Resolution Number: AC/II (20-21).2.RUV2

S. P. Mandali's

Ramnarain Ruia Autonomous College

(Affiliated to University of Mumbai)

RUIA COLLEGE
Explore • Experience • Excel

Syllabus for

Program: Pharma Analytical Sciences

(B. Voc. PAS)

Program Code: RUVPAS

(Credit Based Semester and Grading System
for academic year 2020–2021)

KAUSHAL KENDRA
Perform • Practice • Perfect

PROGRAM OUTCOMES (PO)

For Bachelor in Vocation (B. Voc)

S. P. Mandali's Ramnarain Ruia Autonomous College has adopted the Outcome Based education model for its vocational programs to make its vocational graduates globally competent, ready with skill sets needed for the industry and capable of adapting to the changing needs of the job roles. The Bachelor in Vocation Programme will not only nurture good technical and analytical skills needed for the operation but will also encourage students to reflect on the broader purpose of their vocational education by developing and acquiring skills that go beyond the technical knowledge and prepare them as agents of social good in an unknown future.

PO	PO Description **A student completing Bachelor's Degree in Pharma Analytical Sciences program will be able to:**
PO 1	Recall the knowledge and skills acquired in the program related to the working of the industry for which the student has been trained and effectively apply the job skills to discharge the responsibilities of the job roles in the industry
PO 2	Listen and effectively communicate with peers, seniors and regulators of the industry within the corporate and official settings by rationally handling digital platforms used for information gathering, storing and dissemination and be competent to comprehend, evaluate and comply with the ethical and legal requirements while handling these platforms
PO 3	Apply the knowledge and skills acquired by hands-on experiences to real-life situations and analyse objectively while making individual judgments to solve problems and troubleshoot with keen observation and hypothesis testing for independently reaching a logical conclusion
PO 4	Analyse the information independently and transform it into knowledge as applicable to the contemporary situations of the trade and work cooperatively with peers and manage resources effectively while keeping the team goals over personal goals
PO 5	Interact with people of diverse backgrounds and cultures respecting their beliefs and practices and while effectively engaging within a multicultural society and be able to empathise with the societal needs and be concerned and responsible to

	environmental issues
PO 6	Perform duties ethically and comply with the legal and contemporary regulatory norms related to all areas of the trade with truthful representation of data and results
PO 7	Responsibly take up initiatives and perform as an effective leader while executing different tasks as a team and evolve as a successful entrepreneur with abilities to motivate and organize people and effectively lead them in the right direction to achieve organizational goals
PO 8	Take advantage of their prior learning and join the program during the course of their lifetime as a lifelong learner so as to re-skill themselves and adapt to the changing demands of the trade at any point in life.
PO 9	To inculcate the scientific temperament (Quality and Regulatory aspects) in the students.

PROGRAM SPECIFIC OUTCOMES (PSO)

PSO	Description **A student completing Bachelor's Degree in B. Voc. program in the subject of Pharma Analytical Sciences will be able to:**
PSO 1	Develop knowledge, understanding and expertise in their chosen field of Pharma Analytical sciences (through theory and practical components).
PSO 2	Develop an understanding of regulatory based pharmaceutical quality management processes and impact of analysis on health and environment
PSO 3	Understand theoretical concepts of various analytical instruments that are regularly used in most pharmaceutical laboratories as well as interpret and use data generated in instrumental analyses.
PSO 4	Understand cGLP, cGCP, cGMP, TQM, QMS and Laboratory safety management systems thoroughly used and practicing in the industry.
PSO 5	Make aware, handle and troubleshoot the sophisticated instruments/equipments used for the analysis and Introduce advanced techniques and ideas required in developing area of pharmaceutical analysis.
PSO 6	Carry out experiments in the area of pharmaceutical analysis Qualitative and Quantitative methodologies (organic, in-organic analysis, estimation, separation and chromatographic techniques, derivation process, and potentiometric analysis etc.)
PSO 7	Enhance student's ability to develop statistical models and methods for interpretation of data.
PSO 8	Provide opportunities to excel in academics, research and industry.

PROGRAM OUTLINE

SYLLABUS IN BRIEF: B. Voc. Pharma Analytical Sciences

Semester – I (FY B. Voc. PAS)				
Course Code	**Course Title / Paper**	**Credits**	**Lectures**	**L/Wk**
Skill Component				
RUVPAS101	Units of measurements, Basic Life sciences 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	7	210	14
TOTAL		**12**	**75 + 210**	**5 + 14**
GRAND TOTAL FOR THE SEMESTER		**30**	**195 + 510**	**13 + 34**
Semester – II (FY B. Voc. PAS)				
Course Code	**Course Title / 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	7	210	14
TOTAL		**12**	**75 + 210**	**5 + 14**
GRAND TOTAL FOR THE SEMESTER		**30**	**195 + 510**	**13 + 34**

Semester – III (SY B. Voc. PAS)				
Course Code	**Course Title / 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 and assignments	6 + 4	300	20
TOTAL		**18**	**120 + 300**	**8 + 20**
General Education Component				
RUVPAS305	Extraction Techniques, Life science 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	7	210	14
TOTAL		**12**	**75 + 210**	**5 + 14**
GRAND TOTAL FOR THE SEMESTER		**30**	**195 + 510**	**13 + 34**

Semester – IV (SY B. Voc. PAS)				
Course Code	**Course Title / 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 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	7	210	14
TOTAL		**12**	**75 + 210**	**5 + 14**
GRAND TOTAL FOR THE SEMESTER		**30**	**195 + 510**	**13 + 34**

Semester – V (TY B. Voc. PAS)				
Course Code	**Course Title / 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 (TY B. Voc. PAS)				
Course Code	**Course Title / 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**

Course Code: RUVPAS

Course Title: Pharma Analytical Sciences

Academic year: 2020-21

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)**	• Clear understanding of organizational role of Lab. Technician / Assistant. • Operations of basic laboratory instruments and measuring 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. • 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. • Apply Basic Computer Skills (Ms Office, Internet) at Work. • Opening an e-mail account. • Social digital platform etiquettes. • 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. • 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. • Understand and evaluate Risk and impact of not following defined procedures/work

	instructions and follow the instructions and SOPs • Maintain cleanliness in the work area by doing Pre housekeeping activities, operations & post housing activities • Skills for Planning Laboratory work • Documentation practices and GLP • Clear understanding of regulatory guidelines and requirements • 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 • 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 • 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 • 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)**	• 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. • 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. • 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. • 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. • 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. • 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. • Planning and executing validations. • Calibrate the testing equipment periodically as per the SOP. • 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. • 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. • 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. • 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. • 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.
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)**	• 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. • 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 • 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. • 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 • 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) • Participations in intra-college and intercollegiate research conventions. • Conduction of minor research activities using techniques have been learned in the past semesters. • 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 • 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. • 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. • 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). • 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. • 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.

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 centres 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 when dealing 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)

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 Component	Total credits for the Semester	Total credits for the Year
F Y B. Voc. (Lab Technician/ Assistant)	I	18	12	30	**60**
	II	18	12	30	
S Y B. Voc. (Validation Supervisor)	III	18	12	30	**60**
	IV	18	12	30	
T Y B. Voc. (Quality Control Chemist)	V	18	12	30	**60**
	VI	18	12	30	
Total credits					**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;

(Overall Examination & Marks Distribution Pattern)

SEMESTER I

B. VOC. (Pharma Analytical Sciences)								
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

DETAILED SYLLABUS

SYLLABUS IN DETAIL: B. Voc., Pharma Analytical Sciences

SEMESTER – I				
Code	**Paper**	**Credits**	**Lectures**	**L/Wk**
Skill Component				
RUVPAS101	**Units of measurements, Basic Life sciences and Orientation to QC**	**2**	**30**	**2**
	Orientation to Life science 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			
	Bio-molecules: 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**	**8**	**240**	**8**
	Industrial visits and assignments	**2**	**60**	**2**
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			
	Microbial fermentation for production of antibiotics (for example penicillin)			
	Production of therapeutic proteins (for example insulin)			
	Industrial production of small molecules (for example Aspirin, paracetamol etc.)			
RUVPASP301	**Practical based on Skill Components and assignments**	**6**	**180**	**6**
	Industrial Training (during semester break) (min. 30 days total together with semester IV)	**4**	**120**	**4**
General Education Component				
RUVPAS305	**Extraction Techniques, Life science 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			
	Regulatory requirements of health, safety and security in working environment			
	Different types of health and safety hazards			
	Different types of breaches in health, safety and security norms			
	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			
	Recording in predesigned forms / formats			
	Recording work done and making its reports			
	SOPs - format and designs			
	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:			
	Coding systems for finished materials			
	Quality management systems (ISO 9000, 14001, OHSAS 18000 etc.)			
	GMP guidelines (Schedule M, Schedule T etc.)			
	Systems for documentation and Reporting			
	Measuring devices (availability, usage etc.)			
	Reporting OOS results, measurements etc., and 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			
	Inspection maps and its deployment			
	Validation plans and validation schedules			
	Review and approval of validation protocols and reports			
	Calibration and calibration schedules			
	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			
	Company output requirements and proactive supervision			
	Concepts of process management			
	Tie-ups with outside agencies			
	Work allocation and team management			
	Identifying bottle necks and points of disruptions in work flow			
RUVPASP401	**Practical based on Skill Components and assignments**	**6**	**180**	**6**
	Industrial Training (min. 30 days total together with semester III)	**4**	**120**	**4**
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**	**6**	**180**	**6**
	Industrial visits and assignments			
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			

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 - Derivatization).
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 by using software 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

Manuals provided by LSSSDC

Reference Books

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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.
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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.
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(RRAC/BVOC/PAS/SYL/2020-21)

Modality of Assessment

Theory Examination Pattern:

A) Internal Assessment (40%)

Sr. No.	Evaluation type
1	Class assignments
2	Daily duties (Analyst, QA/QC, Instrument in-charge, Recording of lab parameters, maintaining logs and records etc).
3	Calibration of instruments
4	Preparation of presentation, reports, posters etc.
5	Surprise test (Short answer, MCQs etc.), Group discussion,

B) External Examination (60%)

Semester End Theory Examination:

1. Duration - These examinations shall be of **2 Hr (for 50 marks), 1 Hr (for 20 marks) and Half hour (for 12 marks)** duration.
2. Theory question paper pattern:

Paper Pattern for 50 marks Question paper:

Question	Options	Marks	Questions Based on
Q.1 A		10	**RUVPAS101**
OR			
Q.1 B		10	
Q.2 A		10	
OR			
Q.2 B		10	
Q.3 A		10	
OR			
Q.3 B		10	
Q.4 A		10	
OR			
Q.4 B		10	
Q.5	Write short notes on: (**ANY TWO**)	10	

Practical Examination Pattern:

A) Internal Examination: 40%

Particulars	• Completion of allotted lab duties like calibration, documentation • Participation in team responsibilities and successful completion of allotted duties • Participation in industrial projects/ class projects etc. • Initiative taken in lab management/ quality management / HR management etc. • Completion of respective duties allotted as per lab organogram with respect to hierarchy • Practicing GLP, GCP, GDP, lab Safety • Regularity in attendance and willingness to take responsibilities • Decision making, leadership qualities, team work, communication skills etc. • General conduct and professional attitude etc.
Journal	• Lab note book
Experimental tasks	• During routine practical and in allotted project work (class project and industry projects etc.)

B) External Examination: (60%) for Semester End Practical Examination:

Particulars	• Based on Special Evaluation Methodology (SSBEE) One of the major aspects of successful implementation of a skill based program is to have an effective evaluation of the skills acquired by the students. In an instrumentation intensive course like the B. Voc. in Pharma Analytical Sciences, evaluation of students' skills in handling instruments and sample preparation becomes very important. With several high end instruments being taught in the program, it was not possible to have multiple sets of instruments to cater to a conventional method of evaluating practical skills. To overcome this and to ensure more focused evaluation of the skills a novel technique of "Sequential Station Based Evaluation of Experiments" (SSBEE) was implemented. In SSBEE technique, each experiment or assay is divided into sequential stations where each station is a dedicated site to complete a set of procedural steps. The student starts at "station one" and completes each subsequent station progressively in a sequence to complete an experiment. At each station, the student is required to complete the designated set of procedures within an allotted time before shifting to the next station. Within the sequence, instruments are placed at specific stations where every student uses the instrument individually under the supervision of the evaluator. This arrangement enables the evaluator to examine the student performance individually at various stations.
Journal	• Journal and lab note book
Experimental tasks	• During routine practical and in allotted project work (class project and industry projects etc.)

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