1.3.1. Institution integrates crosscutting issues relevant to Professional Ethics, Gender, Human values, Environment and Sustainability in transacting the Curriculum

Response:

Promoting professional ethics and sustainability, the institution aims to produce competent pharmacy professionals who contribute to health and wellness, fostering strong moral and ethical values. By implementing curricular and co-curricular activities, the institution addresses issues related to gender, human values, environment and sustainability.

Gender Issues:

The institution is actively promoting seminars on gender equality, women's empowerment, entrepreneurship, healthy living and the 3 L's for women's empowerment. The institution celebrates Women's Day and National Girl Child Day and organizes webinars on menstrual hygiene. It also conducts mentoring sessions for female students to promote broader insights and equip them to reject gender discrimination practices, thereby nurturing a more inclusive and supportive environment.

To promote gender equality among the students:

A gender Sensitization Cell is established to address gender based discriminations and grievances aiming to ensure equal representation of both genders in committees, student activities and leadership roles. The cell plays a crucial role in creating awareness about gender related issues and dismantling gender biases. It helps to understand the distinction between sex and gender, recognizing that gender is a socially constructed concept that varies across cultures. Co-curricular and cultural activities like essays, elocution, drawing, painting and rangoli competitions on this theme on Women's Day and mentoring sessions like Rise and Thrive for women are organized annually.

Environment and Sustainability:

The subject "Environmental Sciences" in the second semester for under graduate students focuses on sustainability and environmental issues. The main goal is to learn how the natural world works, to understand how humans interact with the environment, to deal with the environmental problems and live more sustainably. Activities such as Swachha Bharath, paper waste recycling, plastic waste-free campaigns are organized. The NSS team also plays a great role to develop healthy environment among the public.

Human values:

A training programme on CPR & AED is carried out motivating and involving young pharmacists in public service. The student – teacher interaction also helps develop ethics and human value issues. NSS conducts programs on tobacco addiction, Nasha Mukth Bharath Abhiyan, voter enrollment awareness rally, drug free Andhra Pradesh, blood donation camps with the coordination of Red Cross Society.

Professional Ethics:

Professional ethics are principles that govern the behavior of a person in an educational institution and provide rules on how a person should act towards students, colleagues, non-teaching staff, alumni and parents as they must navigate various issues within the institution.

PG programs focus on ethics in research methodology and clinical research. Projects at UG & PG levels and practice schools instill professional ethics. Courses on drug regulatory affairs, pharmaceutical regulatory science and Pharmaceutical Jurisprudence also contribute a larger extent in gaining professional ethics.

Impact:

Eco-friendly campus

Students leave the campus with upright moral principles, good conduct and professional ethics.

Syllabus for the Bachelor of Pharmacy (B. Pharm) Course as approved by Pharmacy Council of India New Delhi

Table-II: Course of study for semester II--------Ist year IInd Semester

R17- B. Pharm

Course Code	Name of the course	No. of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3	1	4
BP203T	Biochemistry – Theory	3	1	4
BP204T	Pathophysiology – Theory	3	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3	-	3
BP206T	Environmental sciences – Theory *	3	-	3
BP207P	Human Anatomy and Physiology II –Practical	4	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practica	4	-	2
BP209P	Biochemistry – Practical	4	-	2
BP210P	Computer Applications in Pharmacy – Practical*	2	-	1
	Total	**32**	**4**	**29**

*Non University Examination (NUE)

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BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Objectives: Upon completion of the course the student shall be able to:

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

Course content:

Unit-I **10hours**

The Multidisciplinary nature of environmental studies Natural Resources Renewable and non-renewable resources: Natural resources and associated problems a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

Unit-II **10hours**

Ecosystems

- Concept of an ecosystem.
- Structure and function of an ecosystem.
- Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

Unit- III **10hours**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers,Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner. 3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd.,Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p 5. Clark R.S., Marine Pollution, Clanderson Press Oxford 6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p 7. De A.K., Environmental Chemistry, Wiley Eastern Ltd. 8. Down of Earth, Centre for Science and Environment

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY K KAKINADA

Syllabus for the Bachelor of Pharmacy (B. Pharm) Course as approved by Pharmacy Council of India

5. **Working days in each semester::**Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from December/January to May/June in every calendar year.
6. **Attendance and progress::**A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately.

Table-V: Course of study for semester V----------3rd Year 1st semester

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Industrial PharmacyI– Theory	3	1	4
BP503T	Pharmacology II – Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3	1	4
BP506P	Industrial PharmacyI – Practical	4	--	2
BP507P	Pharmacology II – Practical	4	--	2
BP508P	Pharmacognosy and Phytochemistry II – Practi	4	--	2
	Total	27	5	26

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BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

UNIT-II **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA),Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties,Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

UNIT-III **10 Hours**

- **Pharmacy Act –1948**: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties
- **Medicinal and Toilet Preparation Act –1955**: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.Offences and Penalties.
- **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**: Objectives,Definitions, Authorities and Officers, Constitution and Functions of narcotic &Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV **08 Hours**

- **Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations,Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-V **07 Hours**

- **Pharmaceutical Legislations** – A brief review, Introduction, Study of drugs enquiry committee. Health survey and development committee, Hathi committee and Mudaliar committee
- **Code of Pharmaceutical ethics** D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- **Medical Termination of Pregnancy Act**
- **Right to Information Act**
- **Introduction to Intellectual Property Rights (IPR)**

Recommended books: (Latest Edition)

1. Forensic Pharmacy by **B. Suresh** 2. Text book of Forensic Pharmacy by **B.M. Mithal** 3. Hand book of drug law-by**M.L. Mehra** 4. A text book of Forensic Pharmacy by **N.K. Jain** 5. Drugs and Cosmetics Act/Rules by **Govt. of India** publications. 6. Medicinal and Toilet preparations act 1955 by **Govt. of India** publications. 7. Narcotic drugs and psychotropic substances act by **Govt. of India** publications 8. Drugs and Magic Remedies act by **Govt. of India** publication 9.Bare Acts of the said laws published by Government. Reference books (Theory)

B.PHARMACY---R17 - Final(4) year 2nd semester

Detailed Syllabus as approved by Pharmacy council of India,New Delhi

Table-VIII: Course of study for semester VIII---------- 4th year 2nd semester

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharma Marketing Management	3 + 3 = 6	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardization of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812ET	Dietary Supplements and Nutraceuticals			
BP813PW	Project Work	12	-	6
	Total	24	4	22

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BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia,UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Objectives: Upon completion of the subject student shall be able to;

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets

Course content:

Unit I **10Hours**

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II **10Hours**

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III **10Hours**

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV **08Hours**

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safetymonitoring in clinical trials

Unit V **07Hours**

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book,Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin. Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition. Drugs and the Pharmaceutical Sciences,Vol.190. 4. Guidebook for drug regulatory submissions SandyWeinberg. By John Wiley &Sons. Inc.5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus. 6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143 7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams 8. Principles and Practices of Clinical Research, Second Edition Edited by John I.Gallin and Frederick P. Ognibene 9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

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BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

Course Content

Unit I — **10 Hours**

Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

Unit II — **10 hours**

Drug and disease classification

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- international Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

- Establishing in a hospital industry
- Establishment & operation of drug safety department in
- Contract Research Organisations (CROs)
- Establishing a national programme

Unit III — **10 Hours**

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

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Pharmacovigilance methods

- Passive surveillance – Spontaneous reports and case series • Stimulated reporting
- Active surveillance – Sentinel sites, drug event monitoring and registries
- Comparative observational studies – Cross sectional study, case control study and cohort study
- Targeted clinical investigations

Communication in pharmacovigilance

- Effective communication in Pharmacovigilance • Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Unit IV **8 Hours**

Safety data generation

- Pre clinical phase • Clinical phase • Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH • Expedited reporting
- Individual case safety reports • Periodic safety update reports
- Post approval expedited reporting • Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies

Unit V **7 hours**

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics • Pregnancy and lactation • Geriatrics

CIOMS

- CIOMS Working Groups • CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers. 2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle,Wiley Publishers. 5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones&Bartlett Publishers. 7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel. Sean Hennessy,Wiley Publishers. 8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G.Parthasarathi, Karin NyfortHansen,Milap C. Nahata
9. National Formulary of India 10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn 3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/.
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

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Table – 12: Course of study for M. Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
	Total	35	21

* Non University Exam

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Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Table – 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105PA	Pharmaceutics Practical I	6	3	6	75
MPH105PB	Pharmaceutical Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Formulation Development of Pharmaceutical and Cosmetic Products	4	4	4	100
MPH205PA	Pharmaceutics Practical III	6	3	6	75
MPH205PB	Pharmaceutics Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

REGULATORY AFFAIRS

(MPH 104T)

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY 60 Hrs

1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. 12 Hrs

   b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA,: ANDA for generic drugs ways and means of US registration for foreign drugs 12 Hrs

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2	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12 Hrs
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
4	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	12 Hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series. Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu\index_en.htm
10. https://www.tga.gov.au/tga-basics

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BAPATLA COLLEGE OF PHARMACY

(Sponsored by Bapatla Education Society), (Recognized by A.I.C.T.E&PCI)
(Affiliated to Jawaharlal Nehru Technological University, Kakinada)
Bapatla, Bapatla (Dist), Andhra Pradesh -522101

Date: 22/6/2022

Program Report

Name of the event : International Yoga Day

Date : 21/6/2022

Venue : Conference Hall (S06)

BCOP celebrates International Yoga Day to raise awareness about this ancient practice and to celebrate the physical and spiritual power that yoga has brought to the world. It relaxes the mind and body and boosting people's immune system. It was attended by Faculty and Students of the college with great enthusiasm. The event began with brief introduction on the theme of the year "Yoga for Humanity", by our Principal Dr. TEGK Murthy. Ms. Shoba, Faculty and also Yoga Instructor has shown up some asanas and students practiced and performed and importance of these were explained simultaneously. The celebration concluded with the speech of the President, Bapatla Education Society encouraged the students to practice regular yoga to remain fit and improve concentration. It ended with a huge success under the supervision of Mr. K. Poorna Chandra Rao, NSS Coordinator.

IQAC COORDINATOR

Bapatla College of Pharmacy * IQAC * Bapatla

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BAPATLA COLLEGE OF PHARMACY

(Sponsored by Bapatla Education Society), (Recognized by A.I.C.T.E&PCI)
(Affiliated to Jawaharlal Nehru Technological University, Kakinada)
Bapatla, Bapatla (Dist), Andhra Pradesh -522101

Name of the event : National Yoga Day Celebrations – 2022

Students practicing asanas

ABN ఆంధ్రజ్యోతి

బాపట్ల ఫార్మశీ కళాశాలలో...

యోగా ఫర్ హ్యూమానిటీ అనే నినాదంతో ఈ ఏడాది అంతర్జాతీయ యోగా దినోత్సవాన్ని నిర్వహించుకుంటున్నామని బాపట్ల ఫార్మశీ కళాశాల ప్రిన్సిపాల్ డాక్టర్ టీఈజీకే మూర్తి అన్నారు. ఈ సందర్భంగా ఆయన మాట్లాడుతూ మానవుని దైనందిన జీవితంలో యోగా ఎంతో ప్రాధాన్యం సంతరించుకున్నదని తెలిపారు. కార్యక్రమంలో బాపట్ల ఎడ్యుకేషన్ సొసైటీ అధ్యక్షుడు ముప్పలనేని శ్రీనివాసరావు, కార్యదర్శి మానం నాగేశ్వరరావు, ఉపాధ్యక్షుడు-1 దొప్పలపూడి రామ్మోహనరావు, ఉపాధ్యక్షులు-2 గెల్లి దిలీప్‌కుమార్, జాయింట్ సెక్రటరీ కొమ్మినేని హరిపద్మ ప్రసాద్, ట్రెజరర్ తాళ్లూరి రామకృష్ణ, అధ్యాపకులు పాల్గొన్నారు.

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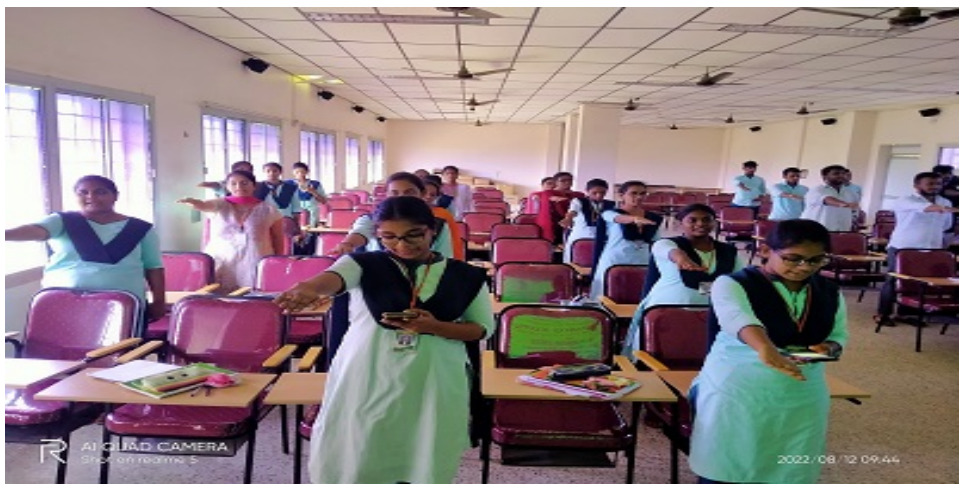
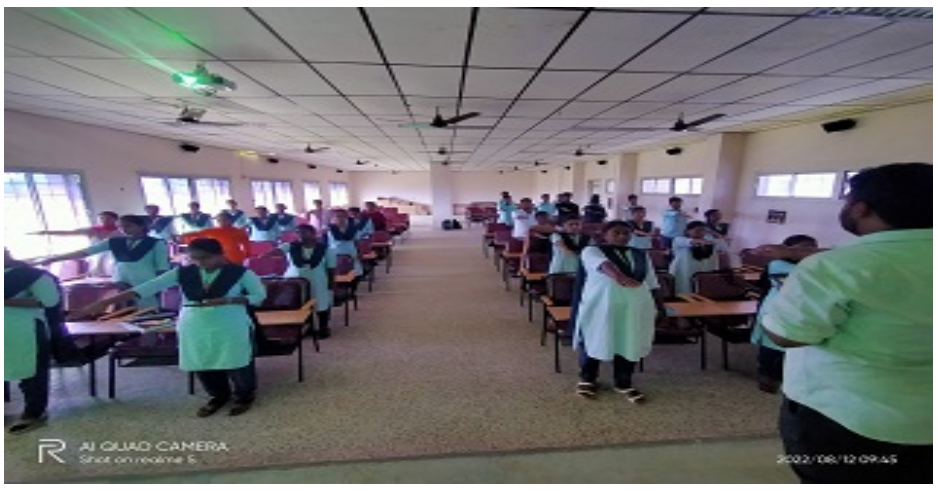
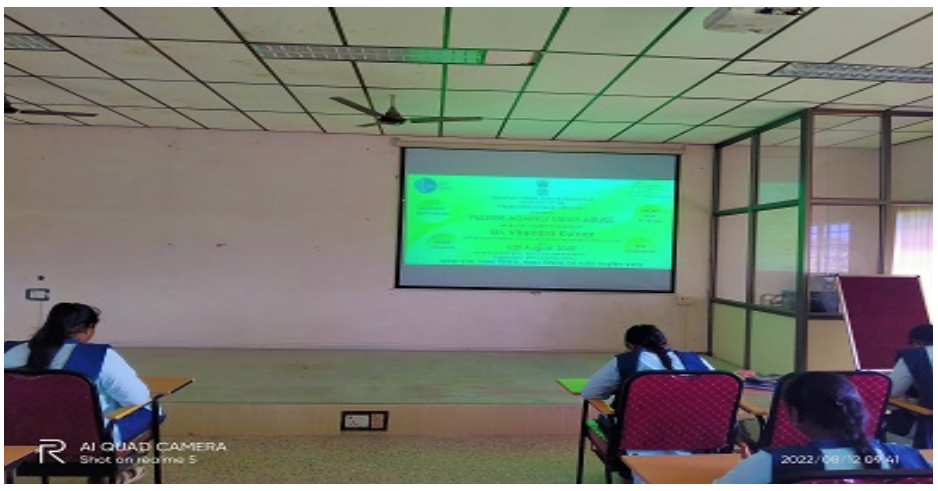
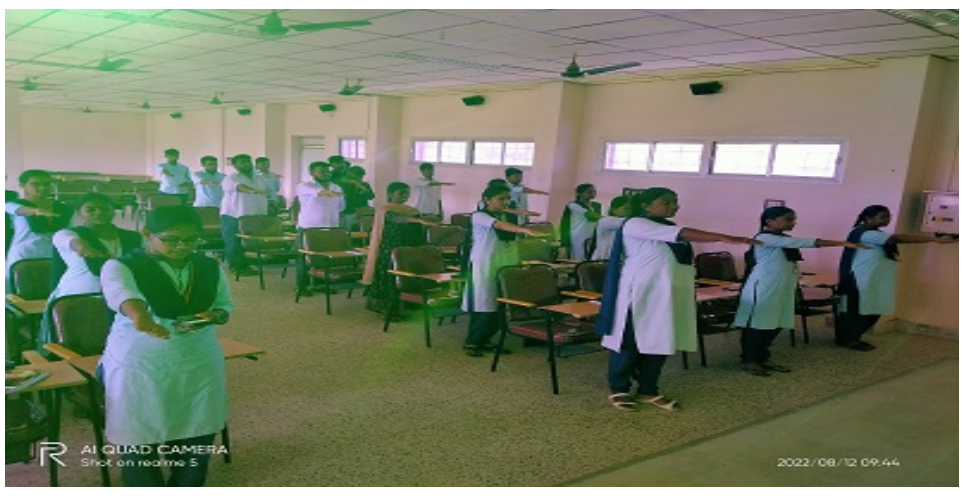
National Service Scheme
JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA
జాతీయ సేవా పథకం

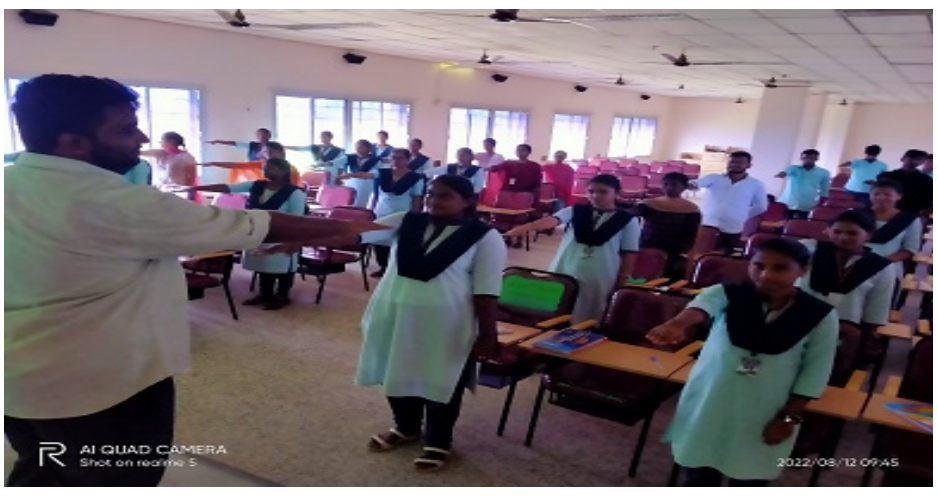
Back	NATIONAL SERVICE SCHEME, JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA		
Activity conducted by	90214701 - Bapatla College of Pharmacy, Bapatla, GBC Road, Karlapalem, Bapatla, Guntur District-522 101		
Activity Type	Other Event	Title of the Event	Nasha Mukth Bharat Abhiyaan
Event Start Date:	12/08/2022	Event End Date:	12/08/2022
Volunteers involved:	55	Male Volunteers involved: Female Volunteers involved:	21 34
Description	Nasha Mukth Bharath Abhiyaan - 12.08.2022 A Pledge was taken against Drug Abuse, Nasha Mukth Bharath Abhiyaan in the college premises. It was conducted by the NSS Unit. NSS Volunteers, UG, PG Department students took the pledge, as per the instructions received by the Department of social justice and Empowerment, Govt. of India. This programme was conducted as a part of Azadi Ka Amrit Mahotsav.		











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Date: 17.09.2022

Programme Report	
NSS Unit Code	90214701
Title of the event	BLOOD DONATION CAMP
Event date	17.09.2022
No. of volunteers involved	32
Description	BLOOD Donation Camp was held at BCOP, Bapatla by college NSS Unit in association with Area Hospital, Bapatla and Red cross Blood Bank, Repalle, Secretary, B.S Narayana Bhatt Co-ordinated the camp smoothly. BES, President, Sri. M Srinivasa Rao, Secretary, Sri M. Nageswara Rao, graced the event and lauded the efforts of NSS unit and appreciated the students for their valuable Blood donation for a cause. Later, Principal Dr. T. E. G. K. Murthy Garu also donated blood followed by senior faculty members of the college. Around 52 units of blood was collected and handed to Red cross unit.

BES President, Shri M Srinivasa Rao Garu at the Blood Donation Camp

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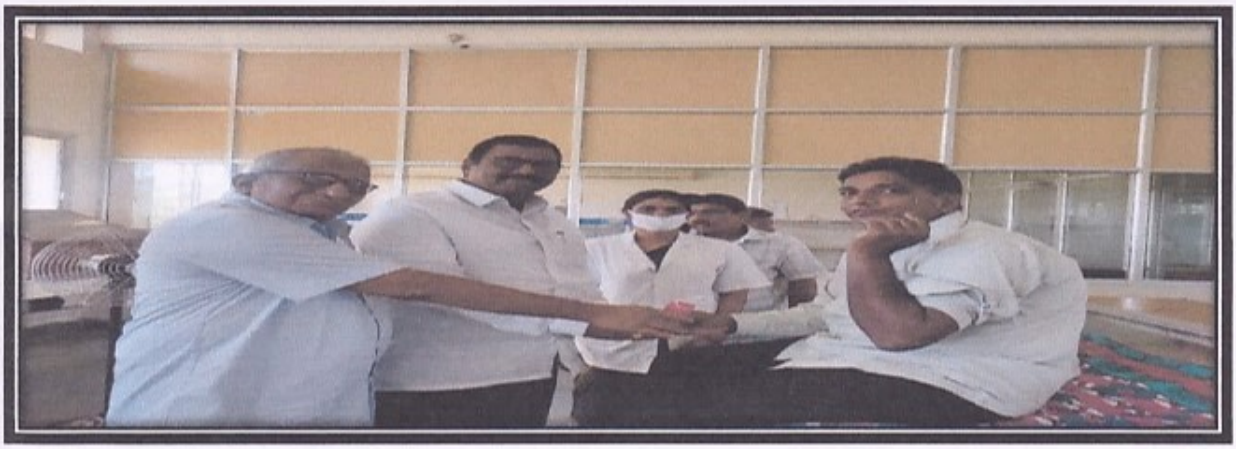
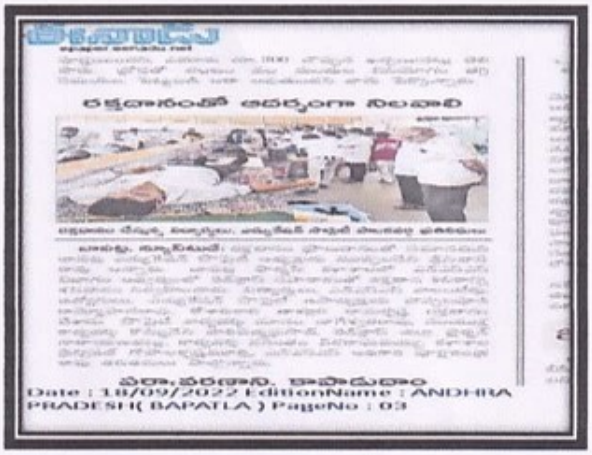
BES Vice-President-I Shri D Ram Mohan Rao Garu donating blood





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Date: 25/1/2023

Program Report

Name of the event : National Girl Child Day

Date : 24/1/2023

Venue : Conference Hall (S06)

BCOP has committed to celebrate National Girl Child Day on 24th January to highlight the importance of protection of girl child in the society, in view of the imbalance of the male female ratio in the society. The theme of the year is "Invest in Girls Rights : Our leadership, Our well being. The day began by inviting Mrs. G. Shiny, Associate Professor as the keynote speaker onto the dais. She addressed the girl students highlighting the need for equal rights and opportunities for girls, as well as to promote their education and overall well being. She also added it is responsibility of all to change society's attitude towards girls, decrease female foeticide and create awareness about the decreasing sex ratio. She explained about various initiatives, Government has implemented to resolve gender bais. She stressed that girls should be strong enough to face challenges of life. Two students also delivered speeches of motivation. The program was a grand success as girls were inspired a lot by the stirring speeches. The program ended by vote of thanks by Mrs. Madhulatha.

IQAC COORDINATOR

PRINCIPAL

Bapatla College of Pharmacy IQAC Bapatla

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Name of the event: National Girl Child Day – 2023

Mrs G. Shiny delivering an empowerment session on National Girl Child Day

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