

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



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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 Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clarendon 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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BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

Scope: This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.

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

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

Course Content:

UNIT-I

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

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

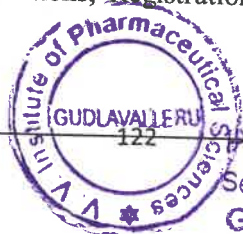
Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

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



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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)

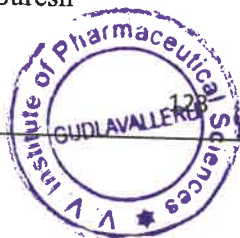
UNIT-V

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** Definition, 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)**

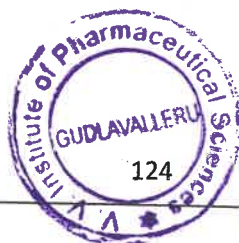
Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh



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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)




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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
- || Pharmacovigilance and process of monitoring in clinical trials.

THEORY

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| | 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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GENDER AUDIT POLICY

Institution has initiated the Gender Audit and measures for the promotion of gender equity during the last five years. Describe the gender equity & sensitization in curricular and co-curricular activities, facilities for women on campus etc., within 500 words.

It's commendable to see that V. V. Institute of Pharmaceutical Sciences is actively addressing gender equality and promoting gender sensitivity through various facilities and initiatives. Here's a summary of the gender-sensitive amenities and initiatives mentioned:

1. Safety and Security
2. High-Tech Surveillance System
3. Hostels
4. Medical Facilities
5. Gender-Segregated Restrooms
6. Counseling
7. Women Protection Cell
8. NSS Unit Activities

1. **Safety and Security:** The Student Grievances Re-dressal Cell handles complaints related to various issues, including victimization, peer bullying, and Faculty discord, ensuring a safe and supportive environment for all students.
2. **High-Tech Surveillance System:** The college employs high-resolution CCTV cameras for continuous surveillance to maintain the safety of the campus and monitor activities. The safety of our pupils is further enhanced by this dispersed recording system, which efficiently keeps an eye out for anyone accessing the college grounds without authorization.
3. **Hostels:** Girls are provided with hostel Facilities, and strict rules and regulations are enforced to ensure the safety of students. ID card checks help prevent unauthorized visitors and strict policies and procedures implemented by wardens aid in keeping an eye on students' safety. Our hostels have large dining rooms.
4. **Medical Facilities:** Students have access to a nearby hospital for medical care. First aid is available both within the college. The hospital ensures the safety and well-being



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of students by providing emergency and specialized care through a committed team of physicians, nurses, and support workers.

5. **Gender-Segregated Restrooms:** Separate, well-ventilated, and sanitary restrooms are provided for both female and male students on each floor, along with common areas tailored for female students needs. Our facilities have separate Washrooms for both girls and Boys on the first and Second floors, which are thoughtfully built to ensure adequate ventilation and sanitation.
6. **Counseling:** The college offers counseling on various topics, addressing women's problems, peer group issues, gender sensitization, and student safety and security through seminars, workshops, and awareness programs led by senior academics and guest lecturers. The Anti-ragging Committee and Women Protection Cell provide support and advice to students.
7. **Women Protection Cell:** This cell focuses on gender sensitization, women's empowerment, and the overall well-being of female students. It encourages their participation in campus and off-campus activities.
8. **NSS Unit Activities:** The NSS unit organizes events and activities to educate students about gender issues. It is encouraged for female students to get involved in events held on and off campus. Furthermore, we place a high priority on empowering young women via healthcare services and holistic development, which includes the development of their bodies, morals, cultures, and skills.

These facilities and initiatives collectively create an environment that prioritizes the safety, well-being, and gender equality of all students at V. V. Institute of Pharmaceutical Sciences. It's essential for educational institutions to continue promoting such values to create a more inclusive and equitable society.



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Restricted Entry of Automobiles: Automobiles entry is Restricted to create pollution free institute.



RESTRICTED ENTRY FOR AUTOMOBILES TO CONTROL THE POLLUTION AT CAMPUS



NO ENTRY FOR VEHICLES WITHIN THE CAMPUS



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NO ENTRY FOR UNAUTHORIZED VEHICLES

The automobile-restricted zone: To prevent huge vehicles from accidentally entering the campus, our institution established a restriction on automobile admission. Our college has a group of buses to transport many students from different places within the city and in suburban areas. This initiative helps in reducing the consumption of petrol. To avoid the Pollution within the Campus. This helps to create a healthy atmosphere at the Campus to maintain good health for the students and the staff.



NO ENTRY FOR AUTOMOBILES



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Event Report

Event Name: National Energy Conservation Day

Dt: 14/12/2022.

Venue- Gudlavalleru.

V. V. Institute of Pharmaceutical Sciences, Gudlavalleru NSS unit conducted the national energy conservation day on 14/12/2022. It is observed on 14th December to spread awareness about the importance of energy and the need of conserving energy by using less energy. As a part of this event our NSS volunteers are participated in the awareness rally.

PHOTOGRAPHS OF THE EVENT



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Event Report

Event Name: Blood Donation Camp.

Date: 16/05/2022.

Venue: Gudlavalleru

On behalf of NSS unit, mega blood donation camp is organized with the collaboration of lions club, Gudlavalleru. This was organized under the guidance of our Principal **Dr. A. Lakshmana Rao**. As a part of this mega blood donation camp several NSS volunteers and faculty actively participated in this event and donated the blood. Our principal Dr. A. Lakshmana Rao while addressing the gathering motivated the students and faculty about importance of the blood donation.

PHOTOGRAPHS OF THE EVENT



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Event Report

Event Name: Medical Camp at Chitram Village

Dt: 25th March 2021.

Venue- Chitram

We started from V. V. Institute of Pharmaceutical Sciences around 9:30AM and reached destination at 9.45 AM before the medical camp our NSS volunteers are announced to village people regarding medical camp. As a part of the medical camp our students and with the help of Gudlavalleru PHC head Dr. K. Sudha rani garu conducted blood grouping tests blood pressure checkup and blood sugar checkup tests to village people. Dr.Sudha rani garu educated the village people regarding healthy food habits and importance of regular exercise. The programme was headed by the NSS Programme officer Mr. V.L.Vinod kumar and students (NSS Volunteers) were actively involved.

PHOTOGRAPHS OF THE EVENT



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