subject selection

4. Favourable Risk- Benefit Ratio.
5. Inform consent form
6. Independent Review
7. Respect to the subjects or volunteers

(1) Social and Clinical Values:-

— All the questions should be answerable.
— The queries of society should be answerable
— Providing ethical information of the study to the society.

(2) Scientific validity:-

— the conducted study should be with sound scientific validity.
— It should maintain highly effective and good quality procedures in conducting the study.

(3) Fair Subject Selection:-

- The volunteers of the clinical research should be selected according to the compliance of the protocol.
- In some cases, the selection of subjects can decide from the trained individuals.
- Fair subject selection should done because to minimize the wastage of product and pain of volunteers.

(4) Favourable Risk - Benefit Ratio:-

- In every study there is an inherited errors, or risks.
- The risk and benefit ratio is choosen to determine whether the study contains more benefit than risk or not.
- Study should contain maximised benefits and minimum risks

(5) Independent Review :-

- All the trial related aspects should be reviewed.
- Is the ethical committee has approved or not?
- Is this study is following the Compliance with the protocol.
- The clinical study / trial should be compliance with ICH- GCP or regulatory authorities.

(6) On form Consent form :-

- All the participants in the study should be explained by the measurements of the clinical trials
- All the benefits and risk of the study should be explained to each individuals.

— Each of content of ICF should be explained to subject and take there will to participate or not.

(7) Respect the all subjects / volunteers.

— should maintain respect to the subjects throughout the clinical trial.

— of any Mental and physical charge of subject noted, medical care should be provided

— should not force them to participate in the study. until and unless they are ready for it.

— In between study, If the subject willing to drop from Clinical trial we should let them to do so.

Ans:- [1b)

ADE:-

- Adverse Drug Event
- Untoward and unintended medical condition to an individual with treatment of normal dose, dosage and right route of administration.
- It is non-specific to the drug or medication.

ADR:-

- Adverse Drug Reaction
- Noxious and unintended medical condition to an individual due to drug is called as ADR.
- It is specific to the drug or medication

* All ADR's are ADE but all ADEs are not ADR.

3AM1 - Roles and Responsibilities of Auditor in Clinical Trials:-
[3Q]

Auditor:- An independent individual appointed by sponser or regulatory authorites for examining the clinical Trials.

Roles and Responsibilities

Investigation site audit
Clinical department process audit
Data Management audit
Safety Department audit
GCP Laboratory audit
Sponser Central division audit

1. Investigation site audit:-

- Auditor audit the investigation site where clinical trial done for

the examination of sponser level of risk.

- Sponser invite the auditor to audit the trial when it is going against to GCP guidelines.

2. Clinical department process audit.

- Auditor audit the clinical department process.
- To minimize the error in the Process and to maintain accuracy.

3. Data Management audit.

- Auditor audit the Data Management
- They audit for further Discrepancies in the retrieved CRFs.
- Is there any violation in the Data Management process.

4. Safety department audit:-
Auditor audit the safety department of the clinical Trial
the condition of the subjects in the clinical trial may be audit.
The safety parameters in compliance with GCP guidelines or not is audited

5. GCP Laboratory audit:-
The Auditor audit and supervise all the GCP Laboratory parameters which involved in the study.
The guidelines should be followed by the conductor of the trial.

6. Sponser Central divison audit:-
Auditor audit all the moves of the sponser and maintain all the

documents of sponsor. Sponsor has all the documents related to the clinical trial and auditor will audit it.

3Ans:- (3b) Role of Investigator in clinical trial.

Investigator:- An individual who is responsible for the conduction of clinical trial is called as Investigator.

Roles of Investigator:-

1. Initial of clinical trial
2. Conduct the trial
3. Study closure.

1. Initial of clinical trials:-

① contract and agreements of Trials:-

— Investigator maintain all the contract and agreements related to the clinical trial.

② IEC, IRB, ERB approval

— Investigator should take approval from the IEC, IRB, ERB for the initiation of the study

③ Clinical study Team

— Clinical study co-ordinator

— Staff Nurse or

— Pharmacist

④ Planning resources and Requirements.

— Investigator planning about all the resources and requirements needed for the clinical study.

⑤ Trial ~~trial~~ training Meeting.

— Investigator plays a role in maintaining trial training meetings

related to the clinical study.

2. Conduct the Trial.

① Selection of subjects :-

— Adding the subjects to the study who are applicable for the clinical trial.

② Medical Care providing :-

— Providing medical care to the subjects of clinical trial in case of severe Adverse drug reactions.

③ Inform consent form.

— All the subjects who are participating into the study should sign the inform consent form to proceed study.

④ Compliance with protocol.

— Investigator should should follow the study according to the protocol module

⑤ compliance with ICH, GCP guidelines.

— Investigator who conducting the trial should follow and obey the ICH, GCP guidelines.

⑥ Investigational product, equipments

— Investigator is responsible for the all investigational products and equipments including in clinical trial.

⑦ Randomized procedure:-

— Investigator should explain the randomized procedures of clinical trials if any Randomized Procedure used in study.

⑧ Financial situation etc.

⑨ Compliance with IEC, IRB, ERB

⑩ communication ⊂ Sponsor, regulatory authority

3. STUDY CLOSURE.

— final study validation., medical coding.

— Archival of the data.

1 Ans.-
(a)

Continuation-

Historical Ethical guidelines.

1) Nuremberg code
2) Declaration of helsinki
3) U.S. code of federal regulations
4) ICH - GCP guidelines
5) ICMR guidelines
6) CIOMR
7) Belmont guidelines

Mid exam marks scored by students are entered in the Mother register

SUB: CLINICAL RESEARCH (LT5101).

S.NO	Reg. NO	Name of the Student	I MID Theory	I MID Practical	II MID Theory	II MID Practical	III MID Theory	III MID Practical	Avg of best of 2 mids Theory	Avg of best of 2 Mids Practical
1	187NIT0001	Alfya	22		29		30		30	
2	187NIT0002	Ambothu. Mamatha	0	N	28	N	28	N	28	N
3	187NIT0003	Amruthavalli. Dasari	29	O	30	O	0	O	30	O
4	187NIT0004	Avuthu Bhagyalakshmi	27	P	30	P	28	P	29	P
5	187NIT0005	Beg kasishma	23	R	29	R	28	R	29	R
6	187NIT0006	Betha Priyankashi	27	A	30	A	30	A	30	A
7	187NIT0007	chittusi. Molitha Nagamalleka	26	C	30	C	30	C	30	C
8	187NIT0008	Ede. Sri lakshmi	0	T	30	T	27	T	30	T
9	187NIT0009	Ganji. komali	20	I	28	I	29	I	29	I
10	187NIT0010	Golla. Supriya	26	C	28	C	28	C	28	C
11	187NIT0011	Jampana Amrutha	28	A	30	A	28	A	29	A
12	187NIT0012	Kothapalli Tharmayee	29	L	30	L	0	L	30	L
13	187NIT0013	Kavuthasapu. Naga Sundhini	20		25		25		25	
14	187NIT0014	Kinthali Sravani	22		28		0		25	

S.No	Reg.no	Name of the Student	I MID Theory	I MID Practical	II MID Theory	II MID Practical	Avg of best of 2 mids Theory	Avg of best of 2 mids Practical
15	187N1T0015	Kokkiligadda Sreevalli	21	N	30	N	27	N
16	187N1T0016	Kuchibhatla Lakshmi Vasdini	24	O	30	O	29	O
17	187N1T0017	LN Sai Priya kanjam	27	P	30	P	30	P
18	187N1T0018	M. Pravallika	27	R	30	R	29	R
19	187N1T0019	Medepalli Prasanthi	23	A	30	A	29	A
20	187N1T0022	Rasheedunnisa	29	C	30	C	0	C
21	187N1T0023	Shaik Heena.	29	T	30	T	0	T
22	187N1T0024	Shaik. Ufefa	22	I	26	I	0	I
23	187N1T0025	Tadichetti Devi Priya	27	C	30	C	28	C
24	187N1T0026	Udde Sharvani	27	A	29	A	28	A
25	187N1T0028	Veeravalli Supriya Devi	27	L	30	L	29	L
26	187N1T0029	P. Supriya Devi	27		30		30	
27	187N1T0030	Katasi Vedasri	23		28		30	
28	177N1T0021	P. Tejaswini	20		29		0	

EXAMS-INCHARGE
VIJAYA INSTITUTE
PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU VIJAYAWADA 521 108

PRINCIPAL
VIJAYA INSTITUTE OF
PHARMACEUTICAL SCIENCES FOR WOMEN
NIKEPADU.VIJAYAWADA 521 108

Mid exam marks uploaded to JNTUK University online portal

HTNO	SUBJECT	MID_1	MID_2	MID_3	FINAL	SUB_TYPE	YEAR
227N1T0102	T4111	24	26	0	25	T	4
227N1T0103	T4111	20	26	0	23	T	4
227N1T0101	T4112	0	0	27	27	L	4
227N1T0102	T4112	0	0	26	26	L	4
227N1T0103	T4112	0	0	26	26	L	4
177N1T0021	T5101	20	29	0	25	T	5
187N1T0001	T5101	22	29	30	30	T	5
187N1T0002	T5101	0	28	28	28	T	5
187N1T0003	T5101	29	30	0	30	T	5
187N1T0004	T5101	27	30	28	29	T	5
187N1T0005	T5101	23	29	28	29	T	5
187N1T0006	T5101	27	30	30	30	T	5
187N1T0007	T5101	26	30	30	30	T	5
187N1T0008	T5101	0	30	29	30	T	5
187N1T0009	T5101	20	28	29	29	T	5
187N1T0010	T5101	26	28	28	28	T	5
187N1T0011	T5101	28	30	28	29	T	5
187N1T0012	T5101	29	30	0	30	T	5
187N1T0013	T5101	20	25	25	25	T	5
187N1T0014	T5101	22	28	0	25	T	5
187N1T0015	T5101	21	30	27	29	T	5
187N1T0016	T5101	24	30	29	30	T	5
187N1T0017	T5101	27	30	30	30	T	5
187N1T0018	T5101	27	30	29	30	T	5
187N1T0019	T5101	23	30	29	30	T	5
187N1T0022	T5101	29	30	0	30	T	5
187N1T0023	T5101	29	30	0	30	T	5
187N1T0024	T5101	22	26	0	24	T	5
187N1T0025	T5101	27	30	28	29	T	5
187N1T0026	T5101	27	29	28	29	T	5
187N1T0028	T5101	27	30	29	30	T	5
187N1T0029	T5101	27	30	30	30	T	5
187N1T0030	T5101	23	28	30	29	T	5
177N1T0021	T5102	29	28	0	29	T	5
187N1T0001	T5102	28	27	0	28	T	5
187N1T0002	T5102	0	23	18	21	T	5
187N1T0003	T5102	30	30	0	30	T	5
187N1T0004	T5102	29	29	0	29	T	5
187N1T0005	T5102	28	29	0	29	T	5
187N1T0006	T5102	29	30	0	30	T	5
187N1T0007	T5102	29	29	0	29	T	5
187N1T0008	T5102	23	27	26	27	T	5
187N1T0009	T5102	28	27	0	28	T	5
187N1T0010	T5102	28	0	29	29	T	5
187N1T0011	T5102	30	30	29	30	T	5
187N1T0012	T5102	30	30	0	30	T	5
187N1T0013	T5102	22	17	24	23	T	5
187N1T0014	T5102	28	27	0	28	T	5

HTNO	SUBJECT	MID_1	MID_2	MID_3	FINAL	SUB_TYPE	YEAR
187N1T0015	T5102	28	29	29	29	T	5
187N1T0016	T5102	28	29	0	29	T	5
187N1T0017	T5102	29	29	27	29	T	5
187N1T0018	T5102	29	29	28	29	T	5
187N1T0019	T5102	29	30	29	30	T	5
187N1T0022	T5102	29	30	0	30	T	5
187N1T0023	T5102	29	29	0	29	T	5
187N1T0024	T5102	0	26	19	23	T	5
187N1T0025	T5102	30	29	29	30	T	5
187N1T0026	T5102	29	28	29	29	T	5
187N1T0028	T5102	30	27	0	29	T	5
187N1T0029	T5102	29	30	0	30	T	5
187N1T0030	T5102	25	27	22	26	T	5
177N1T0021	T5103	0	28	27	28	T	5
187N1T0001	T5103	27	25	29	28	T	5
187N1T0002	T5103	0	10	25	18	T	5
187N1T0003	T5103	29	30	27	30	T	5
187N1T0004	T5103	30	30	24	30	T	5
187N1T0005	T5103	21	20	27	24	T	5
187N1T0006	T5103	29	28	27	29	T	5
187N1T0007	T5103	29	26	26	28	T	5
187N1T0008	T5103	0	24	27	26	T	5
187N1T0009	T5103	28	28	28	28	T	5
187N1T0010	T5103	29	0	28	29	T	5
187N1T0011	T5103	29	29	28	29	T	5
187N1T0012	T5103	30	29	29	30	T	5
187N1T0013	T5103	21	23	23	23	T	5
187N1T0014	T5103	28	24	0	26	T	5
187N1T0015	T5103	29	26	26	28	T	5
187N1T0016	T5103	25	28	28	28	T	5
187N1T0017	T5103	27	28	28	28	T	5
187N1T0018	T5103	29	29	28	29	T	5
187N1T0019	T5103	28	29	27	29	T	5
187N1T0022	T5103	28	29	0	29	T	5
187N1T0023	T5103	30	29	0	30	T	5
187N1T0024	T5103	27	24	0	26	T	5
187N1T0025	T5103	27	28	27	28	T	5
187N1T0026	T5103	27	27	22	27	T	5
187N1T0028	T5103	28	28	25	28	T	5
187N1T0029	T5103	28	28	28	28	T	5
187N1T0030	T5103	25	28	28	28	T	5
177N1T0021	T5104	0	0	24	24	L	5
187N1T0001	T5104	0	0	28	28	L	5
187N1T0002	T5104	0	0	10	10	L	5
187N1T0003	T5104	0	0	29	29	L	5
187N1T0004	T5104	0	0	29	29	L	5
187N1T0005	T5104	0	0	25	25	L	5
187N1T0006	T5104	0	0	28	28	L	5

HTNO	SUBJECT	MID_1	MID_2	MID_3	FINAL	SUB_TYPE	YEAR
187N1T0007	T5104	0	0	25	25	L	5
187N1T0008	T5104	0	0	25	25	L	5
187N1T0009	T5104	0	0	26	26	L	5
187N1T0010	T5104	0	0	25	25	L	5
187N1T0011	T5104	0	0	28	28	L	5
187N1T0012	T5104	0	0	29	29	L	5
187N1T0013	T5104	0	0	25	25	L	5
187N1T0014	T5104	0	0	24	24	L	5
187N1T0015	T5104	0	0	25	25	L	5
187N1T0016	T5104	0	0	25	25	L	5
187N1T0017	T5104	0	0	28	28	L	5
187N1T0018	T5104	0	0	26	26	L	5
187N1T0019	T5104	0	0	28	28	L	5
187N1T0022	T5104	0	0	27	27	L	5
187N1T0023	T5104	0	0	27	27	L	5
187N1T0024	T5104	0	0	25	25	L	5
187N1T0025	T5104	0	0	26	26	L	5
187N1T0026	T5104	0	0	27	27	L	5
187N1T0028	T5104	0	0	25	25	L	5
187N1T0029	T5104	0	0	25	25	L	5
187N1T0030	T5104	0	0	25	25	L	5

Verified by: PRINCIPAL ***Controller of Examinations***

Date:21-06-2023