S. P. Mandali's

Ramnarain Ruia Autonomous College

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Syllabus for the

F.Y., S.Y. and T.Y. B.Voc.

Program: B.Voc.

Course: PHARMA ANALYTICAL SCIENCES

(Credit Based Semester and Grading System
for the academic year **2021 – 2022)**

Preamble:

Indian Pharmaceutical industry:

India accounts for 7% of the GDP by chemical sector and 11% of the national export. There are about 20000 registered pharmaceutical units in India and there are about 250 large units, 8000 small scale units and 5 central public sector units. Additionally, the size of the Indian diagnostic and lab services is about 160 billion.

Not marred by recession or inflation, the pharma sector has a competitive advantage of prospering steadily and thus attracts lots of young professionals looking at pharmaceutical as their prospective career option. With the expected growth rate of 14% per annum, Indian Pharmaceutical sector is expected to create more jobs in India in near future and add 45,000 fresh openings to its current strength.

Since 2009-10 more than 900 new drug approvals have been given by the Indian drug regulator. The regulatory guidelines have been revised since the Supreme Court directives in 2011-12. Regulatory requirements are increasing in production, quality control and R & D laboratories. Therefore, the regulatory department in a Pharmaceutical company not only needs a very broad understanding of the regulatory requirements but also must understand the chemical processes of production and quality control, the analytical tests, the pre-clinical studies and the clinical trial reports. Further there is an international strategy to harmonize the guidelines using ICH. With about 25 leading pharmaceuticals and about 100 smaller units involved in exports the requirement of regulatory executives is constantly increasing. Some of the top Indian pharmaceuticals have more than 75 executives employed in the regulatory department alone.

The need to develop trained employable human resource:

The Indian Pharmaceutical and Chemical Industry have always been experiencing a dearth of skilled and industrially oriented human resource. The Industry despite employing students from chemistry, biology and pharmacy background always spends 6 months to one year for training the students for general industry needs like Good Laboratory Practices, Good Documentation Practices and regulatory compliances. The important component of knowledge and implementation of quality in laboratory analysis is scarce in the graduates of chemistry and pharmacy. The skilled manpower requirement is in the areas of R & D, quality assurance and intellectual property. The Pharmaceutical industry sector in India is the one of the strong Export oriented sectors that needs to comply with a multitude of regulatory compliances for marketing the drug formulations abroad. In India itself, the sector needs to comply to stringent regulatory compliances and audits before the drug formulations are marketed. The training in practice of GLP as per the current regulatory requirements is missing. This course will provide manpower that is work-ready.

Objectives of the Course

The course will address the requirements of conducting, managing and meeting regulatory requirements for R&D and testing laboratories in pharmaceutical and chemical industries. Major hurdle faced by the R&D centers at various Pharma laboratories is the lack of adequately trained and GLP oriented personnel. This forms a major setback when the application of sophisticated technology especially in the bio analytical field is concerned. The lacunae become more evident with newer dosage forms and peptide based drugs. This lacunae needs to addressed very diligently and the proposed programme is a step in this direction.

National Skill Development Corporation (NSDC) has been mandated to set up Sector Skills Councils for the express purpose of sector-specific competencies/skills, developing National Occupation Standards (NOS's) and Qualification Packs (QP's), quality assurance through accreditation of skills acquired by trainees, curriculum development for the skills training, qualification framework and setting of standards and benchmarks, helping in recruitment and placement of trained and skilled workforce, as well as developing a robust LMIS.

The Indian Life Sciences Sector (comprising Pharmaceuticals, Bio Technology and Clinical) has been growing at a CAGR of 17%. In the process, it has been facing a shortage of skilled work force across functions and levels. With this background, CII, in co-operation with NSDC, decided to set up a Sector Skill Council for Life Sciences namely, the Life Sciences Sector Skill Development Council (LSSSDC).

LSSSDC will be Demand led, Comprehensive (taking account of needs of Stakeholders), emphasizing Standards and Quality, with a Sustainable and Scalable model. It will provide industry with a sustained stream of skilled individuals across functional areas and levels, thereby vastly reducing costs associated with re-skilling, attrition and low productivity. In the process it also hopes to help address issue of fake certificates and degrees—an area of major concern to the Life Sciences industry. Alongside, it will provide meaningful livelihood opportunities in the Life Sciences sector to a multitude of job seekers.

The program will have the following objectives;

- To develop trained manpower in the field of Pharma Analytical Sciences with specific emphasis for instrumentation skills needed for analysis
- To amalgamate knowledge of classical analytical techniques with modern sophisticated instrumentation and provide training in the analysis of chemicals, drugs, food and other products.
- To introduce the training with powerful tools of instrumentation analysis in routine analysis at manufacturing, QC and research
- To provide exposure to National & International regulatory requirements with reference to drugs and chemicals
- To provide training in skills of analysis and develop knowledgeable and employable human resource
- To provide training in soft skills for efficient communication, technical writing, entrepreneurship and basic business management,

ELIGIBILITY:

- Higher Secondary School Certificate (10 + 2), Science or its equivalent, preferably with Chemistry and Biology.
- No age bar

DURATION: Six semesters of six months each (total Three Years)

PROGRAM ATTRIBUTES FOR BACHELOR IN VOCATION (BVoc)

Graduate attributes are the qualities, skills and understandings in university based vocational education. Students should develop and acquire vocational skills during their time with the institution that go beyond the disciplinary expertise or technical knowledge that forms the core of BVoc program. They are qualities that not only prepare the graduates for the industry but also prepare graduates as agents of social good in an unknown future.

Personal attributes:
The individual should develop good knowledge of the vocation and the job skills that are required by the industry which is being addressed by the skill based vocational program. Student should have good technical skills needed for the operation and good analytical skills to understand the needs of the operation. Students should demonstrate the ability to understand and predict the future demand of the trade areas that is being addressed by the program. He/she should demonstrate good estimation skills to adapt to the changing demands of the industry. He /she must be ready to explore the option of self-employment as a successful career option.

In addition, the BVoc program is designed to develop following attributes in the graduate;

- **Disciplinary knowledge**
  The student will have sound understanding of the working of the industry to which he / she has been trained. The student will have clear understanding of the responsibilities of the job skills that he / she has acquired under the program and therefore will be industry ready to perform in real-life situations. Additionally, the students will also be having knowledge of related areas and skills which will useful for him / her to understand and adapt to the newer demands of the changing trades.

- **Communication Skills**
  The student will be able to articulate clearly and express unambiguously his / her views and opinions. He / she will be adequately trained in corporate and official communications and communication formats as applicable in the industrial settings. The student will also be trained in communicating with peers, seniors and regulators of the industry for which the vocational program is designed.

- **Information/digital literacy**
  The student is competent to use the contemporary information technological tools for both sourcing information and for disseminating information. He / she will be competent to handle digital platforms used for information sharing and communication. He / she will also be competent to understand and comply with the ethical and legal requirements while handling these platforms.

- **Critical thinking and Analytical reasoning**
  The BVoc program is predominantly focused mainly on practical training and imparting hands-on experiences for the learner in real-life situations of the specific job roles addressed by the program. The learner will be competent to analytically analyse situations, opinions and viewpoints to form clear judgements and conclusions. He / She will be able to analytically reason out the correct from the incorrect, right from the wrong and true from the false in making individual judgments in newer life situations.

- **Problem solving**
  The program will involve role playing, problem solving and troubleshooting training that will make the graduate competent to apply the skills and knowledge acquired during the course of the program to real life situation that he / she had never faced.

- **Research-related skills**
  The BVoc program will involve adequate problem-solving opportunities for the learner.
  He / she will have developed skills of keen observation, understanding the cause and effect relationships, develop hypothesis and testing them in systematic manner to reach logical conclusion independently.

- **Self-directed learning**
  The graduate will have adequate skills to search information from different sources both on-line and off-line related to the situational demands. He / she will be competent to analyse such information and transform them into knowledge as applicable to the contempory situations in the trade.

- **Co-operation/Team work**
  The BVoc program involves several repeated activities that are to be completed by the learners in a cooperative manner with peers. The responsibilities thus are shared by the group / team and the graduate develops skills of human resource management and learns the skills of working as an effective member of the team.

- **Multicultural competence**
  The BVoc graduate will have the skills of interacting with people of diverse backgrounds and cultures. The students will have respect to diverse beliefs and practices and learn to effectively engage with a multicultural society.

- **Moral and ethical awareness/reasoning**
  The BVoc programs will train the learners in ethical work cultures and practices in compliance with the legal and contemporary regulatory norms of the trade that he / she has been trained for. The graduate will be able to distinguish ethical ways of working in all areas of the job skills and always resort to truthful representation of data and results.

- **Leadership readiness/qualities**
  The BVoc will effectively implement several activities in the training program to develop skills of taking initiative and leadership while performing team activities. The graduate will be able to motivate people and effectively lead people in the right direction to meet the team goals.

- **Lifelong learning**
  The BVoc program is designed to recognize the prior learning of its learners so that the learners can continue to join the program during the course of their lifetime. The program will enable the graduate to learn the skill of becoming a lifelong learning so that the graduate can reskill himself / herself to adapt to the changing demands of the trade at any time of life.

<table>
<tr><th colspan="3">Graduates Attributes and Programme Outcome of
B. Voc. Pharma Analytical Sciences</th></tr>
<tr><td colspan="2">Academic Year</td><td>2021-22</td></tr>
<tr><td colspan="2">Name of the Department</td><td>Pharma Analytical Science</td></tr>
<tr><td colspan="3">Graduate attributes are the qualities, skills and understandings in university based higher education. Students should develop and acquire skills during their time with the institution. These attributes include but go beyond the disciplinary expertise or technical knowledge that has traditionally formed the core of most university courses. They are qualities that also prepare graduates as agents of social good in an unknown future.</td></tr>
<tr><td>Course Code:</td><td rowspan="2">Graduates Attributes (GA)</td><td>Programme Outcome (PO)</td></tr>
<tr><td>RUVPAS101 to RUVPAS107 & RUVPAS201 to RUVPAS207</td><td>Personal attributes: The individual should have to develop good knowledge of the Pharmaceutical industry. Student should have good analytical skills and should demonstrate the ability to understand and predict the future demand. He/she should demonstrate good estimation skills.</td></tr>
<tr><td>1st year: Diploma (Lab. Assistant /</td><td>Disciplinary knowledge</td><td>• Clear understanding of organizational role of Lab. Technician / Assistant.
• Operations of basic laboratory instruments and measuring</td></tr>
</table>

Technician), **Job Role:** Lab. Technician/Assistant (LFS/Q0509 of LSSSDC) ***Semester: I and II***		devices. • Clear understanding of Safety and Health guidelines Gain knowledge about Life Science and Pharmaceutical Industry, its rules, regulations and ethical practices. • Carry out preparation of solution and regent , and check the working environment for experimentation.
	Communication Skills	• Introduction to Audits and Audit related preparations. • Introduction to Skills of Team Work and leadership. • Skills of office communication (writing leave applications/ memo/ Log-book entries/ drafting of e-mails. • Gain Complete knowledge of company's standard operating procedure and guidelines and follow them while carrying out proper reporting and documentation for various types of documentation and recording of data/problem/incidents in secure manner. • Assist in recording observation and then calculating results before developing conclusions, and keep accurate and detailed logs of all of their work to ensure adherence to protocol and procedures. • Read the all manuals, health and safety instructions and pictograms. • Read and understand manuals, sops, health and safety instructions, memos, reports, job cards etc. • Reading and understanding various images, graphs, diagrams etc. • Understand the various coding systems as per company norms.
	Information/digital literacy	• Apply Basic Computer Skills (Ms Office, Internet) at Work. • Opening an e-mail account. • Social digital platform etiquettes. • Password protection to various softwares. • Introduction to LIMS and 21 CFR Part 11compliance. • Learn and practice Reading/ writing/ Generic Skills like Record detail of work done using written/typed report or computer based record/e- mails.
	Critical thinking and Analytical reasoning	• Practice Professional skills at work, like decision making, planning & organizing, customer centricity, problem solving, objection handling, analytical thinking, critical thinking • Know about and follow the Escalation matrix for reporting identified issues, hazards and breakage • Report typical instrument faults and related causes, including recognition of signs and symptoms of faulty lab instruments and apparatus /early warning signs of potential problems.
	Problem solving	• Understand and evaluate Risk and impact of not following defined procedures/work instructions and follow the instructions and SOPs
	Research-related skills	• Maintain cleanliness in the work area by doing Pre housekeeping activities, operations & post housing activities
	Self-directed learning	• Skills for Planning Laboratory work
	Co-operation/Team work	• Documentation practices and GLP • Clear understanding of regulatory guidelines and requirements
	Multicultural competence	• Operate, maintain, and install laboratory instruments as well as monitor experiments as they are performed within labs and Help in set up of the experiment • Help the lab/QC Chemists/ Research Associates in performing

		the experiments and analysis
	Moral and ethical awareness/reasoning	• Ensure appropriate measures are taken in Handling of chemicals, their proper labeling and stocking. • Follow the correct methods for carrying out corrective action for each problem • Display commitment to handle and use the chemical properly from initial receipt to ultimate disposal • Ensure all chemical containers are dated • Ensure incompatible chemicals are kept away from each other
	Leadership readiness/qualities	• Help the Lab/QC Chemists/Research associates in performing the experiments and analysis & Carry out inspection and maintenance of equipment and materials
	Lifelong learning	• Work compliance to standards and SOPs • Learn the Basic Concepts of Safety including Hazards, Accidents, Safety Signs and Signals and Henriech's Pyramid and follow and practice same at shop floor.
Course Code:	**Graduates Attributes**	**Programme Outcome (CO)**
RUVPAS301 to RUVPAS307 & RUVPAS401 to RUVPAS407		**Personal Attributes:** To develop good knowledge of standard documentation procedures, rules, regulations and statutory requirements in carrying out validation activities. The individual must demonstrate attention to detail and proactive behavior.
2nd year: Advanced Diploma (Validation Supervisor), **Job Role:** Validation Supervisor (LFS/Q0305 of LSSSDC) ***Semester: III and IV***	**Disciplinary knowledge**	• Clear understanding of organizational role of Validation Supervisor. • Ensure and assist in the implementation of the overall validation program for systems, facilities, equipment, manufacturing processes and cleaning activities. • Skills for planning and executing validation work.
	Communication Skills	• Documentation practices, GMP and GLP Audits and Audit related preparations. • Skills of office communication. • Provide guidance on validation issues and documentation regarding quality checks. • Communicate validation issues and requirements to plant personnel on a frequent basis. • Report any identified breaches in health, safety, and security policies and procedures to the designated person. • Write and update the inspection procedures, protocols and checklists. • Ensures support in preparation of validation protocols, inspection maps and timely review and approval of validation protocols/summary reports, master plans and SOPs. • Record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail. • Maintain proper and concise records as per the given format.
	Information/digital literacy	• Installations, up-gradation, downloading, un-installations of basic computer applications/software. • Record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail write detailed reports for investigation.
	Critical thinking and Analytical reasoning	• Identify defective equipment/apparatus, materials and processes and corrective steps to be taken.

		• Ensure that disposal of waste and leftover tested material is carried on safely as per the SOP. • Ensure the disposal of all materials used in the experiment safely as per health and safety management system of the company. • Take corrective action in response to typical faults and inconsistencies Troubleshoot/ investigate validation related deviations Ensure that all safety measures are in place. • Take up the results of the findings with the appropriate authority. • Use logic and reasoning to identify the strengths and weaknesses of each of the members in the team.
	Problem solving	• Understanding of validation requirements of Manufacturing, Operations. • Quality Operation, calibration, validation and troubleshooting of various laboratory instruments. • Setup appropriate equipment or apparatus for testing. • Use logic and reasoning to identify the strengths and weaknesses of each of the members in the team. • Combine pieces of information to form general rules or conclusions.
	Research-related skills	• The inspection or test points (control points) in the process and the related procedures and recording requirements. • Common causes of variation and corrective action required. • How to carry out statistical analysis of test data. • How to obtain and interpret records, charts, specifications, equipment, manuals, history/ logs, technical support reports and other documents. • Use the right mathematical methods or formulas to solve a problem. • Apply general rules to specific problems to produce answers that make sense.
	Self-directed learning	• Planning and executing validations. • Calibrate the testing equipment periodically as per the SOP.
	Co-operation/Team work	• Ensure support in preparation of validation protocols, inspection maps and timely review and approval of validation protocols/summary reports, master plans and SOPs. • Provide support to supervisor for carrying out investigations related to complaints, batch failures, OOS/ OOT, incidents etc. • work as a team with colleagues and share work as per their or own work load and skills. • Interview team members and colleagues to collect data to be recorded in log books and batch documents. • Support/assign personnel/team members to support internal and external audit activities as per instructions of superiors/supervisor. • Working with colleagues of other departments. • Communicate and discuss work flow related difficulties in order to find solutions with mutual agreement. • Provide documented shift handovers to the next person in the shift.
	Multicultural competence	• Implementation of different quality management systems (ISO and OHSAS). • Communicate confidential and sensitive information discretely to authorized person as per the SOP. • Maintain confidentiality of information and data.

		• Commercial awareness of pharmaceutical products and overall healthcare sector.
	Moral and ethical awareness/reasoning	• Clear understanding of Safety and Health guidelines Fire safety and evacuation procedures. • Work compliance to standards and SOPs. • The method of reporting any anomalies (materials/processes out of specification) to the appropriate authority. • Take responsibility for completing one's own work assignment.
	Leadership readiness/qualities	• Ensure and assist in the implementation of the overall validation. program for systems, facilities, equipment, manufacturing processes and cleaning activities. • Release or hold the production for further inspection as per findings. • Monitor and adjust the processes to achieve required quality outcomes and support teams during tech transfers. • Troubleshoot/investigate validation related deviations. • Review and approve facility equipment and software changes. • Take up the results of the findings with the appropriate authority. • Take initiative to enhance/learn skills in one's area of work. • Basics of tactical decision making on safety, process, scheduling and personnel-related issues. • Suggest improvements (if any) in process based on experience.
	Lifelong learning	• Clear understanding of regulatory guidelines and requirements. • Identification of defect/problem and troubleshooting. • Procedures for reporting any unresolved issues and hazards. • Pharmaceutical GMPs and regulatory requirements (both national and international. • Learn how to multi-task relevant activities.
Course Code:	**Graduates Attributes**	**Programme Outcome (CO)**
RUVPAS501 to RUVPAS504 & RUVPAS601 to RUVPAS604		**Personal Attributes:** The individual should have developed strong analytical technique in chemical testing and instrumental methods of analysis. Good understanding of chemistry and investigational abilities. He/she should have familiarity with guidelines such as GLP, cGMP and principles of Quality Management. The role holder should have attention to detail and excellent organizational skills.
3rd year: **B. Voc. Degree** (Quality Control Chemist) **Job Role:** Quality Control Chemist (LFS/Q1301 of LSSSDC) ***Semester: V and VI***	**Disciplinary knowledge**	• Quality Control Chemist prepares and tests samples from all phases of the manufacturing process to ensure that the product quality meets the standards, prepares documents that report test results and is responsible for preserving workplace safety while handling hazardous materials. • Gain knowledge about Life Sciences Industry, Legal and Regulatory framework and Pharmacopeia to enable him/herself for establishing the Industry Standards in his/her performance. • The individual should have basic lab-work skills and thorough understanding of chemical testing material, equipment and processes. • To study the Quality policy of the company.
	Communication Skills	• Preparation of reports/ articles/ validation logs/ memos/ monographs/ calibration reports/ training logs etc. • Presentation of data by Audio-visual aids, MS-power point

		presentation, posters, banners etc. • Ensure documents pertaining to day-to-day analysis are efficiently completed and handed over to immediate supervisor • Check equipment log books • Reviewing legal and regulatory frameworks relevant to the production work and implications of failing to comply with those specifications. • Reviewing quality Control methods approved by the company. • Format of presenting the information captured during quality checks
	Information/digital literacy	• Preparation of reports, surveys using Google Docs, Google forms etc. • Advance computing, data analysis and interpretation of results by using softwares. • Archival of electronic data, taking backup of various e-records.
	Critical thinking and Analytical reasoning	• Coordinate effectively with personnel in other disciplines to integrate findings and recommendations • Identify causes for out-of-spec products and then recommend changes to improve the product's quality • Analyse root cause of deviations and take corrective actions • Participate in laboratory investigations when required • Regular documentation of all the activities
	Problem solving	• Inspection & calibration of equipment • Troubleshoot malfunctioning of instruments when needed • Operate and maintain all analytical equipments. • Seek clarification on problems from others • Use effective problem solving techniques • Assess the problem (of juniors and subordinates)
	Research-related skills	• Participations in intra-college and intercollegiate research conventions. • Conduction of minor research activities using techniques have been learned in the past semesters.
	Self-directed learning	• Conduct physical inspection in the department • Assist in preparation of specifications, general test procedures, and standard test procedures • Review categorization of samples like control sample, stability sample etc. • Prepare and standardize volumetric solutions within the expiry date in order to ensure storage of various samples as per the prescribed conditions •
	Co-operation/Team work	• Conduct physical inspection in the department • Assist in preparation of specifications, general test procedures, and standard test procedures • Review categorization of samples like control sample, stability sample etc. • Prepare and standardize volumetric solutions within the expiry date in order to ensure storage of various samples as per the prescribed conditions • Pass on relevant information to others.
	Multicultural competence	• Ensure good housekeeping of the laboratory. • Approve batches and incoming raw materials by performing routine analysis of different samples to classify their physical and chemical identity. • Build and maintain positive and effective relationships with

		colleagues and customers • Work with functional, departmental boundaries to harness synergies and realize organizational vision.
	Moral and ethical awareness/reasoning	• Identify and recommend opportunities for improving health, safety, and security to the designated person • Coordinate with colleagues within and outside the department • Work as a team with colleagues and share work as per their or own work load and skills • Work and support colleagues of other departments • Communicate and discuss work flow related difficulties in order to find solutions with mutual agreement • Explain what information means and how it can be used to team members • Document all the control steps undertaken or recommended to be followed as per the standards (GLP).
	Leadership readiness/qualities	• Plan the work in a proper manner so that extensive load should not be there. • Planning of work assigned on a daily basis and provides estimates of time required for each piece of work.
	Lifelong learning	• Provide opinions on work in a detailed and constructive way • Apply balanced judgments to different approaches • Analyze & understand the depth of issue and handle with a proactive approach

COURSE OUTCOMES (CO):

Course code, Semester and Job role	CO (with Description)
RUVPAS101 to RUVPAS107 **&** **RUVPAS201 to RUVPAS207** **Semester: I & II** **1st year: Diploma** **(Lab. Assistant / Technician),** **Job Role: Lab. Technician/Assistant (LFS/Q0509 of LSSSDC)**	1. Clear understanding of organizational role of Lab. Technician / Assistant. 2. Operations of basic laboratory instruments and measuring devices. 3. Clear understanding of Safety and Health guidelines Gain knowledge about Life Science and Pharmaceutical Industry, its rules, regulations and ethical practices. 4. Carry out preparation of solution and regent, and check the working environment for experimentation. 5. Introduction to Audits and Audit related preparations. 6. Introduction to Skills of Team Work and leadership. 7. Skills of office communication (writing leave applications/ memo/ Log-book entries/ drafting of e-mails. 8. Gain complete knowledge of company's standard operating procedure and guidelines and follow them while carrying out proper reporting and documentation for various types of documentation and recording of data/problem/incidents in secure manner. 9. Assist in recording observation and then calculating results before developing conclusions, and keep accurate and detailed logs of all of their work to ensure adherence to protocol and procedures. 10. Read the all manuals, health and safety instructions and pictograms. 11. Read and understand manuals, sops, health and safety instructions, memos, reports, job cards etc. 12. Reading and understanding various images, graphs, diagrams etc. 13. Understand the various coding systems as per company norms. 14. Apply Basic Computer Skills (Ms Office, Internet) at Work. 15. Opening an e-mail account. 16. Social digital platform etiquettes. 17. Introduction to LIMS and 21 CFR Part 11compliance. 18. Learn and practice Reading/ writing/ Generic Skills like Record detail of work done using written/typed report or computer based record/e- mails. 19. Practice Professional skills at work, like decision making, planning & organizing, customer centricity, problem solving, objection handling, analytical thinking, critical thinking 20. Know about and follow the Escalation matrix for reporting identified issues, hazards and breakage 21. Report typical instrument faults and related causes, including recognition of signs and symptoms of faulty lab instruments and apparatus /early warning signs of potential problems. Understand and evaluate Risk and impact of not following defined procedures/work instructions and follow the instructions and SOPs 22. Maintain cleanliness in the work area by doing Pre housekeeping activities, operations & post housing activities

	23. Skills for Planning Laboratory work 24. Documentation practices and GLP 25. Clear understanding of regulatory guidelines and requirements 26. Operate, maintain, and install laboratory instruments as well as monitor experiments as they are performed within labs and Help in set up of the experiment 27. Help the lab/QC Chemists/ Research Associates in performing the experiments and analysis 28. Ensure appropriate measures are taken in Handling of chemicals, their proper labeling and stocking. 29. Follow the correct methods for carrying out corrective action for each problem 30. Display commitment to handle and use the chemical properly fro~~m~~ initial receipt to ultimate disposal 31. Ensure all chemical containers are dated 32. Ensure incompatible chemicals are kept away from each o~~t~~her 33. Help the Lab/QC Chemists/Research associates in performing the experiments and analysis & Carry out inspection and maintenance of equipment and materials Work compliance to standards and SOPs 34. Learn the Basic Concepts of Safety including Hazards, Accidents, Safety Signs and Signals and Henriech's Pyramid and follow and practice same at shop floor.
RUVPAS301 to RUVPAS307 & **RUVPAS401 to RUVPAS407** **Semester: III & IV** **2nd year:** **Advanced Diploma (Validation Supervisor),** **Job Role: Validation Supervisor (LFS/Q0305 of LSSSDC)**	1. Clear understanding of organizational role of Validation Supervisor. 2. Ensure and assist in the implementation of the overall validation program for systems, facilities, equipment, manufacturing processes and cleaning activities. 3. Skills for planning and executing validation work. 4. Documentation practices, GMP and GLP 5. Audits and Audit related preparations. 6. Skills of office communication. 7. Provide guidance on validation issues and documentation regarding quality checks. 8. Communicate validation issues and requirements to plant personnel on a frequent basis. 9. Report any identified breaches in health, safety, and security policies and procedures to the designated person. 10. Write and update the inspection procedures, protocols and checklists. 11. Ensures support in preparation of validation protocols, inspection maps and timely review and approval of validation protocols/summary reports, master plans and SOPs. 12. Record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail. 13. Maintain proper and concise records as per the given format. 14. Installations, up-gradation, downloading, un-installations of basic computer applications/software. 15. Record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail write detailed reports for investigation. 16. Identify defective equipment/apparatus, materials and processes and corrective steps to be taken. 17. Ensure that disposal of waste and leftover tested material is carried on safely as per the SOP. 18. Ensure the disposal of all materials used in the experiment safely as per health and safety management system of the company. 19. Take corrective action in response to typical faults and inconsistencies Troubleshoot/ investigate validation related deviations

	20. Ensure that all safety measures are in place. 21. Take up the results of the findings with the appropriate authority. 22. Use logic and reasoning to identify the strengths and weaknesses of each of the members in the team. 23. Understanding of validation requirements of Manufacturing, Operations. 24. Quality Operation, calibration, validation and troubleshooting of various laboratory instruments. 25. Setup appropriate equipment or apparatus for testing. 26. Use logic and reasoning to identify the strengths and weaknesses of each of the members in the team. 27. Combine pieces of information to form general rules or conclusions. 28. The inspection or test points (control points) in the process and the related procedures and recording requirements. 29. Common causes of variation and corrective action required. 30. How to carry out statistical analysis of test data. 31. How to obtain and interpret records, charts, specifications, equipment, manuals, history/ logs, technical support reports and other documents. 32. Use the right mathematical methods or formulas to solve a problem. 33. Apply general rules to specific problems to produce answers that make sense. 34. Planning and executing validations. 35. Calibrate the testing equipment periodically as per the SOP. 36. Ensure support in preparation of validation protocols, inspection maps and timely review and approval of validation protocols/summary reports, master plans and SOPs. 37. Provide support to supervisor for carrying out investigations related to complaints, batch failures, OOS/ OOT, incidents etc. 38. work as a team with colleagues and share work as per their or own work load and skills. 39. Interview team members and colleagues to collect data to be recorded in log books and batch documents. 40. Support/assign personnel/team members to support internal and external audit activities as per instructions of superiors/supervisor. 41. Working with colleagues of other departments. 42. Communicate and discuss work flow related difficulties in order to find solutions with mutual agreement. 43. Provide documented shift handovers to the next person in the shift. 44. Implementation of different quality management systems (ISO and OHSAS). 45. Communicate confidential and sensitive information discretely to authorized person as per the SOP. 46. Maintain confidentiality of information and data. 47. Commercial awareness of pharmaceutical products and overall healthcare

	sector. 48. Clear understanding of Safety and Health guidelines 49. Fire safety and evacuation procedures. 50. Work compliance to standards and SOPs. 51. The method of reporting any anomalies (materials/processes out of specification) to the appropriate authority. 52. Take responsibility for completing one's own work assignment. 53. Ensure and assist in the implementation of the overall validation. program for systems, facilities, equipment, manufacturing processes and cleaning activities. 54. Release or hold the production for further inspection as per findings. 55. Monitor and adjust the processes to achieve required quality outcomes and support teams during tech transfers. 56. Troubleshoot/investigate validation related deviations. 57. Review and approve facility equipment and software changes. 58. Take up the results of the findings with the appropriate authority. Take initiative to enhance/learn skills in one's area of work. 59. Basics of tactical decision making on safety, process, scheduling and personnel related issues. 60. Suggest improvements (if any) in process based on experience. 61. Clear understanding of regulatory guidelines and requirements. 62. Identification of defect/problem and troubleshooting. 63. Procedures for reporting any unresolved issues and hazards. 64. Pharmaceutical GMPs and regulatory requirements (both national and international. 65. Learn how to multi-task relevant activities.

RUVPAS501 to RUVPAS504 & **RUVPAS601 to RUVPAS604** **Semester: V & VI** **3rd year:** **B. Voc. Degree** **(Quality Control Chemist)** **Job Role: Quality Control Chemist (LFS/Q1301 of LSSSDC)**	1. Prepares and tests samples from all phases of the manufacturing process to ensure that the product quality meets the standards, prepares documents that report test results and is responsible for preserving workplace safety while handling hazardous materials. 2. Knowledge about Life Sciences Industry, Legal and Regulatory framework and Pharmacopeia to enable him/herself for establishing the Industry Standards in his/her performance. 3. The individual has basic lab-work skills and thorough understanding of chemical testing material, equipment and processes. 4. Study the Quality policy of the company. 5. Preparation of reports/ articles/ validation logs/ memos/ monographs/ calibration reports/ training logs etc. 6. Presentation of data by Audio-visual aids, MS-power point presentation, posters, banners etc. 7. Ensure documents pertaining to day-to-day analysis are efficiently completed and handed over to immediate supervisor 8. Check equipment log books 9. Reviewing legal and regulatory frameworks relevant to the production work and implications of failing to comply with those specifications. 10. Reviewing quality Control methods approved by the company. 11. Format of presenting the information captured during quality checks 12. Preparation of reports, surveys using Google Docs, Google forms etc. 13. Advance computing, data analysis and interpretation of results by using softwares. 14. Archival of electronic data, taking backup of various e-records. 15. Coordinate effectively with personnel in other disciplines to integrate findings and recommendations 16. Identify causes for out-of-spec products and then recommend changes to improve the product's quality 17. Analyze root cause of deviations and take corrective actions 18. Participate in laboratory investigations when required 19. Regular documentation of all the activities 20. Inspection & calibration of equipment 21. Troubleshoot malfunctioning of instruments when needed 22. Operate and maintain all analytical equipments. 23. Seek clarification on problems from others 24. Use effective problem solving techniques 25. Assess the problem (of juniors and subordinates) 26. Participations in intra-college and intercollegiate research conventions. 27. Conduction of minor research activities using techniques have been learned in the past semesters. 28. Conduct physical inspection in the department 29. Assist in preparation of specifications, general test procedures, and standard test procedures 30. Review categorization of samples like control sample, stability sample etc. 31. Prepare and standardize volumetric solutions within the expiry date in order to ensure storage of various samples as per the prescribed conditions 32. Conduct physical inspection in the department 33. Pass on relevant information to others. 34. Ensure good housekeeping of the laboratory. 35. Approve batches and incoming raw materials by performing routine analysis of different

	samples to classify their physical and chemical identity. 36. Build and maintain positive and effective relationships with colleagues and customers 37. Work with functional, departmental boundaries to harness synergies and realize organizational vision. 38. Identify and recommend opportunities for improving health, safety, and security to the designated person 39. Coordinate with colleagues within and outside the department 40. Work as a team with colleagues and share work as per their or own work load and skills 41. Work and support colleagues of other departments 42. Communicate and discuss work flow related difficulties in order to find solutions with mutual agreement 43. Explain what information means and how it can be used to team members 44. Document all the control steps undertaken or recommended to be followed as per the standards (GLP). 45. Plan the work in a proper manner so that extensive load should not be there. 46. Planning of work assigned on a daily basis and provides estimates of time required for each piece of work. 47. Provide opinions on work in a detailed and constructive way 48. Apply balanced judgments to different approaches 49. Analyze & understand the depth of issue and handle with a proactive approach.

LEARNING OUTCOMES:

1. Job Role: Lab Technician/Assistant (LFS/Q0509 of LSSSDC) :B. Voc.; Semester I and II

- **Lab technician**, also known as **Lab Assistant**, is responsible to provide all the required technical support to ensure laboratory activities are carried out while adhering to correct procedures and health and safety guidelines. They also ensure that all the necessary equipment; materials etc. are readily available and match the desired standards.
- **Brief Job Description:** The Lab Technician will set up the lab equipment and apparatus for smooth execution of experiments and tests. The role holder will also provide all the required technical support to ensure laboratory activities are carried out while adhering to correct procedures and health and safety guidelines. They also ensure that all the necessary equipment's; materials etc. are readily available and match the desired standards.
- **Personal Attributes:** The individual should have to develop good knowledge of the Pharmaceutical industry. Student should have good analytical skills and should demonstrate the ability to understand and predict the future demand. He/she should demonstrate good estimation skills.
- **Learning Outcomes:**
  - Clear understanding of organisational role of Lab. Technician / Assistant
  - Skills for Planning Laboratory work
  - Operations of basic laboratory instruments and measuring devices
  - Clear understanding of Safety and Health guidelines
  - Fire safety and evacuation procedures
  - Work compliance to standards and SOPs
  - Documentation practices, and GLP
  - Clear understanding of regulatory guidelines and requirements
  - Audits and Audit related preparations
  - Skills of Team Work and leadership
  - Skills of office communication

2. Job Role: Validation Supervisor (LFS/Q0305 of LSSSDC) :B. Voc.; Semester III and IV

- **Validation Supervisor** is responsible for implementation of validation strategy to ensure that the validation deliverables meet the quality standards and requirements of company policies and government regulations.
- **Brief Job Description:** Validation Supervisor has responsibilities for performing and overseeing the qualification and validation of manufacturing processes, cleaning procedures, equipment and media fills. Validation activities include writing and executing protocols that comply with plant and regulatory requirements.
- **Personal Attributes:** To develop good knowledge of standard documentation procedures, rules, regulations and statutory requirements in carrying out validation activities. The individual must demonstrate attention to detail and proactive behaviour.
- **Learning Outcomes:**
  - Clear understanding of organisational role of Validation Supervisor
  - Skills for Planning Validation work

- Understanding of validation requirements of Manufacturing, Operations and Quality
- Operation, calibration, validation and troubleshooting of various laboratory instruments
- Planning and Executing validations
- SOPs of validation
- Clear understanding of regulatory guidelines and requirements
- Clear understanding of Safety and Health guidelines
- Fire safety and evacuation procedures
- Work compliance to standards and SOPs
- Documentation practices, GMP and GLP
- Audits and Audit related preparations
- Skills of Team Work and leadership
- Skills of office communication

3. Job Role: Quality Control Chemist (LFS/Q1301 of LSSSDC) : B. Voc.; Semester V and VI

- A **Quality Control Chemist** is responsible for conducting qualitative and quantitative analysis to ensure specified quality of the manufactured products.
- **Brief Job Description:** A Quality Control Chemist prepares and tests samples from all phases of the manufacturing process to ensure that the product quality meets the standards, prepares documents that report test results and is responsible for preserving workplace safety while handling hazardous materials. Also responsible for testing of in-process/input raw materials & packing materials, in-process samples apart from finished products. Also responsible for testing of process validation samples, product stability samples and cleaning validation samples (Rinse samples/Swab samples etc.).
- **Personal Attributes:** The individual should have developed strong analytical technique in chemical testing and instrumental methods of analysis. Good understanding of chemistry and investigational abilities. He/she should have familiarity with guidelines such as GLP, cGMP and principles of Quality Management. The role holder should have attention to detail and excellent organizational skills.
- **Learning Outcomes:**
  - Clear understanding of organisational role of Quality Chemist
  - Skills for Planning Quality Check
  - Understanding of Quality requirements of Manufacturing, Operations and Finished products
  - Clear understanding of QA and QC roles and responsibilities
  - Operation, calibration and troubleshooting of various laboratory instruments
  - Planning and Executing Quality audits
  - SOPs and protocols; design and review
  - Clear understanding of regulatory guidelines and requirements
  - Clear understanding of Safety and Health guidelines
  - Fire safety and evacuation procedures
  - Work compliance to standards and SOPs
  - Documentation practices, GMP and GLP requirements
  - Audits and Audit related preparations
  - Skills of Team Work and leadership
  - Skills of office communication

Evaluation and Credits:

The evaluation will have 60% weightage to Practical skills while 40% will be for General Component (Theory). The Credit weightage will be one credit for 15 hours of lectures (theory), one credit for 30 hours of laboratory work (practical) and one credit for 30 hours of field work / internship / equivalent training. The credit distribution for the three years B Voc program is listed below:

Year	Semester	Credits for Skill Component	Credits for General Education	Total credits for the Semester	Total credits for the Year
F Y B. Voc.	I	18	12	30	**60**
	II	18	12	30	
S Y B. Voc.	III	18	12	30	**60**
	IV	18	12	30	
T Y B. Voc.	V	18	12	30	**60**
	VI	18	12	30	
Total					**180**

The evaluation will be based on a continuous assessment system with internal and external components. For general education component 60% marks would be for the external evaluation made at each semester-end and 40% marks would be for the internal assessment component during each semester. The internal assessment would involve 50% marks for a Test based evaluation while the remaining 50% marks would be based on assignments, minor projects, quizzes, literature survey, student involvement etc. There would be no internal assessment component for the evaluation of Practical Skill component.

The scheme of examination and allotment of marks for each semester are tabulated below;

SEMESTER I

B. VOC. (PHARMACEUTICAL ANALYSIS)								
FIRST YEAR (1000 MARKS PER SEMESTER)								
THEORY					**PRACTICAL**			
CODE		**Credits**	**MARKS**	**(60:40) SCHEME***	**CODE**		**Credits**	**MARKS**
RUVPAS101	SC-1	02	80	50:30	**RUVPASP101**	SP-1	10	100
RUVPAS102	SC-2	02	80	50:30		SP-2		100
RUVPAS103	SC-3	02	80	50:30		SP-3		100
RUVPAS104	SC-4	02	80	50:30		SP-4		100
RUVPAS105	GC-1	02	30	20:10	**RUVPASP102**	GC-1	07	100
RUVPAS106	GC-2	02	30	20:10		GC-2		100
RUVPAS107	GC-3	01	20	12:08				
	Total	13	400	252 : 148		Total	17	600
	TOTAL MARKS		**400**					**600**
	GRAND TOTAL							**1000**

*** Distribution of marks for External : Internal assessment**

NOTE: SC= Skilled Component, GC= General Component

SEMESTER II

B. VOC. (PHARMACEUTICAL ANALYSIS)								
FIRST YEAR (1000 MARKS PER SEMESTER)								
THEORY					**PRACTICAL**			
CODE		**Credits**	**MARKS**	**(60:40) SCHEME***	**CODE**		**Credits**	**MARKS**
RUVPAS201	SC-1	02	80	50:30	**RUVPASP201**	SP-1	10	100
RUVPAS202	SC-2	02	80	50:30		SP-2		100
RUVPAS203	SC-3	02	80	50:30		SP-3		100
RUVPAS204	SC-4	02	80	50:30		SP-4		100
RUVPAS205	GC-1	02	30	20:10	**RUVPASP202**	GC-1	07	100
RUVPAS206	GC-2	02	30	20:10		GC-2		100
RUVPAS207	GC-3	01	20	12:08				
	Total	13	400	252 : 148		Total	17	600
	TOTAL MARKS		**400**					**600**
	GRAND TOTAL							**1000**

*** Distribution of marks for External : Internal assessment**

NOTE : SC= Skilled Component, GC= General Component

SEMESTER III

B. VOC. (PHARMACEUTICAL ANALYSIS)								
SECOND YEAR (1000 MARKS PER SEMESTER)								
THEORY					**PRACTICAL**			
CODE		**Credits**	**MARKS**	**(60:40) SCHEME***	**CODE**		**Credits**	**MARKS**
RUVPAS301	SC-1	02	80	50:30	**RUVPASP301**	SP-1	10	100
RUVPAS302	SC-2	02	80	50:30		SP-2		100
RUVPAS303	SC-3	02	80	50:30		SP-3		100
RUVPAS304	SC-4	02	80	50:30		SP-4		100
RUVPAS305	GC-1	02	30	20:10	**RUVPASP302**	GC-1	07	100
RUVPAS306	GC-2	02	30	20:10		GC-2		100
RUVPAS307	GC-3	01	20	12:08				
	Total	13	400	252 : 148		Total	17	600
	TOTAL MARKS		**400**					**600**
	GRAND TOTAL							**1000**

*** Distribution of marks for External : Internal assessment**
NOTE : SC= Skilled Component, GC= General Component

SEMESTER IV

B. VOC. (PHARMACEUTICAL ANALYSIS)								
SECOND YEAR (1000 MARKS PER SEMESTER)								
THEORY					**PRACTICAL**			
CODE		**Credits**	**MARKS**	**(60:40) SCHEME***	**CODE**		**Credits**	**MARKS**
RUVPAS401	SC-1	02	80	50:30	**RUVPASP401**	SP-1	10	100
RUVPAS402	SC-2	02	80	50:30		SP-2		100
RUVPAS403	SC-3	02	80	50:30		SP-3		100
RUVPAS404	SC-4	02	80	50:30		SP-4		100
RUVPAS405	GC-1	02	30	20:10	**RUVPASP402**	GC-1	07	100
RUVPAS406	GC-2	02	30	20:10		GC-2		100
RUVPAS407	GC-3	01	20	12:08				
	Total	13	400	252 : 148		Total	17	600
	TOTAL MARKS		**400**					**600**
	GRAND TOTAL							**1000**

*** Distribution of marks for External : Internal assessment**
NOTE : SC= Skilled Component, GC= General Component

SEMESTER V

B. VOC. (PHARMACEUTICAL ANALYSIS)								
THIRD YEAR (800 MARKS PER SEMESTER)								
THEORY					**PRACTICAL**			
CODE		**Credits**	**MARKS**	**(60:40) SCHEME***	**CODE**		**Credits**	**MARKS**
RUVPAS501	SC-1	03	80	50:30	**RUVPASP501**	SC-1	09	80
RUVPAS502	SC-2	03	80	50:30		SC-2		80
RUVPAS503	SC-3	03	80	50:30		SC-3		80
RUVPAS504	GC-1	03	80	50:30	**RUVPASP502**	GC-1	09	240
	Total	12	320	200:120	Total		18	480
	TOTAL MARKS		**320**					**480**
GRAND TOTAL								**800**

*** Distribution of marks for External : Internal assessment**
NOTE : SC= Skilled Component, GC= General Component

SEMESTER VI

B. VOC. (PHARMACEUTICAL ANALYSIS)								
THIRD YEAR (800 MARKS PER SEMESTER)								
THEORY					**PRACTICAL**			
CODE		**Credits**	**Marks**	**(60:40) Scheme***	**CODE**		**Credits**	**Marks**
RUVPAS601	SC-1	03	80	50:30	**RUVPASP601**	SC-1	06	140
RUVPAS602	GC-1	02	80	50:30	**RUVPASP602**	GC-1	04	100
					RUVPASP603	Internship	15	400
	Total	05	160	100:60		Total	25	640
	TOTAL MARKS		**160**					**640**
GRAND TOTAL								**800**

**** Distribution of marks for External : Internal assessment**
NOTE : SC= Skilled Component, GC= General Component

Syllabus in Detail

Ramnarain Ruia Autonomous College
Credit Based, Semester and Grading System
SYLLABUS IN BRIEF: B.VOC, PHARMA ANALYTICAL SCIENCES:

Semester – I

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
RUVPAS101	Units of measurements, Basic Lifesciences and Orientation to QC	2	30	2
RUVPAS102	Molecular Interactions and Basic Laboratory Operations	2	30	2
RUVPAS103	Applied Physics, Biological Systems and Basic Laboratory Management	2	30	2
RUVPAS104	Sampling, Applied Statistics and Laboratory Safety	2	30	2
RUVPASP101	Practical based on Skill Components and assignments	10	300	20
	TOTAL	**18**	**120 + 300**	**8 + 20**
General Education Component				
RUVPAS105	Basic Chemistry, Macromolecules and Cleanliness in Work Area.	2	30	2
RUVPAS106	Basic principles of Chromatography	2	30	2
RUVPAS107	Skills in Communication, Documentation and Computation	1	15	1
RUVPASP102	Practical based on General Education Components	07	210	14
	TOTAL	**12**	**75 + 210**	**5 + 14**
	GRAND TOTAL FOR THE SEMESTER	**30**	**195 + 510**	**13 + 34**

Semester – II

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
RUVPAS201	Laboratory Reagents, Emergency Procedures and Cell Biology	2	30	2
RUVPAS202	Chemical Reactions, Medicinal Chemistry and Comparative Biology	2	30	2
RUVPAS203	Applied Optics and Applied Microbiology	2	30	2
RUVPAS204	Basic Statistics and Chemical Analysis	2	30	2
RUVPASP201	Practical based on Skill Components + Industrial visits and assignments	8 + 2	300	20
	TOTAL	**18**	**120 + 300**	**8 + 20**
General Education Component				
RUVPAS205	Enzymes and Enzyme Kinetics	2	30	2
RUVPAS206	pH, Buffers and Applied Mathematics	2	30	2
RUVPAS207	Effective Communication, Core Skills and Regulatory Agencies	1	15	1
RUVPASP202	Practical based on General Education Components	07	210	14
	TOTAL	**12**	**75 + 210**	**5 + 14**
	GRAND TOTAL FOR THE SEMESTER	**30**	**195 + 510**	**13 + 34**

Semester – III

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
RUVPAS301	Quality Assurance, Quality Control and Validations	2	30	2
RUVPAS302	Separation Techniques, Stereochemistry and Financials of Validation	2	30	2
RUVPAS303	Comparative Physiology and Analytical Applications of Radioisotopes	2	30	2
RUVPAS304	Statistical Evaluation, Genetic code and Industrial Microbiology	2	30	2
RUVPASP301	Practical based on Skill Components + Industrial training (during semester breaks) and assignments	6 + 4	300	20
	TOTAL	**18**	**120 + 300**	**8 + 20**
General Education Component				
RUVPAS305	Extraction Techniques, Lifescience Industry and Monitoring Work Environment	2	30	2
RUVPAS306	Organic Reactions, Photorespiration, Gene Expression and Lab Automation	2	30	2
RUVPAS307	Technical Writing and Technical Documentation	1	15	1
RUVPASP302	Practical based on General Education Components	07	210	14
	TOTAL	**12**	**75 + 210**	**5 + 14**
	GRAND TOTAL FOR THE SEMESTER	**30**	**195 + 510**	**13 + 34**

Semester – IV

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
RUVPAS401	Quality Control Strategies and Validation in Manufacturing	2	30	2
RUVPAS402	Chromatographic Systems, Synthesis of Macromolecules and Validation in Operations	2	30	2
RUVPAS403	Sample Processing, Cellular Signaling and Planning of Validation	2	30	2
RUVPAS404	Statistical Evaluation, Molecular Biology and Managing Validation	2	30	2
RUVPASP401	Practical based on Skill Components + Industrial training (during semester breaks) and assignments	6 + 4	300	20
	TOTAL	**18**	**120 + 300**	**8 + 20**
General Education Component				
RUVPAS405	Solvent-solute Interactions and Metabolic Pathways	2	30	2
RUVPAS406	Analytical techniques for organic Compounds and Basic Immunology	2	30	2
RUVPAS407	Technical Reports, Lab. Automation, Comparative Anatomy, Implementation of Validation.	1	15	1
RUVPASP402	Practical based on General Education Components	07	210	14
	TOTAL	**12**	**75 + 210**	**5 + 14**
	GRAND TOTAL FOR THE SEMESTER	**30**	**195 + 510**	**13 + 34**

Semester – V

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
RUVPAS501	Analysis of OTC products and Regulatory Guidelines	3	45	3
RUVPAS502	Advanced techniques of analysis, Basic Endocrinology and Radioactivity	3	45	3
RUVPAS503	Management of Quality and Regulatory Compliances	3	45	3
RUVPASP501	Practical based on Skill Components Industrial visits and assignments	9	270	18
	TOTAL	**18**	**135 + 270**	**9 + 9**
General Education Component				
RUVPAS504	Drug Delivery systems, LIMS and 21 CFR Part 11	3	45	3
RUVPASP502	Practical based on General Education Components	9	270	18
	TOTAL	**12**	**45 + 270**	**3 + 9**
	GRAND TOTAL FOR THE SEMESTER	**30**	**180 + 540**	**12 + 18**

Semester – VI

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
RUVPAS601	Applied Molecular Biology, Water Systems and Basic Mass Spectrometry	3	45	3
RUVPASP601	Practical based on Skill Components Industrial visits and assignments	6	180	12
	TOTAL	**9**	**45 + 180**	**3 + 6**
General Education Component				
RUVPAS602	Entrepreneurship and Basics of Project Management	2	30	2
RUVPASP602	Practical based on General Education Components	4	120	8
RUVPASP603	Industrial training / Internship / Projects (Min. 90 days, at 5-6 Hr. per day equaling 450 Hr.)	15	90	6
	TOTAL	**21**	**150 + 90**	**6 + 6**
	GRAND TOTAL FOR THE SEMESTER	**30**	**195 + 270**	**9 + 12**

Credit Based, Semester & Grading System
SYLLABUS IN DETAIL: B.VOC, PHARMA ANALYTICAL SCIENCES:

SEMESTER – I

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
RUVPAS101	**Units of measurements, Basic Lifesciences and Orientation to QC**	**2**	**30**	**2**
	• Orientation to Lifescience Industry and Sub-sector • Standards for Manufacturing in Life Sciences and Organization in Life Science Industry • Units of weights and measurements – concept of normality, molarity, molality standard solution and their applications, Bonding and structure of organic compounds, IUPAC Nomenclature • Basics of sample preparation, preservation and storage • Biomolecules: Basic structures and functions • Help the lab/ QC Chemists/Research associates in performing the experiments and analysis.			
RUVPAS102	**Molecular Interactions and Basic Laboratory Operations**	**2**	**30**	**2**
	• Concept of atomic mass, atomic number, isotopes and isomers, Reactions of aliphatic and aromatic compounds • Concept of Ka, Kb and Km (enzymes) and their applications • Basics of Formulations • Cell and basics of cell biology • Carry out preparation of solution and regent • Carry out washing, processing and driving of the glassware/plastic-ware for experiment			

RUVPAS103	**Applied Physics, Biological Systems and Basic Laboratory Management**	**2**	**30**	**2**
	• Concept of electromagnetic spectrum, Dispersion of light, Scattering of light and their applications • Basic mechanics and optics and their applications in instrumentation • Scientific Knowledge about Analytical Equipment and Machinery • Overview of organ systems in plants & animals • Pathogenic and other organisms (food and Pharma industry) • Handling of chemicals before, after experiments, transferring them in smaller containers and labeling them • Maintain records of lab usage, storage of chemicals, labels, date of opening and closing			
RUVPAS104	**Sampling, Applied Statistics and Laboratory Safety**	**2**	**30**	**2**
	• Concept of sample, Sampling techniques, sample statistic, population statistics and their application in Pharma • Statistical Analysis of Laboratory data, Standards and Guidelines for sample handling, Methodology for storage area inspection • Statistics in analytical Chemistry • Clean and Reprocess the instruments before carrying out experiment and sterile packaging, sterilization and storage • Maintain a healthy, safe and secure working environment in the life sciences facility			
RUVPASP101	**Practical based on Skill Components and assignments**	**10**	**300**	**20**
General Education Component				
RUVPAS105	**Basic Chemistry, Macromolecules and Cleanliness in Work Area.**	**2**	**30**	**2**
	• Atomic Structure, Molecules, ions, Chemical Bonds and Chemical Reactions • Life Sciences Industry, its Sub-Sectors and Drug Regulatory Agencies			

	• Carbohydrates, Proteins, fats and their building blocks • Ensure cleanliness in the work area			
RUVPAS106	**Basic principles of Chromatography**	**2**	**30**	**2**
	• Concept of solubility, partition, their applications and water as a universal solvent in living systems • Chromatography: Principles, types and applications			
RUVPAS107	**Skills in Communication, Documentation and Computation**	**1**	**15**	**1**
	• General inter personal communications, General official communications, Communication and Management, Core Skills • Good Documentation Practices, Ensuring data integrity • Basic Concepts of Safety, Process of Safety Analysis • Introduction to computers, Computer components and organization of computers.			
RUVPASP102	**Practical based on General Education Components**	**7**	**210**	**14**

Semester – II

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
RUVPAS201	**Laboratory Reagents, Emergency Procedures and Cell Biology**	**2**	**30**	**2**
	• Principles in the use of indicators, colour reagents, derivatizing agents, Dilutions, dilution techniques and their applications • Orientation with organizational policy, Managing Emergency Procedures and First Aid • Classification of living systems • Structure and function of cell organelles in bacteria, plants and animals			
RUVPAS202	**Chemical Reactions, Medicinal Chemistry and Comparative Biology**	**2**	**30**	**2**
	• Chemical reactions and equilibrium • Comparative biology of prokaryotes and eukaryotes • Basic Medicinal Chemistry • Viruses and Virus Biology			
RUVPAS203	**Applied Optics and Applied Microbiology**	**2**	**30**	**2**
	• Various properties of light, their applications in measurement, Concept of monochromatic light • Microscopy and Basic Microbiology, sterilization and disinfection techniques • Bacteria, Virus and Fungus : Basic Biology and their control • Sources of microbial contamination and their control			
RUVPAS204	**Basic Statistics and Chemical Analysis**	**2**	**30**	**2**
	• Concepts of Quantitative data, qualitative data, their statistical evaluation, Applications of various data representation techniques • Methods of analysis : Gravimetry, Volumetry, Introduction to Thermal methods, types of Volumetric Titrations			

	• Potentiometry and Polarimetry			
RUVPASP201	**Practical based on Skill Components**	**08**	**240**	**08**
	Industrial visits and assignments	**02**	**60**	**02**
General Education Component				
RUVPAS205	**Enzymes and Enzyme Kinetics**	**2**	**30**	**2**
	• Catalysts and their roles in reactions, Concepts of enzymes and enzyme kinetics (Km value) • Coenzymes and co-factors • Electron Transport system and ATP synthesis			
RUVPAS206	**pH, Buffers and Applied Mathematics**	**2**	**30**	**2**
	• Properties of solvents, Concept of pH, buffers and their applications. • Dissociation Constant, Buffering capacity, H&H Equation • Working Principle of pH Meter • Basic Principles of Separation Sciences and critical system parameters • Regression Analysis, Derivatives and their applications in Analysis			
RUVPAS207	**Effective Communication, Core Skills and Regulatory Agencies**	**1**	**15**	**1**
	• Techniques of effective expression of ideas, General written communications, • Documentation in QC process, Core Skills and Professional Skills. • Introduction to ICH, WHO and Other Regulatory Bodies (in the context of Current guidelines) • Introduction to schedules of current D & C Act of India.			
RUVPASP202	**Practical based on General Education Components**	**7**	**210**	**14**

Semester - III

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
RUVPAS301	**Quality Assurance, Quality Control and Validations**	**2**	**30**	**2**

	• Concepts of QA and QC and their significance
	• GLP and its practice
	• Validation concepts
	  ○ Significance of validation
	  ○ Validation guidelines
	  ○ Validation protocol (content, design and deployment)
	  ○ Reference substance
	  ○ Statistics in Validation			

RUVPAS302	**Separation Techniques, Stereochemistry and Financials of Validation**	**2**	**30**	**2**

	• Types of chromatographic separations and their applications
	• Introduction to separation techniques other than chromatography
	• Stereochemistry and Heterocyclic compounds
	• Financials of validation
	  ○ Impact on cost, quality productivity etc. of different practices
	  ○ Costs of deviations and their resolution
	  ○ Costs of documentation, archiving and retrieval
	  ○ Costs of competence testing, audits, reporting etc.
	  ○ Costs of operational Health and safety hazards			

RUVPAS303	**Comparative Physiology and Analytical Applications of Radioisotopes**	**2**	**30**	**2**

	• Sample storage and sample processing • Various extraction techniques and their role in separation • Comparative Physiology of Respiratory, Circulatory and Digestive systems. • Radioisotopes, labelled/tagged probes in bio-analysis (including ELISA), LASER and their uses. • Introduction to X rays and basics of X-ray Crystallography			
RUVPAS304	**Statistical Evaluation, Genetic code and Industrial Microbiology**	**2**	**30**	**2**
	• Data analysis for sample statistics including ANOVA • Concept of sample size and its importance in managing variability • Introduction to central dogma in biology and the genetic code. • Basic Human Genetics: Sex linked, sex influenced, sex limited genes, multiple genes and multiple alleles. Genetic defects : deletion, polyploidy, non-disjunction (one example each) • Concepts of industrial processes o Microbial fermentation for production of antibiotics (for example penicillin) o Production of therapeutic proteins (for example insulin) o Industrial production of small molecules (for example Aspirin, paracetamol etc.)			
RUVPASP301	**Practical based on Skill Components and assignments**	**06**	**180**	**06**
	Industrial Training (min. 30 days total together with semester IV)	**04**	**120**	**04**
General Education Component				
RUVPAS305	**Extraction Techniques, Lifescience Industry and Monitoring Work Environment**	**2**	**30**	**2**

	• Partition coefficient and its applications
	• Selection of methods based on different matrices
	• Pharmaceutical science and chemistry: Materials, Chemicals, equipment and cleaning procedures. Fundamental Science in API Production
	• Monitoring working environment
	  o Regulatory requirements of health, safety and security in working environment
	  o Different types of health and safety hazards
	  o Different types of breaches in health, safety and security norms
	  o Evacuation procedures for workers and visitors			

RUVPAS306	**Organic Reactions, Photorespiration, Gene Expression and Lab Automation**	**2**	**30**	**2**
	• Effect of light on Analytes (photochemistry) • Analytical techniques involving biological matrices and macromolecules • Photosynthesis and Photorespiration in plants • Mutations, recombination and gene expression. • Reaction mechanism of organic reactions • Analysis of Metals • Auto-samplers as simple automation devices.			
RUVPAS307	**Technical Writing and Technical Documentation**	**1**	**15**	**1**

	• Test reports and their formats
	• Basic Computer Skills, Basic understanding of Software's in QC, Information Technology Skills, Database management system
	• Communication Skills and Professional Skills
	• Writing Skills
	  o Recording in predesigned forms / formats
	  o Recording work done and making its reports
	  o SOPs - format and designs
	  o Job cards, memos, instruction charts etc.			

RUVPASP302	**Practical based on General Education Components**	**7**	**210**	**14**

Semester IV

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
RUVPAS401	**Quality Control Strategies and Validation in Manufacturing**	**2**	**30**	**2**
	• Quality of data and significance of data integrity • Fundamentals of Advance QC approaches, Problem Solving / Troubleshooting in QC. • Validation Related to Manufacturing Process: o Coding systems for finished materials o Quality management systems (ISO 9000, 14001, OHSAS 18000 etc) o GMP guidelines (Schedule M, Schedule T etc.) o Systems for documentation and Reporting o Measuring devices (availability, usage etc.) o Reporting OOS results, measurements etc., introduction to Root Cause Analysis. • Laboratory Accreditations and Licences : NABL, GLP, Spirit licence, NDPS Licence etc.			
RUVPAS402	**Chromatographic Systems, Synthesis of Macromolecules and Validation in Operations**	**2**	**30**	**2**

	• Instrumentation and their working in Chromatographic separation
	• Instrumentation and their working in separation techniques other than chromatography
	• Synthesis of Protein, DNA and RNA
	• Validation related to operations
	  ○ Quality requirements of operations
	  ○ Inspection and test points (control points)
	  ○ Shutdown procedures (Routine, Power outage and Emergency)
	  ○ Control of environmental issues
	  ○ Maintaining confidentiality and non-			

	disclosure • Introduction to TGA, CD and Raman Spectroscopy			
RUVPAS403	**Sample Processing, Cellular Signaling and Planning of Validation**	**2**	**30**	**2**
	• Sample pre-treatment techniques • Solid phase extraction & automation in sample treatment • Chemical signals at cellular level – concept of receptors. • Electrodes and electrochemical reactions • Planning of validation o Inspection maps and its deployment o Validation plans and validation schedules o Review and approval of validation protocols and reports o Calibration and calibration schedules o Troubleshooting and corrective action			
RUVPAS404	**Statistical Evaluation, Molecular Biology and Managing Validation**	**2**	**30**	**2**
	• Comparison of samples • Hypothesis testing, Concept of significance and confidence intervals • Plasmids and uses • Gene expression in prokaryotes • Validation in the context of peers o Company output requirements and proactive supervision o Concepts of process management o Tie-ups with outside agencies o Work allocation and team management o Identifying bottle necks and points of disruptions in work flow			
RUVPASP401	**Practical based on Skill Components and assignments**	**06**	**180**	**06**
	Industrial Training (min. 30 days total together with semester III)	**04**	**120**	**04**
General Education Component				

RUVPAS405	**Solvent-solute Interactions and Metabolic Pathways**	**2**	**30**	**2**
	• Concept of resolution, selectivity and specificity of analysis • Importance of solute-solvent interaction in various analysis • Bioorganic chemistry • Anabolic, Catabolic and amphibolic pathway			
RUVPAS406	**Analytical techniques for organic Compounds and Basic Immunology**	**2**	**30**	**2**
	• Analytical techniques for minerals, oils and phytochemicals • Analytical techniques for polymers, dyes and pesticides • Introduction to immunology – concept of antigen, antibody, types of immunity, graft rejection and hypersensitivity • Microbes and their cultivation, types of media, culture storage and various types of cultures.			
RUVPAS407	**Technical Reports, Lab. Automation, Comparative Anatomy, Implementation of Validation.**	**1**	**15**	**1**

	• Technical writing styles and reports
	• Liquid handing systems and automated work stations
	• Comparative account of Circulatory, nervous, and reproductive systems in major phyla of animals.
	• Algorithm, Graphs and Numerical methods
	• Validation in organizational context
	  ○ Disposal procedure and its training to work men
	  ○ Non-conforming products and its storage
	  ○ Escalation matrix for reporting issues
	  ○ Work men training for routine, safety procedures
	  ○ Identification of fault in instruments, process etc.			

RUVPASP402	**Practical based on General Education Components**	**7**	**210**	**10**

SEMESTER V

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
RUVPAS501	**Analysis of OTC products and Regulatory Guidelines**	**3**	**45**	**3**
	• Analytical techniques for food products • Various analytical techniques for of drugs and cosmetics • Residue analysis in finished products. • Regulatory analysis of consumer products • OECD and ICH Guidelines			
RUVPAS502	**Advanced techniques of analysis, Basic Endocrinology and Radioactivity**	**3**	**45**	**3**
	• Applications of atomic properties for analysis and X – ray crystallography, MS Library and its application in MS based analysis, Basics of ICP-MS • Introduction to validation of analytical techniques and its regulatory significance • Hormones, metabolic regulation, chemical signals in microbes like bioluminescence, Analysis based on various properties of organic compounds and macromolecules. • Radiochemical methods of analysis, Detectors of radioactivity			
RUVPAS503	**Management of Quality and Regulatory Compliances**	**3**	**45**	**3**
	• Quality Management System, Overview of Quality Check in QC, Conceptual and Practical Skills required by QC Chemist in Audits. • Concept of TQM and role of analyst • Productivity Concepts. • Responding to an audit / process related query			

	• Practical Techniques of Collaborating with other Groups and Divisions • Various guidelines for analysis (including bio-analysis) • Introduction to preclinical testing and animal testing • Concepts of bioequivalence, bio-similars, pharmacovigilance and their significance • Basics of analytical method development			
RUVPASP501	**Practical based on Skill Components Industrial visits and assignments**	**9**	**270**	**9**
General Education Component				
RUVPAS504	**Drug Delivery systems, LIMS and 21CFR Part11**	**3**	**45**	**3**
	• Various delivery systems and their applications, Analytical approach to standardizing drug delivery systems • Different pharmaceutical, neutraceutical and cosmaceutical preparations and their applications, Analysis of excipients and their significance. • Detailed knowledge of Good Storage practice, Role of Quality Control Chemist • Electronic records and their management, LIMS and their significance, archival of data. • Compliance to 21 CFR part 11, Security of data			
RUVPASP502	**Practical based on General Education Components**	**9**	**270**	**9**

SEMESTER VI

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
RUVPAS601	**Applied Molecular Biology, Water Systems and Basic Mass Spectrometry**	**3**	**45**	**3**
	• PCR and its applications, Restriction enzymes and their applications • Techniques in proteomics, Nano particles and their applications • Water Systems at Plant and Engineering related tools and techniques • Knowledge about Electronic and Optical Sensors and their Operations • Introduction to MS, GC-MS and LC-MS			
RUVPASP601	**Practical based on Skill Components Industrial visits and assignments**	**6**	**180**	**6**
General Education Component				
RUVPAS602	**Entrepreneurship and Basics of Project Management**	**2**	**30**	**2**
	• Management project timelines and deliveries • Management of finances and other resources • Initiating and sustaining star-up projects in analytical services • Planning and financing start-up projects • Introduction to SIX SIGMA principles			
RUVPASP602	**Practical based on General Education Components**	**4**	**120**	**4**

RUVPASP603	**Industrial training / Internship / Projects (min. 90 days, 5-6 Hr per day (totaling 450 Hr.)**	**15**	**90**	**6**

	• **Students will be completing an internship at an industrial unit(min 90 days)**
	  ○ Submit a report
	  ○ Make a presentation
	  ○ Submit an evaluation by the industry personnel (at least two people in the managerial cadre)
	• **Students unable to obtain internship will complete a project (min. 90 days) which will involve project planning, proposal preparation, financials, outcomes and potential applications (guided either by the institutional faculty and/or industrial expert(s)). The students will then;**
	  ○ Submit a project report (supported by raw data)
	  ○ Make a presentation
	  ○ Evaluation by the faculty and an industrial expert in the managerial cadre			

Ramnarain Ruia College
Credit Based, Semester and Grading System
B. VOC. PAS: List of practical (Semester wise)

Semester I:

1. Introduction of Indian Pharmacopoeia.
2. Introduction of Drugs and cosmetics Act (1940).
3. General Safety Precautions in Laboratory.
4. Demonstration of Laboratory layout, Safety Shower and Eye wash.
5. Laboratory Safety Symbols, Pictograms and Signs used for various Chemical, Gases, Instruments and Procedures.
6. Demonstration of Fire Extinguisher.
7. Weighing salts and liquid samples by using Analytical Balance and its supporting documents (SOP, Log book, Instrument manual, Instrument failure record and IQ/OQ/PQ).
8. Introduction to Laboratory Glassware.
9. Laboratory Glassware, its types and Glassware washing and cleaning procedures.
10. Various types of Glass pipettes used in analytical laboratory.
11. Types of Auto-pipettes used in analytical laboratory.
12. Measurement of relative humidity in laboratory by using a Hygrometer (Wet & Dry Hygrometer).
13. Introduction and usage of various types of Water, Distilled Water Apparatus and Milli-Q Apparatus.
14. Calculation of Mean, SD, %CV, % Accuracy by using a MS-Excel.
15. Different types of Gases and Gas Cylinders used in laboratory.
16. Introduction of Various Laboratory Instruments and its usage. (Centrifuge, Cyclo-mixer, Rotary Shaker, Low volume Evaporator, Ultrasonic bath, pH meter and colorimeter).
17. How to issue chemicals/ stationery/ Glassware from Stores.
18. Preparation of Molar solution/ Normal solution / % solution / PPM solution and its Serial and Non-Serial Dilution.

19. pH meter, various types of electrodes and Calibration of pH meter.

20. Various types of Buffers and measurement of pH of various solutions by pH meter.
21. Selection of filters and Absorbance Measurement by using a Colorimeter for various colored solutions.
22. Colorimetric estimation of Potassium dichromate by using a colorimeter.
23. Separation of various coloured dyes by using a Separating Funnel (Partition Separation Technique).
24. Application of electric circuit and assembling of circuit board.
25. Filling of requisition form.
26. Detection and quantitation of Tartrazine from syrups (Colorimetry).
27. Uniformity of Mass for single dose preparation (Weight variation test for uncoated tablets) and Form 39 reporting.

Semester II:

1. Handling and operation of UV-Vis Spectrophotometer (Labindia UV-Win5).
2. Detection and quantitation of Tartrazine from syrups (Spectrophotometry).
3. Preparation of Linear concentration of Caffeine to determine caffeine contents in OTC formulation by using a Spectrophotometer.
4. Determination and Estimation of caffeine from various caffeine containing products by using a Spectrophotometer.
5. Separation of water soluble dye(s) [Potassium dichromate and stamp pad ink] by partition separation technique and its estimation by spectrophotometer.
6. Titration curve: Strong base and strong acid (0.1M KOH and 0.1M HCl).
7. Titration curve: Strong base and weak acid (0.1M KOH and 0.1M HCl).
8. Calibration of Analytical Balance and Micropipettes.
9. Introduction of statistics and its application in pharmaceutical sciences.
    a. Different types of graphs/charts used to represent the data.
    b. Calculation of mean (Arithmetic, Geometric and Weighted mean), Median, Mode, Range and Standard Deviation.
    c. Arrange the raw data in frequency distribution table.
10. Biostatics: ANOVA, Students ‘t’ test and Chi-Square test
11. Measurement of Refractive index of various pharmaceuticals solutions using a refractometer.

12. Determination of hardness of tablets.
13. IQ, OQ, PQ and its importance.
14. Importance of MSDS and COA.
15. Introduction and importance of Laboratory Sieves.
16. Solvent miscibility and Polarity Index of various solvents.
17. Separation of plant pigments by chalk chromatography and paper chromatography (Polar solvent and non-polar solvent).
18. Identification of Paracetamol from various Paracetamol containing formulations by using a Thin Layer Chromatography.
19. Calibration of Auto-pipettes.
20. Determination of disintegration of different tablets.
21. Determination of Melting point and Boiling point of solids and liquids.
22. Handling and operations of digital melting point apparatus (MEPA Labindia).
23. Application of Gas Chromatography and separation of mixture of volatile solvents.
24. Hands on training on: MS-Word®, MS-Excel® and MS-Power point®

Additional Training Modules (Mandatory for First Year):

a) Visit to an industrial unit (preferably semester II)
    i. Check-in/ Check-out of staff
    ii. Security and fire fighting system
    iii. General workflow in QC/QA department
    iv. Dress codes
    v. Emergency exits and layout of work place
    vi. SOP's and their deployment
    vii. Hierarchy of approval of reports
    viii. Organogram of department (QC/QA)
    ix. Instrumentation and workplace arrangements etc.
b) Visit to Exhibitions/ Expo on Pharmaceuticals/ Neutraceuticals/ Cosmaceuticals (preferably semester II)
c) Workshop/ Seminar/ Conference on (one per semester)
    i. Analytical instrumentation

ii. Analytical testing

iii. GMP/ GLP/ GCP principles and practices

d) Report submission of additional training modules

Semester III:

1. Spectrophotometric estimation of sugars by DNSA method.
2. Tap density tester and its applications (Haurner Index Calculation & Compressibility Index Calculation
3. Various types of tools used in pharmaceutical industry.
4. TLC Silica Gel $_{\text{Silica 60}}$: Identification and separation of Fatty Acids by TLC (Omega-3 Fatty acids and cod liver oil).
5. TLC Silica G $_{\text{F-254}}$: Identification and separation of steroidal drugs by TLC (Prednisolone).
6. TLC Silica G $_{\text{F-254}}$: Identification and separation of Caffeine by TLC (100 ppm to 1000 ppm, Nescafe, Bru coffee with chicory beans and Brook bond Tea etc.).
7. Detection of trans-Anethole by TLC using Silica Gel G $_{\text{F 254}}$ from Fennel seeds. (European Pharmacopoeial method) (LLE - LVE - TLC - Short UV - Derivatisation).
8. Liquid-liquid extraction and analysis of Paracetamol (Acetaminophen) from matrix by using a spectrophotometer. (Multiple days experiment including 2 sets of CC's, 2 sets of extracted and un-extracted QC's and unknown samples).
9. Demonstration of IR Spectrophotometry, Gas Chromatography, Atomic Absorption Spectrophotometry and flame photometry.
10. Introduction of HPLC with auto-sampler and data integration system.
11. Detection and separation of caffeine by reverse phase HPLC.
12. Detection of caffeine by reverse phase HPLC and optimization of suitable mobile phase.
13. Analysis of caffeine by using RP-HPLC system with auto-sampler.
14. Detection and separation of paracetamol and caffeine by using RP-HPLC.
15. Detection of Barr-body by using compound microscope.
16. Calibration of ocular micrometer.
17. Determination of particle size by using compound microscope.
18. Inorganic chemistry (Qualitative analysis).
19. Organic chemistry spotting.
20. Deep freezers: -20°C, -70° & their usage

21. Use of scientific calculators.

Semester IV:

1. Analysis of Effluent water : Physical parameter analysis, Colorimetric estimation of iron, Hardness of water by complexometric titration, total dissolved solid, Flame photometric analysis, Determination of refractive index.
2. Introduction of dissolution testing apparatus.
3. Determination of functional group in compound(s) by using Infrared spectroscopy (pellet, ATR and DRS methods).
4. Stability chamber, its use and its calibration requirements.
5. ELISA: Introduction and estimation of suitable analyte using an ELISA kit.
6. Studying changes in protein conformation by Ostwald Viscometer.
7. Filling of requisition and Application for Plasma, Spirit License & renewal, Request of Bio-Waste disposal, Bio waste disposal (Agreement)
8. Volumetric titration (Acid base, Precipitation, With Eriochome black T- indicator, with pH meter).
9. Estimation of Moisture
10. Acid value
11. Saponification Value
12. Iodine value
13. Peroxide value
14. Un-saponifiable matter
15. Conductivity meter (Purity of water and types of water)
16. Nephelometry (Water analysis)
17. Calibration of pH meter, Centrifuge (RPM)
18. Soxhlet extration of total fats from a sample.
19. TLC $_{F-254}$: Identification and separation of Paracetamol by TLC (100ppm to 1000ppm, Paracip 500 and Combiflam).
20. Detection and Separation of Amino acids by TLC using Silica Gel G. (Plummer/one directional).
21. Advance training on: MS-Word®, MS-Excel®Macros and MS-Power point®
22. Levey-Jennings plots and their applications using MS-Excel®.
23. Microbiology: Aseptic Techniques, Gram staining, Isolation, MIC of disinfectant and Evaluation of work area sterility.

Additional Training Modules (Mandatory for Second Year):

a) Workshop/ Seminar/ Conference on (one per semester)
   i. Analytical instrumentation
   ii. Analytical testing
   iii. HPC/ GC

b) Industrial training (one month minimum, during semester breaks)
   i. Instrumentation lab/ QC lab
   ii. Work flow
   iii. Organogram
   iv. Hierarchies of approvals
   v. Calibration
   vi. Archival procedures
   vii. Inventory procedures
   viii. Staff training
   ix. Work ethics

c) Report submission of additional training.

Semester V& VI (Along with internship)

1. Documentation of formulations received for testing and its storage.
2. Documentation of formulation dispense for a trial.
3. Line clearance and dispensing of formulations for clinical trial subjects.
4. Dissolution Testing: USP 1 and USP 2 systems, Monograph requirements.
5. Dissolution of Aspirin tablets: conventional & gastric resistant. Report preparation as per IP.
6. In vitro Dissolution different types of solid dosage forms and their compliance to IP.
7. SOP preparation of various instruments using their manuals.
8. GC: estimation of alcohol content.
9. GC-MS: Use of GC-MS library (Demonstration).
10. LC-MS: Mass spectrum of API and its purity evaluation (Demonstration).
11. Fragmentation pattern in LC-MS using different energies (Demonstration).
12. Estimation of aspirin/ paracetamol from formulations using LC-MS (Demonstration).

13. Linearity and application of IS in LC-MS analysis: spiked plasma samples (Concept with chromatograms).
14. Microbiological testing: sterility testing as per IP.
15. Microbiological testing: Microbial load.
16. Microbiological testing: Vitamin B12 assay as per IP.
17. Microbiological Assay: Ampicillin.
18. Antibiotic Susceptibility Tests.
19. Working under Laminar Flow : Carry out a Microbiological Test.
20. Calibration of HPLC, GC: concepts, need and reporting.
21. Validation of a suitable HPLC method for bioanalysis.
22. QC Audit of Bioanalytical report of a BA/BE study: chromatograms and bioanalysis.
23. QC Audit of clinical report of a BA/BE study :CRFs, Log records and ICF
24. Preparation and facing audits by outside agencies (including US FDA Form 483).
25. Documentation and preparation for submitting a protocol to ethics committee
26. Karl Fischer titration for moisture content.
27. Literature survey and develop a protocol of bioanalytical method for an API
28. Communication skills: Reporting OOS, Troubleshooting, non-compliance etc.
29. HPTLC (spotter & scanner): Linearity and estimation of a bioactive compound from a formulation.
30. FTIR: Interpretation of IR spectrum for molecular characterisation and purity evaluation.
31. PAGE: Separation of milk proteins (different types of milk).
32. Isolation of plasmid and its electrophoretic separation.
33. Stability studies of formulation.
34. Assay of Vitamins.
35. Closure for injections.
36. Indicators and Reference Substance.
37. Calibration of HPLC and Spectrophotometer.
38. Advance computing, data analysis and interpretation of results byusing softwares like Graph Pad prism®, SAS®, WinNonlin®, SPSS® etc. (Demonstration).
39. Vendor assessment and vendor qualification
40. Skills for;

a. Preparing protocols of analysis and validation

b. Preparing schedules and timelines

c. Preparing reports

d. Deciding annexures / supporting documents

e. Archiving and storage of data / samples.

Note:

a) The schedule of practical may be adjusted to accommodate industrial training of students.

b) Practical(s) may be completed at the industry site also (if possible).

c) Report submitted and presentation on industrial internship will be evaluated during examination.

List of books and references:

Regulatory Guidelines:

1. British Pharmacopoeia
2. Drugs and cosmetics Act of India
3. European Pharmacopoeia
4. Indian Pharmacopoeia
5. International Pharmacopoeia
6. United States Pharmacopeia

Reference Books

7. An introduction to Drug design, S.S. Pandey and I R Dumeck, New Age International
8. Analysis of food and beverages, George Charalanbous, Academic press 1978.
9. Analytical Chemistry, G. D. Christian, 4th Ed. John Wiley, New York (1986)
10. Analytical Biochemistry, D, J. Homes and H. Peck, Longman (1983)
11. API (The Ayurvedic pharmacopoeia of India), Part I, Volume II, 1st Ed., Government of India, Ministry of Health and Family Welfare, Department of Indian system of medicine and homoeopathy, New Delhi,1999
12. Applied chemistry, a text book for Engineers and technologists by H.D. Gesser.
13. Arnold D. L., Grice H. C. and Krewski D. R. (Eds.), Handbook of in vitro toxicity testing, Academic Press Ltd. London, 1990.
14. Ballantyne B., Marrs T. and Turner P. (Eds.), General and applied toxicology (Abridge Edition), Macmillan press Ltd., England, 1995.
15. Balunas M. J. and Kinghorn A. D., (2005) Drug discovery from medicinal plants. Life Sciences. 78, 431-441.
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17. Bauer L. A., Applied Clinical Pharmacokinetics, 2nd Ed. The McGraw-Hill Companies, United States of America, 2008.
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20. Bhattaram V. A. and et al., (2002) Pharmacokinetics and Bioavailability of Herbal Medicinal Products.

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21. Bioanalytical Chemistry, S. R. Mikkelesen and E. Corton, John Wiley and sons 2004
22. Bolton S. and Bon C., Pharmaceutical Statistics: Practical and clinical applications. Marcel Dekker, USA, 2004.
23. Bouldin A. S. and et al., (1999) Pharmacy and herbal medicine in the US. Social Science & Medicine. 49, 279-289.
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25. Burgers medicinal chemistry and drug discovery vol- 1(chapter 9 and 14).
26. Chemical analysis of drugs, Higuchi, Interscience 1995
27. Chemical analysis of food by Pearson.
28. Chemical methods of separation, J A Dean, Van Nostrand Reinhold, 1969
29. Chemistry, Emission Control, Radioactive Pollution and Indoor Air Quality Edited by Nicolas Mazzeo, In-Tech Publications (2011).
30. Chromatographic and electrophoresis techniques I Smith Menemann Interscience 1960
31. Coleman M. D., Human Drug Metabolism An Introduction 2nd Ed., Wiley-Blackwell, A John Wiley & Sons, Ltd. Publication, 2010.
32. Connors Text book of pharmaceuticals Analysis, J wiley 2001
33. Cosmetic Technology, Saggarin
34. Cosmetics by W.D. Poucher (Three volumes)
35. Curry S. H. and Whelpton R. Drug Disposition and Pharmacokinetics: From Principles to Applications, John Wiley & Sons Ltd, UK, 2011.
36. De Muth J. E., Basic Statistics and Pharmaceutical Statistical Applications, Marcel Dekker, Inc. New York, 1999.
37. Dewick P., Medicinal Natural Products. A Biosynthetic Approach, John Wiley & Sons Ltd., Chichester, 2002.
38. Dikshith T. and Diwan P., Industrial guide to chemical and drug Safety. John Wiley & Sons, Inc., Hoboken, New Jersey, 2003.
39. Dong M., Modern HPLC for practicing scientist, John Wiley and Sons, Inc. New Jersey, 2006.
40. Duffus J. H. and Worth H. G. J. (Eds.), Fundamental toxicology for chemists, the royal society of chemistry, UK, 1996.
41. Electroanalytical Chemistry, J.J . Lingane, 2nd Ed Interscience, New York (1958)

42. Electrochemical Methods, A. J. Bard and L.R. Faulkner, John Wiley, New YORK, (1980)

43. Encyclopaedia of industrial chemical analysis, Snell et al Inter science
44. Environmental law in India, Mohammad Naseem, Wolters Kluwer.
45. Environmental Protection, Law And Policy In India Kailash Thakur google books (1997).
46. Extraction Chromatography T. Braun, G. Ghersene, Elsevier Publications 1978.
47. Food Analysis, Edited by S. Suzanne Nielsen, Springer
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