PITHAPUR RAJAH'S GOVERNMENT COLLEGE

An Outcome Based Autonomous Institution Accredited with NAAC Grade "A" (3.17 CGPA)

Affiliated to Adikavi Nannaya University Rajamahendravaram

KAKINADA - 533 001, AP.

BOARD OF STUDIES OF CHEMISTRY

B.VOC PHARMACEUTICAL CHEMISTRY

UNDER NSQF SCHEME

Meeting Minutes/ Resolutions

*Convened on 30 April 2024*AY 2024- 25

DEPARTMENT OF CHEMISTRY

PITHAPUR RAJAH'S GOVERNMENTCOLLEGE (AUTONOMOUS)

Opp. Mc. Laurin High School, Raja Ram Mohan Roy Road, Kakinada

www.prgc.edu.in; e-mail: chemistry@prgc.edu.in

PROCEEDINGS OF THE PRINCIPAL,

P.R. GOVERNMENT COLLEGE (A)KAKINADA- A.P

Present: Dr. B. V. Tirupanyam, M. Sc;

Ph.D.R.C.No.2/A.C./BOS/2024-25,

Dated: 23.04.2024

SUB: P.R. Government College (A), Kakinada-UG Board of Studies (BOS)- B.VOC-Pharmaceutical Chemistry-Nomination of Members-Orders issued.

REF: 1. UGC Guidelines for Autonomous Colleges-2018.

ORDERS:

The Principal, P.R. Government College (A), Kakinada is pleased to constitute UG Boards of Studies in CHEMISTRY for framing the syllabi in respective Subject for all Semesters duly following the norms of the UGC Autonomous guidelines.

S. No	Name of the Person	Designation
1	V. Sanjeeva Kumar	Chairman & Lecturer In charge
2	Dr. K.Deepthi Assistant Professor& Head of the Department of Chemistry, AKNU, Rajamahendravaram	University Nominee
3	Sri. V. Mallikarjuna Sarma Lecturer in Chemistry GDC, Jaggampeta.	Subject Expert -I
4	Sri. A. Sravani Ratnam Lecturer in Pharmaceutical Chemistry, Govt. College, (Autonomous), Rajamahendravaram	Subject Expert - II
5	Dr. N. Ratnakar, Aarkish Pharmaceuticals INS NJ, New Jersey	Representative from Industry
6	T. V. V. Satyanarayana	Member
7	T.V.V.Satyanarayana	Member
8	P. Vijay Kumar	Member
9	V. Ram babu	Member
10	G. Pavani	Member
11	Dr. N. Bujji Babu	Member
12	Dr. Ch. Praveen	Member
13	V. Venkateswara Rao	Member
14	U.S.N. Prasad	Member
15	M.S.S.V. Uma Gayathri	Member
16	K. Raju	Alumni Member
17	A. P. Adidurga	Student Member
18	B. Swapna	Student Member

The above members are requested to attend the BoS meeting on 30-04-2024 and share their valuable reviews, and suggestions on the following functionaries.

- Prepare syllabi for the subject keeping in view the objectives of the college, the interest of the stakeholders and National requirements for consideration and approval of the IQAC and Academic Council.
- Suggest the panel of Paper Setters & Examiners to the academic council for appointment of Paper Setters& Examiners.
- Suggested methodologies for innovative teaching and evaluation techniques.
- Coordinate research, teaching, extension and other activities in the Department of the college.

PRINCIPAL
P. R. Government College(A),
Kakinada

PITHAPUR RAJAH'S GOVERNMENT COLLEGE (A)
DEPARTMENT OF CHEMISTRY

Meeting of Board of Studies in Pharmaceutical Chemistry is convened on 30 April 2024 through offline/ onlineat P.R. Govt. College (A), Kakinada, at 10.00 AM.

Venue: JKC AC HALLS, Dt: 30-04-2024, Tuesday – 10.00 A.M.

The Principal Dr. B.V. Tirupanyam; Chairman V. Sanjeeva Kumar; University Nominee Dr. K. Deepthi, Assistant Professor& Head of the Department of Chemistry, AKNU, Rajamahendravaram; Dr. N. Ratnakar, Aarkish Pharmaceuticals INS NJ, New Jersey Industrialist: Subject Experts Sri. V. Mallikarjuna Sarma, Lecturer in Chemistry, GDC, Jaggampeta and Sri. A. Sravani Ratnam Lecturer in Pharmaceutical Chemistry, Govt. College, (Autonomous),Rajamahendravaram all the faculty members of the Chemistry Department and student alumni attended the meeting.

Agenda:

1. To discuss the Semester System and revised Choice Based Credit System (CBCS) being implemented for the Past 04 years, i.e., w.e.f. 2020-21.
2. To discuss and approve the Continuation/Modifications of the syllabus for the Semester-V for 2024-25.
3. Grant of Extra credits for Online SWAYAM MOOCs etc.
4. Syllabus, Model Question Papers and Model Blueprints, POs, PSOs & COs mappingfor V Semester.
5. Minimum of 60% integration of ICT into transaction of curriculum.
6. Minimum attendance of 75% for both I mid-term examination, and II mid- term examination under CIA component shall be the benchmark for attendance and itshall be approved in the BOS.
7. Teaching learning methodology by 50:50 (External: Internal) ratio for the present-III-Year Students. w.e.f. 2023-24.
8. Remedial coaching and assignments for slow learners, project works, research, Conferences, Industrial /academic tours & PG Entrance Coaching etc., for advanced learners.
9. Panel of paper setters and examiners.
10. Implementation of compulsory Community Service Project (CSP)/ Internships/ Apprenticeship and Extension activities for the benefit of the society.
11. Department action plan for 2024-25. To discuss and resolve the minor modifications/refinement if any.
12. Any Other Proposal with the Permission of the Chairman.

Resolution:

1. It is resolved to approve the syllabus as per the recommendations of the BOS for the Semester System and revised Choice Based Credit System (CBCS)being implemented for the past 04 years, i.e., i.e. 2020-21.
2. It is resolved to implement the suggestions discussed during the BOS for Continuation/Modifications of the syllabus for the Fifth Semester of III Year for 2024-25.
3. It is resolved to approve the Extra credits for Online SWAYAM MOOCs, edX, Coursera etc. which is as per the guidelines of Autonomous examination Cell.
4. It is resolved to approve Syllabus, Model Question Papers and Model Blue Prints, Cos, POs, & PSOs mapping for V Semester. With respect to the discussions held in the BOS.
5. It is resolved to approve Minimum of 50% integration of ICT in transaction of curriculum.
6. It is resolved to implement the Minimum attendance of 75% for both I mid-term examination and II mid- term examination under CIA component shall be the benchmark for attendance.
7. It is resolved to approve Teaching learning methodology by 50:50 (External: Internal) ratio III Year Students commenced w.e.f. 2021-22.
8. It is resolved to implement Remedial coaching and assignments for slow learners, project works, research works, Conferences, Industrial /academic tours & PG Entrance Coaching etc., for advanced learners.
9. It is resolved to propose Panel of paper setters and examiners for the academic year 2024-25.
10. It is resolved that the mandatory Community Service Project (CSP)/ Internships/ Apprenticeship and Extension activities are mandatory for overall growth of the student and benefit to the society.
11. It is resolved to implement the Departmental action plan for the AY 2024-25.

It is resolved to introduce the following new courses in the programme B.VOC. Pharmaceutical Chemistry from the AY 2024-25

S. No	Course Code	Title of the new course	Programmes in which it is introduced
1		Nil	Nil

DEPARTMENT OF CHEMISTRY

ACTION PLAN

ACADEMIC YEAR 2024-2025

S.No	Month	Activity planned
1	July 2024	Enrollment of 3 months MOOCS/SWAYAM/NPTL/Edex etc by staff
2	July 2024	Placement Drive through JKC
3	August 2024	Invited talk
4	August 2024	Study tour
5	August 2024	Certificate/ Diploma course
6	September 2024	National seminar/ online/offline
7	September 2024	Sep 16 Ozone Day
8	October 2024	Certificate course/Diploma course
9	November 2024	Invited talk
10	December 2024	Enrollment of 3 months MOOCS/SWAYAM/NPTL/Edex etc by students
11	December 2024	International webinar
12	December 2024	10 December National Chemistry Day
13	January 2025	Invited talk
14	January 2025	Career Guidance
15	February 2025	Community outreach program (In connection with the National Science Day)
16	March 2025	Review of Research Publications for 24-25

PITHAPUR RAJAH'S GOVERNMENT COLLEGE(A)

KAKINADA

IMPORTNANT DAYS OF OBSERVATION FOR AY 2024-25

MONTH	DATE	NAME OF DAY	DEPARTMENT/STUDENT SUPPORTING WING
JANUARY	26th	Republic Day	All Departments and student supporting wings
FEBRUARY	28th	National Science Day	All Science departments
MARCH	22nd	World Water Day	Chemistry
JUNE	5th	World Environment Day	All Science departments
JULY	11th	World Population Day	All Arts depts.
	28th	World Nature Conservation Day	Life sciences
AUGUST	15th	Independence Day	All Departments and student supporting wings
SEPTEMBER	16th	World Ozone Day	Chemistry
	21st	International Day of Peace	History
	23rd	Mole Day	Chemistry
NOVEMBER	11th	National Education Day	

Signatures of the Members who attended the Board of Studies meeting in Pharmaceutical Chemistry on 30 April 2024. At 4:00 PM. Mode of Conduct of meeting: Offline & online

S.No	Name of the Nominee	Mobile Number	Signature
1	Sri. V. Sanjeeva kumar	9849324966	V. S
2	Prof .K.Deepthi Assit. Professor & Head of the Department of Chemistry,AKNU, Rajamahendravaram.	9985469607	K Deepthi
3	Sri .V. Mallikarjuna Sarma Lecturer in Chemistry Government degree college. Jaggampeta.	8341546804	
4	Ms. A. Sravani Ratnam Lecturer in Pharmaceutical Chemistry GDC(A) Rajamahendravaram.	8886653337	A. Sravani Ratnam
5	Dr. N. Ratnakar Aarkish Pharmaceuticals INS NJ, New Jersey.		N.
6	T.V.V. Satya Narayana	9490876913	
7	P. Vijay Kumar	9652023082	
8	V. Rambabu	9948485537	
9	G. Pavani	99125 21493	
10	Dr. N. Bujji Babu	9441394782	
11	Dr. Ch. Praveen	9491185518	
12	V. Venkateswara Rao	9885105588	
13	U.S.N Prasad	6300882584	
14	M.S.S.V. Uma Gayathri	7396789819	
15	K.Raju	7729922972	K. Raju
16	A. P.Adidurga	9989524720	P. Adi Durga
17	B. A.Swapna	9346018853	A. Swapna

About B.Voc Pharmaceutical chemistry

The University Grants Commission (UGC) had launched a scheme on 27 February, 2014 for skillsdevelopment based higher education as part of college/university education, leading to Bachelor of Vocational (B.Voc.) degree with multiple entry and exit points. Considering the implementationmodalities, the guidelines of the scheme have been revised in the year 2015. The B.Voc. Programme is focused on universities and colleges providing undergraduate studies which would also incorporate specific job roles and their NOS s along with broad based general education. Thiswould enable the graduates completing B. Voc to make a meaningful participation in accelerating India's economy by gaining appropriate employment, becoming entrepreneurs and creating appropriate knowledge.

Objectives

1. To provide judicious mix of skills relating to a profession and appropriate content of general education.
2. To ensure that the students have adequate knowledge and skills, so that they are work ready a teach exit point of the programme.
3. To provide flexibility to students by means of pre-defined entry and multiple exitpoints.
4. To integrate NSQF with in the undergraduate level of higher education in order to enhance employability of the graduates and meet industry requirements. Such graduates apart from meeting the needs of local and national industry are also expected to be equipped to become part of the global work force.
5. To provide vertical mobility to students coming out of (a) 10+2 with vocational subjects; and (b) Community Colleges.

Course Objectives:

To make student

1. Understand the basic concepts of Organic Chemistry
2. Understand different types of organic reactions
3. Acquire knowledge on qualitative and quantitative chemical analysis
4. Develop skills in the usage and application of laboratory instruments
5. Understand the mechanisms of various organic reactions
6. Acquire knowledge on various types of Pharmacopoeia.
7. Understand various forms of medicines and the role of additives informulations
8. Acquire knowledge on different types of instrumentation techniques inchemical analysis.
9. Understand stereochemistry of carbon compounds its importance in organicchemistry

10. Acquire knowledge on the basic concepts of computers
11. Develop skills in MS word, MS Excel and MS PowerPoint applications.
12. Develop communication and soft skills.
13. Visit pharmaceutical industries and understand the functioning of plant

Course Outcomes:

At the end of the course, the student will be able to

1. Acquire competence and skills in various techniques in chemical analysis.
2. Ready to get a suitable position or job role such as Quality Control Chemist,Quality Assurance Chemist, Production Chemist in a Pharmaceutical Industry
3. Choose for an academic progression under vertical mobility for higher studies.
4. Eligible for various competitive examinations in various posts recruited byState and Central Governments.

P.R. GOVERNMENT COLLEGE(A),

KAKINADA

DEPARTMENT OF CHEMISTRY

B.VOC (PHARMACEUTICALCHEMISTRY)

CURRICULAR FRAME WORK

(CREDITS TABLE)

Semester–V

Category	Subject/Paper	Course	Theory /Practical	No.of Hrs./ Week	No of credits	Evaluation		
						Internal	External	TOTAL
Vocational	Pharma Regulatory Affairs	C9	Theory	4	4	50	50	100
	Pharma Regulatory Affairs		Practical	2	1		50	50
	Pharmaceutical Inorganic Chemistry	C10	Theory	4	4	50	50	100
	Pharmaceutical Inorganic Chemistry		Practical	2	1		50	50
	Advanced Analytical Chemistry	C11	Theory	4	4	50	50	100
	Advanced Analytical Chemistry		Practical	2	1		50	50
	Basic Quality Control and Quality Assurance	C12	Theory	4	4	50	50	100
	Basic Quality Control and Quality Assurance		Practical	2	1		50	50
	Documentation for Quality Control	C13	Theory	4	4	50	50	100
	Documentation for Quality Control		Practical	2	1		50	50
	Pharmaceutical and Medicinal Chemistry	C14	Theory	4	4	50	50	100
	Pharmaceutical and Medicinal Chemistry		Practical	2	1		50	50

			TOTAL	36	30	240	660	900

P.R. GOVERNMENT COLLEGE(A), KAKINADA

DEPARTMENTOFCHEMISTRY

B.VOC (PHARMACEUTICAL CHEMISTRY)

CURRICULAR FRAME WORK

(CREDITS TABLE)

Semester-VI

Subject/Paper	Theory /Practical	No of credits	Evaluation
First Phase of Apprenticeship between n 1st and 2nd year (Summer Vacation)		**04**	**100**
Second Phase of Apprenticeship between 2nd and 3rd year (Summer Vacation)		**04**	**100**
INDUSTRIALINTERNSHIP		**12**	**200**
TOTAL		**20**	**400**

P.R.GOVERNMENTCOLLEGE(AUTONOMOUS)KAKINADA

CURRICULAR FRAME WORK FOR B.VOC COURSES UNDER NSQF FOR THE YEAR 2023-24

B.Voc Pharmaceutical Chemistry(Maths stream/ Biology stream)

SUBJECT/SEMESTER		I		II		III		IV		V		VI			
		H/W	C	H/W	C	H/W	C	H/W	C	H/W	C	H/W	C		
English		4	3	4	3	4	3								
Second Language(Telugu/Hindi/Sanskrit)		4	3	4	3	4	3								
Life Skill Courses		2	2	2	2	2+2	2+2								
Skill Development Courses		2	2	2+2	2+2	2	2								
Core Subjects															
MajorSubject-1	C1 to C5Maths/Botany (Theory&Practicals)	6/4+2	4+1	6/4+2	4+1	6/4+2	4+1	4+2 4+2	4+1 4+1						
MajorSubject-2	C1 to C5Chemistry (Theory&Practicals)	4+2	4+1	4+2	4+1	4+2	4+1	4+2 4+2	4+1 4+1						
Vocational	C1toC14includingSECPharmaceuticalChemistry(Theory&Practicals)	4+2	4+1	4+2	4+1	4+2	4+1	 4+2 4+2	 4+1 4+1	4+2 4+2 4+2	4+1 4+1 4+1				

Third Phase of Apprenticeship for the entire V/VI Semester

rstandSecondPhase(2Spells)ofApprenticeshipbetween1stand2ndyearandbetween2ndand3rdyearSummer Vacation

	C2, C4, C6 (Theory and Lab/Institutional/IndustrialTraining PharmaceuticalChemistry	2+2	2+1	2+2	2+1	2+2	2+1			4+2 4+2 4+2	4+1 4+1 4+1				
TotalHrs/Week(AcademicCredits)		34	**28**	36	**30**	36	**30**	36	**30**	36	**30**		**12**	**4**	**4**
ExtensionActivities															
NCC/NSS/Sports/ExtraCurricular									**2**						
Yoga							**1**		**1**						
ExtraCredits															
Hrs/W(TotalCredits)		34	**28**	36	**30**	36	**31**	36	**33**	36	**30**		**12**	**4**	**4**

Marks and Credits distribution

S.No.	Course Type	No. of Courses	Course wise Teaching Hrs/Week	Credits for each Course	Total Credits	Each Course Evaluation				Total (Theory +Practical)	TotalMarks (Maths Stream/ Biology Stream
						Theory			Practical (Maths Stream/ Biology		
						Continuous Assessment	End Semester	Total			
1	English	3	4	3	9	50	50	100		100	300
2	Second Language	3	4	3	9	50	50	100		100	300
3	Life Skill Courses	4	2	2	8	0	50	50		50	200
4	Skill Development Courses	4	2	2	8	0	50	50		50	200
5	Core/SE–I Maths/Botany	5	6/4+2	4+1	25	50	50	100	0/50	100/150	500/750
6	Core/SE–II Chemistry	5	4+2	4+1	25	50	50	100	0/50	100/150	750
7	Vocational Courses (C1toC14) Pharmaceutical Chemistry	11	4+2	4+1	55	50	50	100	50	150	1650
	Vocational Courses C2,C4,C6 Pharmaceutical Chemistry	3	2+2	2+1	9		50	50	50	100	300
8	Summer Vacation Internship	2		4	8					100	200

9	Industrial Internship for one Full Semester	1		12	12					200	200
10	Extension Activities (Non Academic Credits)										
	NCC/NSS/Sports/Extra Curricular			2	2						
	Yoga	2		1	2						
	Extra Credits										
	Hrs/W(Total Credits)&Marks	**43**			**172**						**4600/4850**

PITHAPURRAJAH'S GOVERNMENT COLLEGE (AUTONOMOUS),KAKINADA			
B.VOC COURSES UNDER NSQF SCHEME			
STUDENTS ELIGIBILITY AND FACULTY ELIGIBILITY			
S.NO.	NAMEOFTHECOURSE	STUDENTS ELIGIBILITY (10+2OEQUIVALENTWITHSPECIFICGROUPIFANY)	FACULTY ELIGIBILITY WITH SPECIALIZATION
1	B.VOC(COMMERCIAL AQUACULTURE)	Intermediate/10+2or Equivalent with Bi.P.C/Biology	M.Sc Aquaculture/Marine Biology/ Zoology with fishery biologyspecialization
2	B.VOC(HORTICULTURE)	Intermediate/10+2 or Equivalent with Bi.P.C/Biology	M.Sc Horticulture/Biology/Botany with Horticulture Specialization
3	B.VOC(PHARMACEUTICAL CHEMISTRY)	Intermediate or10+2 withMPC/BiPC group	M.Pharm/M.Sc (Pharmaceutical Chemistry) /M.Sc(Chemistry)
4	B.VOC(FOOD TECHNOLGY)	Intermediate or 10+2withMPC/BiPC group	M.Sc (Food Technology)/ M.Sc (Food Processing) /M.Sc (Food and Nut rition)
5	B.VOC(JOURNALISM AND MASS COMMUNICATION)	Intermediate or 10+2 or equivalent	M.A(Journalism)
6	B.VOC(HOTEL MANAGEMENT)	Intermediate/ 10+2 or equivalent	MBA(Hotel Management/ M.Com Hotel Management /M.Com orMBA with Diploma in Hotel Management

SEMESTER-V

	P.R.GOVERNMENT COLLEGE(A),KAKINADA	**Program & Semester** B. Voc., Pharmaceutical chemistry (V Semester)			
Course Code	**TITLE OF THE COURSE** **PHARMA REGULATORY AFFAIRS**				
Teaching	Hours Allocated: 60 (**Theory**)	L	T	P	C
Pre-requisites	fundamental knowledge about regulatory affairs	60	10	30	4+1

Course Objectives:

To make the student

I. Understand the different types of hazards
II. Understand the Good laboratory practices.
III. Understanding the Investigation of new drug.

On Completion of the course, the students will be able to	
CO1	The Pharmaceutical legislations and their implications in thedevelopment and marketing of pharmaceuticals.
CO2	The regulatory authorities and agencies governing themanufacture and sale of Laws pharmaceuticals
CO3	Know different and Acts that regulate pharmaceutical industry.
CO4	Learn marketing of pharmaceuticals

Course with focus on employability / entrepreneurship / Skill Development modules

Skill Development			**Employability**			**Entrepreneurship**	

Syllabus:

UNIT :1

Good laboratory Practice, responsibilities of personnel Standard operating procedure, StandardTestingprocedure, Certificate of Analysis, Method of Analysis, good receipt note.

UNIT - II

Approval of new drugs-Investigational New Drugs (IND) submission, format & content of IND, content of investigator Brochure, general consideration of new drugApproval (NDA), specific requirements, content & format of NDA, manufacturing control requirement of NDA,

UNIT-III

GMP, TQM, ICH ,CGMP

UNIT:IV

Occupational Health and Hazards, Safety at workplace, Accident preventiontechniques, Safety Management system, list of hazardous chemicals and handling of toxic andhazardous chemicals,acids,ether & etc.

Unit No	Additions	Deletions	Expected levels of learning as per Blooms taxonomy assessment of CO	Percentage added/deleted
I	--	--	K_2, K_3	
II	--	--	K_1, K_2	
III	--	ISO 9000	K_3, K_6	5%
IV	--	--	K_1, K_2	

K_1= Remembering, K_2= Understanding, K_3= Applying, K_4= Analysing, K_5= Evaluating, K_6=Create

Text Books & Reference Books

S. No	Author	Title	Publisher
1	J.A Dean	analytical chemistry handbook	McGrew hill Inc., 1st Ed,. 1995.
2	LE Limbard	Goodman & Gilman:	siddarth prakashan publishers, 2008.
3	JG Hardman	Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines forClinical Trials on pharmaceutical Products in India.	New Delhi: Ministry of Health; 2001.

Web Links

https://www.youtube.com/watch?v=2gxTcaAP1PI
https://www.youtube.com/watch?v=DQ7JPNgU8Wg
https://www.youtube.com/watch?v=TG3bEni1CiM
https://www.youtube.com/watch?v=OvRSlJ8YsKU

Course outcomes and programme outcomes mapping

On Completion of the course, the students will be able to	
CO1	The Pharmaceutical legislations and their implications in thedevelopment and marketing of pharmaceuticals.
CO2	The regulatory authorities and agencies governing themanufacture and sale of Laws pharmaceuticals
CO3	Know different and Acts that regulate pharmaceutical industry.
CO4	Learn marketing of pharmaceuticals

CO-POMapping:

(1:Slight[Low]; 2:Moderate [Medium]; 3:Substantial [High], '-':No Correlation)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3
CO1	2	3	2	3	3	3	1	2	2	3	2	3	3
CO2	3	2	3	3	2	3	3	1	3	3	2	3	2
CO3	3	3	3	3	2	2	2	2	2	3	3	3	2
CO4	3	2	2	2	2	2	3	3	1	1	3	3	3
Avg.	**2.75**	**2.5**	**2.5**	**2.75**	**2.25**	**2.5**	**2.25**	**2**	**2**	**2.5**	2.5	3	2.5

Programme outcomes

PO1 : Knowledge in Pharmaceutical Chemistry : Apply the knowledge of different dosage forms and their routes of administration.

PO2: Problem analysis: Identify, formulate, review research literature, and analyze simple to complex problems reaching substantiated conclusions using fundamental principles of pharmaceutical chemistry.

PO3: Design/development of solutions: Design solutions for simple to complex problems and designing novel routes for the synthesis of bioactive / active pharmaceutical ingredients.

PO4: Conduct investigations on new drug discoveries: Use fundamental research-based knowledge and available research methodologies including design of experiments, analysis and interpretation of data, and synthesis of the drug molecules.

PO5 : Modern tool usage: Create, select, and apply appropriate techniques, resources, and IT tools for drug modeling and interpretation of simple to complex drug molecules.

PO6 : Society: Applying the contextual knowledge to assess societal, health, safety, legalissues.

PO7: Environment and sustainability: Understand the importance of synthetic drug chemistry for various discoveries in the field of health science and demonstrate the knowledge for sustainable development.

PO8 : Ethics: Apply ethical principles and commit to professional ethics and responsibilities and norms of the pharmaceutical manufacturing practice.

PO9 : Communication: Communicate effectively on issues related to pharmaceutical chemistry with the medical community, being able to write the effective reports and documentations and presentations.

PO10: Life-long learning: Recognize the need for, and have the preparation and ability toengage in independent and lifelong learning in the broadest context of technological change new drug investigations for new diseases.

Progarmme specific outcomes

PSO-1: To have a firm foundation in the fundamentals/concepts/theories and its applications in pharmaceutical chemistry.

PSO-2: To understand the structure and properties of drugs, Characteristics mechanisms

of chemical reactions and their usage in pharmaceutical chemistry

PSO-3: To acquaint with safety measures that are to be taken in pharmaceutical chemistry laboratory and develop skills in proper manufacturing methods of pharmaceuticals and usage of different apparatus/instruments and carry out experimental procedures, recordthe observations and results and present the inference/conclusion

P.R.GOVERNMENTCOLLEGE(A),KAKINADA

B.Voc (PHARMACEUTICALCHEMISTRY)

THIRD YEAR V SEMESTER Course–

9 PHARMAREGULATORY AFFAIRS

WEIGHTAGE TO CONTENT

S No.	Course Content	Essay (10M)	Short (5M)	Total marks	Question Relates as per Bloom's Taxonomy
1.	UNIT-I	2	2	30	Understanding. Skill
2.	UNIT-II	2	2	30	Remembering, Understanding
3.	UNIT-III	1	2	20	Remembering, Knowledge
4.	UNIT-IV	1	1	15	Evaluating, Understanding
	Total	6	7	95	

P.R.GOVERNMENT COLLEGE (A), KAKINADA

B.Voc (PHARMACEUTICAL CHEMISTRY)

V SEMESTER

Course – 9 PHARMAREGULATORY AFFAIRS

Model Question Paper

Time 2hrs. **Max. Marks-50M**

SECTION-A

Answer any THREE questions choosing at least ONE question from each part

PART-A **3x10=30M**

1. One question from unit-I
2. One question from unit-I
3. One question from unit-II

PART-B

4. One question from unit-II
5. One question from unit-III
6. One question from unit-IV

SECTION-B

Answer any FOUR questions from the following **4x5=20M**

7. One question from unit-I
8. One question from unit-I
9. One question from unit-II
10. One question from unit-II
11. One question from unit-III
12. One question from unit-III
13. One question from unit-IV

QUESTION BANK
(ESSAY QUESTIONS)

UNIT-1

1. Write about GLP

2. Why are the reserve samples maintained.
3. State the contents of S O P on handling of the rejecting material.

UNIT-II

1. What are the content of NDA.
2. What are the content of IND.
3. Explain the submission of IND.

UNIT-III

1. Write about ICH guidelines
2. Write about GMP and CGMP

UNIT-IV

1. Write a note on first aid
2. List out the hazardous chemicals in pharmaceuticals.
3. Describe various safety rules at work place.

SHORT QUESTIONS

UNIT-I

1. Write about certificate of Analysis
2. Write the prinicples of GLP
3. Write about generating STP

UNIT-II

1. Explain the content of investigator Brochure.
2. What are the specific requirements, content & format of NDA
3. 3.What are the manufacturing control requirement of NDA.

UNIT-III

1. Define GMP protocol
2. Write a note on TQM

UNIT-IV

1. Write about personnel protective equipment
2. Write about fire extinguishers
3. Write about safety signs and signal

	P.R.GOVERNMENT COLLEGE(A),KAKINADA	Program & Semester: B. Voc., Pharmaceutical chemistry (V Semester)			
Course Code	**TITLE OF THE COURSE PHARMAREGULATORY AFFAIRS PRACTICAL**				
Teaching	Hours Allocated: 30 (**Practical**)	L	T	P	C
Pre-requisites	fundamental knowledge about regulatory affairs	-	-	30	4+1

Practicals:

1. Fraibility test for different solid dosage forms
2.Disintegration test for different solid dosage forms
3.Dissolution test for different solid dosage forms
2 Give the application & format of IND
5. Give the application & format of INDA

	P.R.GOVERNMENT COLLEGE(A),KAKINADA	**Program & Semester** B. Voc., Pharmaceutical chemistry (V Semester)			
Course Code	**TITLE OF THE COURSE** **PHARMACEUTICAL INORGANIC CHEMISTRY**				
Teaching	Hours Allocated: 60 (**Theory**)	L	T	P	C
Pre-requisites	fundamental knowledge about impurities	60	10	30	4+1

Course Objectives:

Upon completion of this course the student should be able to:

i. Understand the different types of impurities.
ii. Understand the different types of anti-oxidants.
iii. Understanding the radiopharmaceuticals

Course Outcomes:

On Completion of the course, the students will be able to	
CO1	Learn about various types of impurities in pharmaceutical substances
CO2	Understand the concept of pharmaceutical aids
CO3	Learn about various types of anti-oxidants and compounds that are used asThem
CO4	Illustrate about the effects and precautions to be taken while using the radioactive agents

Course with focus on employability / entrepreneurship / Skill Developmentmodules

Skill Development			**Employability**			**Entrepreneurship**	

Syllabus:

UNIT I

Impurities in pharmaceutical substances: Impurities commonly found in medicinal preparations. Sources of impurities in pharmaceutical chemicals, effect of impurities on

pharmaceutical preparations. Permissible impurities in pharmaceutical Substances. Methods used to purify inorganic substances. Principle and method involved in the limittest for Chlorides, Sulphate, Iron, Lead.

UNIT II

Pharmaceutical aids: definition and classification-Role of different pharmaceutical aids (acidifiers, alkalizing agents, buffers, anti-oxidants and preservatives, desiccants,emulsifiers, coloring, flavoring, and sweetening agents, solvents) in pharmaceutical preparations.

Unit III

Antioxidants: Definition, criteria for a substance to act as antioxidant. Compounds used as antioxidants (Sodium metabisulphite, Nitrogen, Sodium thiosulphate, sodium bisulphite, sodium nitride) and their uses.

Gastrointestinal agents: Definition, examples. Acidifying reagents or Acidifiers and their types. Antacids- Definition, antacid therapy, role and criteria and side effects of antacids, examples of compounds used as antacids
Cathartics, purgatives and laxatives: Definition and examples.

Unit IV

Radio pharmaceuticals: Radio activity, radioactive rays (Alfa, beta and gamma rays), isotopes definition and examples, units of radioactivity, biologicaleffects of radiation, precautions to be taken while handing and storage of radioactive isotopes ,applications of radioactive in research, diagnosis and medicines.

Water: Water as universal pharmaceutical vehicle. Water: official water (water, purified water, water of injection, bacteriostatic water for injection, sterile water for injection).

Unit No	Additions	Deletions	Expected levels of learning as per Blooms taxonomy assessment of CO	Percentage added/deleted
I	--	--	K_2, K_3	
II	--	--	K_1, K_2	
III	--	--	K_3, K_6	
IV	--	--	K_1, K_2	

K_1= Remembering, K_2= Understanding, K_3= Applying, K_4= Analysing, K_5= Evaluating, K_6=Create

Text Books & Reference Books

S. No	Author	Title	Publisher
1	Kaza somasekhara Rao,Ch.VenkataSuresh	Pharmaceutical inorganic chemistry	McGrew hill Inc., 1st Ed,. 1995.
2	G.R.Chatwal.	Pharmaceutical inorganic chemistry:	siddarth prakashan publishers, 2008.

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https://www.youtube.com/watch?v=nVz37y5LREA

https://www.youtube.com/watch?v=AJdAbL0HnqE

https://www.youtube.com/watch?v=i7lfOyhvDuE

Course outcomes and programme outcomes mapping

Course Outcomes:

On Completion of the course, the students will be able to	
CO1	Learn about various types of impurities in pharmaceutical substances
CO2	Understand the concept of pharmaceutical aids
CO3	Learn about various types of anti-oxidants and compounds that are used asThem
CO4	Illustrate about the effects and precautions to be taken while using the radioactive agents

CO-POMapping:

(1:Slight[Low]; 2:Moderate [Medium]; 3:Substantial [High], '-':No Correlation)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3
CO1	2	3	2	3	3	3	1	2	2	3	2	3	3
CO2	3	2	3	3	2	3	3	1	3	3	2	3	2
CO3	3	3	3	3	2	2	2	2	2	3	3	3	2
CO4	3	2	2	2	2	2	3	3	1	1	3	3	3
Avg.	**2.75**	**2.5**	**2.5**	**2.75**	**2.25**	**2.5**	**2.25**	**2**	**2**	**2.5**	2.5	3	2.5

Programme outcomes

PO1 : Knowledge in Pharmaceutical Chemistry : Apply the knowledge of different dosage forms and their routes of administration.

PO2: Problem analysis: Identify, formulate, review research literature, and analyze simple to complex problems reaching substantiated conclusions using fundamental principles of pharmaceutical chemistry.

PO3: Design/development of solutions: Design solutions for simple to complex problems and designing novel routes for the synthesis of bioactive / active pharmaceutical ingredients.

PO4: Conduct investigations on new drug discoveries: Use fundamental research-based knowledge and available research methodologies including design of experiments, analysis and interpretation of data, and synthesis of the drug molecules.

PO5 : Modern tool usage: Create, select, and apply appropriate techniques, resources, and IT tools for drug modeling and interpretation of simple to complex drug molecules.

PO6 : Society: Applying the contextual knowledge to assess societal, health, safety, legalissues.

PO7: Environment and sustainability: Understand the importance of synthetic drug chemistry for various discoveries in the field of health science and demonstrate the knowledge for sustainable development.

PO8 : Ethics: Apply ethical principles and commit to professional ethics and responsibilities and norms of the pharmaceutical manufacturing practice.

PO9 : Communication: Communicate effectively on issues related to pharmaceutical chemistry with the medical community, being able to write the effective reports and documentations and presentations.

PO10: Life-long learning: Recognize the need for, and have the preparation and ability toengage in independent and lifelong learning in the broadest context of technological change new drug investigations for new diseases.

Programme specific outcomes

PSO-1: To have a firm foundation in the fundamentals/concepts/theories and its applications in pharmaceutical chemistry.

PSO-2: To understand the structure and properties of drugs, Characteristics mechanisms of chemical reactions and their usage in pharmaceutical chemistry

PSO-3: To acquaint with safety measures that are to be taken in pharmaceutical chemistry laboratory and develop skills in proper manufacturing methods of pharmaceuticals and usage of different apparatus/instruments and carry out experimental procedures, recordthe observations and results and present the inference/conclusion

P.R.GOVERNMENTCOLLEGE(A),KAKINADA

B.Voc(PHARMACEUTICAL CHEMISTRY)

V SEMESTER

Course–10: PHARMACEUTICAL INORGANIC CHEMSTRY

WEIGHTAGETOCONTENT

S No.	Course Content	Essay (10M)	Short (5M)	Total marks	Question Relates as per Bloom's Taxonomy
1.	UNIT-I	2	2	30	Understanding. Skill
2.	UNIT-II	2	2	30	Remembering, Understanding
3.	UNIT-III	1	2	20	Remembering, Knowledge
4.	UNIT-IV	1	1	15	Evaluating, understanding
	Total	6	7	95	

P.R.GOVERNMENT COLLEGE (A), KAKINADA

B.Voc (PHARMACEUTICAL CHEMISTRY)

V SEMESTER

Course – 10: PHARMACEUTICAL INORGANIC CHEMSTRY

Model Question Paper

Time 2hrs. **Max. Marks-50M**

SECTION-A

Answer any THREE questions choosing at least ONE question from each part

PART-A **3x10=30M**

1. One question from unit-I
2. One question from unit-I
3. One question from unit-II

PART-B

4. One question from unit-II
5. One question from unit-III
6. One question from unit-IV

SECTION-B

Answer any FOUR questions from the following **4x5=20M**

7. One question from unit-I
8. One question from unit-I
9. One question from unit-II
10. One question from unit-II
11. One question from unit-III
12. One question from unit-III
13. One question from unit-IV

Question bank

Essay questions (10M)

Unit-I

1. Explain different sources of impurities in medicinal preparations.
2. Explain principle and method involved in the limit test for a) chloride b) iron.
3. Explain principle and method involved in the limit test for a) sulphate b) lead

Unit-II

1. Explain the role of acidifiers,buffers,and anti oxidants in pharmaceuticalpreparations.
2. Explain the role of preservatives,emulsifiers and solvents in pharmaceutical preparations.
3. Explain the role of coloring, flavoring, sweetening agents and desiccants in pharmaceutical preparations.

Unit-III

1. Define anti oxidants. Explain the uses of sodium thiosulphates sodiumbisulphate and nitrogen as anti oxidants.
2. Define antacids. Explain the criteria ,uses and side effects of antacids.
3. Define gastrointestinal agents. Explain different types of acidifiers withexamples.

Unit-IV

1. Explain the precautions to be taken while handling radioactive meterials.
2. Write the applications of radioactive isotopes in medicine and research.
3. Explain different types of water used in pharmaceutical preparations.

Short answer questions (5M)

Unit-I

1. Explain some common impurities found in medicinal preparation.
2. Write effect of impurity on pharmaceutical preparations.
3. Write some permissible impurities in pharmaceutical substances.

Unit-II

1. Define pharmaceutical aids and classify them.
2. Explain the role of preservatives in pharmaceutical preparations.
3. Explain the role of anti oxidants in pharmaceutical preparations.

Unit-III

1. Define anti oxidants and write the criteria for a substances to act as antioxidants.
2. Write the uses of sodium nitride as anti oxidant.
3. Define gastrointestinal agents give examples.

Unit-IV

1. Define isotopes and give examples write the units of radioactivity.
2. Write the biological effects of radiation.

	P.R.GOVERNMENT COLLEGE(A),KAKINADA	Program & Semester: B. Voc., Pharmaceutical chemistry (V Semester)			
Course Code	**TITLE OF THE COURSE PHARMACEUTICAL INORGANICCHEMISTRY PRACTICAL**				
Teaching	Hours Allocated: 30 (**Practical**)	L	T	P	C
Pre-requisites	fundamental knowledge about limit tests	-	-	30	4+1

PRACTICALS :

1. Limit tests for chlorides
2. Limit tests for sulphate
3. Limit test for iron
4. Preparation of basic buffer
5. Preparation of acidic buffer

	P.R.GOVERNMENT COLLEGE(A),KAKINADA	**Program & Semester** B. Voc., Pharmaceutical chemistry (V Semester)			
Course Code	**TITLE OF THE COURSE ADVANCED ANALYTICAL CHEMISTRY**				
Teaching	Hours Allocated: 60 (**Theory**)	L	T	P	C
Pre-requisites	fundamental knowledge about chromatography	60	10	30	4+1

Course Objectives:

Upon completion of this course the student should be able to:

i. Understand the chromatography techniques.

ii. Understand the solvent extraction process.

iii. Understand the common separation techniques

Understanding the common separation techniques

Course Outcomes:

On Completion of the course, the students will be able to	
CO1	Understand the concept of some common separation techniques
CO2	Learn about the principle and process involved in solvent extraction
CO3	Learn about the principles and development of chromatogram
CO4	Learn about the principles and applications of gas- liquid chromatography and highperformance liquid chromatography.

Course with focus on employability / entrepreneurship / Skill Development modules

Skill Development			**Employability**			**Entrepreneurship**	

Syllabus:

Unit – I:

Some common separation techniques: Principles and applications Crystallization, Filtration, Decantation, Sublimation, Evaporation, Simple distillation, Fractional distillation, Centrifugation

Unit – II:

Solvent Extraction- definition- principle and process – Nernst distribution law andits limitations- Types of solvent extraction- batch extraction and continuous extraction- applications of solvent extraction

Unit – III:

Chromatography- definition- classification –paper chromatography- principle and experimental details- R_f value definition and factors affecting R_f factor- development of chromatogram- ascending, descending, two dimensional and radial chromatography- applications of paperchromatography.

Thin Layer chromatography- principle and experimental details- superiority of thin layerchromatography over paper chromatography- applications of thin layer chromatography.

Unit – IV:

Column chromatography- principle and experimental details- applications of column chromatography.

Gas- Liquid Chromatography: Principle, Experimental details, Instrumentation and applications.

High Performance Liquid Chromatography: Principle, Experimental details,Instrumentation andapplications

Unit No	Additions	Deletions	Expected levels of learning as per Blooms taxonomy assessment of CO	Percentage added/deleted
I	--	--	K_2, K_3	
II	--	--	K_1, K_2	
III	--	--	K_3, K_6	
IV	--	--	K_1, K_2	

K_1= Remembering, K_2= Understanding, K_3= Applying, K_4= Analysing, K_5= Evaluating, K_6=Create

Text Books & Reference Books

S. No	Author	Title	Publisher
1	Skoog andMiller	Analytical Chemistry	CBS publishers
2	A.I.Vogel	A textbook of qualitative inorganic analysis:	CBS publishers
3	Geoffrey Ozin	Nanochemistry	AndreArsenault

Web Links

https://www.youtube.com/watch?v=M6lMHwCShkg

https://www.youtube.com/watch?v=ABwhvhA5sTI&list=PLOxj- B 7rZRao709ygAzF3xbugxDL9MASOv

https://www.youtube.com/watch?v=0KqaIKHzHE8

Course outcomes and programme outcomes mapping

Course Outcomes:

On Completion of the course, the students will be able to	
CO1	Understand the concept of some common separation techniques
CO2	Learn about the principle and process involved in solvent extraction
CO3	Learn about the principles and development of chromatogram
CO4	Learn about the principles and applications of gas- liquid chromatography and highperformance liquid chromatography.

CO-POMapping:

(1:Slight[Low]; 2:Moderate [Medium]; 3:Substantial [High], '-':No Correlation)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3
CO1	2	3	2	3	3	3	1	2	2	3	2	3	3
CO2	3	2	3	3	2	3	3	1	3	3	2	3	2
CO3	3	3	3	3	2	2	2	2	2	3	3	3	2
CO4	3	2	2	2	2	2	3	3	1	1	3	3	3
Avg.	**2.75**	**2.5**	**2.5**	**2.75**	**2.25**	**2.5**	**2.25**	**2**	**2**	**2.5**	2.5	3	2.5

Programme outcomes

PO1 : Knowledge in Pharmaceutical Chemistry : Apply the knowledge of different dosage forms and their routes of administration.

PO2: Problem analysis: Identify, formulate, review research literature, and analyze simple to complex problems reaching substantiated conclusions using fundamental principles of pharmaceutical chemistry.

PO3: Design/development of solutions: Design solutions for simple to complex problems and designing novel routes for the synthesis of bioactive / active pharmaceutical ingredients.

PO4: Conduct investigations on new drug discoveries: Use fundamental research-based knowledge and available research methodologies including design of experiments, analysis and interpretation of data, and synthesis of the drug molecules.

PO5 : Modern tool usage: Create, select, and apply appropriate techniques, resources, and IT tools for drug modeling and interpretation of simple to complex drug molecules.

PO6 : Society: Applying the contextual knowledge to assess societal, health, safety, legal issues.

PO7: Environment and sustainability: Understand the importance of synthetic drug chemistry for various discoveries in the field of health science and demonstrate the knowledge for sustainable development.

PO8 : Ethics: Apply ethical principles and commit to professional ethics and responsibilities and norms of the pharmaceutical manufacturing practice.

PO9 : Communication: Communicate effectively on issues related to pharmaceutical chemistry with the medical community, being able to write the effective reports and documentations and presentations.

PO10: Life-long learning: Recognize the need for, and have the preparation and ability to engage in independent and lifelong learning in the broadest context of technological change new drug investigations for new diseases.

Programme specific outcomes

PSO-1: To have a firm foundation in the fundamentals/concepts/theories and its applications in pharmaceutical chemistry.

PSO-2: To understand the structure and properties of drugs, Characteristics mechanismsof chemical reactions and their usage in pharmaceutical chemistry

PSO-3: To acquaint with safety measures that are to be taken in pharmaceutical chemistry laboratory and develop skills in proper manufacturing methods of pharmaceuticals and usage of different apparatus/instruments and carry out experimental procedures, recordthe observations and results and present the inference/conclusion

P.R.GOVERNMENTCOLLEGE(A),KAKINADA

B.Voc(PHARMACEUTICAL CHEMISTRY)

V SEMESTER

Course–11: ADVANCED ANALYTICAL CHEMISTRY

WEIGHTAGETOCONTENT

S No.	Course Content	Essay (10M)	Short (5M)	Total marks	Question Relates as per Bloom's Taxonomy
1.	UNIT-I	2	2	30	Understanding. Skill
2.	UNIT-II	2	2	30	Remembering, Understanding
3.	UNIT-III	1	2	20	Remembering, Knowledge
4.	UNIT-IV	1	1	15	Evaluating, understanding
	Total	6	7	95	

P.R.GOVERNMENT COLLEGE (A), KAKINADA

B.Voc (PHARMACEUTICAL CHEMISTRY)

V SEMESTER

Course – 11: ADVANCED ANALYTICAL CHEMISTRY

Model Question Paper

Time 2hrs. **Max. Marks-50M**

SECTION-A

Answer any THREE questions choosing at least ONE question from each part

PART-A **3x10=30M**

1. One question from unit-I
2. One question from unit-I
3. One question from unit-II

PART-B

4. One question from unit-II
5. One question from unit-III
6. One question from unit-IV

SECTION-B

Answer any FOUR questions from the following **4x5=20M**

7. One question from unit-I
8. One question from unit-I
9. One question from unit-II
10. One question from unit-II
11. One question from unit-III
12. One question from unit-III
13. One question from unit-IV

QUESTION BANK

ESSAY QUESTIONS (10 MARKS)

Unit – I:

1. Write the principle and application of simple distillation
2. Write the principle and application of fractional distillation.
3. Write the principles and applications of crystallization.

Unit – II:

1. Explain Nernst distribution law with limitations.
2. What are types of solvent extraction? Explain in detail.

Unit – III:

1. Explain the principle and experimental details of paper chromatography.
2. Write the classification of paper chromatography.
3. Explain the principle and experimental details of thin layer chromatography.

Unit – IV:

1. Explain the principle and experimental details of column chromatography.
2. Explain the principle and experimental details of gas-liquid chromatography.
3. Explain The principle and experimental details of high performance liquid chromatography.

Short answer questions (5M)

Unit-I:

1. Write the principle of centrifugation.
2. What are applications of sublimation?
3. What are applications of filtration?

Unit – II

1. Write the principle of solvent extraction with examples.
2. Write the applications of solvent extraction

Unit – III:

1. Define R_f value. What factors affecting R_f value?
2. Explain the superiority of thin layer chromatography over paper chromatography.
3. Write the applications of paper chromatography.
4. Write the applications of thin layer chromatography

Unit – IV:

1. Write the applications of column chromatography.
2. Write the applications of gas-liquid chromatography
3. the instrumentation of gas-liquid chromatography.
4. Write the instrumentation of high performance liquid chromatography.

	P.R.GOVERNMENT COLLEGE(A),KAKINADA	Program & Semester B. Voc., Pharmaceutical chemistry (V Semester)			
Course Code	**TITLE OF THE COURSE ADVANCED ANALYTICAL CHEMISTRY PRACTICAL**				
Teaching	Hours Allocated: 30 (**Practical**)	L	T	P	C
Pre-requisites	fundamental knowledge on different conventionaldosage forms.	-	-	30	4+1

PRACTICALS:

1. Separation of any two components by using simple distillation method.
2. Determination of Rf values of amino acid using paperchromatography
3. Determination of Rf value of amino acid using thin layer chromatography
4. Separation of methylene blue & methyl orange by using Column chromatography.

	P.R.GOVERNMENT COLLEGE(A),KAKINADA	**Program & Semester** B. Voc., Pharmaceutical chemistry (V Semester)			
Course Code	**TITLE OF THE COURSE BASIC QUALITYCONTROL ANDQUALITYASSURANCE**				
Teaching	Hours Allocated: 60 (**Theory**)	L	T	P	C
Pre-requisites	fundamental knowledge about QA and QC	60	10	30	4+1

Course Objectives:

Upon completion of this course the student should be able to:

1. Understand the cGMP aspects in a pharmaceutical industry.
2. Appreciate the importance of documentation
3. Understand the responsibilities of QA & QC departments

Course Outcomes:

On Completion of the course, the students will be able to	
CO1	Understand about various types of precautions to be taken during samplePreparation
CO2	Learn about the process of production in pharmaceutical industry
CO3	Correlate GLP with GMP in the documentation process
CO4	Learn about the practice of documentation in pharmaceutical industry

Course with focus on employability / entrepreneurship / Skill Developmentmodules

Skill Development		**Employability**		**Entrepreneurship**		**Syllabus:**

Unit –I

Basics of sample preparation, preservation & storage:

Sampling process-purpose of sampling-classes and types of pharmaceutical products-sampling facilities-sampling process-sampling procedure-sampling operation and precautions-Toxicity and carcinogenicity in handling critical samples-Standards and guidelines for sample handling- sample handling and stability-Good storage practices.

Unit –II

Over view of Production Process for Life Sciences Industry

Fundamental science of API Production API Definition-Role of APIs – Top API Manufactures Need for conversation of drugs into formulations-Principles of Manufacturing operations.

Unit –III

Validation in Pharmaceuticals

What is validation- Definition- difference between calibration- validation – Types of validation- Raw material validation & process validation - Change Control Management-Define change request

Unit –IV Documentation practices

Documents practices required by cGMP-Different types of documents,SOPs and records-Document preparation, document/record issuance and retrieval-Good Document practices-Documentation in line with GLP and GMP, Batch release documents

Unit No	Additions	Deletions	Expected levels of learning as per Blooms taxonomy assessment of CO	Percentage added/deleted
I	--	--	K_2, K_3	
II	--	--	K_1, K_2	
III	--	--	K_3, K_6	
IV	--	--	K_1, K_2	

K_1= Remembering, K_2= Understanding, K_3= Applying, K_4= Analysing, K_5= Evaluating, K_6=Create

Text Books & Reference Books

S. No	Author	Title	Publisher
1	Lachman L., Liberman H.A., and Kanig J.L	Theory and Practice of Industrial Pharmacy	USA., latest edition.
2	Sambhamurthy	Pharmaceutical Engineering	New Age Publishers, latestedition
3	Sethi PD	Quantitative analysis of drugs in pharmaceutical formulations	CBS publications, New Delhi, 2008

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https://youtu.be/7cYa_7GZjPU?si=3VBaK3B0xRLeStrg

https://youtu.be/vmfGukpcdjI?si=53juGc5n6J6R541N

https://youtu.be/ICcVaVhkM-g?si=FNsa5okOMH77Nv6p

https://youtu.be/L5mT8i8H8hE?si=1lUr-6OaxmreZhgM

Course outcomes and programme outcomes mapping

Course Outcomes:

On Completion of the course, the students will be able to	
CO1	Understand about various types of precautions to be taken during samplePreparation
CO2	Learn about the process of production in pharmaceutical industry
CO3	Correlate GLP with GMP in the documentation process
CO4	Learn about the practice of documentation in pharmaceutical industry

CO-POMapping:

(1:Slight[Low]; 2:Moderate [Medium]; 3:Substantial [High], '-':No Correlation)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3
CO1	2	3	2	3	3	3	1	2	2	3	2	3	3
CO2	3	2	3	3	2	3	3	1	3	3	2	3	2
Avg.	**2.75**	**2.5**	**2.5**	**2.75**	**2.25**	**2.5**	**2.25**	**2**	**2**	**2.5**	2.5	3	2.5

Programme outcomes

PO1 : Knowledge in Pharmaceutical Chemistry : Apply the knowledge of different dosage forms and their routes of administration.

PO2: Problem analysis: Identify, formulate, review research literature, and analyze simple to complex problems reaching substantiated conclusions using fundamental principles of pharmaceutical chemistry.

PO3: Design/development of solutions: Design solutions for simple to complex problems and designing novel routes for the synthesis of bioactive / active pharmaceutical ingredients.

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PO5 : Modern tool usage: Create, select, and apply appropriate techniques, resources, and IT tools for drug modeling and interpretation of simple to complex drug molecules.

PO6 : Society: Applying the contextual knowledge to assess societal, health, safety, legalissues.

PO7: Environment and sustainability: Understand the importance of synthetic drug chemistry for various discoveries in the field of health science and demonstrate the knowledge for sustainable development.

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PO9 : Communication: Communicate effectively on issues related to pharmaceutical chemistry with the medical community, being able to write the effective reports and documentations and presentations.

PO10: Life-long learning: Recognize the need for, and have the preparation and ability toengage in independent and lifelong learning in the broadest context of technological change new drug investigations for new diseases.

Programme specific outcomes

PSO-1: To have a firm foundation in the fundamentals/concepts/theories and its applications in pharmaceutical chemistry.

PSO-2: To understand the structure and properties of drugs, Characteristics mechanisms of chemical reactions and their usage in pharmaceutical chemistry

PSO-3: To acquaint with safety measures that are to be taken in pharmaceutical chemistry laboratory and develop skills in proper manufacturing methods of pharmaceuticals and usage of different apparatus/instruments and carry out experimental procedures, recordthe observations and results and present the inference/conclus

P.R.GOVERNMENTCOLLEGE(A),KAKINADA

B.Voc(PHARMACEUTICAL CHEMISTRY)

V SEMESTER

Course–12: BASIC QUALITY CONTROL AND QUALITY ASSURANCE

WEIGHTAGETOCONTENT

S No.	Course Content	Essay (10M)	Short (5M)	Total marks	Question Relates as per Bloom's Taxonomy
1.	UNIT-I	2	2	30	Understanding. Skill
2.	UNIT-II	2	2	30	Remembering, Understanding
3.	UNIT-III	1	2	20	Remembering, Knowledge
4.	UNIT-IV	1	1	15	Evaluating, understanding
	Total	6	7	95	

P.R.GOVERNMENT COLLEGE (A), KAKINADA

B.Voc (PHARMACEUTICAL CHEMISTRY)

V SEMESTER

Course–12: BASIC QUALITY CONTROL AND QUALITY

ASSURANCE

Model Question Paper

Time 2hrs. **Max. Marks-50M**

SECTION-A

Answer any THREE questions choosing at least ONE question from each part

PART-A **3x10=30M**

1. One question from unit-I
2. One question from unit-I
3. One question from unit-II

PART-B

4. One question from unit-II
5. One question from unit-III
6. One question from unit-IV

SECTION-B

Answer any FOUR questions from the following **4x5=20M**

7. One question from unit-I
8. One question from unit-I
9. One question from unit-II
10. One question from unit-II
11. One question from unit-III
12. One question from unit-III
13. One question from unit-IV

QUESTION BANK

ESSAY

QUESTIONS

UNIT-I

1. What are the various sampling process involved in pharmaceutical Industry
2. Describe the sampling procedure for raw materials in pharmaceutical industry
3. Describe the sampling procedure for powdered starting materials
4.

UNIT-II

1. What is the need for conversion of drug into formulation.
2. What are the various prinicples of manufacturing

UNIT-III

1. Write short note on process validation.
2. Write about equipment validation.
3. Explain about concurrent validation.

UNIT IV

1. Write about good documentation practices.
2. Explain the guidelines for document preparation.

SHORT ANSWERS

UNIT-I

1. Differentiate toxicogenicity & carcinogenicity
2. Describe the five steps in sampling procedure
3. Describe the steps to weigh the sample

UNIT-II

1. Enlist the various types of SOPs and discuss them briefly
2. Write a short notes on MSDS preparation
3. Give a short notes on (a) Batch record documentation (b) Log Books

UNIT-III

1. Define calibration, valdation and qualification
2. Explain the change control procedure in pharmaceutical industry

UNIT IV

1. What are the various types of documents .
2. Write a short note on SOP
3. Explain the guidelines for document preparation.

	P.R.GOVERNMENT COLLEGE(A),KAKINADA	Program & Semester			
Course Code	TITLE OF THE COURSE BASIC QUALITY CONTROL AND QUALITY ASSURANCE PRACTICAL	B. Voc., Pharmaceutical chemistry (V Semester)			
Teaching	Hours Allocated: 30 (**Practical**)	L	T	P	C
Pre-requisites	fundamental knowledge about QA and QC	-	-	30	4+1

PRACTICALS

1. Extraction of caffeine from tea powder.
2. Extraction of Lactose from milk.
3. Extraction of Lycopene from tomato.
4. Extraction of piperine from pepper.
5. Extraction of carotene from carrot.

	P.R.GOVERNMENT COLLEGE(A),KAKINADA	**Program & Semester** B. Voc., Pharmaceutical chemistry (V Semester)			
Course Code	**TITLE OF THE COURSE DOCUMENTATION FOR QUALITY CONTROL**				
Teaching	Hours Allocated: 60 (**Theory**)	L	T	P	C
Pre-requisites	fundamental knowledge on different conventionaldosage forms.	60	10	30	4+1

Course Objectives:

Upon completion of this course the student should be able to:

1. understand the Quality management system.
2. appreciate the importance of documentation
3. 3.understand the advance R& D approaches

Course Outcomes:

On Completion of the course, the students will be able to	
CO1	Understand the concept of validation and qualification
CO2	Understand the concept of quality management system
CO3	Learn the rules and regulations for documentation in pharma industry as a partof quality control
CO4	Learn about the fundamentals of R&D

Course with focus on employability / entrepreneurship / Skill Development modules

Skill Development			**Employability**			**Entrepreneurship**	

Syllabus:

Unit –I validation

What is validation?- Validation versus Qualification- what has to be validated- phases of validation

–validation time line-DQ,IQ-OQ-PQ-OQ-validation report-settingthe specification in DQ – Installation qualification (IQ) and operational qualification (OQ)-on going performance (PQ)-

Operating instruments like stability chambers- BOD incubators-stability programme for validation

Unit –II Quality Management System (OOS, OOT)

Definition-QbD system-Need for QbD-handling of market complaints-correctionactions- deviations and incidents-reporting, investigation and disposition of incidents,CAPA definition-flow chart of QA

Unit –III Documentation practices

Ten commandments of cGMP-cGMP enforcement and Guidelines-Code of FederalRegulation (CFR-210 & 211)- Audit & Self inspection-Quality audit-Documents practices required by cGMP- Different types of documents, SOPs and records-Document preparation, document/record issuanceand retrieval-Good Document practices-Documentation in line with GLP and GMP

Unit –IV Fundamentals of Advance R&D approaches

Method Transfer Process and how to manage the Quality Risk-Quality Risk Management (QRM)-Responding to an Audit/Process related Query-Change Management

Unit No	Additions	Deletions	Expected levels of learning as per Blooms taxonomy assessment of CO	Percentage added/deleted
I	--	--	K_2, K_3	
II	--	--	K_1, K_2	
III	--	--	K_3, K_6	
IV	--	--	K_1, K_2	

K_1= Remembering, K_2= Understanding, K_3= Applying, K_4= Analysing, K_5= Evaluating, K_6=Create

Text Books & Reference Books

S. No	Author	Title	Publisher
1	Lachman L., Liberman H.A., and Kanig J.L	Theory and Practice of Industrial Pharmacy	USA., latest edition.
2	Sambhamurthy	Pharmaceutical Engineering	New Age Publishers, latestedition
3	Sethi PD	Quantitative analysis of drugs in pharmaceutical formulations	CBS publications, New Delhi, 2008

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https://youtu.be/bEeZtyfE_BA?si=VW4SbWP8S2css6WV
https://youtu.be/0iXxoNlTxr8?si=7oIMqHPZiXegcsJ-
https://youtu.be/nNlySVarLQg?si=DbVMRb6EHC8Uu6Zk

Course outcomes and programme outcomes mapping

Course Outcomes:

On Completion of the course, the students will be able to	
CO1	Understand the concept of validation and qualification
CO2	Understand the concept of quality management system
CO3	Learn the rules and regulations for documentation in pharma industry as a partof quality control
CO4	Learn about the fundamentals of R&D

CO-POMapping:

(1:Slight[Low]; 2:Moderate [Medium]; 3:Substantial [High], '-':No Correlation)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3
CO1	2	3	2	3	3	3	1	2	2	3	2	3	3
CO2	3	2	3	3	2	3	3	1	3	3	2	3	2
CO3	3	3	3	3	2	2	2	2	2	3	3	3	2
CO4	3	2	2	2	2	2	3	3	1	1	3	3	3
Avg.	**2.75**	**2.5**	**2.5**	**2.75**	**2.25**	**2.5**	**2.25**	**2**	**2**	**2.5**	2.5	3	2.5

Programme outcomes

PO1 : Knowledge in Pharmaceutical Chemistry : Apply the knowledge of different dosage forms and their routes of administration.

PO2: Problem analysis: Identify, formulate, review research literature, and analyze simple to complex problems reaching substantiated conclusions using fundamental principles of pharmaceutical chemistry.

PO3: Design/development of solutions: Design solutions for simple to complex problems and designing novel routes for the synthesis of bioactive / active pharmaceutical ingredients.

PO4: Conduct investigations on new drug discoveries: Use fundamental research-based knowledge and available research methodologies including design of experiments, analysis and interpretation of data, and synthesis of the drug molecules.

PO5 : Modern tool usage: Create, select, and apply appropriate techniques, resources, and IT tools for drug modeling and interpretation of simple to complex drug molecules.

PO6 : Society: Applying the contextual knowledge to assess societal, health, safety, legalissues.

PO7: Environment and sustainability: Understand the importance of synthetic drug chemistry for various discoveries in the field of health science and demonstrate the knowledge for sustainable development.

PO8 : Ethics: Apply ethical principles and commit to professional ethics and responsibilities and norms of the pharmaceutical manufacturing practice.

PO9 : Communication: Communicate effectively on issues related to pharmaceutical chemistry with the medical community, being able to write the effective reports and documentations and presentations.

PO10: Life-long learning: Recognize the need for, and have the preparation and ability toengage in independent and lifelong learning in the broadest context of technological change new drug investigations for new diseases.

Programme specific outcomes

PSO-1: To have a firm foundation in the fundamentals/concepts/theories and its applications in pharmaceutical chemistry.

PSO-2: To understand the structure and properties of drugs, Characteristics mechanisms of chemical reactions and their usage in pharmaceutical chemistry

PSO-3: To acquaint with safety measures that are to be taken in pharmaceutical chemistry laboratory and develop skills in proper manufacturing methods of pharmaceuticals and usage of different apparatus/instruments and carry out experimental procedures, recordthe observations and results and present the inference/conclusion

P.R.GOVERNMENTCOLLEGE(A),KAKINADA

B.Voc(PHARMACEUTICAL CHEMISTRY)

V SEMESTER

Course–13: DOCUMENTATION FOR QUALITY CONTROL

WEIGHTAGETOCONTENT

S No.	Course Content	Essay (10M)	Short (5M)	Total marks	Question Relates as per Bloom's Taxonomy
1.	UNIT-I	2	2	30	Understanding. Skill
2.	UNIT-II	2	2	30	Remembering, Understanding
3.	UNIT-III	1	2	20	Remembering, Knowledge
4.	UNIT-IV	1	1	15	Evaluating, understanding
	Total	6	7	95	

P.R.GOVERNMENT COLLEGE (A), KAKINADA

B.Voc (PHARMACEUTICAL CHEMISTRY)

V SEMESTER

Course–13: DOCUMENTATION FOR QUALITY CONTROL

Model Question Paper

Time 2hrs. **Max. Marks-50M**

SECTION-A

Answer any THREE questions choosing at least ONE question from each part

PART-A **3x10=30M**

1. One question from unit-I
2. One question from unit-I
3. One question from unit-II

PART-B

4. One question from unit-II
5. One question from unit-III
6. One question from unit-IV

SECTION-B

Answer any FOUR questions from the following **4x5=20M**

7. One question from unit-I
8. One question from unit-I
9. One question from unit-II
10. One question from unit-II
11. One question from unit-III
12. One question from unit-III
13. One question from unit-IV

QUESTION BANK

ESSAY QUESTIONS

UNIT I

1. Define validation; write its importance and types. Write about validation master plan
2. Explain the validation protocol for cleaning process
3. How to perform Analytical method validation

UNIT-II

1. What are the salient features of CAPA
2. Explain different types of documents.
3. What are incidents? Explain reporting, investigation and deposition ofincidents.

UNIT-III

1. Enumerate 10 principles of cGMP
2. What are Standard Operating Procedures (SOP)
3. What do you understand by master formula record. Write a brief note.

UNIT-IV

1. Explain quality risk management system.
2. What is method transfer process. Write the process related query.

SHORT ANSWER TYPE QUESTIONS (5M)

UNIT-I

1. Write about validation master plan
2. Validation timeline for DQ and IQ.
3. What are phases of validation?

UNIT-II

1. Write a short note on batch record documentation.
2. Define CAPA. Explain flowchart of QA.
3. Define QbD. Explain the need of QbD.

UNIT-III

1. Write about GdP.
2. Explain importance of documentation in Pharmaceutical industries.
3. Explain quality audit.

UNIT-IV

1. Write a short note on complaint files.
2. Write a short note on log books.

	P.R.GOVERNMENT COLLEGE(A),KAKINADA	Program & Semester: B. Voc., Pharmaceutical chemistry (V Semester)			
Course Code	**TITLE OF THE COURSE DOCUMENTATION FOR QUALITYCONTROL PRACTICAL**				
Teaching	Hours Allocated: 30 (**Practical**)	L	T	P	C
Pre-requisites	fundamental knowledge on different conventionaldosage forms.	-	-	30	4+1

PROJECT WORK

	P.R.GOVERNMENT COLLEGE(A),KAKINADA	**Program & Semester** B. Voc., Pharmaceutical chemistry (V Semester)			
Course Code	**TITLE OF THE COURSE PHARMACEUTICAL AND MEDICINAL CHEMISTRY**				
Teaching	Hours Allocated: 60 (**Theory**)	L	T	P	C
Pre-requisites	fundamental knowledge about various drugs	60	10	30	4+1

Course Objectives:

Upon completion of this course the student shouldbe able to:

1. Understand the Pharma dynamics of a drug.
2. learn terminology of drugs.
3. 3.learn HIV therapeutic drugs.

Course Outcomes:

On Completion of the course, the students will be able to	
CO1	Learn about pharmaceutical chemistry and its terminology
CO2	Understand the concept of pharmacodynamics and pharmacokinetics
CO3	Learn about the classification of drugs based on the structure and therapeuticActivity
CO4	Illustrate the mechanism of AIDS and the drugs available for the prevention

Course with focus on employability / entrepreneurship / Skill Developmentmodules

Skill Development			**Employability**			**Entrepreneurship**	

Syllabus:UNIT-I

Pharmaceutical chemistry Terminology: Pharmacy, Pharmacology, Pharmacophore, Pharmacodynamics, Pharmacokinetics (ADME, Receptors - brief treatment) Metabolites and Antimetabolites.

UNIT-II

Drugs:

Nomenclature: Chemical name, Generic name and trade names with examples Classification: Classification based on structures and therapeutic activity with one example each.

Dosage forms: need for conversion drugs into medicines, different types of dosage forms based on physical state, Route of admistration

UNIT-III

Synthesis and therapeutic activity ofthecompounds:

a. Chemo therapeutic Drugs

1. Sulphadrugs(Sulphamethoxazole) 2.Antibiotics - β-Lactam Antibiotics, MacrolideAntibiotics, 3. Anti malarial Drugs (chloroquine)

b. Psycho therapeutic Drugs:

1. Anti pyretics(Paracetamol) 2.Hypnotics, 3.Tranquilizers(Diazepam)4.Levodopa
2. Anti viral drugs (acyclovir)

UNIT-IV

PharmacodynamicDrugs:

1. Antiasthma Drugs (Solbutamol) 3. Antianginals (Glycerol Trinitrate)

4. Diuretics (Frusemide) HIV-AIDS

Immunity - CD-4cells, CD-8cells, Retro virus, Replication in human body, Investigation available, prevention of AIDS, Drugs available - examples with structures: PIS: Indivanir (crixivan),Nelfinavir(Viracept).

Unit No	Additions	Deletions	Expected levels of learning as per Blooms taxonomy assessment of CO	Percentage added/deleted
I	--	--	K_2, K_3	
II	--	--	K_1, K_2	
III	--	--	K_3, K_6	
IV	--	--	K_1, K_2	

K_1= Remembering, K_2= Understanding, K_3= Applying, K_4= Analysing, K_5= Evaluating, K_6=Create

Text Books & Reference Books

S. No	Author	Title	Publisher
1	Dr. B.V.Ramana	Medicinal Chemistry	USA., latest edition.
2	O.D.Tyagi	Synthetic Drugs	New Age Publishers, latestedition
3	R.S Satoshkar & S.D.Bhandenkar	Pharmacology& Pharmacotherapeutics	CBS publications, New Delhi, 2008

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Course outcomes and programme outcomes mapping

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On Completion of the course, the students will be able to	
CO1	Learn about pharmaceutical chemistry and its terminology
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CO3	3	3	3	3	2	2	2	2	2	3	3	3	2
CO4	3	2	2	2	2	2	3	3	1	1	3	3	3
Avg.	**2.75**	**2.5**	**2.5**	**2.75**	**2.25**	**2.5**	**2.25**	**2**	**2**	**2.5**	2.5	3	2.5

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P.R.GOVERNMENTCOLLEGE(A),KAKINADA

B.Voc(PHARMACEUTICAL CHEMISTRY)

V SEMESTER

Course–14: PHARMACEUTICAL AND MEDICINAL CHEMISTRY

WEIGHTAGETOCONTENT

S No.	Course Content	Essay (10M)	Short (5M)	Total marks	Question Relates as per Bloom's Taxonomy
1.	UNIT-I	2	2	30	Understanding. Skill
2.	UNIT-II	2	2	30	Remembering, Understanding
3.	UNIT-III	1	2	20	Remembering, Knowledge
4.	UNIT-IV	1	1	15	Evaluating, understanding
	Total	6	7	95	

P.R.GOVERNMENT COLLEGE (A), KAKINADA

B.Voc (PHARMACEUTICAL CHEMISTRY)

V SEMESTER

Course–14: PHARMACEUTICAL AND MEDICINAL CHEMISTRY

Model Question Paper

Time 2hrs. **Max. Marks-50M**

SECTION-A

Answer any THREE questions choosing at least ONE question from each part

PART-A **3x10=30M**

1. One question from unit-I
2. One question from unit-I
3. One question from unit-II

PART-B

4. One question from unit-II
5. One question from unit-III
6. One question from unit-IV

SECTION-B

Answer any FOUR questions from the following **4x5=20M**

7. One question from unit-I
8. One question from unit-I
9. One question from unit-II
10. One question from unit-II
11. One question from unit-III
12. One question from unit-III
13. One question from unit-IV

QUESTIONBANK

(Essayquestions10marks)

UNIT-I

1. Explain metabolites and anti metabolites with an example each
2. Explain ADME in pharmacokinetics.

Unit-II

1. Explain the classification of drugs based on structure.
2. Explain the classification of drugs based on therapeutic activity.

UNIT-III

1. Write the synthesis and therapeutic activity sulphamethoxazole
2. Write the synthesis and therapeutic activity chloroquine
3. Write the synthesis and therapeutic activity diazepam

UNIT-IV

1. Write the synthesis and therapeutic activity solbutamol
2. Write the synthesis and therapeutic activity glycerol trinitrate.
3. Write the synthesis and therapeutic activity frusemide.

Short answer questions(5M)

UNIT-I

1. Explain the terms pharmacy and pharmacology.
2. Explain Pharmacophore with two examples.

Unit-II

3. Explain chemical name generic name and trade name with examples.
4. Write different types of dosage forms based on a) physical state b) route ofadmistration

UNIT-III

1. Write sort note on anti biotics

2. Write short notes on anti pyretics
3. What are hypnotics and tranquilizers give examples

UNIT-IV

1. Write about methods of prevention of AIDS.
2. Write the structures of drugs a) indivanir b) Nelfinavir.

	P.R.GOVERNMENT COLLEGE(A),KAKINADA	Program & Semester B. Voc., Pharmaceutical chemistry (V Semester)			
Course Code	**TITLE OF THE COURSE** **PHARMACEUTICAL AND MEDICINAL CHEMISTRY PRACTICAL**				
Teaching	Hours Allocated: 30 (**Practical**)	L	T	P	C
Pre-requisites	fundamental knowledge about drugs	-	-	30	4+1

1. Preparation of aspirin.
2. Preparation of benzanilide.
3. Preparation of salicylic acid.
4. Preparation of 2, 4, 6 tri bromo phenol.
5. Preparation of beta Naphthol azo dye.