

17  
**P.R.Government College(Autonomous)  
Kakinada**

(Affiliated to AdikaviNannaya University)



**Department of Chemistry**

**B.Voc(Pharmaceutical Chemistry)**

**Under NSQF Scheme**

**Board of studies**

**2021-22**

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**Note:** BOS is to provide final soft copy in PDF and word formats and four copies of hard copies in bounded form to the office of Dean Academic affairs.

**P.R.Government College(Autonomous),KakinadaRe  
commendedCompositionoftheBoardofStudiesofB.Voc  
(PharmaceuticalChemistry)  
Andit'sFunctionsofanAutonomousC  
ollege2021-22**

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**Composition**

**1.Chairman,BoardofStudies:**

**Sri T.V.V.SatyaNarayanaM.Sc.,**

**NodalOfficerforB.Voc.(PharmaceuticalChemistry)**

**2.Theentirefacultyofeachspecialization.**

- 1. Dr.D.Rama Rao**
- 2. Dr. D. Chenna Rao**
- 3. V. Sanjeev Kumar**
- 4. P. Vijay Kumar**
- 5. V.RamaBabu**
- 6. N.BujjiBabu**
- 7. T.UmaMaheswara Rao**
- 8. Dr.A.ChandraLeela**
- 9. Dr.Ch.Praveen**

**3.SubjectexpertsfromoutsidethecollegetobenominatedbytheAcademicCouncil**

**SriV.MallikharjunaSharma, LecturerinChemistry, ASD women  
Govt.College(A),Kakinada**

**Dr.k. Jhansi, LecturerinChemistry.**

**4.OneexperttobenominatedbytheVice-Chancellorfromapanelofsix**

**RecommendedbytheCollegePrincipal,  
Prof.K.Deepthi, AdikaviNannayaUniversity, Rajamundry.**

**5.Expertfromindustry**

- 1 Ch.S.N.Murthy, Director, Venky pharma pvt.Ltd, Yanam.**

**6.One postgraduatemeritoriousalumnusnominatedbythePrincipal.**

**V.MallikarjunaSarma, M.Sc., OrganicChemistry**



Signatures of the members who attended the Board of studies in B. Voc (Pharmaceutical Chemistry)

**Date:10.12.2021 Time: 3.00 Pm**

**Mode of conduct of meeting: offline mode in P.R. Govt. College(A), Kakinada.**

| S.no | Name of the member                       | Designation                                                                                 | Signature                         |
|------|------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------|
| 1    | Sri. T. V. V. Satyanarayana              | Chairman, Board of Studies, Nodal Officer for B. Voc (Pharmaceutical Chemistry)             | T. V. V. Satyanarayana 10/12/2021 |
| 2    | Prof. K. Deepthi                         | University Nominee Asst. Professor & Head of the Department of Chemistry, AKNU, Rajamundry. | K. Deepthi                        |
| 3    | Sri. K,anand                             | Subject Expert                                                                              | K. Anand 10/11/21                 |
| 4    | DR.RAMESH BOGA                           | Founder & MD Boga R Laboratories, Peddapuram & Suvane, USA                                  |                                   |
| 5    | V. Mallikarjuna Sarma                    | Lecturer in Chemistry A.S.D Govt College Kakinada                                           | V. Mallikarjuna Sarma 10/12/2021  |
| 7    | Dr. D. Chenna Rao                        | Member Lecturer in chemistry Department of Chemistry                                        | Dr. D. Chenna Rao 10/12/2021      |
| 8    | V. Sanjeev Kumar                         | Member Lecturer in chemistry                                                                | V. Sanjeev Kumar                  |
| 9    | P. Vijay Kumar                           | Member Lecturer in Chemistry                                                                | P. Vijay Kumar                    |
| 10   | V. Rama Babu                             | Member Lecturer in Chemistry                                                                | V. Rama Babu                      |
| 11   | Student members: Hephshibah. K Mohan. Ph | Admn No:5215422 Admn No:5215420                                                             | Hephshibah. K Mohan. Ph           |



ACTION PLAN BOS MEETING-CHEMISTRY HELD ON 06-04-2021.

Department activities for the academic year 2020-2021.

Annexure I

**1. Organizing National/State level seminars/Workshops/Conferences/Training programmes etc., with topics and other details.**

**(Mandatory for each Department)**

- i) Staff development programme
- ii) Training in the use of HPLC
- iii) Awareness on OZONE protection
- iv) National Chemistry day
- v) Chem.fest
- vi) National Science day 2020
- vii) Guest lectures
- viii) Training in water analysis

**2. Change of modules in the syllabus content.**

Syllabus designed for first and second and final years as per university regulations. CBCS introduced for final year w.e.f. 2018-19 & CBCS introduced for I & II year w.e.f. 2020-21.

**3. Plan for utilization of funds for Autonomous/UGC/other grants available for arranging guest lectures, faculty improvement programmes, study tours, equipping laboratories, reference books & other necessary teaching-learning material with ICT enabled teaching.**

**I. Study visits to:**

**Rs, 50,000**

- 1. Hetero Laboratories, Nakkapally
- 2. Dr. Reddy's Laboratories, Yanam.
- 3. National Institute of Hydrology, Kakinada.
- 4. Nagarjuna Fertilizers and Chemicals Ltd, Kakinada.
- 5. Coromandel International Ltd., Kakinada
- 6. Venky Parenterals, Yanam

**II.**

**1. Sophisticated version UV-Visible spectrophotometer-**

**5.0 lakhs**

**2. Other equipment**

**1.50 lakhs**

**3. Consumables**

**1.98 lakhs**

**4. Plan for organizing subject oriented community outreach programmes & allocation of necessary funds. (Mandatory for each Department)**

- |     |                              |     |        |
|-----|------------------------------|-----|--------|
| i)  | Adoption of village          | Rs. | 20,000 |
| ii) | Medical Awareness programmes | Rs. | 10,000 |

**5. Institution of new medals/incentives/prizes etc., from alumni, philanthropists, parents, faculty etc., - Strategies to be recommended**

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**6. Introduction of new Online programmes –PG/UG/Diploma and certificate courses.**

**Swayam online course**

Industrial Pharmacy

**7. Any other programme that enhance the learning capacity of students and their employable & knowledge skills.**

Training in the use of instruments like AAS, UV-

Vis, HPLC, flame photometer, uranium analyzer, soil and water analysis projects, air quality projects.

**8. Change in internal assessment exams for conducting Mid Semester by way of Project work/Assignment.**

It is proposed to conduct an online Examination for Mid Semester Examination from 2020-21.

**9. Suggest panel of examiners/papers setters & other experts/nominees for BOS deliberations.**

**Chemistry:**

1. Dr. D. S. V. N. N. Rama Murthy, GDC(A), Tuni
2. Sri V. Sridhar, Arts College, Rajahmundry
3. Dr. B. Mallikarjuna, Arts College, Rajahmundry

Department of B.Voc (Pharmaceutical Chemistry) Board of Studies Meeting

Dt. 10-12-2021

Resolutions:

The meeting of Board of studies in B.Voc (Pharmaceutical Chemistry) is convened on 10-12-2021 at dept of chemistry in P.R. Govt. College (A). The Principal Dr. B.V. Tirupanyam, Dr. K. Deepthi, University Nominee, Sri K. Anand, GDC Pithapuram..., Subject Expert, Sri V. Mallikarjuna Sarma, GDC (W), Kakinada, all members of the faculty of Chemistry and student representatives attended the meeting. Agenda items are discussed and resolutions are made.

1. It is resolved to follow the revised Choice Based Credit System for B. Voc courses scrupulously as per the directions of Andhra Pradesh State Council of Higher Education (APSCHE), Vijayawada and also as per the directions of Adikavi Nannaya University, Rajamahendravaram with effect from the academic year 2020-21.
2. It is resolved to follow the revised curricular framework for B. Voc courses scrupulously as per the directions of Andhra Pradesh State Council of Higher Education (APSCHE), Vijayawada and also as per the directions of Adikavi Nannaya University, Rajamahendravaram with effect from the academic year 2020-21.
3. It is resolved to choose Life Skill courses and Skill Development Courses in concurrence with the vocational course.
4. It is resolved to conduct industrial visits for B. Voc students to make them acquainted with the industrial environment.
5. It is resolved to admit both Intermediate (MPC) stream and Intermediate (Bi.P.C) stream students into B. Voc courses and design the curriculum accordingly.
6. It is resolved to run B.Voc (Pharmaceutical Chemistry) in two streams namely
  - i. B.Voc (Pharmaceutical Chemistry) Maths stream and



II. B.Voc(Pharmaceutical Chemistry) Biology stream

7. It is resolved to organize Guest lectures by eminent professors and Industrial Experts.
8. Resolved to implement pass minimum for internal assessment for CBSE pattern students as the pattern is learner oriented.
9. Resolved \_\_\_\_\_ to \_\_\_\_\_ submit proposals to conduct a faculty development programme in instrumentation techniques/advanced topics with the assistance of industry representatives and university representatives.
10. Resolved to conduct Industrial Internship for a period of two months during the summer after completion of semester end examinations.
11. It is resolved to make it mandatory for the students in the entire V semester to undergo industrial internship for a period of 6 months in a Pharma Industry.
12. It is resolved to get the students of B.Voc(Pharmaceutical Chemistry) registered in NAPS (National Apprenticeship Promotion Scheme).
13. It is resolved that the B.Voc(Pharmaceutical Chemistry) course is restructured in B.Sc(Professional)(Pharmaceutical Chemistry). The proposal is put forward to Academic Council and General Body Meeting.
14. It is resolved to follow strictly the guidelines of UGC under NSQF scheme for the recruitment and engagement of faculty and non-teaching staff.
15. It is resolved to follow the \_\_\_\_\_ same \_\_\_\_\_ syllabi for English, Second Language, Life Skill Courses and Skill Development Courses as those prescribed for UG Courses by APSCHE, Vijayawada.
16. It is resolved to follow the same syllabi for main subjects namely Mathematics, Botany and Chemistry as those prescribed for UG Courses by APSCHE, Vijayawada.
17. It is resolved to implement 50% external & 50% internal marks for both theory & practicals from the academic year 2020-2021 for first year students only.
18. It is resolved to implement 60% external & 40% internal marks for both theory & practicals from the academic year 2020-2021 for second & third year students
19. Resolved to reduce 40 marks of Theory internal to 20 marks for mid exams and 20 marks for co-curricular activities (Seminar / Assignment / Quiz / Group Discussion) and reduce 50 marks of theory internal to 25 marks for mid exams and 25 marks for co-curricular activities (Seminar / Assignment / Quiz / Group Discussion).
20. Resolve to conduct practical examinations semester wise.

The following paper setters are recommended

- i) Dr. D. S. V. N. N. Rama Murthy, GDC(A), Tuni
- ii) K. Anand, GDC Pithapuram.,
- iii) Sri V. Mallikarjuna Sarma, GDC(W), Kakinada

## About B.Voc (Pharmaceutical Chemistry)

The University Grants Commission (UGC) had launched a scheme on 27 February, 2014 for skills development based higher education as part of college/university education, leading to Bachelor of Vocation (B.Voc.) degree with multiple entry and exit points. Considering the implementation modalities, 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 along with broad based general education. This would 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 at each exit point of the programme.
3. To provide flexibility to students by means of pre-defined entry and multiple exit points.
4. To integrate NSQF within the undergraduate level of higher education in order to enhance employability of the graduates and meet industry requirements. Such graduates apart from meeting the need of local and national industry are also expected to be equipped to become part of the global workforce.
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 in formulations
8. Acquire knowledge on different types of instrumentation techniques in chemical analysis.
9. Understand stereochemistry of carbon compounds and its importance in organic chemistry
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. Undergo industrial training and acquire skills in various instrumentation techniques.
14. 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 roles 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 by State and Central Governments.



Sem-I

| Category       | Subject/Paper           | Course | Theory /Practical | No.of Hrs./ Week | No offered | Evaluation |          |       |
|----------------|-------------------------|--------|-------------------|------------------|------------|------------|----------|-------|
|                |                         |        |                   |                  |            | Internal   | External | TOTAL |
| Firstlanguage  | ENGLISHPRAXISCOURSE-I   |        | Theory            | 4                | 3          | 50         | 50       | 100   |
|                | SecondLanguage          |        | Theory            | 4                | 3          | 50         | 50       | 100   |
|                | LifeSkillCourses        |        | Theory            | 2                | 2          |            | 50       | 50    |
|                | SkillDevelopment Course |        | Theory            | 2                | 2          |            | 50       | 50    |
| MajorSubject-1 | ElectricalAppliances    |        | Theory            | 2                | 2          |            | 50       | 50    |
|                | Mathematics /           | C1     | Theory            | 6                | 5          | 50         | 50       | 100   |
|                | Chemistry               | C1     | Theory            | 4                | 4          | 50         | 50       | 100   |
|                | Chemistry               |        | Practical         | 2                | 1          |            | 50       | 50    |
|                | BasicPharmaceutics-I    | C1     | Theory            | 4                | 4          | 50         | 50       | 100   |
|                | BasicPharmaceutics-I    |        | Practical         | 2                | 1          |            | 50       | 50    |
|                | BasicPharmaceutics-II   | C2     | Theory            | 2                | 2          | -          | 50       | 50    |
| Vocational     | BasicPharmaceutics-II   |        | Practical         | 2                | 1          |            | 50       | 50    |
|                |                         |        | <b>TOTAL</b>      | 34               | 28         | 250        | 550      | 800   |

**P.R.GOVERNMENT COLLEGE(A), KAKINADA DEPARTMENT OF CHEMISTRY  
B.VOC(PHARMACEUTICAL CHEMISTRY)(MATHS STREAM) CURRICULAR FRAMEWORK (CREDIT STABLE)  
SEMESTER - II**

| Category                   | Subject/Paper                            | Course | Theory / Practical | No. of Hrs./ Week | No of credits | Evaluation |                |
|----------------------------|------------------------------------------|--------|--------------------|-------------------|---------------|------------|----------------|
|                            |                                          |        |                    |                   |               | Internal   | External TOTAL |
| First language             | ENGLISH PRACTICE COURSE-II               |        | Theory             | 4                 | 3             | 50         | 50 100         |
| Second Language            | Telugu/Sanskrit/Hindi                    |        | Theory             | 4                 | 3             | 50         | 50 100         |
| Life Skill Courses         | Information and Communication Technology |        | Theory             | 2                 | 2             | -          | 50 50          |
| Skill Development Course-1 | Food Adulteration                        |        | Theory             | 2                 | 2             | -          | 50 50          |
| Skill Development Course-1 | Dairy technology                         |        | Theory             | 2                 | 2             | -          | 50 50          |
| Major Subject-1            | Mathematics                              | C2     | Theory             | 6                 | 5             | 50         | 50 100         |
| Major Subject-2            | Chemistry                                | C2     | Theory             | 4                 | 4             | 50         | 50 100         |
|                            | Chemistry                                |        | Practical          | 2                 | 1             |            | 50 50          |
| Vocational                 | Basic Analytical Chemistry-I             | C3     | Theory             | 4                 | 4             | 50         | 50 100         |
|                            | Basic Analytical Chemistry-I             |        | Practical          | 2                 | 1             |            | 50 50          |
|                            | Health Education and Community Pharmacy  | C4     | Theory             | 2                 | 2             | -          | 50 50          |
|                            | Health Education and Community Pharmacy  |        | Project            | 2                 | 1             | -          | 50 50          |
|                            | ;                                        |        | TOTAL              | 36                | 30            | 250        | 600 850        |



**P.R.GOVERNMENT COLLEGE(A),  
KAKINADA DEPARTMENT OF CHEMISTRY  
B.VOC(PHARMACEUTICAL CHEMISTRY)(MATHS STREAM) CU  
CURRICULAR FRAMEWORK (CREDIT TABLE)**

**Semester-III**

| Category                 | Subject/Paper                          | Course | Theory /Practical | No. of Hrs./ Week | No of credits | Evaluation |            |            |
|--------------------------|----------------------------------------|--------|-------------------|-------------------|---------------|------------|------------|------------|
|                          |                                        |        |                   |                   |               | Internal   | External   | TOTAL      |
| First Language           | ENGLISH PRACTICE COURSE-III            |        | Theory            | 4                 | 3             | 40         | 60         | 100        |
| Second Language          | Telugu/Sanskrit/Hindi                  |        | Theory            | 4                 | 3             | 40         | 60         | 100        |
| Life Skill Course-I      | Environment Education                  |        | Theory            | 2                 | 2             | -          | 50         | 50         |
| Life Skill Course-II     | Personality Development and Leadership |        | Theory            | 2                 | 2             | -          | 50         | 50         |
| Skill Development Course | Environment Audit                      |        | Theory            | 2                 | 2             | -          | 50         | 50         |
| Major Subject-1          | Mathematics                            | C3     | Theory            | 6                 | 5             | 40         | 60         | 100        |
| Major Subject-2          | Chemistry                              | C3     | Theory            | 4                 | 4             | 40         | 60         | 100        |
|                          | Chemistry                              |        | Practical         | 2                 | 1             |            | 50         | 50         |
|                          | Advanced Pharmaceutics-I               | C5     | Theory            | 4                 | 4             | 40         | 60         | 100        |
|                          | Advanced Pharmaceutics-I               |        | Practical         | 2                 | 1             |            | 50         | 50         |
|                          | Advanced Pharmaceutics-II              | C6     | Theory            | 2                 | 2             | -          | 50         | 50         |
|                          | Advanced Pharmaceutics-II              |        | Project           | 2                 | 1             | -          | 50         | 50         |
|                          |                                        |        | <b>TOTAL</b>      | <b>36</b>         | <b>30</b>     | <b>200</b> | <b>650</b> | <b>850</b> |



**P.R.GOVERNMENT COLLEGE(A),  
KAKINADA DEPARTMENT OF CHEMISTRY  
B.VOC(PHARMACEUTICAL CHEMISTRY)(MATHS STREAM) CURRICU  
LAR FRAMEWORK (CREDIT TABLE)  
Semester – IV**

| Category        | Subject/Paper                    | Course | Theory<br>/Practical<br>I | No. of<br>Hrs./<br>Week | No<br>of credits | Evaluation |            |            |
|-----------------|----------------------------------|--------|---------------------------|-------------------------|------------------|------------|------------|------------|
|                 |                                  |        |                           |                         |                  | Internal   | External   | TOTAL      |
| Major Subject-1 | Mathematics                      | C4     | Theory                    | 6                       | 5                | 40         | 60         | 100        |
|                 | Mathematics                      | C5     | Theory                    | 6                       | 5                | 40         | 60         | 100        |
| Major Subject-2 | Chemistry                        | C4     | Theory                    | 4                       | 4                | 40         | 60         | 100        |
|                 | Chemistry                        |        | Practical                 | 2                       | 1                |            | 50         | 50         |
|                 | Chemistry                        | C5     | Theory                    | 4                       | 4                | 40         | 60         | 100        |
|                 | Chemistry                        |        | Practical                 | 2                       | 1                |            | 50         | 50         |
| Vocational      | Basic Analytical Chemistry-II    | C7     | Theory                    | 4                       | 4                | 40         | 60         | 100        |
|                 | Basic Analytical Chemistry-II    |        | Practical                 | 2                       | 1                |            | 50         | 50         |
|                 | Industrial Safety and Management | C8     | Theory                    | 4                       | 4                | 40         | 60         | 100        |
|                 | Industrial Safety and Management |        | Practical                 | 2                       | 1                |            | 50         | 50         |
|                 |                                  |        | <b>TOTAL</b>              | <b>36</b>               | <b>30</b>        | <b>300</b> | <b>500</b> | <b>800</b> |

P. R. GOVERNMENT COLLEGE(A),  
KAKINADA DEPARTMENT OF CHEMISTRY  
B.VOC(PHARMACEUTICAL CHEMISTRY)(MATHS)STREAM CURRICU-  
LAR FRAMEWORK(CREDIT TABLE)

Semester-V

| Subject/Paper                                                                                             | Theory<br>/Practical<br>t | No<br>of credit<br>s | Evaluation |
|-----------------------------------------------------------------------------------------------------------|---------------------------|----------------------|------------|
| First Phase of Apprenticeship bet-<br>ween 1 <sup>st</sup> and<br>2 <sup>nd</sup> year (Summer Vacation)  |                           | 04                   | 100        |
| Second Phase of Apprenticeship be-<br>tween 2 <sup>nd</sup> and<br>3 <sup>rd</sup> year (Summer Vacation) |                           | 04                   | 100        |
| INDUSTRIAL INTERNSHIP                                                                                     |                           | 12                   | 300        |
| TOTAL                                                                                                     |                           | 20                   | 400        |

**P.R.GOVERNMENT COLLEGE(A),  
KAKINADA DEPARTMENT OF CHEMISTRY  
B.VOC(PHARMACEUTICAL CHEMISTRY)(MATHS STREAM) CURRICU  
LAR FRAMEWORK (CREDIT TABLE)  
Semester – VI**

| Category   | Subject/Paper                               | Course | Theory<br>/Practical | No. of<br>Hrs./<br>Week | No<br>of<br>Credits | Evaluation |                   |
|------------|---------------------------------------------|--------|----------------------|-------------------------|---------------------|------------|-------------------|
|            |                                             |        |                      |                         |                     | Internal   | External<br>TOTAL |
| Vocational | Pharma Regulatory Affairs                   | C9     | Theory               | 4                       | 4                   | 40         | 60                |
|            | Pharma Regulatory Affairs                   |        | Practical            | 2                       | 1                   |            | 50                |
|            | Pharmaceutical Inorganic Chemistry          | C10    | Theory               | 4                       | 4                   | 40         | 60                |
|            | Pharmaceutical Inorganic Chemistry          |        | Practical            | 2                       | 1                   |            | 50                |
|            | Advanced Analytical Chemistry               | C11    | Theory               | 4                       | 4                   | 40         | 60                |
|            | Advanced Analytical Chemistry               |        | Practical            | 2                       | 1                   |            | 50                |
|            | Basic Quality Control and Quality Assurance | C12    | Theory               | 4                       | 4                   | 40         | 60                |
|            | Basic Quality Control and Quality Assurance |        | Practical            | 2                       | 1                   |            | 50                |
|            | Documentation for Quality Control           | C13    | Theory               | 4                       | 4                   | 40         | 60                |
|            | Documentation for Quality Control           |        | Practical            | 2                       | 1                   |            | 50                |
|            | Pharmaceutical and Medicinal Chemistry      | C14    | Theory               | 4                       | 4                   | 40         | 60                |
|            | Pharmaceutical and Medicinal Chemistry      |        | Practical            | 2                       | 1                   |            | 50                |
|            |                                             |        | <b>TOTAL</b>         | <b>36</b>               | <b>30</b>           | <b>240</b> | <b>660</b>        |
|            |                                             |        |                      |                         |                     |            | <b>900</b>        |



**P.R.GOVERNMENTCOLLEGE(A),KAKINADADEPARTM  
ENTOFCHEMISTRY**

**B.VOC(PHARMACEUTICALCHEMISTRY)(BIOLOGYSTREAM)CU  
RICULARFRAMEWORK(CREDITSTABLE)**

**SEMESTER-I**

| Category                   | Subject/Paper         | Course | Theory<br>/Practical | No.<br>ofHr<br>s./<br>Week | No<br>ofcredi<br>ts | Evaluation |          |
|----------------------------|-----------------------|--------|----------------------|----------------------------|---------------------|------------|----------|
|                            |                       |        |                      |                            |                     | Internal   | External |
| <b>Firstlanguage</b>       | ENGLISHPRAXISCOURSE-I |        | Theory               | 4                          | 3                   | 50         | 50       |
| SecondLanguage             | Telugu/Sanskrit/Hindi |        | Theory               | 4                          | 3                   | 50         | 50       |
| LifeSkillCourse            | ComputerApplications  |        | Theory               | 2                          | 2                   | -          | 50       |
| SkillDevelopment<br>Course | Plantnursery          |        | Theory               | 2                          | 2                   | -          | 50       |
| MajorSubject-1             | Botany                | C1     | Theory               | 4                          | 4                   | 50         | 50       |
|                            | Botany                |        | Practical            | 2                          | 1                   |            | 50       |
| MajorSubject-2             | Chemistry             | C1     | Theory               | 4                          | 4                   | 50         | 50       |
|                            | Chemistry             |        | Practical            | 2                          | 1                   |            | 50       |
| <b>Vocational</b>          | BasicPharmaceutics-I  | C1     | Theory               | 4                          | 4                   | 50         | 50       |
|                            | BasicPharmaceutics-I  |        | Practical            | 2                          | 1                   |            | 50       |
|                            | BasicPharmaceutics-II | C2     | Theory               | 2                          | 2                   | -          | 50       |
|                            | BasicPharmaceutics-II |        | Practical            | 2                          | 1                   |            | 50       |
|                            |                       |        | <b>TOTAL</b>         | 34                         | 28                  | 250        | 600      |
|                            |                       |        |                      |                            |                     |            | 850      |

| Category                   | Subject/Paper                            | Course | Theory /Practical<br>I | No. ofHrs./<br>Week | No ofcredits | Evaluation |          |       |
|----------------------------|------------------------------------------|--------|------------------------|---------------------|--------------|------------|----------|-------|
|                            |                                          |        |                        |                     |              | Internal   | External | TOTAL |
| First language             | ENGLISH PRAXIS COURSE-II                 |        | Theory                 | 4                   | 3            | 50         | 50       | 100   |
| Second Language            | Telugu/Sanskrit/Hindi                    |        | Theory                 | 4                   | 3            | 50         | 50       | 100   |
| Life Skill Courses         | Information and Communication Technology |        | Theory                 | 2                   | 2            | -          | 50       | 50    |
| Skill Development Course-1 | Food Adulteration                        |        | Theory                 | 2                   | 2            | -          | 50       | 50    |
| Skill Development Course-2 | Fruits and vegetables preservation       |        | Theory                 | 2                   | 2            | -          | 50       | 50    |
| Major Subject-1            | Botany                                   | C2     | Theory                 | 4                   | 4            | 50         | 50       | 100   |
|                            | Botany                                   |        | Practical              | 2                   | 1            |            | 50       | 50    |
| Major Subject-2            | Chemistry                                | C2     | Theory                 | 4                   | 4            | 50         | 50       | 100   |
|                            | Chemistry                                |        | Practical              | 2                   | 1            |            | 50       | 50    |
| Vocational                 | Basic Analytical Chemistry-I             | C3     | Theory                 | 4                   | 4            | 50         | 50       | 100   |
|                            | Basic Analytical Chemistry-I             |        | Practical              | 2                   | 1            |            | 50       | 50    |
|                            | Health Education and Community Pharmacy  | C4     | Theory                 | 2                   | 2            | -          | 50       | 50    |
|                            | Health Education and Community Pharmacy  |        | Project                | 2                   | 1            | -          | 50       | 50    |
|                            |                                          |        | <b>TOTAL</b>           | 36                  | 30           | 250        | 650      | 900   |





| Category                 | Subject/Paper                          | Course | Theory /Practical | No. ofHrs./ Week | No offered | Evaluation |            |            |
|--------------------------|----------------------------------------|--------|-------------------|------------------|------------|------------|------------|------------|
|                          |                                        |        |                   |                  |            | Internal   | External   | TOTAL      |
| First language           | ENGLISH PRAXIS COURSE-III              |        | Theory            | 4                | 3          | 40         | 60         | 100        |
| Second Language          | Telugu/Sanskrit/Hindi                  |        | Theory            | 4                | 3          | 40         | 60         | 100        |
| Life Skill Course-I      | Environment Education                  |        | Theory            | 2                | 2          | -          | 50         | 50         |
| Life Skill Course-II     | Personality Development and Leadership |        | Theory            | 2                | 2          | -          | 50         | 50         |
| Skill Development Course | Environment Audit                      |        | Theory            | 2                | 2          | -          | 50         | 50         |
| Major Subject-1          | Botany                                 | C3     | Theory            | 4                | 4          | 40         | 60         | 100        |
|                          | Botany                                 |        | practical         | 2                | 1          |            | 50         | 50         |
| Major Subject-2          | Chemistry                              | C3     | Theory            | 4                | 4          | 40         | 60         | 100        |
|                          | Chemistry                              |        | Practical         | 2                | 1          |            | 50         | 50         |
|                          | Advanced Pharmaceutics-I               | C5     | Theory            | 4                | 4          | 40         | 60         | 100        |
|                          | Advanced Pharmaceutics-I               |        | Practical         | 2                | 1          |            | 50         | 50         |
| Vocational               | Advanced Pharmaceutics-II              | C6     | Theory            | 2                | 2          | -          | 50         | 50         |
|                          | Advanced Pharmaceutics-II              |        | Project           | 2                | 1          | -          | 50         | 50         |
|                          |                                        |        | <b>TOTAL</b>      | <b>36</b>        | <b>30</b>  | <b>200</b> | <b>700</b> | <b>900</b> |

**P.R.GOVERNMENT COLLEGE(A),  
KAKINADA DEPARTMENT OF CHEMISTRY  
B.VOC(PHARMACEUTICAL CHEMISTRY)(BIOLOGY STREAM)CU  
RICULAR FRAMEWORK(CREDIT TABLE)  
Semester-IV**

| Category        | Subject/Paper                    | Course | Theory<br>/Practical<br>I | No.<br>of Hr<br>s./<br>Week | No<br>of credi<br>ts | Evaluation |            |            |
|-----------------|----------------------------------|--------|---------------------------|-----------------------------|----------------------|------------|------------|------------|
|                 |                                  |        |                           |                             |                      | Internal   | External   | TOTAL      |
| Major Subject-1 | Botany                           | C4     | Theory                    | 4                           | 4                    | 40         | 60         | 100        |
|                 | Botany                           |        | Practical                 | 2                           | 1                    |            | 50         | 50         |
|                 | Botany                           | C5     | Theory                    | 4                           | 4                    | 40         | 60         | 100        |
|                 | Botany                           |        | Practical                 | 2                           | 1                    |            | 50         | 50         |
| Major Subject-2 | Chemistry                        | C4     | Theory                    | 4                           | 4                    | 40         | 60         | 100        |
|                 | Chemistry                        |        | Practical                 | 2                           | 1                    |            | 50         | 50         |
|                 | Chemistry                        | C5     | Theory                    | 4                           | 4                    | 40         | 60         | 100        |
|                 | Chemistry                        |        | Practical                 | 2                           | 1                    |            | 50         | 50         |
| Vocational      | Basic Analytical Chemistry-II    | C7     | Theory                    | 4                           | 4                    | 40         | 60         | 100        |
|                 | Basic Analytical Chemistry-II    |        | Practical                 | 2                           | 1                    |            | 50         | 50         |
|                 | Industrial Safety and Management | C8     | Theory                    | 4                           | 4                    | 40         | 60         | 100        |
|                 | Industrial Safety and Management |        | Practical                 | 2                           | 1                    |            | 50         | 50         |
|                 |                                  |        | <b>TOTAL</b>              | <b>36</b>                   | <b>30</b>            | <b>255</b> | <b>645</b> | <b>900</b> |

P.R.GOVERNMENT COLLEGE(A),  
KAKINADADEPARTMENT OF CHEMISTRY  
B.VOC(PHARMACEUTICAL CHEMISTRY)(BIOLOGY STREAM)CU  
RICULAR FRAMEWORK(CREDIT STABLE)

Semester-V

| Subject/Paper                                                                                     | Theory<br>/Practical | No of credits | Evaluation |
|---------------------------------------------------------------------------------------------------|----------------------|---------------|------------|
| First Phase of Apprenticeship between 1 <sup>st</sup> and 2 <sup>nd</sup> year (Summer Vacation)  |                      | 04            | 100        |
| Second Phase of Apprenticeship between 2 <sup>nd</sup> and 3 <sup>rd</sup> year (Summer Vacation) |                      | 04            | 100        |
| INDUSTRIAL INTERNSHIP                                                                             |                      | 12            | 200        |
| TOTAL                                                                                             |                      | 20            | 400        |



**P.R.GOVERNMENT COLLEGE(A),  
KAKINADA DEPARTMENT OF CHEMISTRY  
B.VOC(PHARMACEUTICAL CHEMISTRY)(BIOLOGY STREAM) CU  
RRICULAR FRAMEWORK (CREDIT TABLE)  
Semester - VI**

| Category   | Subject/Paper                               | Course | Theory /Practical | No. of Hrs./ Week | No offered | Evaluation |            |            |
|------------|---------------------------------------------|--------|-------------------|-------------------|------------|------------|------------|------------|
|            |                                             |        |                   |                   |            | Internal   | External   | TOTAL      |
| Vocational | Pharma Regulatory Affairs                   | C9     | Theory            | 4                 | 4          | 40         | 60         | 100        |
|            | Pharma Regulatory Affairs                   |        | Practical         | 2                 | 1          |            | 50         | 50         |
|            | Pharmaceutical Inorganic Chemistry          | C10    | Theory            | 4                 | 4          | 40         | 60         | 100        |
|            | Pharmaceutical Inorganic Chemistry          |        | Practical         | 2                 | 1          |            | 50         | 50         |
|            | Advanced Analytical Chemistry               | C11    | Theory            | 4                 | 4          | 40         | 60         | 100        |
|            | Advanced Analytical Chemistry               |        | Practical         | 2                 | 1          |            | 50         | 50         |
|            | Basic Quality Control and Quality Assurance | C12    | Theory            | 4                 | 4          | 40         | 60         | 100        |
|            | Basic Quality Control and Quality Assurance |        | Practical         | 2                 | 1          |            | 50         | 50         |
|            | Documentation for Quality Control           | C13    | Theory            | 4                 | 4          | 40         | 60         | 100        |
|            | Documentation for Quality Control           |        | Practical         | 2                 | 1          |            | 50         | 50         |
|            | Pharmaceutical and Medicinal Chemistry      | C14    | Theory            | 4                 | 4          | 40         | 60         | 100        |
|            | Pharmaceutical and Medicinal Chemistry      |        | Practical         | 2                 | 1          |            | 50         | 50         |
|            |                                             |        | <b>TOTAL</b>      | <b>36</b>         | <b>30</b>  | <b>255</b> | <b>645</b> | <b>900</b> |

**P.R.GOVERNMENT COLLEGE(AUTONOMOUS)KAKINADA**  
**CURRICULAR FRAMEWORK FOR B.VOC COURSE UNDER NSQF FOR THE YEAR 2020-21**  
**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   |     |     |     |     |     |     |
| <b>Core Subjects</b>                     |                                                                                        |       |     |       |     |       |     |     |     |     |     |     |     |
| Major Subject-1                          | C1 to C5 Maths/Botany (Theory & Practicals)                                            | 6/4+2 | 4+1 | 6/4+2 | 4+1 | 6/4+2 | 4+1 | 4+2 | 4+1 |     |     |     |     |
|                                          | C1 to C5 Chemistry (Theory & Practicals)                                               | 4+2   | 4+1 | 4+2   | 4+1 | 4+2   | 4+1 | 4+2 | 4+1 |     |     |     |     |
| Vocational                               | C1 to C14 including SECP pharmaceutical Chemistry (Theory & Practicals)                | 4+2   | 4+1 | 4+2   | 4+1 | 4+2   | 4+1 | 4+2 | 4+1 | 4+2 | 4+1 | 4+2 | 4+1 |
|                                          | C2, C4, C6 (Theory and Lab/Institutional/Industrial Training Pharmaceutical Chemistry) | 2+2   | 2+1 | 2+2   | 2+1 | 2+2   | 2+1 | 4+2 | 4+1 | 4+2 | 4+1 | 4+2 | 4+1 |
| <b>Total Hrs/Week (Academic Credits)</b> |                                                                                        | 34    | 28  | 36    | 30  | 36    | 30  | 36  | 30  | 36  | 30  | 36  | 30  |
| <b>Extension Activities</b>              |                                                                                        |       |     |       |     |       |     |     |     |     |     |     |     |
| NCC/NSS/Sports/Extra Curricular          |                                                                                        |       |     |       |     |       |     |     |     |     |     |     |     |
| Yoga                                     |                                                                                        |       |     |       |     |       | 1   |     |     |     |     |     |     |
| Extra Credits                            |                                                                                        |       |     |       |     |       |     |     |     |     |     |     |     |
| <b>Hrs/W (Total Credits)</b>             |                                                                                        | 34    | 28  | 36    | 30  | 36    | 31  | 36  | 33  | 36  | 30  | 12  | 4   |

Third Phase of Apprenticeship for the entire V/VI Semester  
 and Second Phase (2 Spells) of Apprenticeship between I and II semester  
 and between II and III year Summer Vacation

### 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) | Total Marks (Maths Stream/Biology Stream) |
|-------|---------------------------------------------------------|----------------|-------------------------------|-------------------------|---------------|------------------------|--------------|----------------------------------|-------|----------------------------|-------------------------------------------|
|       |                                                         |                |                               |                         |               | Theory                 |              | Practical (Maths Stream/Biology) |       |                            |                                           |
|       |                                                         |                |                               |                         |               | Continuous Assessment  | End Semester |                                  | Total |                            |                                           |
| 1     | English                                                 | 3              | 4                             | 3                       | 9             | 40                     | 60           |                                  | 100   | 100                        | 300                                       |
| 2     | Second Language                                         | 3              | 4                             | 3                       | 9             | 40                     | 60           |                                  | 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            | 40                     | 60           | 0/50                             | 100   | 100/150                    | 500/750                                   |
| 6     | Core/SE-II Chemistry                                    | 5              | 4+2                           | 4+1                     | 25            | 40                     | 60           | 0/50                             | 100   | 100/150                    | 750                                       |
| 7     | Vocational Courses (C1 to C14) Pharmaceutical Chemistry | 11             | 4+2                           | 4+1                     | 55            | 40                     | 60           | 50                               | 100   | 150                        | 1650                                      |
|       |                                                         |                |                               |                         |               |                        | 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.VOCCOURSES UNDER NSQF SCHEME**

**STUDENT ELIGIBILITY AND FACULTY ELIGIBILITY**

| S.NO | NAME OF THE COURSE                        | STUDENTS ELIGIBILITY<br>(10+2 OR EQUIVALENT WITH SPECIFIC GROUP IF ANY) | FACULTY ELIGIBILITY WITH SPECIALIZATION                                                    |
|------|-------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| 1    | B.VOC (COMMERCIAL AQUACULTURE)            | Intermediate/10+2 or equivalent with Bi.P.C/Biology                     | M.Sc<br>Aquaculture/Marine Biology/Zoology with fishery biology spe                        |
| 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 or 10+2 with MPC/BiPC group                                | M.Pharm/M.Sc (Pharmaceutical Chemistry)/M.Sc (Chemistry)                                   |
| 4    | B.VOC (FOOD TECHNOLOGY)                   | Intermediate or 10+2 with MPC/BiPC group                                | M.Sc (Food Technology)/M.Sc (Food Processing)/M.Sc (Food and Nutrition)                    |
| 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.Comor MBA with Diploma in Hotel Management |

## QUESTIONPAPERSETTERSFORB.VOC(PHARMACEUTICALCHEMISTRY)

The following papersetters for Vocational (Pharmaceutical Chemistry) papers are recommended.

| S. No. | Name of the Faculty     | Designation           | Address for Correspondence                                                          | Mobile Number          | E-mail ID                     |
|--------|-------------------------|-----------------------|-------------------------------------------------------------------------------------|------------------------|-------------------------------|
| 1      | Sri V. Sanjeev Kumar    | Lecturer in Chemistry | P.R. Government Degree College, Kakinada, East Godavari District.                   | 9849324966             | skvudi1972@gmail.com          |
| 2      | Malikarjuna Sarma       | Lecturer in Chemistry | A.S.D. GOVERNMENT COLLEGE for women (A), Kakinada Kakinada, East Godavari District. | 9676822550             | V.mallikarjunasarma@gmail.com |
| 3      | Sri V. Sridhar          | Lecturer in Chemistry | Government arts college (A), RAJAMUNDRY, East Godavari District                     | 8919262964, 7386048119 | sridhar.vegi07@gmail.com      |
| 4      | Dr. B. Malikarjuna      | Lecturer in Chemistry | Government College (Autonomous), Rajahmundry                                        | 8985503523             | mallik.chem@gmail.com         |
| 5      | Dr. G. Venkata Rao      | Lecturer in Chemistry |                                                                                     | 9440444223             | gnrgjcn@gmail.com             |
| 6      | Sri B. Venkata Rao      | Lecturer in Chemistry | Government arts college (A), RAJAMUNDRY, East Godavari District                     |                        | venkatbasa@gmail.com          |
| 7      | Smt. Manchiraju Padmaja | Lecturer in Chemistry | Government arts college (A), RAJAMUNDRY, East Godavari District                     | 9441653995             | padmaja717@gmail.com          |

P.R.GOVERNMENT COLLEGE(A), KAKINADA  
B.Voc(PHARMACEUTICAL CHEMISTRY)T  
HIRD YEAR SEMESTER-V  
Course 9: PHARMA REGULATORY AFFAIRS

PAPER: PHARMA REGULATORY AFFAIRS

Course Scope:

To make the student

- Understand the different types of hazards
- Understand the Good laboratory practices.
- Understanding the investigation of new drug.

Learning Objectives:

Upon completion of the course, the students shall be able to understand:

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
2. The regulatory authorities and agencies governing the manufacture and sale of Pharmaceuticals
3. Know different Acts that regulate pharmaceutical industry

UNIT: I

Good laboratory Practice, Standard operating procedure, Standard

Testing procedure, Certificate of Analysis, Method of Analysis, good receipt note. *responsibilities*  
*quality Audits*

UNIT: II

Approval of new drugs-

Investigational New Drugs (IND) submission, format & content of IND, content of investigator Brochure, general consideration of new drug Approval (NDA), specific requirements, content & format of NDA, manufacturing control requirement of NDA. *clinical trials*

UNIT: III

GMP, ISO 9000, TQM, ICH. *(phases I, II, III, IV)*  
*CGMP*

UNIT: IV

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

Reference Books:

1. J. A Dean, analytical chemistry handbook, McGraw Hill Inc., 1st Ed., 1995.
2. Ethical Guidelines for Biomedical research on human subjects 2000. Indian Council of Medical



Research, New Delhi.

3. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

4. Central Drugs Standard Control Organization. Good Clinical Practices - Guidelines for Clinical Trials

on pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

**P.R. GOVERNMENT COLLEGE (A), KAKINADA B.  
Voc (PHARMACEUTICAL  
CHEMISTRY) THIRD YEAR SEMESTER-V  
Course 9: PHARMA REGULATORY AFFAIRS**

**PAPER -: PHARMA REGULATORY AFFAIRS**

**WEIGHTAGE TO CONTENT**

| Sl.No. | Course Content | Essay (10M) | Short (5M) | Total marks |
|--------|----------------|-------------|------------|-------------|
| 1.     | UNIT-I         | 2           | 2          | 30          |
| 2.     | UNIT-II        | 2           | 2          | 30          |
| 3.     | UNIT-III       | 2           | 2          | 30          |
| 4.     | UNIT-IV        | 2           | 2          | 30          |
|        | Total          | 8           | 8          | 120         |

P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARSEMESTER-V  
Course9:PHARMAREGULATORYAFFAIRS

PAPER:-PHARMAREGULATORYAFFIARS

Time2hrs.30min

Maxmarks-60M

SECTION-A

Answerthefollowingquestions

4x10=40M

1. Onequestionistobesetfromunit-I

Or

Onequestionistobesetfromunit-I

2. Onequestionistobesetfromunit-IIOr

Onequestionistobesetfromunit-II

3. Onequestionistobesetfromunit-IIIOr

Onequestionistobesetfromunit-III

4. Onequestionistobesetfromunit-IVOr

Onequestionistobesetfromunit-IV

SECTION-B

AnsweranyFOURquestions

4x5=20M

5. Onequestionistobesetfromunit-I

6. Onequestionistobesetfromunit-I

7. Onequestionistobesetfromunit-II

8. Onequestionistobesetfromunit-II

9. Onequestionistobesetfromunit-III

10. Onequestionistobesetfromunit-III

11. Onequestionistobese!fromunit-IV

12. Onequestionistobesetfromunit-IV

P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARSEMESTER-V  
Course9:PHARMAREGULATORYAFFAIRS

QUESTIONBANK(ESSAY  
QUESTIONS)

UNIT-1

1. WriteanessayonGLP
2. Whyarethereservesamplesmaintained.
3. StatethecontentsofSOPonhandlingoftherejectingmaterial.

UNIT-II

1. WhatarethecontentofNDA.
2. WhatarethecontentofIND.
3. ExplainthesubmissionofIND.

UNIT-III

1. Whatisapatent?Describeimportanceofpatentinresearch
2. WhyprotectionisneededonIntellectualproperty

UNIT-IV

1. Writeanoteonfirstaid
2. Listoutthehazardouschemicalsinpharmaceuticals.
3. Describevariousafetyrulesatworkplace.

SHORTQUESTIONS

UNIT-I

1. WriteaboutcertificateofAnalysis
2. WritetheprinicplesofGLP
3. WriteaboutgeneratingSTP

UNIT-II

1. ExplainthecontentofinvestigatorBrochure.
2. Whatarethespecificrequirements,content&formatofNDA
3. WhatarethemanufacturingcontrolrequirementofNDA.

UNIT-III

1. DefineGMPprotocol
2. WriteanoteonUSFDA
3. WriteanoteonCDSCO



#### UNIT-IV

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

P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARSEMESTER-V  
Course9:PHARMAREGULATORYAFFAIRS

PAPER:-PHARMAREGULATORYAFFAIRS

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 -
- 4.Effect of drugs on locomotory activity by using Actophotometer
- 5.Analgesic activity by tail flick method

P.R.GOVERNMENT COLLEGE(A), KAKINADA B.  
Voc (PHARMACEUTICAL  
CHEMISTRY) THIRD YEAR SEMESTER-V  
Course 10:  
PHARMACEUTICAL INORGANIC CHEMISTRY  
PHARMACEUTICAL  
INORGANIC CHEMISTRY

**Course Scope:**

To make the student

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

**Learning Objectives:**

Upon completion of the course, the students shall be able to understand: 1 To learn permissible impurities in pharmaceutical substances.

1. To learn role & criteria of antacids.

**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 limit test for Chlorides, Sulphate, Iron, Lead.

*quality control & test box purity*

**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 nitrite) 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**

**Radiopharmaceuticals:** Radioactivity, radioactive rays (Alpha, beta and gamma rays), isotopes definition and examples, units of radioactivity, biological effects of



radiation, precautions to be taken while handling and storage of radioactive isotopes, applications of radioactive isotopes in research, diagnosis and medicines.

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

**Reference Books:**

1. Pharmaceutical inorganic chemistry by K. S. Somasekhara Rao, Ch. Venkata Suresh.
2. Pharmaceutical inorganic chemistry by G. R. Chatwal.

**P.R. GOVERNMENT COLLEGE (A), KAKINADA B.  
Voc (PHARMACEUTICAL  
CHEMISTRY) THIRD YEAR SEMESTER-V  
Course 10: PHARMACEUTICAL INORGANIC CHEMISTRY**

**WEIGHTAGE TO CONTENT**

| Sl.No. | Course Content | Essay (10M) | Short (5M) | Total marks |
|--------|----------------|-------------|------------|-------------|
| 1.     | UNIT-I         | 2           | 2          | 30          |
| 2.     | UNIT-II        | 2           | 2          | 30          |
| 3.     | UNIT-III       | 2           | 2          | 30          |
| 4.     | UNIT-IV        | 2           | 2          | 30          |
|        | Total          | 8           | 8          | 120         |

P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARSEMESTER-V  
Course10:PHARMACEUTICALINORGANICCHEMSTRY

Time2hrs.30min

Maxmarks-60

**SECTION-A**

Answerthefollowingquestions

4x10=40M

1. Onequestionistobesetfromunit-I  
Or  
Onequestionistobesetfromunit-I
2. Onequestionistobesetfromunit-IIOr  
Onequestionistobesetfromunit-II
3. Onequestionistobesetfromunit-IIIOr  
Onequestionistobesetfromunit-III
4. Onequestionistobesetfromunit-IVOr  
Onequestionistobesetfromunit-IV

**SECTION-B**

AnsweranyFOURquestions

4x5=20M

5. Onequestionistobesetfromunit-I
6. Onequestionistobesetfromunit-I
7. Onequestionistobesetfromunit-II
8. Onequestionistobesetfromunit-II
9. Onequestionistobesetfromunit-III
10. Onequestionistobesetfromunit-III
11. Onequestionistobesetfromunit-IV
12. Onequestionistobesetfromunit-IV

P.R.GOVERNMENT COLLEGE(A), KAKINADA B.  
Voc (PHARMACEUTICAL  
CHEMISTRY) THIRD YEAR SEMESTER-V  
Course 10: PHARMACEUTICAL INORGANIC CHEMISTRY

**Question bank Essay questions (10M)**

**Unit-I**

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

**Unit-II**

1. Explain the role of acidifiers, buffers and antioxidants in pharmaceutical preparations.
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 antioxidants. Explain the uses of sodium thiosulphate and sodium bisulphate and nitrogen as antioxidants.
2. Define antacids. Explain the criteria, uses and side effects of antacids.
3. Define gastrointestinal agents. Explain different types of acidifiers with examples.

**Unit-IV**

1. Explain the precautions to be taken while handling radioactive materials.
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 antioxidants in pharmaceutical preparations.



### Unit-III

1. Define antioxidants and write the criteria for a substance to act as antioxidants.
2. Write the uses of sodium nitrite as antioxidant.
3. Define gastrointestinal agents give examples.
4. What is anti-acid therapy and give examples of anti-acids.

### Unit-IV

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

P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARESEMESTER-V  
Course10:PHARMACEUTICALINORGANICCHEMSTRY

PRACTICALS

LIMITTESTS:

- 1.Limittestforchloride.
- 2.Limittestforsulphate.
- 3.Limittestforiron.
- 4.Limittestforlead.

5 preparation of phosphate buffers

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Voc (PHARMACEUTICAL  
CHEMISTRY) THIRD YEAR SEMESTER-V  
Course 11: ADVANCED ANALYTICAL CHEMISTRY

**Course Scope:**

To make the student

- i. Understand the chromatography techniques.
- ii. Understand the solvent extraction process.
- iii. Understanding the common separation techniques.

**Learning Objectives:**

Upon completion of the course, the students shall be able to understand: 1. To learn application of chromatography.  
2. To learn application of solvent extraction process.

**Unit-I:**

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

**Unit- II:**

**Solvent Extraction**- definition- principle and process – Nernst distribution law and its limitations- Types of solvent extraction-  
batch extraction and continuous extraction- application 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-  
application of paper chromatography.

**Thin Layer chromatography**- principle and experimental details- superiority of  
thin layer chromatography over paper chromatography-  
application of thin layer chromatography.

**Unit-IV:**

**Column chromatography**- principle and experimental details- *& instrumentation*  
application of column chromatography.

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



**High Performance Liquid Chromatography:** Principle, Experimental details, Instrumentation and applications

**List of Reference Books**

1. Analytical Chemistry by Skoog and Miller
2. A text book of qualitative inorganic analysis by A.I. Vogel
3. Nanochemistry by Geoffrey Ozin and Andre Arsenault
4. Stereochemistry by D. Nasipuri
5. Organic Chemistry by Clayden

**P.R. GOVERNMENT COLLEGE(A), KAKINADA B.**  
**Voc (PHARMACEUTICAL**  
**CHEMISTRY) THIRD YEAR SEMESTER-V**  
**Course 11: ADVANCED ANALYTICAL CHEMISTRY**

**WEIGHTAGE TO CONTENT**

| Sl.No. | Course Content | Essay(10M) | Short(5M) | Total marks |
|--------|----------------|------------|-----------|-------------|
| 1.     | UNIT-I         | 2          | 2         | 30          |
| 2.     | UNIT-II        | 2          | 2         | 30          |
| 3.     | UNIT-III       | 2          | 2         | 30          |
| 4.     | UNIT-IV        | 2          | 2         | 30          |
|        | Total          | 8          | 8         | 120         |

P.R.GOVERNMENT COLLEGE(A), KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY) THIRD YEAR SEMESTER-V  
Course 11: ADVANCED ANALYTICAL CHEMISTRY

Time 2hrs.30min

Max marks-60

**SECTION-A**

Answer the following questions

4x10=40M

1. One question is to be set from unit-I  
Or  
One question is to be set from unit-I
2. One question is to be set from unit-II Or  
One question is to be set from unit-II
3. One question is to be set from unit-III Or  
One question is to be set from unit-III
4. One question is to be set from unit-IV Or  
One question is to be set from unit-IV

**SECTION-B**

Answer any FOUR questions

4x5=20M

5. One question is to be set from unit-I
6. One question is to be set from unit-I
7. One question is to be set from unit-II
8. One question is to be set from unit-II
9. One question is to be set from unit-III
10. One question is to be set from unit-III
11. One question is to be set from unit-IV
12. One question is to be set from unit-IV

P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARSEMESTER-V  
Course11:ADVANCEDANALYTICALCHEMISTRY

QUESTIONBANKESSA  
YQUESTIONS(10M)

**Unit-I:**

1. Writetheprincipleandapplicationofsimpliedistillation
2. Writetheprincipleandapplicationoffractionaldistillation.
3. Writetheprinciplesandapplicationsofcrystallization.

**Unit- II:**

1. ExplainNernstdistributionlawwithlimitations.
2. Whataretypesofsolventextraction?Explainindetail.

**Unit-III:**

1. Explaintheprincipleandexperimentaldetailsofpaperchromatography.
2. Writetheclassificationofpaperchromatography.
3. Explaintheprincipleandexperimentaldetailsofthinlayerchromatography.

**Unit-IV:**

1. Explaintheprincipleandexperimentaldetailsofcolumnchromatography.
2. Explaintheprincipleandexperimentaldetailsofgas-liquidchromatography:
3. Explain the principle and experimental details of high performance liquidchromatography.

**Shortanswerquestions(5M)**

**Unit-I:**

1. Writetheprincipleofcentrifugation.
2. Whatareapplicationsofsublimation?
3. Whatareapplicationsoffiltration?

**Unit- II**

1. Writetheprincipleofsolventextractionwithexamples.
2. Writetheapplicationsofsolventextraction.

**Unit-III:**

1. Define $R_f$ value.Whatfactorsaffecting $R_f$ value?
2. Explainthesuperiorityofthinlayerchromatographyoverpaperchromatography.
3. Writetheapplicationsofpaperchromatography.
4. Writetheapplicationsofthinlayerchromatography

**Unit-IV:**

1. Writetheapplicationsofcolumnchromatography.
2. Writetheapplicationsofgas-liquidchromatography.
3. Writetheinstrumentationofgas-liquidchromatography.
4. Writetheinstrumentationofhighperformanceliquidchromatography.
5. Writetheapplicationsofhighperformanceliquidchromatography.



P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARSEMESTER-V  
Course11:ADVANCEDANALYTICALCHEMISTRY

**PRACTICALS:**

- 1..Determinetheviscosityoforganiccompound-1
- 2.Determinetheviscosityoforganiccompound-2
- 3Determinethesurfacetensionoforganiccompound-1 .
- 4.Determinethesurfacetensionoforganiccompound-2 .
5. Determination of  $R_f$  value of Aminoacids using Paper chromatography
6. Determination of  $Fe^{3+}$  by solvent extraction.
7. Determination of  $R_f$  value of Aminoacids using Thin Layer Chromatography

P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARSEMESTER-V  
Course12:BASICQUALITYCONTROL&QUALITYASSURANCE

**LearningObjective:** Upon completion of the course students shall be able to:

1. Understand the cGMP aspects in pharmaceutical industry.
2. Appreciate the importance of documentation

**Scope:**

1. Scope of quality certifications applicable to pharmaceutical industries
2. Understand the responsibilities of QA&QC departments

**Unit-I Basic 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.  
*personnel; responsibilities and training hygiene for sample storage*

**Unit-II Overview of Production Process for Life Sciences Industry**

Fundamental science of API Production API Definition-Role of APIs – Top API Manufacturers Need for conversion 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*

#### REFERENCEBOOKS:

1. LachmanL., LibermanH.A., and KanigJ.L., TheoryandPracticeofIndustrialPharmacyLea&Febiger, USA., latestedition.
2. Sambhamurthy, PharmaceuticalEngineering, NewAgePublishers, latestedition
3. SethiPD. Quantitativeanalysisofdrugsinpharmaceuticalformulations, 3rded., CBSpublications, NewDelhi, 2008
4. TextbookofPharmaceutics-I&IIbyA.K.Gupta
5. IndianPharmacopiea-2014(oraclestEdition)
6. PharmaceuticalDrugAnalysis-Kar, Ashutosh

**P.R.GOVERNMENTCOLLEGE(A), KAKINADAB.**  
**Voc (PHARMACEUTICAL**  
**CHEMISTRY)THIRDYEARSEMESTER-V**  
**Course12: BASICQUALITYCONTROL&QUALITYASSURANCE**

#### WEIGHTAGETOCONTENT

| Sl.No. | CourseContent | Essay(10M) | Short(5M) | Totalmarks |
|--------|---------------|------------|-----------|------------|
| 1.     | UNIT-I        | 2          | 2         | 30         |
| 2.     | UNIT-II       | 2          | 2         | 30         |
| 3.     | UNIT-III      | 2          | 2         | 30         |
| 4.     | UNIT-IV       | 2          | 2         | 30         |
|        | Total         | 8          | 8         | 120        |



P.R.GOVERNMENT COLLEGE(A), KAKINADA B.  
Voc (PHARMACEUTICAL  
CHEMISTRY) THIRD YEAR SEMESTER-V  
Course 12: BASIC QUALITY CONTROL & QUALITY ASSURANCE

Time 2hrs.30min

Max marks-60

**SECTION-A**

Answer the following questions

4x10=40M

1. One question is to be set from unit-I  
Or  
One question is to be set from unit-I
2. One question is to be set from unit-II Or  
One question is to be set from unit-II
3. One question is to be set from unit-III Or  
One question is to be set from unit-III
4. One question is to be set from unit-IV Or  
One question is to be set from unit-IV

**SECTION-B**

Answer any FOUR questions

4x5=20M

5. One question is to be set from unit-I
6. One question is to be set from unit-I
7. One question is to be set from unit-II
8. One question is to be set from unit-II
9. One question is to be set from unit-III
10. One question is to be set from unit-III
11. One question is to be set from unit-IV
12. One question is to be set from unit-IV

P.R.GOVERNMENT COLLEGE(A), KAKINADA B.  
Voc (PHARMACEUTICAL  
CHEMISTRY) THIRD YEAR SEMESTER-V  
Course 12: BASIC QUALITY CONTROL & QUALITY ASSURANCE

Question  
Bank (ESSAY QUESTI  
ONS)

UNIT-I

1. What are the various sampling processes involved in pharmaceutical industry
2. Describe the sampling procedure for raw materials in pharmaceutical industry
3. Describe the sampling procedure for packaging materials

UNIT-II

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

UNIT-III

1. Write short note on process validation.
2. Write about equipment validation.
3. Explain about concurrent validation.
4. Define validation, write its importance and its types

UNIT IV

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

SHORT ANSWERS

UNIT-I

1. What is stability and importance of stability studies
2. Describe the five steps in sampling procedure
3. Describe the steps to weigh the sample

UNIT-II

1. Define API
2. Write a detail note on format and content of product regulatory documents
3. Enlist the various types of SOPs and discuss them briefly
4. Give a short note - Batch record documentation

UNIT-III

1. Define calibration, validation and qualification
2. Write about equipment validation.
3. Explain about concurrent validation.
4. 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.GOVERNMENTCOLLEGE(A),KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARESEMESTER-V  
Course12:BASICQUALITYCONTROL&QUALITYASSURANCE

**PRACTICALS**

1. Determination of alkalinity of water.
2. Determination of acidity of water.
3. Determination of hardness of water.
4. Determination of free chloride in water.
5. Determination of PH of water.

**P.R. GOVERNMENT COLLEGE (A), KAKINADA B.  
Voc (PHARMACEUTICAL CHEMISTRY) THIRD YEAR  
AR SEMESTER - V  
Course 13: DOCUMENTATION FOR QUALITY CONTROL**

**Learning Objective:** Upon completion of the course students shall be able to: 1. understand the Quality management system.

2. appreciate the importance of documentation

**Scope:**

1. Scope of quality certifications applicable to pharmaceutical industries 2. understand the advanced R&D approaches

**Unit-I validation**

What is validation? - Validation versus Qualification - what has to be validated - phases of validation - validation timeline - DQ, IQ, OQ, PQ, OQ - validation report - setting the specification in DQ -

Installation qualification (IQ) and operational qualification (OQ) - ongoing performance (PQ) - Operating instruments like stability chambers - BOD incubators - stability programme for validation batches, commercial batches - cleaning validation.

**Unit-II Quality Management System (OOS, OOT)**

Definition - QbD system - Need for QbD - handling of market complaints - correction actions - deviations and incidents - reporting, investigation and disposition of incidents, CAPA definition - flowchart of QA

**Unit-III Documentation practices**

Ten commandments of cGMP - cGMP Enforcement and Guidelines - Code of Federal Regulation (CFR-210 & 211) - Audit & Self-inspection - Quality audit - 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, EUROREX-4

**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

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Voc (PHARMACEUTICAL  
CHEMISTRY) THIRD YEAR SEMESTER-V  
Course 13: DOCUMENTATION FOR QUALITY CONTROL

**WEIGHTAGE TO CONTENT**

| Sl.No. | Course Content | Essay(10M) | Short(5M) | Total marks |
|--------|----------------|------------|-----------|-------------|
| 1.     | UNIT-I         | 2          | 2         | 30          |
| 2.     | UNIT-II        | 2          | 2         | 30          |
| 3.     | UNIT-III       | 2          | 2         | 30          |
| 4.     | UNIT-IV        | 2          | 2         | 30          |
|        | Total          | 8          | 8         | 120         |



**P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.**  
**Voc (PHARMACEUTICAL**  
**CHEMISTRY)THIRDYEARSEMESTER-V**  
**Course13:DOCUMENTATIONFORQUALITYCONTROL**

**Time2hrs.30min**

**Maxmarks-60**

**SECTION-A**

**Answerthefollowingquestions**

**4x10=40M**

1. Onequestionistobesetfromunit-I  
Or  
Onequestionistobesetfromunit-I
2. Onequestionistobesetfromunit-IIOr  
Onequestionistobesetfromunit-II
3. Onequestionistobesetfromunit-IIIOr  
Onequestionistobesetfromunit-III
4. Onequestionistobesetfromunit-IVOr  
Onequestionistobesetfromunit-IV

**SECTION-B**

**AnsweranyFOURquestions**

**4x5=20M**

5. Onequestionistobesetfromunit-I
6. Onequestionistobesetfromunit-I
7. Onequestionistobesetfromunit-II
8. Onequestionistobesetfromunit-II
9. Onequestionistobesetfromunit-III
10. Onequestionistobesetfromunit-III
11. Onequestionistobesetfromunit-IV
12. Onequestionistobesetfromunit-IV

P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARSEMESTER-V  
Course13:DOCUMENTATIONFORQUALITYCONTROL

Question  
Bank(ESSAYQUESTIONS)

**UNIT-I**

1. Define validation;write its importance and types.  
Writeaboutvalidationmasterplan
2. Explainthevalidationprotocolforcleaningprocess
3. HowtoperformAnalyticalmethodvalidation

**UNIT-II**

1. WhatarethesalientfeaturesofCAPA
2. Explaindifferenttypesofdocuments.
3. Whatareincidents?Explainreporting,investigationanddepositionofincidents.

**UNIT-III**

1. Enumerate10principlesofcGMP
2. WhatareStandardOperatingProcedures(SOP)
3. Whatdoyouunderstandbymasterformularecord.Writeabriefnote.

**UNIT-IV**

1. Explainqualityriskmanagementsystem.
2. Whatismethodtransferprocess.Writetheprocessrelatedquery.

**SHORTANSWERTYPEQUESTIONS(5M)**

**UNIT-I**

1. Writeaboutvalidationmasterplan
2. ValidationtimelineforDQandIQ.
3. Whatarephasesofvalidation?

**UNIT-II**

1. Writeashortnoteonbatchrecorddocumentation.
2. DefineCAPA.ExplainflowchartofQA.
3. DefineQbD.ExplaintheneedofQbD.

### 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 logbooks.



P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.Voc(P  
HARMACEUTICALCHEMISTRY)  
THIRDYEARESEMESTER-V  
Course13:DOCUMENTATIONFORQUALITYCONTROL

PRACTICALS

1. Preparation of aspirin.
2. Preparation of benzanilide.
3. Preparation of salicylic acid.
4. Preparation of 2,4,6-tribromophenol.
5. Preparation of beta-Naphthol azo dye.

P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARSEMESTER-V  
Course14:PHARMACEUTICALANDMEDICINALCHEMISTRY

**Scope:**

1. Scopeoftherapeuticactivityofdrugs.
2. UnderstandthePharmadynamicsofadrug.

**LearningObjective:**Uponcompletionofthecoursestudentshallbeableto:

1. Tolearnterminologyofdrugs.
2. TolearnHIVtherapeuticdrugs.

**UNIT-I**

**PharmaceuticalchemistryTerminology:**Pharmacy,Pharmacology,Pharmacophore,P  
harmacodynamics,Pharmacokinetics(ADME,Receptors-  
brieftreatment)MetabolitesandAntimetabolites.

**UNIT-II**

**Drugs:**

Nomenclature:Chemicalname,GenericnameandtradenameswithexamplesClassificatio  
n: Classification based on structures and therapeutic activity with oneexampleeach.

Dosage forms: need for conversion drugs into medicines, different types of  
dosageformsbasedonphysicalstate,Routeofadmistration

**UNIT-III**

**Synthesisandtherapeuticactivityofthecompounds:**

- a. ChemotherapeuticDrugs
  1. Sulphadrugs(Sulphamethoxazole)2.Antibiotics- $\beta$ -  
LactamAntibiotics,MacrolideAntibiotics,3.AntimalarialDrugs(chloroquine)
- b. PsychotherapeuticDrugs:
  1. Antipyretics(Paracetamol)2.Hypnotics,3.Tranquilizers(Diazepam)4.Levodopa

**UNIT-IV**

**PharmacodynamicDrugs:**

1. AntiasthmaDrugs(Solbutamol)3.Antianginals(GlycerolTrinitrate)
- 4.Diuretics(Frusemide)

2. Antiviral (Acyclovir)

**HIV-AIDS:**

Immunity-CD-4cells,CD-

8cells,Retrovirus,Replicationinhumanbody,preventionofAIDS,Drugsavailable-exampleswithstructures;PIS:Indinavir,Nelfinavir(Viracept).

**ListofReferenceBooks:**

1.MedicinalChemistrybyDr.B.V.Ramana2.Syntheti

c Drugsby

O.D.Tyagi&M.Yadav3.MedicinalChemistrybyAshu

toshkar4.MedicinalChemistrybyP.Parimoo

5. Pharmacology&PharmacotherapeuticsR.S.Satoshkar&S.D.Bhandenkar6.M  
edicinalChemistrybyKadametalP-I&P.II

**P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.**

**Voc (PHARMACEUTICAL**

**CHEMISTRY)THIRDYEARSEMESTER-V**

**Course14:PHARMACEUTICALANDMEDICINALCHEMISTRY**

**WEIGHTAGETOCONTENT**

| Sl.No. | CourseContent | Essay(10M) | Short(5M) | Totalmarks |
|--------|---------------|------------|-----------|------------|
| 1.     | UNIT-I        | 2          | 2         | 30         |
| 2.     | UNIT-II       | 2          | 2         | 30         |
| 3.     | UNIT-III      | 2          | 2         | 30         |
| 4.     | UNIT-IV       | 2          | 2         | 30         |
|        | Total         | 8          | 8         | 120        |

P.R.GOVERNMENTCOLLEGE(A),KAKIHADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARSEMESTER-V  
Course14:PHARMACEUTICALANDMEDICINALCHEMISTRY

Time2hrs.30min

Maxmarks-60

**SECTION-A**

Answerthefollowingquestions

4x10=40M

1. Onequestionistobesetfromunit-I  
Or  
Onequestionistobesetfromunit-I
2. Onequestionistobesetfromunit-IIOr  
Onequestionistobesetfromunit-II
3. Onequestionistobesetfromunit-IIIOr  
Onequestionistobesetfromunit-III
4. Onequestionistobesetfromunit-IVOr  
Onequestionistobesetfromunit-IV

**SECTION-B**

AnsweranyFOURquestions

4x5=20M

5. Onequestionistobesetfromunit-I
6. Onequestionistobesetfromunit-I
7. Onequestionistobesetfromunit-II
8. Onequestionistobesetfromunit-II
9. Onequestionistobesetfromunit-III
10. Onequestionistobesetfromunit-III
11. Onequestionistobesetfromunit-IV
12. Onequestionistobesetfromunit-IV



**P.R.GOVERNMENT COLLEGE(A), KAKINADAB.**  
**Voc (PHARMACEUTICAL**  
**CHEMISTRY) THIRD YEAR SEMESTER-V**  
**Course 14: PHARMACEUTICAL AND MEDICINAL CHEMISTRY**

**Question bank Essay**  
**questions (10M)**

**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 of sulphamethoxazole
2. Write the synthesis and therapeutic activity of chloroquine
3. Write the synthesis and therapeutic activity of paracetamol
4. Write the synthesis and therapeutic activity of diazepam

**UNIT-IV**

1. Write the synthesis and therapeutic activity of salbutamol
2. Write the synthesis and therapeutic activity of glycerol trinitrate.
3. Write the synthesis and therapeutic activity of 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 of administration

**UNIT-III**

1. Write short note on antibiotics

2. Write short notes on antipyretics
3. What are tranquilizers give examples

#### **UNIT-IV**

1. Write about methods of prevention of AIDS.
2. Write the structures of drugs a) indinavir b) Nelfinavir.
3. Explain CD-4 cells and CD-8 cells.

**P.R.GOVERNMENTCOLLEGE(A),KAKINADAB.  
Voc (PHARMACEUTICAL  
CHEMISTRY)THIRDYEARSEMESTER-V  
Course14:PHARMACEUTICALANDMEDICINALCHEMISTRY**

**Practicals**

**Projectwork-50marks**

**SEMESTER-VI  
INDUSTRIAL INTERSHIP  
FOR THE ENTIRE  
SEMESTER**





PITHAPUR RAJAH'S GOVERNMENT COLLEGE (AUTONOMOUS), KAKINADA  
KAKINADA 533 001-ANDHRA PRADESH  
An AUTONOMOUS and NAAC Accredited Institution (A Grade- 3.17 CGPA)  
(Affiliated to ADIKAVI NANNAYA UNIVERSITY, Rajamahendravaram.)

### ACADEMIC CELL

(Certificate to be issued by the University Nominee/Subject Expert/Member of BOS)

Board of Studies - 2021-22

Department Name: B. Voc (Pharmaceutical Chemistry)

Name of the BOS Member: K. Anand, Subject Expert (Lecturer in Chemistry)  
GDC, Pithapuram.

I certify that the syllabus submitted by the B. Voc (Pharmaceutical Chemistry) Department for the year 2021-22 is verified by me and I recommend the following suggestions:

1. The weightage of internal and external (50:50) may be modified and the old procedure may
2. be (40: 60) followed for two or three years.
- 3.
- 4.
- 5.
- 6.



Signature with Date & Seal

Note: BOS Members are requested to fill the above details with necessary suggestions and send back to the Head of the department along with the syllabus



PITHAPUR RAJAH'S GOVERNMENT COLLEGE (AUTONOMOUS), KAKINADA  
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(Affiliated to ADIKAVI NANNAYA UNIVERSITY, Rajamahendravaram.)

## ACADEMIC CELL

(Certificate to be issued by the University Nomine/Subject Expert/Member of BOS)

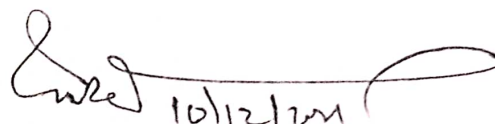
Board of Studies - 2021-22

Department Name: B. Voc (Pharmaceutical Chemistry)

Name of the BOS Member: V. Mallikarjuna Sharma, Subject expert & Meritorious Alumni  
Lecturer in Chemistry  
ASD College(w) Kakinada.

I certify that the syllabus submitted by the B. Voc (Pharmaceutical Chemistry) Department for the year 2021-22 is verified by me and I recommend the following suggestions:

1. Weightage to examinations (50:50) to Internal and external examinations may be modified to 40:60 respectively.
2. Internal ~~exam~~ Assessment (CEE) may be conducted online so that the record may be preserved for a long time.
- 3.
- 4.
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- 6.

  
Signature with Date & Seal  
(V.M. SARMA)



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### ACADEMIC CELL

(Certificate to be issued by the University Nominee/Subject Expert/Member of BOS)

Board of Studies - 2021-22

Department Name: B. Voc (Pharmaceutical Chemistry)

Name of the BOS Member: Prof. K. Deepthi, University nominee  
Asst Prof & H.O. dept of Chemistry  
AKNU, Rajamahendravaram.

I certify that the syllabus submitted by the B. Voc (Pharmaceutical Chemistry) Department for the year 2021-22 is verified by me and I recommend the following suggestions:

1. Subject experts may be invited to deliver lectures for more industry related skills.

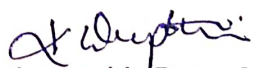
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Signature with Date & Seal