



**CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
(AUTONOMOUS)**

Accredited by NBA (B.Pharmacy) and NAAC with 'A' Grade
Affiliated to Acharya Nagarjuna University, Guntur, Approved by AICTE
Chalapathi Nagar, Lam, GUNTUR – 522034, A.P.

**1.3.2 & 1.3.3 Value-added courses
For the year 2020-2021**

BP 305 T

II/IV B.PHARMACY - 3RD SEMESTER BP305T-PROFESSIONAL ETHICS AND HUMAN VALUES (THEORY) (30 HOURS)

Scope of the Subject :

1. To bring awareness among pharmacy graduates on ethics and human values.
2. to understand and ethical theories and their application to work ethics.
3. To know various codes of ethics used by professional bodies.
4. To understand the concepts of corruption and its measures.
5. To learn about professional responsibility as a pharmacist.

Outcomes of the subject :

The student will be able to :

- a) Develop awareness on ethics and human values
- b) Become morally and socially responsible.
- c) Motivate others on moral values.

Course Outcome :

| | |
|--------|--|
| C305.1 | To remember and recall the human values and professional ethics. |
| C305.2 | To outline the ethical norms, anti corruption measures and central vigilance bodies. |
| C305.3 | To apply moral concepts and reasoning in pharmacy. |
| C305.4 | To discover ethical issues in clinical pharmacy practice and manufacturing of pharmaceutical products. |
| C305.5 | To appraise professional societies and various pharmaceutical associations. |
| C305.6 | To adapt social pharmacy and code of pharmaceutical ethics. |

Course Content:

| TOPIC | Duration (hrs) | References |
|--|----------------|---|
| UNIT-I Human Values: Morals, Values and ethics-Integrity-Work ethics-Service Learning, Civic virtue- Respect for others, Living Peacefully-Caring, Sharing, Honesty, Courage, Valuing time, Co-operations, Commitment, Empathy, Self confidence, Character and Spirituality. | 04 | R.S.Naagarazan professional ethics and Human values edition I, New Age International Pvt. Ltd., edition -1, Chapter-1 |
| UNIT-II Introduction to professional ethics, corruption and its measures: Need of ethics in pharmacy, changing times, RPSGB guidance, ethical norms, moral relativism, facts and values; ethical theories and concepts. Corruption i | 05 | Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceutical press, Edition I, Chapter I. |



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public life, economic impact of corruption, payments that equate supply and demand; bribes as incentive payments, bribes to reduce costs, organized crime and corruption. Anti-corruption measures – Anti corruption Bureau (ACB), Central Vigilance Commission (CVC), Central Bureau of Investigation (CBI), lokadalats, Ombudsman, Comptroller and auditor general (CAG) and right to information.

UNIT-III
Moral concepts and reasoning in Pharmacy: Moral issues, rational inquires, moral autonomy, moral reasoning and pharmacist, moral development theories, justice and human rights, trust and truthfulness and moral dilemmas

05

1.R.S.Naagarazan professional ethics and Human values edition I, New Age International Pvt. Ltd., edition -1, Chapter-2
 2.Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceutical press, Edition I, Chapter-4.

UNIT-IV
Professionalism and Industrial ethics: Pharmacy and professionalism, ethical basis in professionalism and accountability, industrial ethics, pharmacist in different clusters with different ethical issues – ethical issues in clinical pharmacy practice, community pharmacy and manufacturing of pharmaceutical products.

05

1.Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceutical press, Edition I, Chapter-4
 2.R.S.Naagarazan professional ethics and Human values edition I, New Age International Pvt. Ltd., edition -1, Chapter-2

UNIT-V
Professional societies and various pharmaceutical associations: Indian Pharmaceutical Congress Association, Indian Pharmaceutical Association, Indian Hospital Pharmacists Association, Indian Pharmacy Graduates Association, Association of Pharmaceutical Teachers of India, The All India Drug Control Officers Confederation, Indian Society for Technical Education, National Pharmaceutical Pricing Authority and other allied professional societies/associations.

06

1. Professional Pharmacy- M.L.Schroff
 2. Harikishan Singh: History of Pharmacy in India and related aspects, Volume-I, II and III Pharmacopoeias and formularies, 1st Edition, Vallabh Prakashan, 2005



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UNIT-V**Social Pharmacy and code of Pharmaceutical ethics:**

The Concept and context of social pharmacy, principles of ethics, Morality, ethical codes, Pharmaceutical Ethics in relation to job, trade, profession and medical profession. Pharmacist Oath.

05

1.N.K.Jain, Forensic Pharmacy, Eight edition, 2014, 484-492.
2.B.M.Mithal, A Text book of Forensic Pharmacy, Valla Prakasan, 10th edition, Chapter-14

Further Readings:

01. NK Jain, Health Education and community Pharmacyby , CBS, Publ. and Distributors, New Delhi.
02. R.M.Metha, Dispensing pharmacy
03. Pharmacoethics: A problem based approach by G.Vidya Sagar
04. Gupta AK, Health Education and Community Pharmacy, CBS, Publ. and Distribution, New Delhi.



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II/IV B.PHARMACY FOR THE ACADEMIC YEAR 2014-2015 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To create awareness of communication skills and human refinement ideologies to a student in the right perspective.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.

COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English | 3 hours |
| 2 | Importance of Communication Skills | 2 hours |
| 3 | Qualities of a speaker / listener | 2 hours |
| 4 | How to speak without fear-Mock practice | 10 hours |
| 5 | Importance of soft skills | 3 hours |
| 6 | Qualities / Duties of a student | 2 hours |
| 7 | Social Etiquette | 2 hours |
| 8 | Telephone Etiquette | 2 hours |
| 9 | Successful tips for exams | 2 hours |
| 10 | Behavioural approach and attitude | 2 hours |

| | |
|---------------------|--|
| Name of the Faculty | C. Anthony Reddy, Asst. Professor in English |
|---------------------|--|



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I/IV B.PHARMACY FROM THE ACADEMIC YEAR 2015-2016 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To create awareness of communication skills and human refinement ideologies to a student in the right perspective.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.

COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English | 2 hours |
| 2 | Importance of Communication Skills | 2 hours |
| 3 | Qualities of a speaker / listener | 2 hours |
| 4 | How to speak without fear-Mock practice | 10 hours |
| 5 | Importance of soft skills | 4 hours |
| 6 | Qualities / Duties of a student | 2 hours |
| 7 | Social Etiquette | 2 hours |
| 8 | Telephone Etiquette | 2 hours |
| 9 | Successful tips for exams | 2 hours |
| 10 | Behavioural approach and attitude | 2 hours |

Name of the Faculty

C. Anthony Reddy, Asst. Professor in English




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III/IV B.PHARMACY FOR THE ACADEMIC YEAR 2016-2017 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To enhance communication skills, value of group discussions and global exposure.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.


COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English and Communication Skills | 2 hours |
| 2 | Qualities of a speaker / listener | 2 hours |
| 3 | Importance of Soft skills | 2 hours |
| 4 | Importance of Viva voce skills | 2 hours |
| 5 | Speaking / Writing tasks | 6 hours |
| 6 | Human Refinement tips | 2 hours |
| 7 | Mnemonics (memory tips) | 2 hours |
| 8 | Group discussions | 4 hours |
| 9 | Extempore practice | 4 hours |
| 10 | Presentation skills | 4 hours |

| | |
|---------------------|--|
| Name of the Faculty | C. Anthony Reddy, Asst. Professor in English |
|---------------------|--|




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**IV/IV B.PHARMACY 8th SEMESTER
ENTREPRENEURSHIP SKILLS**

Academic Year : **2019-2020**

No. of Hours : **30**

- | | |
|--|-----------|
| 1. Being an Entrepreneur | (2 hours) |
| 2. Skills Required to become an entrepreneur | (3 hours) |
| 3. Entrepreneur vs Manager | (2 hours) |
| 4. Entrepreneurship skills in students | (2 hours) |
| 5. Key skills of an Entrepreneur | (2 hours) |
| 6. Five skills required for every Entrepreneur | (2 hours) |
| 7. Entrepreneur knowledge to start a business | (2 hours) |
| 8. Knowledge based innovation | (2 hours) |
| 9. Communication and soft skills in business successes | (2 hours) |
| 10. Career planning strategies | (2 hours) |
| 11. How to be a successful Entrepreneur | (2 hours) |
| 12. Marketing strategies and concepts | (2 hours) |
| 13. Procedure to establish a pharmacy | (2 hours) |
| 14. To establish drug testing laboratory | (1 hour) |
| 15. How to get approval for test licence | (1 hour) |
| 16. How to establish small scale formulation unit | (1 hour) |




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DEPARTMENT OF PHARMACEUTICAL ANALYSIS
SKILL ORIENTED CERTIFICATE PROGRAMME ON

ICH ELECTRONIC COMMON TECHNICAL DOCUMENT (eCTD) – SUBMISSION PROCESS

OBJECTIVES:

- The main objective of this course is to provide guidelines in ICH electronic common technical document (eCTD) and its submission process.
- The course objectives also include getting the basic knowledge on marketing the drugs or biological products in US along with knowledge on product dossier requirements and filing process.

COURSE OUTCOMES:


1. Students can able to apply for Intellectual Property (IP) law principles to real problems and analyse the social impact of IPR policy.
2. Students shall get an adequate knowledge on patent drafting and filing for their own innovative research work.
3. Students can able to identify the how to access and use of eCTD specifications and ICH guidelines.
4. Students are able to identify the submission process of eCTD via electronic submission gateway (ESW).

Date: 09/12/2020 – 12/12/2020

Duration: 30 hrs

| S.No | Date | Topic Names | Time Duration | Faculty Name |
|------|------------|--|---------------|----------------|
| 1 | 09/12/2020 | Introduction to IPR <ul style="list-style-type: none">• Patent• Trademark• Copyright• Industrial Designs• Geographical Indications | 7 hrs | Mr. Y. Koushik |
| 2 | 10/12/2020 | Current IP practices in India | 4 hrs | Mr. T. Sreenu |




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| S.No | Date | Topic Names | Time Duration | Faculty Name |
|------|------------|---|---------------|----------------|
| 3 | 10/12/2020 | Prior art Search <ul style="list-style-type: none"> • ipindia.nic.in • uspto • wipo | 4 hrs | Mr. T. Sreenu |
| 4 | 11/12/2020 | ICH eCTD | 7 hrs | Mr. Y. Koushik |
| 5 | 12/12/2020 | Dossier filing process | 5 hrs | Mr. Y. Koushik |
| 6 | 12/12/2020 | eCTD submission to US FDA | 3 hrs | Mr. Y. Koushik |



Y. Koushik
09/12/2020

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DEPARTMENT OF PHARMACEUTICAL ANALYSIS

SKILL DEVELOPMENT COURSE

MODERN TECHNIQUES INVOLVED INSYNTHESIS AND ANALYSIS OF DRUGS

Programme: III/IV B.Pharmacy (Academic year 2020-2021)

Duration: 30 Hrs

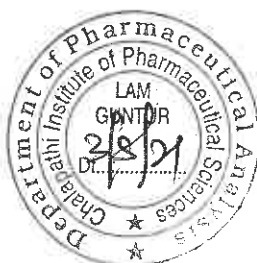
| S.No | Experiment | Duration |
|------|--|----------|
| 01 | Synthesis and characterization of benzimidazole using Parallel Synthesizer | 4hr |
| 02 | Study of drug molecules by using ChemSketch software | 4hr |
| 03 | TLC analysis of selected medicinal compounds | 3hr |
| 04 | Chemistry of Remdesivir and Favipiravir | 2hr |
| 05 | Microwave extraction and isolation of piperine from black pepper | 4hr |
| 06 | Determination of pKa value of selected drugs. | 3hr |
| 07 | Computation tools for studying ADMET properties in drug designing | 4hr |
| 08 | Lipinski rule of five for studying physicochemical properties of drug molecule | 3hr |
| 09 | Assay of Glipizide Tablets | 3hr |


***Note:**

Assessment test on skill development course will be conducted on final day after completion of course.




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Head of the Department
Department of Pharmaceutical Analysis
Chalapathi Institute of Pharmaceutical Sciences
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Department of Pharmaceutics

**Skill oriented certificate Program Programme on Advanced Pharmacokinetics Principles and
Molecular Biotechnique Practices**

Scope: The scope of this skill oriented certificate program on "Advanced Pharmacokinetics Principles and Molecular Biotechnique Practices" is intended for III / IV B. Pharmacy program (6th semester) students to improve their practical knowledge and career opportunities in the field of biopharmaceutics, Pharmaceutical biotechnology.

Objectives:

- Performing dissolution rate test and analysis of the data.
- Deriving integrated equations associated with pharmacokinetic models
- Modeling of plasma concentration vs time data into Pharmacokinetic models
- Understanding of factors which affect the absorption, distribution, metabolism and excretion of drugs.
- Calculation of Pharmacokinetic parameters from biological data using relevant software programs.
- Practicing molecular biotechniques.

| S.No | Topic | Didactic | Duration (30 hrs) |
|-------|---|----------------------|-------------------|
| 1. | Dissolution rate test and analysis of data | Practical | 3 hrs |
| 2. | Introduction to Pharmacokinetics (PK): Mathematical models, statistical applications, and Graphical Methods | Practical/ Theory | 1 hr |
| 3. | Pharmacokinetic models: Compartment one Vs Two and Non compartment kinetics, Chronopharmacokinetics | Practical/ Theory | 1 hr |
| 4. | Calculation of bioavailability parameters: Area under the curve, absolute bioavailability and relative bioavailability, bioequivalence data | Practical/ Theory | 3 hr |
| 5. | Determination of absorption rate constant (Ka) by method of residuals and Wagner Nelson method | Practical | 2hr |
| 6. | Elimination kinetics from plasma and urinary excretion data | Practical | 2hr |
| 7. | Determination of pharmacokinetics parameters by two compartment kinetics | Practical | 2hr |
| 8. | Application of Loo- Reigelman method for two compartment kinetics | Practical | 2hr |
| 9. | Diagnostic test: Westron Blotting techniques | Practical | 2hr |
| 10. | <i>In vitro</i> – <i>In vivo</i> correlation: Calculation using <i>in vitro</i> and <i>in vivo</i> data | Practical | 2hr |
| 11. | Polymerase chain reaction (PCR) technique in molecular biology | Practical | 2hr |
| Total | | | 30 hrs |

Program out comes:

By the end of this skill development program, students will be expertise in the following

1. Understand the concepts of Pharmacokinetic Models.
2. Identify the various factors affecting dissolution rate and absorption of drugs.
3. Apply various Pharmacokinetic models in the measurement of Bioavailability.
4. Determine various Pharmacokinetic parameters.
5. Develop *In vitro* – *In vivo* correlation.



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**DEPARTMENT OF PHARMACOLOGY
SYLLABUS FOR SKILL DEVELOPMENT COURSE ON**

**“RECENT TRENDS IN EXPERIMENTAL PHARMACOLOGY AND ANALYSIS OF HERBAL
DRUGS”**

Department : Pharmacology


Participants : IV/IV B.Pharmacy and III/VI Pharm D students

Duration : 30 Hrs

| COURSE OUTCOMES | |
|-----------------|--|
| CO-1 | To demonstrate the significance of CPCSEA guidelines and to demonstrate various routes of drug administration and blood collection techniques for laboratory animals |
| CO-2 | To summarize screening models for Psychotropic/neurotropic, learning and memory activities. |
| CO-3 | To interpret various preclinical models for drugs acting on CVS and PNS |
| CO-4 | To compile analysis of herbal drugs, DNA barcoding. |

- CPCSEA Guidelines** 4 hrs
Goal and Objectives, Composition, activities, IAEC – Functioning, Requirements for animal house, Maintenance of Records.
- Laboratory Animals** 4 hrs
Identification of animal species, sex, strain and breeding. Handling of animals, routes of administration, dosing and blood collection techniques.
- Animal House Facility** 3 hrs
Environment, Physical Facilities, Animal procurement, Quarantine, Stabilization, Separation, Breeding, Housing, Maintenance of Laboratory animals, Surveillance, Diagnosis, Treatment and control of disease, Personal Hygiene.
- Psychotropic and neurotropic activity:** 4 hrs
Anti-epileptic activity (electroconvulsimeter), anti-aggressive activity (agressometer), behavior (Locomotor activity –actophotometer, hole board test), anxiolytic activity (elevated plus maze, open field test), antipsychotic activity (CAR).
- Nootropic or learning and memory activity:** 5 hrs
Spatial long term memory (Elevated Plus Maze), Working memory (8 Arm Radial Maze), Spatial working memory (Y Maze, Rectangular Maze), Learning, memory & reasoning (Hebbs William Maze & Labyrinth Maze).
- Cardiovascular activity:** 5 hrs
Anti- hypertensive activity by non-invasive blood pressure measurement technique [NIBP] / Invasive blood pressure measurement (2-channel physiograph), anti-hyper lipidemic activity (high fat diet induced/streptozotocin).
- Analgesic activity (Eddy’s hot plate/ tail-flick analgesiometer) / anti-inflammatory activity (digital plethysmometer) / Anti-diabetic activity (alloxan/streptozotocin)/ Diuretic activity** 3 hrs
- Analysis of Herbal drugs and DNA bar coding of Herbs:** 2 hrs




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SKILL ORIENTED CERTIFICATE PROGRAM (Non-Credit) ON

ADVANCES IN FORMULATION AND EVALUATION OF NOVEL DRUG DELIVERY SYSTEMS

Scope: A short-term skill-oriented certificate program on Advances in Formulation and Evaluation of Novel Drug Delivery System shall provide practical training in the formulation and evaluation of drug delivery systems for IV/IV B Pharmacy and III/VI Pharm.D students. The objective is to impart skill to develop drug delivery systems and to meet the demand in academic and industrial environment.

Duration: 30 hours

Objectives:

- To understand the fundamentals of novel drug delivery systems (NDDS).
- To impart practical training on formulation aspect various categories of NDDS
- To study the oral, site specific and targeted drug delivery systems
- To familiarize the use of various equipment in the design and evaluation of NDDS
- To evaluate the importance of various drug delivery systems
- To interpret how the NDDS will affect therapeutic benefit to patient with change in drug release characteristics.

Program outcomes: By the end of this skill development program, students get expertise in the following aspects

- Understand the fundamentals of novel drug delivery system.
- Apply the design principles and development methodologies to fabricate NDDS
- Experienced in the care and practices during the evaluation of NDDS.
- Observe the process variables and their impact on product quality.
- Enlighten the role of evaluation tests to ensure the product quality and performance.
- Acquire the ability to handle various equipment and instruments.

| S.No | Course Content | Duration (30 hr) |
|-----------------|--|------------------|
| Module-1 | Oral Controlled release systems | |
| A. | Formulation and Evaluation of sustained release (SR) matrix tablets | 2 |
| B. | Formulation and Evaluation of microcapsules by ionic gelation technique | 2 |
| C. | Formulation and Evaluation of microspheres made by solvent evaporation technique | 3 |
| D. | Formulation and Evaluation of sustained release pellets | 5 |
| E. | Formulation of extended release pellets by fluid bed coater | 3 |
| Module-2 | Site specific drug delivery systems | |
| F. | Formulation and Evaluation of floating tablets | 2 |
| G. | Formulation and Evaluation of Transdermal patches | 2 |
| Module-3 | Targeted drug delivery systems (Parenteral) | |
| H. | Formulation and evaluation of niosomes made by thin-film hydration technique | 2 |



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| | | |
|-----------------|---|---|
| Module-4 | Liquid and Topical or <i>in-situ</i> systems | |
| I. | Formulation and evaluation of in-situ gels or hydrogels | 2 |
| J. | Formulation and evaluation of micro-emulsions | 2 |
| Module-5 | Colloidal Systems | |
| k | Aerosol Formulation Development | 3 |
| L | Aerosol Filling Process | 2 |



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DEPARTMENT OF PHARMACY PRACTICE



PRADHAN MANTRI BHARATIYA JANAUSHADI KENDRA (PMBJAK)

COMMUNITY PHARMACY-ENTREPRENEURSHIP SKILL DEVELOPMENT PROGRAMME - 30 hrs

Scope: A short term skill oriented certificate programme on Community pharmacy-Entrepreneurship skills shall provide practical training on establishment of community pharmacy / Pradhan Mantri Bharatiy Janaushadhi Kendra, health screening, first aid, dispensing, inventory control, drug administration and patient counseling.

Objective: To improve entrepreneur skills of the students interested in establishing community pharmacy by training them in various activities which are required for the smooth running of community pharmacy/ Pradhan Mantri Bharatiy Janaushadhi Kendra.

Programme outcomes:

1. Understanding the process of establishment of community pharmacy and Pradhan Mantri Bharatiy Janaushadhi Kendra.
2. Acquiring the skills required to become an eminent community pharmacist having good understanding about inventory control, patient counseling, dispensing and first aid services.
3. To survey the health status of patients in the community by participating on health screening services and to build the ability to manage minor ailments.
4. To improve the professional skills about health, balance diet, family planning, health promotion and prevention of communicable diseases in community.
5. To learn to utilize the computer applications and their advantages in community pharmacy.




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| S.NO | TOPIC | Theory/ Practical | HOURS |
|------|--|----------------------|---------------|
| 1. | Documents and process for the establishment of community pharmacy/Pradhan Mantri Bharatiy Janaushadi Kendra: Need of generic medication and their importance. | Theory | 3hrs |
| 2. | Health promotion ad Health screening services: Blood pressure monitoring, BMI monitoring, Blood sugar monitoring, Blood group Determination | Theory | 3hrs |
| | | Practical | |
| 3. | Medication adherence : Medication non adherence and tools to improve medication adherence | Theory | 3hrs |
| | | Practical | |
| 4. | First aid services: First aid for leg fracture, First aid for nosebleed, First aid for burns, First aid for simple Bleeding | Theory | 3hrs |
| | | Practical | |
| 5. | Inventory control: Steps for inventory control, Inventory control methods and drug Procurement | Theory | 3hrs |
| | | Practical | |
| 6. | Dispensing of drugs: Guidelines for dispensing OTC Medication, Prescription medication, Narcotic medication. | Theory | 2hrs |
| | | Practical | |
| 7. | Responding to symptoms of minor ailments: Pain, fever, dyspepsia, diarrhea, vomiting, Constipation, and ophthalmic symptoms. | Theory | 3hrs |
| | | Practical | |
| 8. | Specialized drug administration procedures: Ear drops, Eye drops, Nasal drops, Inhalers, Trans-dermal patches and Suppositories. | Theory | 3hrs |
| | | Practical | |
| 9. | Patient counseling and communication skills required for patient counseling, Preparation of Patient Information Leaflets, Prescription Analysis | Theory | 3hrs |
| | | Practical | |
| 10. | Drug Information Services: Drug information resources, approach for answering drug information query, Critical evaluation of drug information and literature, Preparation of written and verbal reports. | Theory | 4hrs |
| | Total hours / | | 30 hrs |



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2020-21



CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (AUTONOMOUS)

DEPARTMENT OF PHARMACEUTICAL ANALYSIS SKILL ORIENTED CERTIFICATE PROGRAMME ON

"INSTRUMENTATION, TROUBLE SHOOTING OF ANALYTICAL EQUIPMENT AND SPECTRAL INTERPRETATION OF ORGANIC COMPOUNDS" (2019-20) *(M-Jayaraman Pharmaceutical Analysis)*

Scope: A short term skill oriented certificate program on "Instrumentation, Trouble shooting of Analytical Equipment and Spectral Interpretation of Organic Compounds" shall provide knowledge on instrumentation of analytical equipment, trouble shooting and interpretation. The objective of this program is to give more knowledge by making the students interactive which can lead to a successful career in pharmaceutical industrial.

Date: 09/12/2020 to 12/12/2020

Duration: 30 Hrs

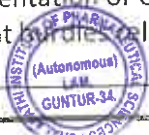
Objectives:

- To recall the concepts of analytical techniques.
- To make the students gain knowledge briefly about the analytical instrumentation.
- To provide knowledge on trouble shooting.
- To make the students understand the concept of interpretation.

Course outcomes:

- Students can be able to learn the analytical knowledge on various analytical instruments and apply the new methods for drugs quantification.
- Students can be understanding the concept of interpretation and determine the structure of compound.
- Students can be able to learn the calibration analytical instruments and its importance in drugs quantification.
- Students shall get an adequate knowledge on trouble shooting of HPLC and resolve the problems her research work time.
- Students shall get an appropriate knowledge on analytical method development and validation concepts and apply the her own research work.

| S.No | Date | Topic Names | Time Duration | Faculty Name |
|------|----------|--|---------------|--------------|
| 1 | 09/12/20 | UV Visible spectrophotometer (a) Principle and instrumentation of UV Different dyes related to UV | 5 hrs | K. Swathi |




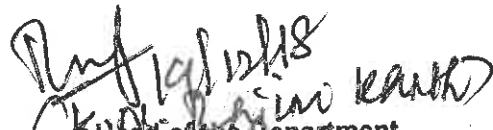
K. Swathi
12/8/2021
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| | | | | |
|---|---------------------------|---|-------|--------------------|
| | | (b) Trouble shooting methods | | |
| 2 | 09/12/20 & 10/12/20 | High performance liquid chromatography (a) Principle and instrumentation of HPLC (b) Different hurdles related to HPLC (c) Trouble shooting methods | 5 hrs | Mr. M. Siva Prasad |
| 3 | 10/12/20 | Structure elucidation using different spectras (a) Index of hydrogen deficiency (b) Rule 13 Deriving molecular formula from mass number (c) Molecular structure using different spectrums | 5 hrs | M. Siva Prasad |
| 4 | 11/12/20 | Calibration of analytical instruments (a) Importance of calibration and preparation of SOP (b) Calibration of UV, IR, HPLC, DSC (c) Calibration of analytical balance, flame photometer, KF Titrator, fluorimeter | 5 hrs | P. Prachet |
| 5 | 11/12/20 & 12/12/20 | Design and development of analytical methods and validation (a) Analytical method development and introduction to ICH guidelines (b) Analytical method validation | 5 hrs | P. Prachet |
| 6 | 12/12/20 | Design and development of analytical methods and validation (a) Analytical method development and introduction to FDA guidelines (b) Development Of Analytical Method | 5 hrs | P.Abhinandana |



(Assessment test on skill development course will be conducted on 12/12/2020 between 04.00 PM to 05.00 PM)


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 Department of Pharmaceutical Analysis
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 LAM, GUNTUR-522 034.



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IV/IV B.PHARMACY FOR THE ACADEMIC YEAR 2016-2017 ONWARDS

TITLE : INTERVIEW COMPETENCE AND GROUP DISCUSSIONS

No. of Hours : 30

OBJECTIVE : To create awareness of interview skills and group discussion and aid them to face the challenging corporate world.

The objective of the course is to develop the students as effective communicators and to face the corporate challenges confidently such as JAM session, interviews and group discussion. The content will prepare the student to gain entrepreneurial and leadership traits and emerge as a daring, dashing and dynamic personality in all walks of their career.

COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Understanding the purpose of professional interviews. |
| 2 | Identify the different types of professional interviews. |
| 3 | Obtain important tips on preparing for the professional interview. |
| 4 | Articulate the importance of self presentation. |

| S.No. | Contents | Prescribed hours |
|-------|--|------------------|
| 1 | Importance of Communication Skills | 2 hours |
| 2 | Importance of Soft Skills | 2 hours |
| 3 | Social Etiquette | 2 hours |
| 4 | Telephone Etiquette | 2 hours |
| 5 | Basics of JAM Skills | 2 hours |
| 6 | Basics of Interview Skills | 2 hours |
| 7 | How to face an interview board | 2 hours |
| 8 | Ten worst interview blunders | 2 hours |
| 9 | Interview skills Mock practice – Questions and Answers | 10 hours |
| 10 | Importance of Group discussion | 2 hours |
| 11 | Resume preparation | 1 hour |
| 12 | Key to success in life | 1 hour |

| | |
|---------------------|--|
| Name of the Faculty | C. Anthony Reddy, Asst. Professor in English |
|---------------------|--|



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Affiliated to Acharya Nagarjuna University, Guntur, Approved by AICTE
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**1.3.2 & 1.3.3 Value-added courses
For the year 2019-2020**

BP 305 T

II/IV B.PHARMACY - 3RD SEMESTER BP305T-PROFESSIONAL ETHICS AND HUMAN VALUES (THEORY) (30 HOURS)

Scope of the Subject :

1. To bring awareness among pharmacy graduates on ethics and human values.
2. to understand and ethical theories and their application to work ethics.
3. To know various codes of ethics used by professional bodies.
4. To understand the concepts of corruption and its measures.
5. To learn about professional responsibility as a pharmacist.

Outcomes of the subject :

The student will be able to :

- a) Develop awareness on ethics and human values
- b) Become morally and socially responsible.
- c) Motivate others on moral values.

Course Outcome :

| | |
|--------|--|
| C305.1 | To remember and recall the human values and professional ethics. |
| C305.2 | To outline the ethical norms, anti corruption measures and central vigilance bodies. |
| C305.3 | To apply moral concepts and reasoning in pharmacy. |
| C305.4 | To discover ethical issues in clinical pharmacy practice and manufacturing of pharmaceutical products. |
| C305.5 | To appraise professional societies and various pharmaceutical associations. |
| C305.6 | To adapt social pharmacy and code of pharmaceutical ethics. |

Course Content:

| TOPIC | Durat- ion (hrs) | References |
|--|------------------------|---|
| UNIT-I Human Values: Morals, Values and ethics-Integrity-Work ethics-Service learning, Civic virtue, Respect for others, Living Peacefully-Caring, Sharing, Honesty, Courage, Valuing time, Co-operations, Commitment, Empathy, Self confidence, Character and Spirituality. | 04 | R.S.Naagarazan professional ethics and Human values edition I, New Age International Pvt. Ltd., edition -1, Chapter-1 |
| UNIT-II Introduction to professional ethics, corruption and its measures: Need of ethics in pharmacy, changing times, RPSGB guidance, ethical norms, moral relativism, facts and values; ethical theories and concepts. Corruption in | 05 | Joy Wingfield and David Badcott, Pharmacy ethics and decision making Pharmaceutical press, (Autonomous) Edition I, Chapter-1. |



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public life, economic impact of corruption, payments that equate supply and demand; bribes as incentive payments, bribes to reduce costs, organized crime and corruption. Anti-corruption measures – Anti corruption Bureau (ACB), Central Vigilance Commission (CVC), Central Bureau of Investigation (CBI), lokadalats, Ombudsman, Comptroller and auditor general (CAG) and right to information.

UNIT-III
Moral concepts and reasoning in Pharmacy: Moral issues, rational inquires, moral autonomy, moral reasoning and pharmacist, moral development theories, justice and human rights, trust and truthfulness and moral dilemmas

05

1.R.S.Naagarazan professional ethics and Human values edition I, New Age International Pvt. Ltd., edition -1, Chapter-2
 2.Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceutical press, Edition I, Chapter-4.

UNIT-IV
Professionalism and Industrial ethics: Pharmacy and professionalism, ethical basis in professionalism and accountability, industrial ethics, pharmacist in different clusters with different ethical issues – ethical issues in clinical pharmacy practice, community pharmacy and manufacturing of pharmaceutical products.

05

1.Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceutical press, Edition I, Chapter-4
 2.R.S.Naagarazan professional ethics and Human values edition I, New Age International Pvt. Ltd., edition -1, Chapter-2

UNIT-V
Professional societies and various pharmaceutical associations: Indian Pharmaceutical Congress Association, Indian Pharmaceutical Association, Indian Hospital Pharmacists Association, Indian Pharmacy Graduates Association, Association of Pharmaceutical Teachers of India, The All India Drug Control Officers Confederation, Indian Society for Technical Education, National Pharmaceutical Pricing Authority and other allied professional societies/associations.

06

1. Professional Pharmacy- M.L.Schroff
 2. Harikishan Singh: History of Pharmacy in India and related aspects, Volume-I, II and III Pharmacopoeias and formularies, 1st Edition, Vallabh Prakashan, 2005



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UNIT-V**Social Pharmacy and code of Pharmaceutical ethics:**

The Concept and context of social pharmacy, principles of ethics, Morality, ethical codes, Pharmaceutical Ethics in relation to job, trade, profession and medical profession. Pharmacist Oath.

05

1.N.K.Jain, Forensic Pharmacy, Eight edition, 2014, 484-492.
2.B.M.Mithal, A Text book of Forensic Pharmacy, Valla Prakasan, 10th edition, Chapter-14

Further Readings:

01. NK Jain, Health Education and community Pharmacyby , CBS, Publ. and Distributors, New Delhi.
02. R.M.Metha, Dispensing pharmacy
03. Pharmacoethics: A problem based approach by G.Vidya Sagar
04. Gupta AK, Health Education and Community Pharmacy, CBS, Publ. and Distribution, New Delhi.



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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

CHALAPATHI NAGAR, LAM, GUNTUR - 522034

II/IV B.PHARMACY FOR THE ACADEMIC YEAR 2014-2015 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To create awareness of communication skills and human refinement ideologies to a student in the right perspective.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.


COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English | 3 hours |
| 2 | Importance of Communication Skills | 2 hours |
| 3 | Qualities of a speaker / listener | 2 hours |
| 4 | How to speak without fear-Mock practice | 10 hours |
| 5 | Importance of soft skills | 3 hours |
| 6 | Qualities / Duties of a student | 2 hours |
| 7 | Social Etiquette | 2 hours |
| 8 | Telephone Etiquette | 2 hours |
| 9 | Successful tips for exams | 2 hours |
| 10 | Behavioural approach and attitude | 2 hours |

Name of the Faculty C. Anthony Reddy, Asst. Professor in English




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I/IV B.PHARMACY FROM THE ACADEMIC YEAR 2015-2016 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To create awareness of communication skills and human refinement ideologies to a student in the right perspective.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.

COURSE OUTCOMES: On completion of the course, student will be able to


| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English | 2 hours |
| 2 | Importance of Communication Skills | 2 hours |
| 3 | Qualities of a speaker / listener | 2 hours |
| 4 | How to speak without fear-Mock practice | 10 hours |
| 5 | Importance of soft skills | 4 hours |
| 6 | Qualities / Duties of a student | 2 hours |
| 7 | Social Etiquette | 2 hours |
| 8 | Telephone Etiquette | 2 hours |
| 9 | Successful tips for exams | 2 hours |
| 10 | Behavioural approach and attitude | 2 hours |

Name of the Faculty

C. Anthony Reddy, Asst. Professor in English




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III/IV B.PHARMACY FOR THE ACADEMIC YEAR 2016-2017 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To enhance communication skills, value of group discussions and global exposure.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.


COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English and Communication Skills | 2 hours |
| 2 | Qualities of a speaker / listener | 2 hours |
| 3 | Importance of Soft skills | 2 hours |
| 4 | Importance of Viva voce skills | 2 hours |
| 5 | Speaking / Writing tasks | 6 hours |
| 6 | Human Refinement tips | 2 hours |
| 7 | Mnemonics (memory tips) | 2 hours |
| 8 | Group discussions | 4 hours |
| 9 | Extempore practice | 4 hours |
| 10 | Presentation skills | 4 hours |

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|---------------------|--|
| Name of the Faculty | C. Anthony Reddy, Asst. Professor in English |
|---------------------|--|




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**IV/IV B.PHARMACY 8th SEMESTER
ENTREPRENEURSHIP SKILLS**

Academic Year : **2019-2020**

No. of Hours : **30**

- | | |
|--|-----------|
| 1. Being an Entrepreneur | (2 hours) |
| 2. Skills Required to become an entrepreneur | (3 hours) |
| 3. Entrepreneur vs Manager | (2 hours) |
| 4. Entrepreneurship skills in students | (2 hours) |
| 5. Key skills of an Entrepreneur | (2 hours) |
| 6. Five skills required for every Entrepreneur | (2 hours) |
| 7. Entrepreneur knowledge to start a business | (2 hours) |
| 8. Knowledge based innovation | (2 hours) |
| 9. Communication and soft skills in business successes | (2 hours) |
| 10. Career planning strategies | (2 hours) |
| 11. How to be a successful Entrepreneur | (2 hours) |
| 12. Marketing strategies and concepts | (2 hours) |
| 13. Procedure to establish a pharmacy | (2 hours) |
| 14. To establish drug testing laboratory | (1 hour) |
| 15. How to get approval for test licence | (1 hour) |
| 16. How to establish small scale formulation unit | (1 hour) |



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2019-20

2016-2017 — 100 | 100
2017-2018
2019-2020



CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR.

(AUTONOMOUS)

DEPARTMENT OF PHARMACY PRACTICE

CERTIFICATE COURSE IN PHARMACOVIGILANCE – 50 Hrs

Scope of the course:

This course will help students acquire a basic understanding of the concepts and practices in the field of Pharmacovigilance. This course is intended to sensitize students and equip them with knowledge on Pharmacovigilance practices worldwide and on the Indian scenario in detail. This course is intended to enrich the knowledge of Pharmacovigilance among students. This course will enable the students to better understand the requirements within the Pharmacovigilance industry and government organization in India in the aspects of patient safety.


Objectives:

1. To provide the basic knowledge of pharmacovigilance.
2. To understand risk assessment and type of events being collected.
3. To become familiar in pharmacovigilance and risk management systems, risk management plans, inspections.
4. To understand the utility of Argus software.
5. To understand pharmacovigilance inspections and audits quality assessment.

Programme outcomes:

1. To benefit the patient care and safety in relation to the use of medicines and their interventions.
2. Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public and health care professionals.
3. Contribute to the assessment of risk, benefit and effectiveness medicines.
4. To detect problems related to the use of medicines and communicate the findings in a timely manner.
5. Encourage the safe rational and more effective medicines to improve public health.




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COURSE CONTENT

| S. No | TOPIC | Hrs |
|-------|--|-------|
| 1. | Pharmacovigilance Basics 1.1 Introduction To Pharmacovigilance (History, Need and Scope) 1.2 Terminologies used in Pharmacovigilance | 3 hrs |
| 2. | Fundamental Clinical Aspects of ADRs 2.1 Types and mechanisms of ADRs 2.2 Clinical management of ADRs. | 3 hrs |
| 3. | Current perspective of Pharmacovigilance 3.1 Pharmacovigilance Programme of India (PvPI) 3.2 Global scenario of Pharmacovigilance | 1 hr |
| 4. | ICSR's 4.1 Guidelines for Detecting and Reporting ICSR's 4.2 Content, structure and validity of reports and reporting procedures 4.3 Case Assessment 4.4 Repots related to Vaccines herbals and specific situations | 6 hrs |
| 5. | PV in Clinical Trials 5.1 Characteristics of Pharmacovigilance in Clinical Trials 5.2 Collection of Safety Data (Safety Plan, Complaint Plan) 5.3 Guidance and regulatory Framework 5.4 Risk Assessment and type of events being collected 5.5 Expedited Reporting 5.6 Role of DSMB | 5 hrs |
| 6. | Aggregate Reporting 6.1 Purpose and General Principles 6.2 Sources of Information 6.3 Types of aggregate reports across all phases of the product lifecycle 6.4 Line listings and/or Summary Tabulations 6.5 Format and contents of Aggregate reports, Template 6.6 Reporting Timelines | 5 hrs |
| 7. | Regulations and Guidelines in PV 7.1 ICH guidelines for Pharmacovigilance 7.2 Mandatory tasks and procedures from legislation at industry Expedited reporting and post approval expedited reporting, Study reports, Periodic Safety Update Reports (PSURs), Periodic Benefit Risk Evaluation Reports (PBRERs), Other documents: DSUR; RMP, REMS; renewal dossiers; reports on request 7.3 Facilities at regulatory authorities Pharmacovigilance system and SOPs, crisis management plan 7.4 Mandatory tasks and procedures from legislation at regulatory authorities ADR collection and storing in an electronic database, signal detection and management | 6 hrs |




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| | | |
|-----|--|---------------|
| 8. | Signal Detection and Management 8.1 Definition of a signal; sources, potentials, detection by non-statistical medical means 8.2 Disproportionality statistics for signal detection in spontaneous ISCR databases 8.3 Special issues in disproportionality approaches 8.4 Prioritization | 3 hrs |
| 9. | Benefit-Risk Assessment and Risk Management Planning 9.1 'Benefit-risk': definitions, methodological approaches; disease as criterion of benefit 9.2 Drug-related risks (ADRs): analyzing, weighting and combining their components 9.3 Pharmacovigilance and Risk Management Systems, Risk Management Plans (RMPs), Inspections | 3 hrs |
| 10. | Pharmacovigilance Inspections and Audits, Quality Assessment 10.1 Purpose, frequency and actors 10.2 Indicators of capacity and performance of the pharmacovigilance system 10.3 External Inspections by competitive authorities 10.4 Internal Audits in companies and regulatory authorities 10.5 Quality Assurance and benchmarking processes 10.6 Legislation and guidelines | 3 hrs |
| 11. | Tools used in Pharmacovigilance 11.1 Argus tool and its utility | 2 hrs |
| 12. | Drug Product Recalls and Field Alert Reports 12.1 Drug product recalls due to safety and efficacy reasons and other than safety and efficacy reasons. 12.2 Field alert reports. 12.3 Submission of field alert reports to drug regulatory agency | 5 hrs |
| 13. | Case Handling Activities 13.1 Causality assessment of adverse drug reactions 13.2 Case narratives 13.3 Signal detection and risk management 13.4 Argus software | 5 hrs |
| | Total Hours | 50 hrs |

REFERENCES:

1. World Health Organization, the Uppsala Centre for International Drug Monitoring. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva: World Health Organization; 2002.

2. The Uppsala Monitoring Centre. UMC Pharmacovigilance Training Course. Available from: <http://www.who-umc.org/>.



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**CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,
GUNTUR (AUTONOMOUS)**

Department of Pharmaceutical Analysis

**“SKILL DEVELOPMENT COURSE FOR III/IV B.PHARMACY AND
III/VI PHARM.D PROGRAMME”**

Academic year: 2019-2020

Topic: Synthesis, Characterization, estimation of drugs and biomolecules

Objective:

The course mainly aims at imparting additional skills to students in the area of pharmaceutical organic chemistry and medicinal chemistry. The course mainly emphasizes on calibration of basic analytical instruments, synthesis of organic compounds by parallel synthesizer, study of physicochemical parameters, drafting and filing Indian patent, application procedure for license for pharmacy and assay of drugs.

Date: 09-12-2020 to 12-12-2020

Duration: 30 hrs

Course outcomes:

- Students can able to learn the calibration of basic analytical instruments.
- Students shall get an appropriate knowledge on green synthesis of drug molecules.
- Students can able to understand the concept analysis of medicinal compounds by TLC and assay of drugs
- Students shall get an appropriate knowledge on drafting and filing procedure for Indian patent and application procedure for obtaining license for pharmacy.
- Students shall get an adequate knowledge on HPTLC and resolve the problems during research work time.
- Students can able to learn the determination of Pka value for drugs




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| S. No. | Course Content | Faculty | Duration (Hr) |
|--------|--|------------------------|---------------|
| 01 | Synthesis and characterization of benzimidazole derivatives using parallel synthesizer | Mr. G. Naga Raju | 04 |
| 02 | Calibration of basic analytical instruments (pH meter, analytical balance, UV-Visible Spectrophotometer) | Ms. P.Abhinandana | 05 |
| 03 | Analysis of medicinal compounds by TLC | Prof. K.N.Rajini Kanth | 04 |
| 04 | Assay of Glipizide tablets and assay of Amantadine HCl capsules | Mr. SK. Munwar | 04 |
| 05 | Determination of Pka value for drugs | Ms. A. Aneesha | 04 |
| 06 | Drafting and filing procedure for Indian patent and application procedure for obtaining license for pharmacy | Mr. Y.Koushik | 05 |
| 07 | Theory, principle, applications of HPTLC | Mr. P.Prachet | 04 |

Note: Examination will be conducted after completion of the course and students who secured more than 40% marks will be awarded with participation certificates)



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 Head of the Department
 Department of Pharmaceutical Analysis
 Chalapathi Institute of Pharmaceutical Sciences
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 LAM, GUNTUR-522 034.

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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
(AUTONOMOUS)

DEPARTMENT OF PHARMACOLOGY
SYLLABUS FOR SKILL DEVELOPMENT COURSE ON

“RECENT TRENDS IN EXPERIMENTAL PHARMACOLOGY AND ANALYSIS OF HERBAL
DRUGS”

Department : Pharmacology

Participants : IV/IV B.Pharmacy and III/VI Pharm D students

Duration : 30 Hrs

| COURSE OUTCOMES | |
|-----------------|--|
| CO-1 | To demonstrate the significance of CPCSEA guidelines and to demonstrate various routes of drug administration and blood collection techniques for laboratory animals |
| CO-2 | To summarize screening models for Psychotropic/neurotropic, learning and memory activities. |
| CO-3 | To interpret various preclinical models for drugs acting on CVS and PNS |
| CO-4 | To compile analysis of herbal drugs, DNA barcoding. |

- 1. CPCSEA Guidelines** 4 hrs
Goal and Objectives, Composition, activities, IAEC – Functioning, Requirements for animal house, Maintenance of Records.
- 2. Laboratory Animals** 4 hrs
Identification of animal species, sex, strain and breeding. Handling of animals, routes of administration, dosing and blood collection techniques.
- 3. Animal House Facility** 3 hrs
Environment, Physical Facilities, Animal procurement, Quarantine, Stabilization, Separation, Breeding, Housing, Maintenance of Laboratory animals, Surveillance, Diagnosis, Treatment and control of disease, Personal Hygiene.
- 4. Psychotropic and neurotropic activity:** 4 hrs
Anti-epileptic activity (electroconvulsimeter), anti-aggressive activity (agressometer), behavior (Locomotor activity –actophotometer, hole board test), anxiolytic activity (elevated plus maze, open field test), antipsychotic activity (CAR).
- 5. Nootropic or learning and memory activity:** 5 hrs
Spatial long term memory (Elevated Plus Maze), Working memory (8 Arm Radial Maze), Spatial working memory (Y Maze, Rectangular Maze), Learning, memory & reasoning (Hebbs William Maze & Labyrnth Maze).
- 6. Cardiovascular activity:** 5 hrs
Anti- hypertensive activity by non-invasive blood pressure measurement technique [NIBP]/ Invasive blood pressure measurement (2-channel physiograph), anti-hyper lipidemic activity (high fat diet induced/streptozotocin).
- 7. Analgesic activity (Eddy’s hot plate/ tail-flick analgesiometer) / anti-inflammatory activity (digital plethysmometer) / Anti-diabetic activity (alloxan/streptozotocin)/ Diuretic activity** 3 hrs
- 8. Analysis of Herbal drugs and DNA bar coding of Herbs.** 2 hrs





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Recognized by UGC2f and 12 (B) and DSIR for Scientific and Industrial Research

ISO 9001:2015 Certified Institute, Approved by All India Council of Technical Education (AICTE), Pharmacy Council of India (PCI), New Delhi and Affiliated to

DEPARTMENT OF PHARMACEUTICS

SKILL ORIENTED CERTIFICATE PROGRAM (Non-Credit) ON

ADVANCES IN FORMULATION AND EVALUATION OF NOVEL DRUG DELIVERY SYSTEMS

Scope: A short-term skill-oriented certificate program on Advances in Formulation and Evaluation of Novel Drug Delivery System shall provide practical training in the formulation and evaluation of drug delivery systems for IV/IV B Pharmacy and III/VI Pharm.D students. The objective is to impart skill to develop drug delivery systems and to meet the demand in academic and industrial environment.

Duration: 30 hours

Objectives:

- To understand the fundamentals of novel drug delivery systems (NDDS).
- To impart practical training on formulation aspect various categories of NDDS
- To study the oral, site specific and targeted drug delivery systems
- To familiarize the use of various equipment in the design and evaluation of NDDS
- To evaluate the importance of various drug delivery systems
- To interpret how the NDDS will affect therapeutic benefit to patient with change in drug release characteristics.

Program out comes: By the end of this skill development program, students get expertise in the following aspects

- A. Understand the fundamentals of novel drug delivery system.
- B. Apply the design principles and development methodologies to fabricate NDDS
- C. Experienced in the care and practices during the evaluation of NDDS.
- D. Observe the process variables and their impact on product quality.
- E. Enlighten the role of evaluation tests to ensure the product quality and performance.
- F. Acquire the ability to handle various equipment and instruments.

| S.No | Course Content | Duration (30 hr) |
|-----------------|--|------------------|
| Module-1 | Oral Controlled release systems | |
| A. | Formulation and Evaluation of sustained release (SR) matrix tablets | 2 |
| B. | Formulation and Evaluation of microcapsules by ionic gelation technique | 2 |
| C. | Formulation and Evaluation of microspheres made by solvent evaporation technique | 3 |
| D. | Formulation and Evaluation of sustained release pellets | 5 |
| E. | Formulation of extended release pellets by fluid bed coater | 3 |
| Module-2 | Site specific drug delivery systems | |
| F. | Formulation and Evaluation of floating tablets | 2 |
| G. | Formulation and Evaluation of Transdermal patches | 2 |
| Module-3 | Targeted drug delivery systems (Parenteral) | |
| H. | Formulation and evaluation of niosomes made by thin-film hydration technique | 2 |



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| | | |
|-----------------|---|---|
| Module-4 | Liquid and Topical or <i>in-situ</i> systems | |
| I. | Formulation and evaluation of in-situ gels or hydrogels | 2 |
| J. | Formulation and evaluation of micro-emulsions | 2 |
| Module-5 | Colloidal Systems | |
| k | Aerosol Formulation Development | 3 |
| L | Aerosol Filling Process | 2 |



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**CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, GUNTUR
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Department of Pharmaceutics

Skill oriented program

On

ADVANCES IN MANUFACTURING AND QUALITY CONTROL TECHNIQUES OF ORAL SOLIDS

Scope:

A short-term skill-oriented certificate program on Advances in oral solids manufacturing and Quality Control Techniques shall provide practical training in formulation and evaluation of oral solid dosage forms for III/IV B. Pharmacy students. The objective is to impart competency in students for bridging the gap between academic and industrial environment.

Module:

- Demonstration and handling of various equipment and instrument.
- Formulation of oral solid dosage forms
- Evaluation of oral solid dosage forms.

Duration: 30 hours

| S. No. | Course Content | Didactic | Duration 30 (Hrs) |
|--------|---|---------------------|-------------------|
| 1. | Formulation and Evaluation of Tablets (Conventional and Novel) | Theory Practical | 6 hrs |
| 2. | Tablet coating methodology using R & D coater (Film Coating and Sugar Coating) | Theory Practical | 4 hrs |
| 3. | In process quality control tests for tablets and capsules | Theory Practical | 2 hrs |
| 4. | Fluidized bed coating by using Fluidized Bed Processor | Theory Practical | 4 hrs |
| 5. | Palletization and Granulation by using Kalweka all-purpose equipment | Theory Practical | 2 hrs |
| 6. | Drying of materials using Spray drier | Theory Practical | 2 hrs |
| 7. | Dissolution rate testing of pharmaceutical dosage forms • Dissolution testing methodology- Compendial methods. • Dissolution data handling, Kinetics and Modelling. | Theory | 6hrs |
| 8. | PCP Disso software: Dissolution data handling and kinetics- Graphs and interpretation. | Practical | |
| 9. | In Vitro release testing and flux determination of pharmaceutical dosage forms (ointments, Gels, Transdermal Patches) | Theory Practical | 4 hrs |



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Program out comes:

By the end of this skill development program, students will be expertise in the following

1. Understand the concepts and principles involved in the manufacturing of oral solids.
2. Identify the various unit operations involved in the manufacturing of oral solids.
3. Enlighten the role of quality control tests to ensure the product quality and performance.
4. Acquire the ability to handle various equipment and instruments.
5. Gain the knowing about process variables and their impact on the product quality.

Training on following list of equipment:

| S. No | Equipment Name |
|-------|---------------------------------------|
| 1. | 16 station Rotary Compression Machine |
| 2. | Fluidized Bed Processor (FBP) |
| 3. | Spray drier |
| 4. | R and D Coater |
| 5. | Planetary Mixer |
| 6. | 48 plate- Tray drier |
| 7. | Kalweka wet granulator |
| 8. | Kalweka pelletizer |
| 9. | Double cone blender |
| 10. | Disintegration test apparatus |
| 11. | Tablet friability tester |
| 12. | USP Dissolution rate test apparatus |
| 13. | Automatic tablet hardness tester |
| 14. | 8 stage diffusion cell apparatus |

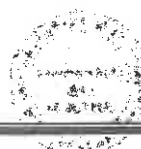


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**CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, GUNTUR
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**Department of Pharmaceutics
Skill oriented certificate program on**

Pharmaceutical Optimization and Quality by Design (QbD) in Pharmaceutical Development

Scope: A shore term skill-oriented certificate program on “**Pharmaceutical optimization and quality by design (QbD) in product development**” shall provide hands on experience to the students of I/II Pharmacy 2nd semester Pharmaceutics on fundamentals of optimization process and applying QbD approach for drug product development. The objective of this program is to render students proficient and make their career lucrative in formulative research and development.

Duration: 30 Hours

Objectives:

- To recall the concept and techniques of pharmaceutical optimization and Quality by design.
- To illustrate and classify methods and approaches of design of experiments and QbD
- To choose and apply suitable DoE to develop any product with high quality.
- To analyze and infer the results of experimentation using design expert software.
- To Justify the optimized formula with aid of statistical tools.
- To validate and maximize the results for scale up of desired formula as per DoE.

| S. No | Course Content | Duration (30Hrs) |
|-------|---|------------------|
| 1. | Pharmaceutical optimization: Need and scope, basic terminology, and approaches. | 1 hr |
| 2. | Statistics: Mean, Median, Mode, Standard deviation. Population Vs Sample | 1 hr |
| 3. | Statistics: Normal distribution, Confidence interval and estimates. | 1 hr |
| 4. | Testing of Hypothesis: Student t test. Its understanding and exercises. | 1 hr |
| 5. | Discussion on optimization: Methods from research publications. | 1 hrs |
| 6. | ANOVA: Understanding and calculation. | 2 hrs |
| 7. | Factorial Designs: Introduction and types | 1 hrs |
| 8. | Rationality of Factorial design: Quadratic equations | 1 hrs |
| 9. | Design Expert: Introduction to software and its use | 2 hrs |
| 10. | Working Exercises 1 and 2: Factorial designs using design Expert. | 3 hrs |
| 11. | Quality by Design: Introduction and scope | 4 hrs |
| 12. | QbD tools and approaches | 2 hrs |
| 13. | Case Studies 1: oral dosage form | 3 hrs |
| 14. | Case Studies 2: Liquid dosage form | 3 hrs |
| 15. | Case studies 3: Parenteral dosage form | 3 hrs |



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|-----|-----------------|------|
| 16. | Assessment Test | 1 hr |
|-----|-----------------|------|

Program out comes:

By the end of this skill development program, students will be expertise in the following

1. Understand the concepts of optimization.
2. Identify the various critical process parameters which will affect the quality of product.
3. Apply Factorial design for formulation optimization.
4. Explain QbD tools and approaches.
5. Develop QbD protocol for dosage form development.



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DEPARTMENT OF PHARMACY PRACTICE



PRADHAN MANTRI BHARATIYA JANAUSHADI KENDRA (PMBJAK)

COMMUNITY PHARMACY-ENTREPRENEURSHIP SKILL DEVELOPMENT PROGRAMME - 30 hrs

Scope: A short term skill oriented certificate programme on Community pharmacy-Entrepreneurship skills shall provide practical training on establishment of community pharmacy / Pradhan Mantri Bharatiya Janaushadhi Kendra, health screening, first aid, dispensing, inventory control, drug administration and patient counseling.

Objective: To improve entrepreneur skills of the students interested in establishing community pharmacy by training them in various activities which are required for the smooth running of community pharmacy/ Pradhan Mantri Bharatiya Janaushadhi Kendra.

Programme outcomes:


1. Understanding the process of establishment of community pharmacy and Pradhan Mantri Bharatiya Janaushadhi Kendra.
2. Acquiring the skills required to become an eminent community pharmacist having good understanding about inventory control, patient counseling, dispensing and first aid services.
3. To survey the health status of patients in the community by participating on health screening services and to build the ability to manage minor ailments.
4. To improve the professional skills about health, balance diet, family planning, health promotion and prevention of communicable diseases in community.
5. To learn to utilize the computer applications and their advantages in community pharmacy.



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| S.NO | TOPIC | Theory/ Practical | HOURS |
|------|--|----------------------|---------------|
| 1. | Documents and process for the establishment of community pharmacy/Pradhan Mantri Bharatiy Janaushadi Kendra: Need of generic medication and their importance. | Theory | 3hrs |
| 2. | Health promotion ad Health screening services: Blood pressure monitoring, BMI monitoring, Blood sugar monitoring, Blood group Determination | Theory | 3hrs |
| | | Practical | |
| 3. | Medication adherence : Medication non adherence and tools to improve medication adherence | Theory | 3hrs |
| | | Practical | |
| 4. | First aid services: First aid for leg fracture, First aid for nosebleed, First aid for burns, First aid for simple Bleeding | Theory | 3hrs |
| | | Practical | |
| 5. | Inventory control: Steps for inventory control, Inventory control methods and drug Procurement | Theory | 3hrs |
| | | Practical | |
| 6. | Dispensing of drugs: Guidelines for dispensing OTC Medication, Prescription medication, Narcotic medication. | Theory | 2hrs |
| | | Practical | |
| 7. | Responding to symptoms of minor ailments: Pain, fever, dyspepsia, diarrhea, vomiting, Constipation, and ophthalmic symptoms. | Theory | 3hrs |
| | | Practical | |
| 8. | Specialized drug administration procedures: Ear drops, Eye drops, Nasal drops, Inhalers, Trans-dermal patches and Suppositories. | Theory | 3hrs |
| | | Practical | |
| 9. | Patient counseling and communication skills required for patient counseling, Preparation of Patient Information Leaflets, Prescription Analysis | Theory | 3hrs |
| | | Practical | |
| 10. | Drug Information Services: Drug information resources, approach for answering drug information query, Critical evaluation of drug information and literature, Preparation of written and verbal reports. | Theory | 4hrs |
| | Total hours | | 30 hrs |




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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
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DEPARTMENT OF PHARMACEUTICAL ANALYSIS

SKILL ORIENTED CERTIFICATE PROGRAMME ON (2018-2019)

"INSTRUMENTATION, TROUBLE SHOOTING OF ANALYTICAL EQUIPMENT AND SPECTRAL INTERPRETATION OF ORGANIC COMPOUNDS"

(M-Pharmacy Pharmaceutical Analysis)

Scope: A short term skill oriented certificate program on "Instrumentation, Trouble shooting of Analytical Equipment and Spectral Interpretation of Organic Compounds" shall provide knowledge on instrumentation of analytical equipment, trouble shooting and interpretation. The objective of this program is to give more knowledge by making the students interactive which can lead to a successful career in pharmaceutical industrial.

Date: 05/07/2019 to 09/07/2019

Duration: 30 Hrs

Objectives:

- To recall the concepts of analytical techniques.
- To make the students gain knowledge briefly about the analytical instrumentation.
- To provide knowledge on trouble shooting.
- To make the students understand the concept of interpretation.

Course outcomes:

- Students can be able to learn the analytical knowledge on various analytical instruments and apply the new methods for drugs quantification.
- Students can be understanding the concept of interpretation and determine the structure of compound.
- Students can be able to learn the calibration analytical instruments and its importance in drugs quantification.
- Students shall get an adequate knowledge on trouble shooting of HPLC and resolve the problems her research work time.
- Students shall get an appropriate knowledge on analytical method development and validation concepts and apply the her own research work.

| S.No | Date | Topic Names | Time Duration | Faculty Name |
|------|----------|--|---------------|--------------|
| 1 | 05/07/19 | UV Visible spectrophotometer (a) Principle and instrumentation of UV Different hurdles related to UV | 5 hrs | K. Swathi |



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| | | (b) Trouble shooting methods | | |
| 2 | 05/07/19 & 06/07/19 | High performance liquid chromatography (a) Principle and instrumentation of HPLC (b) Different hurdles related to HPLC (c) Trouble shooting methods | 5 hrs | P.Abhinandana |
| 3 | 06/07/2019 | Structure elucidation using different spectras (a) Index of hydrogen deficiency (b) Rule 13 Deriving molecular formula from mass number (c) Molecular structure using different spectrums | 5 hrs | G.Naga malleswari |
| 4 | 08/07/19 | Calibration of analytical instruments (a) Importance of calibration and preparation of SOP (b) Calibration of UV, IR, HPLC, DSC (c) Calibration of analytical balance, flame photometer, KF Titrator, fluorimeter | 5 hrs | P. Prachet |
| 5 | 08/07/19 & 09/07/19 | Design and development of analytical methods and validation (a) Analytical method development and introduction to ICH guidelines (b) Analytical method validation | 5 hrs | A.Elphine prabahar |
| 6 | 09/07/19 | Design and development of analytical methods and validation (a) Analytical method development and introduction to FDA guidelines (b) Development Of Analytical Method | 5 hrs | V.Divya |



(Assessment test on skill development course will be conducted on 09/07/2019 between 04.00 PM to 05.00 PM)

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(Signature) 10/3/2018
(K.N. RAJIA KANTH)
Head of the Department
Department of Pharmaceutical Analysis
Chalapathi Institute of Pharmaceutical Sciences
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LAM, GUNTUR-522 034.



**CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
(AUTONOMOUS)**

DEPARTMENT OF PHARMACEUTICAL ANALYSIS

**SKILL ORIENTED CERTIFICATE PROGRAMME ON
INTELLECTUAL PROPERTY RIGHTS AND PATENT DRAFTING,
FILING & PROCESSING**

OBJECTIVES:

- The main objective of the IPR course is to make the students aware of their rights for protection of their invention done in their research work.
- To get IPR registration in our country and foreign states of their own invention, design and thesis or theory written by the students during their project work and for this they must have knowledge of patents, copy right, trademark, design and information technology regulations.

COURSE OUTCOMES:

1. Students can able to apply for Intellectual Property (IP) law principles to real problems and analyse the social impact of IPR policy.
2. Students shall get an adequate knowledge on patent drafting and filing for their own innovative research work.
3. Students are able to analyse ethical and professional issues which arise in the IP law context.
4. Pave the way for the students to catch up IP as a career option.

Date: 05/07/19 – 09/07/19

Duration: 30 hrs


| S.No | Date | Topic Names | Time Duration | Faculty Name |
|------|----------|--|---------------|----------------|
| 1 | 05/07/19 | Introduction to IPR <ul style="list-style-type: none">• Patent• Trademark• Copyright• Industrial Designs• Geographical Indications | 7 hrs | Mr. Y. Koushik |
| 2 | 06/07/19 | Current IP practices in India | 4 hrs | Mr. Y. Koushik |




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| S.No | Date | Topic Names | Time Duration | Faculty Name |
|------|----------|---|---------------|--------------------------|
| 3 | 06/07/19 | Prior art Search <ul style="list-style-type: none"> • ipindia.nic.in • uspto • wipo | 4 hrs | DR. N. Lakshmi Prasanthi |
| 4 | 08/07/19 | Documentation | 7 hrs | Mr. Y. Koushik |
| 5 | 08/07/19 | Establishing patentability | 5 hrs | DR. N. Lakshmi Prasanthi |
| 6 | 08/07/19 | Claims drafting and Interpretation | 3 hrs | DR. N. Lakshmi Prasanthi |




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IV/IV B.PHARMACY FOR THE ACADEMIC YEAR 2016-2017 ONWARDS

TITLE : INTERVIEW COMPETENCE AND GROUP DISCUSSIONS

No. of Hours : 30

OBJECTIVE : To create awareness of interview skills and group discussion and aid them to face the challenging corporate world.

The objective of the course is to develop the students as effective communicators and to face the corporate challenges confidently such as JAM session, interviews and group discussion. The content will prepare the student to gain entrepreneurial and leadership traits and emerge as a daring, dashing and dynamic personality in all walks of their career.

COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Understanding the purpose of professional interviews. |
| 2 | Identify the different types of professional interviews. |
| 3 | Obtain important tips on preparing for the professional interview. |
| 4 | Articulate the importance of self presentation. |

| S.No. | Contents | Prescribed hours |
|-------|--|------------------|
| 1 | Importance of Communication Skills | 2 hours |
| 2 | Importance of Soft Skills | 2 hours |
| 3 | Social Etiquette | 2 hours |
| 4 | Telephone Etiquette | 2 hours |
| 5 | Basics of JAM Skills | 2 hours |
| 6 | Basics of Interview Skills | 2 hours |
| 7 | How to face an interview board | 2 hours |
| 8 | Ten worst interview blunders | 2 hours |
| 9 | Interview skills Mock practice – Questions and Answers | 10 hours |
| 10 | Importance of Group discussion | 2 hours |
| 11 | Resume preparation | 1 hour |
| 12 | Key to success in life | 1 hour |

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| Name of the Faculty | C. Anthony Reddy, Asst. Professor in English |
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DEPARTMENT OF PHARMACY PRACTICE

**SKILL ORIENTED CERTIFICATE PROGRAMME ON
READING AND UNDERSTANDING A PRIMARY RESEARCH PAPER**

Objectives:

1. To guide research process with necessary knowledge and skills to undertake a piece of research work in the area of life sciences.
2. To train the students various methods, tools and techniques of conducting research by explaining them the methodology of various research study designs.
3. To enable Students, in developing appropriate methodology for their research studies.
4. To improve skills of critical evaluation of biomedical literature.

Programme Outcomes

1. Understanding the methods of research.
2. Acquiring knowledge on basic aspects of reading, understanding and analyzing a research paper.
3. Obtaining skills to understand presence of bias in research studies and overcoming bias.

Course content:

| S.NO | TOPIC | HOURS |
|------|--|---------------|
| 1. | Framing a research question | 2 hrs |
| 2. | Observational and experimental research | 2 hrs |
| 3. | Bias and confounding in biomedical research Types of errors in observational research | 2 hrs |
| 4. | Critical evaluation of a cohort study | 3 hrs |
| 5. | Critical evaluation of a case control study | 3 hrs |
| 6. | Critical evaluation of a cross sectional study | 3 hrs |
| 7. | Critical evaluation of a RCT | 3 hrs |
| 8. | Critical evaluation of systemic reviews | 3 hrs |
| 9. | Critical evaluation of meta analysis | 3 hrs |
| 10. | Writing literature Review and bibliography | 3 hrs |
| 11. | Determining the quality of research study | 3 hrs |
| | Total hours | 30 hrs |

Students who scored 50% or more in the assessment test will be awarded with certificate.



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DEPARTMENT OF PHARMACY PRACTICE

PROGRAMME SCHEDULE

| S.NO | Date | TOPIC | FACULTY | HOURS |
|------|------------|--|---------------------|--------|
| 1. | 21-01-2021 | Framing a research question | N.V. Rama Rao | 2 hrs |
| 2. | 21-01-2021 | Observational and experimental research | N.V. Rama Rao | 2 hrs |
| 3. | 21-01-2021 | Bias and confounding in biomedical research Types of errors in observational research | T. Sreenu | 2 hrs |
| 4. | 21-01-2021 | Critical evaluation of a cohort study | T. Jai Divya | 3 hrs |
| 5. | 22-01-2021 | Critical evaluation of a case control study | J. Venkateswara Rao | 3 hrs |
| 6. | 22-01-2021 | Critical evaluation of a cross sectional study | K. Sandeep | 3 hrs |
| 7. | 22-01-2021 | Critical evaluation of a RCT | P. Prachet | 3 hrs |
| 8. | 23-01-2021 | Critical evaluation of systemic reviews | G. Siva Bharath | 3 hrs |
| 9. | 23-01-2021 | Critical evaluation of meta analysis | G. Siva Bharath | 3 hrs |
| 10. | 23-01-2021 | Writing literature Review and bibliography | D. Eswar Tony | 3 hrs |
| 11. | 23-01-2021 | Determining the quality of research study | J. Venkateswara Rao | 3 hrs |
| 12. | | TOTAL | | 30 hrs |



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**1.3.2 & 1.3.3 Value-added courses
For the year 2018-2019**

BP 305 T

II/IV B.PHARMACY - 3RD SEMESTER
BP305T-PROFESSIONAL ETHICS AND HUMAN VALUES
(THEORY) (30 HOURS)

Scope of the Subject :

1. To bring awareness among pharmacy graduates on ethics and human values.
2. To understand and ethical theories and their application to work ethics.
3. To know various codes of ethics used by professional bodies.
4. To understand the concepts of corruption and its measures.
5. To learn about professional responsibility as a pharmacist.

Outcomes of the subject :

The student will be able to :

- a) Develop awareness on ethics and human values
- b) Become morally and socially responsible.
- c) Motivate others on moral values.

Course Outcome :

| | |
|--------|--|
| C305.1 | To remember and recall the human values and professional ethics. |
| C305.2 | To outline the ethical norms, anti corruption measures and central vigilance bodies. |
| C305.3 | To apply moral concepts and reasoning in pharmacy. |
| C305.4 | To discover ethical issues in clinical pharmacy practice and manufacturing of pharmaceutical products. |
| C305.5 | To appraise professional societies and various pharmaceutical associations. |
| C305.6 | To adapt social pharmacy and code of pharmaceutical ethics. |

Course Content:

| TOPIC | Duration (hrs) | References |
|--|----------------|---|
| UNIT-I Human Values: Morals, Values and ethics-Integrity-Work ethics-Service learning, Civic virtue, Respect for others, Living Peacefully-Caring, Sharing, Honesty, Courage, Valuing time, Co-operations, Commitment, Empathy, Self confidence, Character and Spirituality. | 04 | R.S.Naagarazan professional ethics and Human values edition I, New Age International Pvt. Ltd., edition -1, Chapter-1 |
| UNIT-II Introduction to professional ethics, corruption and its measures: Need of ethics in pharmacy, changing times, RPSGB guidance, ethical norms, moral relativism, facts and values; ethical theories and concepts. Corruption i | 05 | Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceutical press, Edition I, Chapter-I. |



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public life, economic impact of corruption, payments that equate supply and demand; bribes as incentive payments, bribes to reduce costs, organized crime and corruption. Anti-corruption measures – Anti corruption Bureau (ACB), Central Vigilance Commission (CVC), Central Bureau of Investigation (CBI), lokadalats, Ombudsman, Comptroller and auditor general (CAG) and right to information.

UNIT-III

Moral concepts and reasoning in

Pharmacy: Moral issues, rational inquires, moral autonomy, moral reasoning and pharmacist, moral development theories, justice and human rights, trust and truthfulness and moral dilemmas

05

1.R.S.Naagarazan professional ethics and Human values edition I, New Age International Pvt. Ltd., edition -1, Chapter-2
2.Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceutical press, Edition I, Chapter-4.

UNIT-IV

Professionalism and Industrial

ethics: Pharmacy and professionalism, ethical basis in professionalism and accountability, industrial ethics, pharmacist in different clusters with different ethical issues – ethical issues in clinical pharmacy practice, community pharmacy and manufacturing of pharmaceutical products.

05

1.Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceutical press, Edition I, Chapter-4
2.R.S.Naagarazan professional ethics and Human values edition I, New Age International Pvt. Ltd., edition -1, Chapter-2

UNIT-V

Professional societies and various pharmaceutical associations:

Indian Pharmaceutical Congress Association, Indian Pharmaceutical Association, Indian Hospital Pharmacists Association, Indian Pharmacy Graduates Association, Association of Pharmaceutical Teachers of India, The All India Drug Control Officers Confederation, Indian Society for Technical Education, National Pharmaceutical Pricing Authority and other allied professional societies/associations.

06

1. Professional Pharmacy- M.L.Schroff
2. Harikishan Singh: History of Pharmacy in India and related aspects, Volume-I, II and III Pharmacopoeias and formularies, 1st Edition, Vallabh Prakashan, 2005



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UNIT-V**Social Pharmacy and code of Pharmaceutical ethics:**

The Concept and context of social pharmacy, principles of ethics, Morality, ethical codes, Pharmaceutical Ethics in relation to job, trade, profession and medical profession. Pharmacist Oath.

05

1.N.K.Jain, Forensic Pharmacy, Eight edition, 2014, 484-492.
2.B.M.Mithal, A Text book of Forensic Pharmacy, Valla Prakashan, 10th edition, Chapter-14

Further Readings:

01. NK Jain, Health Education and community Pharmacyby , CBS, Publ. and Distributors, New Delhi.
02. R.M.Metha, Dispensing pharmacy
03. Pharmacoethics: A problem based approach by G.Vidya Sagar
04. Gupta AK, Health Education and Community Pharmacy, CBS, Publ. and Distribution, New Delhi.



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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

CHALAPATHI NAGAR, LAM, GUNTUR - 522034

II/IV B.PHARMACY FOR THE ACADEMIC YEAR 2014-2015 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To create awareness of communication skills and human refinement ideologies to a student in the right perspective.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.

COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English | 3 hours |
| 2 | Importance of Communication Skills | 2 hours |
| 3 | Qualities of a speaker / listener | 2 hours |
| 4 | How to speak without fear-Mock practice | 10 hours |
| 5 | Importance of soft skills | 3 hours |
| 6 | Qualities / Duties of a student | 2 hours |
| 7 | Social Etiquette | 2 hours |
| 8 | Telephone Etiquette | 2 hours |
| 9 | Successful tips for exams | 2 hours |
| 10 | Behavioural approach and attitude | 2 hours |

Name of the Faculty **C. Anthony Reddy, Asst. Professor in English**



Anthony Reddy
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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

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I/IV B.PHARMACY FROM THE ACADEMIC YEAR 2015-2016 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To create awareness of communication skills and human refinement ideologies to a student in the right perspective.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.

COURSE OUTCOMES: On completion of the course, student will be able to


| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English | 2 hours |
| 2 | Importance of Communication Skills | 2 hours |
| 3 | Qualities of a speaker / listener | 2 hours |
| 4 | How to speak without fear-Mock practice | 10 hours |
| 5 | Importance of soft skills | 4 hours |
| 6 | Qualities / Duties of a student | 2 hours |
| 7 | Social Etiquette | 2 hours |
| 8 | Telephone Etiquette | 2 hours |
| 9 | Successful tips for exams | 2 hours |
| 10 | Behavioural approach and attitude | 2 hours |

Name of the Faculty

C. Anthony Reddy, Asst. Professor in English




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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

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III/IV B.PHARMACY FOR THE ACADEMIC YEAR 2016-2017 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To enhance communication skills, value of group discussions and global exposure.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.

COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English and Communication Skills | 2 hours |
| 2 | Qualities of a speaker / listener | 2 hours |
| 3 | Importance of Soft skills | 2 hours |
| 4 | Importance of Viva voce skills | 2 hours |
| 5 | Speaking / Writing tasks | 6 hours |
| 6 | Human Refinement tips | 2 hours |
| 7 | Mnemonics (memory tips) | 2 hours |
| 8 | Group discussions | 4 hours |
| 9 | Extempore practice | 4 hours |
| 10 | Presentation skills | 4 hours |

| | |
|---------------------|--|
| Name of the Faculty | C. Anthony Reddy, Asst. Professor in English |
|---------------------|--|




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2018-19

2016-2017 — 100/100
2017-2018
2019-2020



CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR.

(AUTONOMOUS)

DEPARTMENT OF PHARMACY PRACTICE

CERTIFICATE COURSE IN PHARMACOVIGILANCE – 50 Hrs

Scope of the course:

This course will help students acquire a basic understanding of the concepts and practices in the field of Pharmacovigilance. This course is intended to sensitize students and equip them with knowledge on Pharmacovigilance practices worldwide and on the Indian scenario in detail. This course is intended to enrich the knowledge of Pharmacovigilance among students. This course will enable the students to better understand the requirements within the Pharmacovigilance industry and government organization in India in the aspects of patient safety.

Objectives:

1. To provide the basic knowledge of pharmacovigilance.
2. To understand risk assessment and type of events being collected.
3. To become familiar in pharmacovigilance and risk management systems, risk management plans, inspections.
4. To understand the utility of Argus software.
5. To understand pharmacovigilance inspections and audits quality assessment.

Programme outcomes:

1. To benefit the patient care and safety in relation to the use of medicines and their interventions.
2. Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public and health care professionals.
3. Contribute to the assessment of risk, benefit and effectiveness medicines.
4. To detect problems related to the use of medicines and communicate the findings in a timely manner.
5. Encourage the safe rational and more effective medicines to improve public health.



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COURSE CONTENT

| S. No | TOPIC | Hrs |
|-------|--|-------|
| 1. | Pharmacovigilance Basics 1.1 Introduction To Pharmacovigilance (History, Need and Scope) 1.2 Terminologies used in Pharmacovigilance | 3 hrs |
| 2. | Fundamental Clinical Aspects of ADRs 2.1 Types and mechanisms of ADRs 2.2 Clinical management of ADRs. | 3 hrs |
| 3. | Current perspective of Pharmacovigilance 3.1 Pharmacovigilance Programme of India (PvPI) 3.2 Global scenario of Pharmacovigilance | 1 hr |
| 4. | ICSR's 4.1 Guidelines for Detecting and Reporting ICSR's 4.2 Content, structure and validity of reports and reporting procedures 4.3 Case Assessment 4.4 Repots related to Vaccines herbals and specific situations | 6 hrs |
| 5. | PV in Clinical Trials 5.1 Characteristics of Pharmacovigilance in Clinical Trials 5.2 Collection of Safety Data (Safety Plan, Complaint Plan) 5.3 Guidance and regulatory Framework 5.4 Risk Assessment and type of events being collected 5.5 Expedited Reporting 5.6 Role of DSMB | 5 hrs |
| 6. | Aggregate Reporting 6.1 Purpose and General Principles 6.2 Sources of Information 6.3 Types of aggregate reports across all phases of the product lifecycle 6.4 Line listings and/or Summary Tabulations 6.5 Format and contents of Aggregate reports, Template 6.6 Reporting Timelines | 5 hrs |
| 7. | Regulations and Guidelines in PV 7.1 ICH guidelines for Pharmacovigilance 7.2 Mandatory tasks and procedures from legislation at industry Expedited reporting and post approval expedited reporting, Study reports, Periodic Safety Update Reports (PSURs), Periodic Benefit Risk Evaluation Reports (PBRERs), Other documents: DSUR; RMP, REMS; renewal dossiers; reports on request 7.3 Facilities at regulatory authorities Pharmacovigilance system and SOPs, crisis management plan 7.4 Mandatory tasks and procedures from legislation at regulatory authorities ADR collection and storing in an electronic database, signal detection and management | 6 hrs |




| | | |
|-----|--|---------------|
| 8. | Signal Detection and Management 8.1 Definition of a signal; sources, potentials, detection by non-statistical medical means 8.2 Disproportionality statistics for signal detection in spontaneous ISCR databases 8.3 Special issues in disproportionality approaches 8.4 Prioritization | 3 hrs |
| 9. | Benefit-Risk Assessment and Risk Management Planning 9.1 'Benefit-risk': definitions, methodological approaches; disease as criterion of benefit 9.2 Drug-related risks (ADRs): analyzing, weighting and combining their components 9.3 Pharmacovigilance and Risk Management Systems, Risk Management Plans (RMPs), Inspections | 3 hrs |
| 10. | Pharmacovigilance Inspections and Audits, Quality Assessment 10.1 Purpose, frequency and actors 10.2 Indicators of capacity and performance of the pharmacovigilance system 10.3 External Inspections by competitive authorities 10.4 Internal Audits in companies and regulatory authorities 10.5 Quality Assurance and benchmarking processes 10.6 Legislation and guidelines | 3 hrs |
| 11. | Tools used in Pharmacovigilance 11.1 Argus tool and its utility | 2 hrs |
| 12. | Drug Product Recalls and Field Alert Reports 12.1 Drug product recalls due to safety and efficacy reasons and other than safety and efficacy reasons. 12.2 Field alert reports. 12.3 Submission of field alert reports to drug regulatory agency | 5 hrs |
| 13. | Case Handling Activities 13.1 Causality assessment of adverse drug reactions 13.2 Case narratives 13.3 Signal detection and risk management 13.4 Argus software | 5 hrs |
| | Total Hours | 50 hrs |

REFERENCES:

1. World Health Organization, the Uppsala Centre for International Drug Monitoring. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva: World Health Organization; 2002.
2. The Uppsala Monitoring Centre. UMC Pharmacovigilance Training Course. Available from: <http://www.who-umc.org/>.




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**CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,
GUNTUR (AUTONOMOUS)**

Department of Pharmaceutical Analysis

“SKILL DEVELOPMENT COURSE FOR II/IV B.PHARMACY PROGRAMME”

Academic year: 2018-2019

Topic: Synthesis, Characterization, estimation of drugs and biomolecules

Objective:

The course mainly aims at imparting additional skills to students in the area of pharmaceutical organic chemistry, biochemistry and medicinal chemistry. The course mainly emphasizes on construction of stereo models, calibration of apparatus, synthesis of organic compounds by conventional and microwave assisted techniques, study of physicochemical parameters and estimation of biomolecules in body fluids.

Date: 05-07-2019 to 09-07-2019

Duration: 30 hrs

Course outcomes:

- Students can able to recall the structure of molecules by using ball and stick stereomodels.
- Students can able to learn the calibration of equipments and glassware.
- Students shall get an appropriate knowledge on green synthesis of drug molecules.
- Students can able to understand the concept of filtration techniques and purification of compounds.
- Students shall get an appropriate knowledge on estimation of bio-molecules in blood




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| S. No. | Course Content | Faculty | Duration (Hr) | Lab No |
|--------|--|------------------------|---------------|--------|
| 01 | Stereo models of organic compounds & Demo on synthesizing the drugs using parallel synthesizer | Mr. G.Naga Raju | 04 | 202 |
| 02 | Calibration of equipments and glassware | Mrs. S.Radhika | 03 | 413 |
| 03 | Purification and characterization of organic compounds by Crystallization and Distillation | Prof. K.N.Rajini Kanth | 04 | 204 |
| 04 | Filtration techniques and Mixed melting point | Prof. K.N.Rajini Kanth | 03 | 202 |
| 05 | Synthesis of organic compounds by Two-step process | Mr. Sk.Munwar | 04 | 303 |
| 06 | Synthesis of organic compounds by Microwave irradiation technique & Determination of partition co-efficient and Log P value of drugs | Ms. A. Aneesha | 04 | 204 |
| 07 | Estimation of bio-molecules in blood (Cholesterol & Creatinine) | Dr. J.Venkateswar Rao | 04 | 207 |
| 08 | Estimation of bio-molecules in blood (Glucose & SGPT/SGOT) | Dr. T.Jai Divya | 04 | 207 |

(Note: Examination will be conducted after completion of the course and students who secured more than 40% marks will be awarded with participation certificates)




 19/3/2018
 (K.N. Rajini Kanth)
 Head of the Department
 Department of Pharmaceutical Analysis
 Chalapathi Institute of Pharmaceutical Sciences
 (Autonomous)
 LAM, GUNTUR-522 034.


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**CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, GUNTUR
(AUTONOMOUS)**

Department of Pharmaceutics

Skill oriented program

On

ADVANCES IN MANUFACTURING AND QUALITY CONTROL TECHNIQUES OF ORAL SOLIDS

Scope:

A short-term skill-oriented certificate program on Advances in oral solids manufacturing and Quality Control Techniques shall provide practical training in formulation and evaluation of oral solid dosage forms for III/IV B. Pharmacy students. The objective is to impart competency in students for bridging the gap between academic and industrial environment.

Module:

- Demonstration and handling of various equipment and instrument.
- Formulation of oral solid dosage forms
- Evaluation of oral solid dosage forms.

Duration: 30 hours

| S. No. | Course Content | Didactic | Duration 30 (Hrs) |
|--------|---|---------------------|-------------------|
| 1. | Formulation and Evaluation of Tablets (Conventional and Novel) | Theory Practical | 6 hrs |
| 2. | Tablet coating methodology using R & D coater (Film Coating and Sugar Coating) | Theory Practical | 4 hrs |
| 3. | In process quality control tests for tablets and capsules | Theory Practical | 2 hrs |
| 4. | Fluidized bed coating by using Fluidized Bed Processor | Theory Practical | 4 hrs |
| 5. | Palletization and Granulation by using Kalweka all-purpose equipment | Theory Practical | 2 hrs |
| 6. | Drying of materials using Spray drier | Theory Practical | 2 hrs |
| 7. | Dissolution rate testing of pharmaceutical dosage forms • Dissolution testing methodology- Compendial methods. • Dissolution data handling, Kinetics and Modelling. | Theory | 6hrs |
| 8. | PCP Disso software: Dissolution data handling and kinetics- Graphs and interpretation | Practical | |
| 9. | In Vitro release testing and flux determination of pharmaceutical dosage forms (ointments, Gels, Transdermal Patches) | Theory Practical | 4 hrs |



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Program outcomes:

By the end of this skill development program, students will be expert in the following

1. Understand the concepts and principles involved in the manufacturing of oral solids.
2. Identify the various unit operations involved in the manufacturing of oral solids.
3. Enlighten the role of quality control tests to ensure the product quality and performance.
4. Acquire the ability to handle various equipment and instruments.
5. Gain the knowing about process variables and their impact on the product quality.

Training on following list of equipment:

| S. No | Equipment Name |
|-------|---------------------------------------|
| 1. | 16 station Rotary Compression Machine |
| 2. | Fluidized Bed Processor (FBP) |
| 3. | Spray drier |
| 4. | R and D Coater |
| 5. | Planetary Mixer |
| 6. | 48 plate- Tray drier |
| 7. | Kalweka wet granulator |
| 8. | Kalweka pelletizer |
| 9. | Double cone blender |
| 10. | Disintegration test apparatus |
| 11. | Tablet friability tester |
| 12. | USP Dissolution rate test apparatus |
| 13. | Automatic tablet hardness tester |
| 14. | 8 stage diffusion cell apparatus |



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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM GUNTUR- 522034

(Autonomous); NAAC- A Grade and NBA (B. Pharmacy) Accredited Institute

Recognized by UGC2f and 12 (B) and DSIR for Scientific and Industrial Research

ISO 9001:2015 Certified Institute, Approved by All India Council of Technical Education (AICTE), Pharmacy Council of India (PCI), New Delhi and Affiliated to

DEPARTMENT OF PHARMACEUTICS

SKILL ORIENTED CERTIFICATE PROGRAM (Non-Credit) ON

ADVANCES IN FORMULATION AND EVALUATION OF NOVEL DRUG DELIVERY SYSTEMS

Scope: A short-term skill-oriented certificate program on Advances in Formulation and Evaluation of Novel Drug Delivery System shall provide practical training in the formulation and evaluation of drug delivery systems for IV/IV B Pharmacy and III/VI Pharm.D students. The objective is to impart skill to develop drug delivery systems and to meet the demand in academic and industrial environment.

Duration: 30 hours

Objectives:

- To understand the fundamentals of novel drug delivery systems (NDDS).
- To impart practical training on formulation aspect various categories of NDDS
- To study the oral, site specific and targeted drug delivery systems
- To familiarize the use of various equipment in the design and evaluation of NDDS
- To evaluate the importance of various drug delivery systems
- To interpret how the NDDS will affect therapeutic benefit to patient with change in drug release characteristics.

Program outcomes: By the end of this skill development program, students get expertise in the following aspects

- Understand the fundamentals of novel drug delivery system.
- Apply the design principles and development methodologies to fabricate NDDS
- Experienced in the care and practices during the evaluation of NDDS.
- Observe the process variables and their impact on product quality.
- Enlighten the role of evaluation tests to ensure the product quality and performance.
- Acquire the ability to handle various equipment and instruments.

| S.No | Course Content | Duration (30 hr) |
|-----------------|--|------------------|
| Module-1 | Oral Controlled release systems | |
| A. | Formulation and Evaluation of sustained release (SR) matrix tablets | 2 |
| B. | Formulation and Evaluation of microcapsules by ionic gelation technique | 2 |
| C. | Formulation and Evaluation of microspheres made by solvent evaporation technique | 3 |
| D. | Formulation and Evaluation of sustained release pellets | 5 |
| E. | Formulation of extended release pellets by fluid bed coater | 3 |
| Module-2 | Site specific drug delivery systems | |
| F. | Formulation and Evaluation of floating tablets | 2 |
| G. | Formulation and Evaluation of Transdermal patches | 2 |
| Module-3 | Targeted drug delivery systems (Parenteral) | |
| H. | Formulation and evaluation of niosomes made by thin-film hydration technique | 2 |



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DEPARTMENT OF PHARMACEUTICS

| Module-4 | Liquid and Topical or <i>in-situ</i> systems | |
|----------|--|---|
| I. | Formulation and evaluation of <i>in-situ</i> gels or hydrogels | 2 |
| J. | Formulation and evaluation of micro-emulsions | 2 |
| Module-5 | Colloidal Systems | |
| k | Aerosol Formulation Development | 3 |
| L | Aerosol Filling Process | 2 |



10/07/2022
12/8/2022

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**CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
(AUTONOMOUS)**

DEPARTMENT OF PHARMACEUTICAL ANALYSIS, (2018-2019)
SKILL ORIENTED CERTIFICATE PROGRAMME ON *onwards*

“INSTRUMENTATION, TROUBLE SHOOTING OF ANALYTICAL EQUIPMENT AND SPECTRAL INTERPRETATION OF ORGANIC COMPOUNDS”

(IV.B. Pharmacy and III phchem-D programmes)
Scope: A short term skill oriented certificate program on “Instrumentation, Trouble shooting of Analytical Equipment and Spectral Interpretation of Organic Compounds” shall provide knowledge on instrumentation of analytical equipment, trouble shooting and interpretation. The objective of this program is to give more knowledge by making the students interactive which can lead to a successful career in pharmaceutical industrial.

Date: 03/09/2018 to 06/09/2018

Duration: 30 Hrs

Objectives:

- To explain the different analytical techniques employed in analysing drugs and pharmaceuticals.
- To provide practical skills for the students to identify and quantify drugs in formulations.
- To train the students in the area of calibration and trouble shooting of analytical equipment's.

Course outcomes:

- Students can be able to learn the analytical knowledge on various analytical instruments and apply the new methods for drugs quantification.
- Students can be understanding the concept of interpretation and determine the structure of compound.
- Students can be able to learn the calibration analytical instruments and its importance in drugs quantification.
- Students shall get an adequate knowledge on trouble shooting of HPLC and resolve the problems her research work time.
- Students shall get an appropriate knowledge on analytical method development and validation concepts and apply the her own research work.



| S.No | Date | Topic Names | Time Duration | Faculty Name |
|------|----------|---|---------------|---|
| 1 | 03/09/18 | UV Visible spectrophotometer (a): Principle and instrumentation of UV Different hurdles related to UV (b) Trouble shooting methods | 5 hrs | <i>K. Swathi</i> PRINCIPAL Chalapathi Institute of Pharmaceutical Sciences (Autonomous) Chalapathi Nagar LAM, GUNTUR-34 |

| | | | | |
|---|---------------------------|---|-------|-------------------|
| 2 | 03/09/18 & 04/09/18 | High performance liquid chromatography (a) Principle and instrumentation of HPLC (b) Different hurdles related to HPLC (c) Trouble shooting methods | 5 hrs | P.Abhinandana |
| 3 | 04/09/2018 | Structure elucidation using different spectras (a) Index of hydrogen deficiency (b) Rule 13 Deriving molecular formula from mass number (c) Molecular structure using different spectrums | 5 hrs | G.Naga mallewari |
| 4 | 05/09/18 | Calibration of analytical instruments (a) Importance of calibration and preparation of SOP (b) Calibration of UV, IR, HPLC, DSC (c) Calibration of analytical balance, flame photometer, KF Titrator, fluorimeter | 5 hrs | P. Prachet |
| 5 | 05/09/18 & 06/09/18 | Design and development of analytical methods and validation (a) Analytical method development and introduction to ICH guidelines (b) Analytical method validation | 5 hrs | A.Elphine prabhar |
| 6 | 06/09/18 | Design and development of analytical methods and validation (a) Analytical method development and introduction to FDA guidelines (b) Development Of Analytical Method | 5 hrs | V.Divya |

(Assessment test on skill development course will be conducted on 06/09/2018 between 04.00 PM to 05.00 PM)



Leena
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Chalapathi Institute of Pharmaceutical Sciences
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Chalapathi Nagar - LAM, GUNTUR-34

Dr. N. Rajini Karthi
19/8/2018
Dr. N. RAJINI KARTHI
Head of the Department
Department of Pharmaceutical Analysis
Chalapathi Institute of Pharmaceutical Sciences
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LAM, GUNTUR-522 034.



CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
(AUTONOMOUS)

DEPARTMENT OF PHARMACEUTICAL ANALYSIS
SKILL ORIENTED CERTIFICATE PROGRAMME ON

INTELLECTUAL PROPERTY RIGHTS AND PATENT DRAFTING,

FILING & PROCESSING

(A-Y. 2018-2019)
ONWARDS

DATE: 05/07/2019 to 09/07/2019

(M. PHARMACY PHARM. REGULATORY AFFAIRS)

OBJECTIVES:

- The main objective of the IPR course is to make the students aware of their rights for protection of their invention done in their research work.
- To get IPR registration in our country and foreign states of their own invention, design and thesis or theory written by the students during their project work and for this they must have knowledge of patents, copy right, trademark, design and information technology regulations.


COURSE OUTCOMES:

1. Students can able to apply for Intellectual Property (IP) law principles to real problems and analyse the social impact of IPR policy.
2. Students shall get an adequate knowledge on patent drafting and filing for their own innovative research work.
3. Students are able to analyse ethical and professional issues which arise in the IP law context.
4. Pave the way for the students to catch up IP as a career option.

Duration: 30 hrs

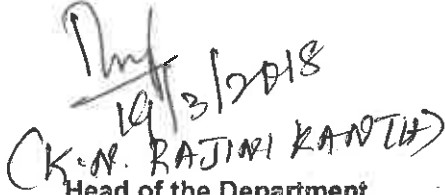
| S.No | Topic Names | Time Duration |
|------|--|---------------|
| 1 | Introduction to IPR <ul style="list-style-type: none">• Patent• Trademark• Copyright• Industrial Designs• Geographical Indications | 7 hrs |
| 2 | Current IP practices in India | 4 hrs |





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| S.No | Topic Names | Time Duration |
|------|--|---------------|
| 3 | Prior art Search <ul style="list-style-type: none"> • ipindia.nic.in • uspto • wipo | 4 hrs |
| 4 | Documentation | 7 hrs |
| 5 | Establishing patentability | 5 hrs |
| 6 | Claims drafting and Interpretation | 3 hrs |




 19/3/2018
 K. R. RAJINI KANTU
 Head of the Department
 Department of Pharmaceutical Analysis
 Chalapathi Institute of Pharmaceutical Sciences
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 LAM, GUNTUR-522 034.


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DEPARTMENT OF PHARMACY PRACTICE



PRADHAN MANTRI BHARATIYA JANAUSHADI KENDRA (PMBJAK)

COMMUNITY PHARMACY-ENTREPRENEURSHIP SKILL DEVELOPMENT PROGRAMME - 30 hrs

Scope: A short term skill oriented certificate programme on Community pharmacy-Entrepreneurship skills shall provide practical training on establishment of community pharmacy / Pradhan Mantri Bharatiya Janaushadhi Kendra, health screening, first aid, dispensing, inventory control, drug administration and patient counseling.

Objective: To improve entrepreneur skills of the students interested in establishing community pharmacy by training them in various activities which are required for the smooth running of community pharmacy/ Pradhan Mantri Bharatiya Janaushadhi Kendra.

Programme outcomes:

1. Understanding the process of establishment of community pharmacy and Pradhan Mantri Bharatiya Janaushadhi Kendra.
2. Acquiring the skills required to become an eminent community pharmacist having good understanding about inventory control, patient counseling, dispensing and first aid services.
3. To survey the health status of patients in the community by participating on health screening services and to build the ability to manage minor ailments.
4. To improve the professional skills about health, balance diet, family planning, health promotion and prevention of communicable diseases in community.
5. To learn to utilize the computer applications and their advantages in community pharmacy.



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| S.NO | TOPIC | Theory/ Practical | HOURS |
|------|--|----------------------|---------------|
| 1. | Documents and process for the establishment of community pharmacy/Pradhan Mantri Bharatiy Janaushadi Kendra: Need of generic medication and their importance. | Theory | 3hrs |
| 2. | Health promotion ad Health screening services: Blood pressure monitoring, BMI monitoring, Blood sugar monitoring, Blood group Determination | Theory | 3hrs |
| | | Practical | |
| 3. | Medication adherence : Medication non adherence and tools to improve medication adherence | Theory | 3hrs |
| | | Practical | |
| 4. | First aid services: First aid for leg fracture, First aid for nosebleed, First aid for burns, First aid for simple Bleeding | Theory | 3hrs |
| | | Practical | |
| 5. | Inventory control: Steps for inventory control, Inventory control methods and drug Procurement | Theory | 3hrs |
| | | Practical | |
| 6. | Dispensing of drugs: Guidelines for dispensing OTC Medication, Prescription medication, Narcotic medication. | Theory | 2hrs |
| | | Practical | |
| 7. | Responding to symptoms of minor ailments: Pain, fever, dyspepsia, diarrhea, vomiting, Constipation, and ophthalmic symptoms. | Theory | 3hrs |
| | | Practical | |
| 8. | Specialized drug administration procedures: Ear drops, Eye drops, Nasal drops, Inhalers, Trans-dermal patches and Suppositories. | Theory | 3hrs |
| | | Practical | |
| 9. | Patient counseling and communication skills required for patient counseling, Preparation of Patient Information Leaflets, Prescription Analysis | Theory | 3hrs |
| | | Practical | |
| 10. | Drug Information Services: Drug information resources, approach for answering drug information query, Critical evaluation of drug information and literature, Preparation of written and verbal reports. | Theory | 4hrs |
| | Total hours | | 30 hrs |



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2017-2018

2018-2019



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DEPARTMENT OF PHARMACOLOGY
SYLLABUS FOR SKILL DEVELOPMENT COURSE ON

“RECENT TRENDS IN EXPERIMENTAL PHARMACOLOGY”

Department : Pharmacology

Participants : IV/IV B.Pharmacy and III/VI Pharm D students

Duration : 30 Hrs

| COURSE OUTCOMES | |
|-----------------|--|
| CO-1 | To demonstrate the significance of CPCSEA guidelines and to demonstrate various routes of drug administration and blood collection techniques for laboratory animals |
| CO-2 | To summarize screening models for Psychotropic/neurotropic, learning and memory activities. |
| CO-3 | To interpret the advanced methods of screening for Learning and Memory activity |
| CO-4 | To compile various preclinical models for drugs acting on CVS and PNS |

- CPCSEA Guidelines** 4 hrs
Goal and Objectives, Composition, activities, IAEC – Functioning, Requirements for animal house, Maintenance of Records.
- Laboratory Animals** 4 hrs
Identification of animal species, sex, strain and breeding. Handling of animals, routes of administration, dosing and blood collection techniques.
- Animal House Facility** 4 hrs
Environment, Physical Facilities, Animal procurement, Quarantine, Stabilization, Separation, Breeding, Housing, Maintenance of Laboratory animals, Surveillance, Diagnosis, Treatment and control of disease, Personal Hygiene.
- Psychotropic and neurotropic activity:** 5 hrs
Anti-epileptic activity (electroconvulsimeter), anti-aggressive activity (agressometer), behavior (Locomotor activity –actophotometer, hole board test), anxiolytic activity (elevated plus maze, open field test), antipsychotic activity (CAR).
- Nootropic or learning and memory activity:** 5 hrs
Spatial long term memory (Elevated Plus Maze), Working memory (8 Arm Radial Maze), Spatial working memory (Y Maze, Rectangular Maze), Learning, memory & reasoning (Hebbs William Maze & Labyrnth Maze).
- Cardiovascular activity:** 5 hrs
Anti- hypertensive activity by non-invasive blood pressure measurement technique [NIBP]/Invasive blood pressure measurement (2-channel physiograph), anti-hyperlipidemic activity (high fat diet induced/streptozotocin).
- Analgesic activity (Eddy’s hot plate/ tail flick analgesiometer) / anti-inflammatory activity (digital plethysmometer) / anti-diabetic activity (alloxan/streptozotocin) Diuretic activity** 3 hrs



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What are occupational standards (OS)?

OS describe what individuals need to do, know and understand in order to carry out a particular job role or function

OS are performance standards that individuals must achieve when carrying out functions in the workplace, together with specifications of the underpinning knowledge and understanding



Contents

1. Introduction and Contacts.....
2. Qualifications Pack.....
3. Glossary of Key Terms
4. NOS Units.....
5. Annexure: Nomenclature for QP &.....
6. Assessment Criteria.....

Introduction

Qualifications Pack-Drug Regulatory Affairs Chemist

SECTOR: LIFE SCIENCES

SUB-SECTOR: PHARMACEUTICAL AND BIOPHARMACEUTICAL

OCCUPATION: RESEARCH AND DEVELOPMENT

REFERENCE ID: LFS/Q0501

ALIGNED TO: NCO-2004/NIL

Drug Regulatory Affairs Chemist prepares dossiers to support approval, licensing, marketing and legal compliance of products, ensure products comply with regulations and carry out proper documentation and reporting.

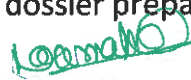
Brief Job Description: DRA Chemists are responsible for making applications submitted to the various markets and also ensure completion for forms and carry out filling of regulatory forms.

Personal Attributes: The individual should have good knowledge of the Pharmaceutical industry. He should have good documentation skills and understanding of regulatory and ethical frameworks. He should be well versed with compliance and statutory requirements for dossier preparations.

Contact Us:
New Delhi

E-mail:




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| | | | |
|--------------------------|--------------------------------------|------------------|----------|
| Qualifications Pack Code | LFS/Q0501 | | |
| Job Role | Drug Regulatory Affairs Chemist | | |
| Credits(NSQF) | TBD | Version number | |
| Industry | Life Sciences | Drafted on | 9/12/14 |
| Sub-sector | Pharmaceutical and Biopharmaceutical | Last reviewed on | 25/02/15 |
| Occupation | Research and Development | Next review date | 25/02/16 |
| NSQC Clearance on | 20/07/2015 | | |

| | |
|--|---|
| Job Role | Drug Regulatory Affairs Chemist |
| Role Description | Responsible for making dossiers to be submitted to the various markets and also fill forms and take regulatory permission forms. |
| NSQF level | 5 |
| Minimum Educational Qualifications | Mechanical & Chemical Engineering/ Graduate in Science/ B.Pharmacy (Preferable) |
| Maximum Educational Qualifications | Masters in science/ M. Pharmacy (Preferable) |
| Training (Suggested but not mandatory) | On the job training, On the job training, GLP Training |
| Minimum Job Entry Age | 20 Years |
| Experience | 0-2 years (if company is making only CTD), else 1-3 years experience |
| Applicable National Occupational Standards (NOS) | <p>Compulsory:</p> <ol style="list-style-type: none"> 1. LFS/N0501: Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products. 2. LFS/N0503: Ensure that the products comply with the regulations 3. LFS/N0502: Carryout reporting and documentation for dossier preparation 4. LFS/N0105: Coordinate with manager and team members for smooth functioning |



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LFS/N0501 : Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products

National Occupational Standard

| | |
|---|--|
| Unit Code | LFS/N0501 |
| Unit Title (Task) | Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products. |
| Description | This NOS is about a DRA chemist to ensure appropriate licensing, marketing and compliance of pharmaceutical and medical products |
| Scope | The unit/task covers the following: <ul style="list-style-type: none"> • Preparing protocols and reports to ensure compliance for licensing activities • Assisting scientists and manufacturers on regulatory requirements |
| Performance Criteria (PC) w.r.t. the Scope | |
| Element | Performance Criteria |
| Licensing Activities | To be competent, the user/individual on the job must be able to: <p>PC1. prepare documents, non-conformance reports and corrective action preventative action documents for current products and procedures to ensure compliance with applicable regulation</p> <p>PC2. develop and write clear arguments and explanations for new product licence and licence renewals</p> <p>PC3. monitor and set timelines for licence variations and renewal approvals</p> <p>PC4. write clear, accessible product labels and patient information leaflets</p> <p>PC5. undertake and manage regulatory inspections</p> <p>PC6. prepare dossiers/ documents for IND, NDA, ANDA, CTD Submissions and all support registrations of the new entities</p> <p>PC7. liaison with, and make presentations to, regulatory authorities</p> <p>PC8. develop and register new medicines, vaccines, diagnostic tests and pharmaceutical products with regulatory authorities like MHRA, MCC, USFDA, TGA, Malaysia, European Union etc in concurrence with the regulations promulgated by a whole range of agencies like the Environmental Protection Agency, Federal Trade Commission, Occupational Safety & Health Administration and Drug Enforcement Administration</p> <p>PC9. manage and oversee the laboratory work</p> <p>PC10. review company practices and providing advice on changes to systems</p> <p>PC11. identify and assess regulatory risks and project issues and make recommendations to regulatory management</p> <p>PC12. associating with the marketing personnel to ensure applicability of regulatory framework</p> <p>PC13. keep abreast of international legislation, guidelines and customer practices: all countries where the Company sells its products</p> |
| Assistance to other team | PC14. assist scientists, medical writers and manufacturers on regulatory requirements <p>PC15. provide regulatory related advice to senior management throughout the development of a new product</p> <p>PC16. assist project managing teams of colleagues involved with the development of new products</p> |

LFS/N0501 : Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products

Knowledge and Understanding (K)

A. Organisational Context
(Knowledge of the Company/ Organisation and its processes)

The user/individual on the job needs to know and understand:

- KA1. different quality management systems (ISO-9000, ISO-14001, OHSAS-18000), good laboratory and manufacturing practices
- KA2. organizational Coding system of finished material, compounds and comp manual
- KA3. escalation matrix for reporting identified issues
- KA4. records to be maintained and implications of non-maintenance of the sa
- KA5. health, Safety and Environment guidelines, legislation and regulations a: applicable
- KA6. the reason and impact of the occurrence of problems
- KA7. measures, steps and possible solutions that have been taken/identified address the previous problems
- KA8. the correct method for carrying out corrective actions outlined for each problem

B. Technical Knowledge

The user/individual on the job needs to know and understand:

- KB1. broad knowledge of Regulatory Affairs and specific working knowledge o current regulations and guidance
- KB2. excellent knowledge of IND, NDA, ANDA, CTD Submissions
- KB3. knowledge of regulatory authorities like MHRA, MCC, USFDA, TGA, Mala European Union etc in concurrence with the regulations promulgated by whole range of agencies like the Environmental Protection Agency, Feder Trade Commission, Occupational Safety & Health Administration and Dru Enforcement Administration
- KB4. associated experience in Quality Assurance and Document Control is req in certain cases
- KB5. knowledge of pharmaceutical dossiers like the master formula of the pro manufacturing procedure and the equipments list used in the productior Stability data, preclinical and clinical data, specifications used in testing t final product and other regulatory documents
- KB6. adequate training for the competent performance of tests, operation of equipment and basic techniques, e.g. counting of colonies, plate pouring serial dilutions, etc.
- KB7. training in necessary procedures for filing licenses and liaising with regulatory authorities of different countries
- KB8. good knowledge of GMP, GLP and Safety requirements
- KB9. use of sophisticated scientific/laboratory instruments
- KB10. testing equipment and related test method and purpose of tests
- KB11. national/international standard test methods for different compounds
- KB12. factors that adversely affect integrity of the sample


LFS/N0501 : Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products

| Skills (S) | | |
|---|---|---|
| A. Core Skills/Generic Skills | Writing Skills | |
| | SA1. excellent report writing skills SA2. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail SA3. maintain proper records as per given format | |
| | Reading & Understanding Skills | |
| | SA4. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc SA5. read images, graphs, diagrams SA6. understand the various coding systems as per company norms | |
| | Oral Communication (Listening and Speaking skills) | |
| | SA7. communication with upstream and downstream teams SA8. communicate with job owners like sample originating section, supplier etc SA9. work in a team and other behavioral skills required to support the small group activities (eg. quality circle, cross functional team, suggestion scheme) SA10. disclose information only to those who have the right and need to know SA11. maintain confidentiality of information | |
| | B. Professional Skills | Decision Making |
| | | The user/individual on the job needs to know and understand how to: SB1. act objectively, rather than impulsively or emotionally when faced with difficult/stressful or emotional situations |
| | | Analytical Thinking |
| | | SB2. arithmetic aptitude SB3. application of statistics to analyse trends and data SB4. use of computer/ application software SB5. attention to detail SB6. use the existing data to arrive at specific point |
| | | Plan and Organise |
| SB7. planning skills with the ability to multi-task and adapt SB8. ability to prioritize needs and effectively schedule work to effectively support multiple projects at one time SB9. take responsibility for completing one's own work assignment SB10. take initiative to enhance/learn skills in one's area of work SB11. the capacity to learn from experience in a range of settings and scenarios the capacity to reflect on and analyse one's learning SB12. is open to new ways of doing things SB13. the capacity to envisage and articulate personal goals; to develop strategies and take action to achieve them | | |
| Problem Solving | | |
| SB14. ability to identify, define and resolve problems using a structured methodology | | |

LFS/N0501 : Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products

| | |
|--|---|
| | SB15. resolve any difficulties in relationships with colleagues , or get help from a appropriate person, in a way that preserves goodwill and trust |
| | Critical Thinking |
| | SB16. suggest improvements(if any) in process based on experience |





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LFS/N0501 : Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products

NOS Version Control

| NOS Code | LFS/N0501 | | |
|---------------------|---|------------------|----------|
| Credits(NSQF) | TBD | Version number | |
| Industry | Life Sciences | Drafted on | 09/12/14 |
| Industry Sub-sector | Pharmaceutical and Bio Pharmaceuticals | Last reviewed on | 25/02/15 |
| Occupation | R&D | Next review date | 25/02/16 |




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LFS/N0503 : Ensure that the products comply with the regulations

National Occupational Standard

| | |
|---|--|
| Unit Code | LFS/N0503 |
| Unit Title (Task) | Ensure that the products comply with the regulations |
| Description | This NOS is about a DRA chemist to ensure that the products comply with regulat |
| Scope | <p>The unit/task covers the following:</p> <ul style="list-style-type: none"> • Ensure that quality is maintained • Support research • Validate test methods |
| Performance Criteria (PC) w.r.t. the Scope | |
| Element | Performance Criteria |
| Quality Checks | <p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. ensure that the product is according to standards and regulations PC2. ensure that GMP and GLP are followed PC3. evaluate compliance procedures for new products</p> |
| Research | <p>PC4. supervise the work of biological technicians and other workers to evaluate accuracy of their results PC5. work with technicians, chemists and scientists of other fields as many scier research projects involve multiple disciplines PC6. present research findings to scientists, non-scientist executives, engineers ,other colleagues, and the public PC7. work with specialist computer software to undertake studies and research</p> |
| Validate test methods | <p>PC8. support continuous process performance evaluation and continuous proce improvement for highest efficiency PC9. keep up with new research PC10. minimize the risks of cross-contamination, false-positive results and false-negative PC11. define alert and action limits</p> |
| Knowledge and Understanding (K) | |
| <p>A. Organisational Context (Knowledge of the Company/ Organisation and its processes)</p> | <p>The user/individual on the job needs to know and understand:</p> <p>KA1. different quality management systems (ISO-9000, ISO-14001, OHSAS-18000), good laboratory and manufacturing practices KA2. organizational coding system of finished material, compounds and compar manual KA3. implications of not adhering to quality control procedures KA4. quality requirements and products and processes KA5. quality and damage checks to be done and importance of the same KA6. quality control procedures followed by the company and importance of the same</p> |

LFS/N0503 : Ensure that the products comply with the regulations

| | |
|---|---|
| | <p>KA7. escalation matrix for reporting identified issues</p> <p>KA8. records to be maintained and implications of non-maintenance of the same</p> <p>KA9. impact of poor practices on health, safety and environment</p> <p>KA10. impact of various practices on cost, quality, productivity, delivery and safety</p> <p>KA11. handover/ takeover the equipment/ work area as per company's SOP</p> <p>KA12. the levels of hygiene required by workplace and importance of maintaining same</p> <p>KA13. reporting incidents where standard operating procedures are not followed</p> <p>KA14. the importance of complete and accurate documentation</p> <p>KA15. the importance of quality control procedures</p> <p>KA16. the reason and impact of the occurrence of problems</p> <p>KA17. measures, steps and possible solutions that have been taken/identified to address the previous problems</p> <p>KA18. the correct method for carrying out corrective actions outlined for each problem</p> |
| <p>B. Technical Knowledge</p> | <p>The user/individual on the job needs to know and understand:</p> <p>KB1. broad knowledge of regulatory affairs and specific working knowledge of current regulations and guidance</p> <p>KB2. characteristics and composition of products</p> <p>KB3. health, safety and environment guidelines, legislation and regulations as applicable</p> <p>KB4. associated experience in quality assurance and document control is required in certain cases</p> <p>KB5. knowledge of pharmaceutical dossiers like the master formula of the product, manufacturing procedure and the equipments list used in the production, stability data, preclinical and clinical data, specifications used in testing the final product and other regulatory documents</p> <p>KB6. training in necessary procedures for filing licenses and liaising with regulatory authorities</p> <p>KB7. broad knowledge of GMP, GLP and Safety requirements</p> <p>KB8. importance of quality checks along with quality and production targets</p> <p>KB9. standard method of drawing samples and preparing them for testing</p> <p>KB10. methods and techniques involved in evaluating information</p> <p>KB11. current knowledge of starting-up and qualifying new facilities, tech transfers and manufacturing operations</p> |
| <p>Skills (S)</p> | |
| <p>A. Core Skills / Generic Skills</p> | <p>Writing Skills</p> <p>SA1. excellent report writing skills</p> <p>SA2. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail</p> <p>SA3. maintain proper records as per given format</p> |

LFS/N0503 : Ensure that the products comply with the regulations

| | |
|--|---|
| | Reading & Understanding Skills |
| | SA4. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc |
| | SA5. read images, graphs, diagrams |
| | SA6. understand the various coding systems as per company norms |
| | Oral Communication (Listening and Speaking skills) |
| | SA7. communication with upstream and downstream teams |
| | SA8. communicate with job owners like sample originating section, supplier etc |
| | SA9. work in a team and other behavioral skills required to support the small group activities (eg. quality circle, cross functional team, suggestion scheme) |
| | SA10. disclose information only to those who have the right and need to know |
| | SA11. maintain confidentiality of information |
| | B. Professional Skills |
| | The user/individual on the job needs to know and understand how to: |
| | SB1. act objectively, rather than impulsively or emotionally when faced with difficult/stressful or emotional situations |
| | Analytical Thinking |
| | SB2. arithmetic aptitude |
| | SB3. application of statistics to analyse trends and data |
| | SB4. use of computer/ application software |
| | SB5. attention to detail |
| | SB6. use the existing data to arrive at specific point |
| | Plan and Organise |
| | SB7. planning skills with the ability to multi-task and adapt |
| | SB8. ability to prioritize needs and effectively schedule work to effectively support multiple projects at one time |
| | SB9. take responsibility for completing one's own work assignment |
| | SB10. take initiative to enhance/learn skills in one's area of work |
| | SB11. the capacity to learn from experience in a range of settings and scenarios the capacity to reflect on and analyse one's learning |
| | SB12. is open to new ways of doing things |
| | SB13. the capacity to envisage and articulate personal goals; to develop strategies and take action to achieve them |
| | Problem Solving |
| | SB14. ability to identify, define and resolve problems using a structured methodology |
| | SB15. resolve any difficulties in relationships with colleagues, or get help from an appropriate person, in a way that preserves goodwill and trust |
| | Critical Thinking |
| | SB16. suggest improvements(if any) in process based on experience |



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| S. no. | Application ID | Institute Name | State | Region | Sector | Specialization | NSQF Level | Minimum Qualification | No. of Hours* | Int'l Recommendation |
|--------|----------------|--|----------------|--------|-----------------------------|--|------------|--|---------------|----------------------|
| 7944 | 1-3516032228 | Chalapathi Institute Of Pharmaceutical Sciences | Andhra Pradesh | SCRO | Life Sciences 11/10/2018 | 2476 Drug Regulatory Affairs Chemist | 5 | Diploma in Pharmacy / Mechanical & Chemical Engineering / Graduate in Science / B.Pharmacy (Preferable); NO Experience required if hiring company is making only CTD, else minimum 1 year's experience | 300 | 25 |
| 7945 | 1-3516032228 | Chalapathi Institute Of Pharmaceutical Sciences | Andhra Pradesh | SCRO | Life Sciences | Life Sciences | 3 | 10th / 10+2 (Preferred) | 265 | 25 |
| 7946 | 1-3516032228 | Chalapathi Institute Of Pharmaceutical Sciences | Andhra Pradesh | SCRO | Life Sciences | Maintenance Supervisor/in Charge - HVAC - Life Sciences | 5 | ITI / Polytechnic Diploma / B.Sc. | 375 | 25 |
| 7947 | 1-3516032228 | Chalapathi Institute Of Pharmaceutical Sciences | Andhra Pradesh | SCRO | Life Sciences | Medical Sales Representative | 4 | Diploma in Pharmacy / Any Graduate (Preferably in Science) | 480 | 25 |
| 7948 | 1-3516032228 | Chalapathi Institute Of Pharmaceutical Sciences | Andhra Pradesh | SCRO | Life Sciences | Production / Machine Operator - Life Sciences | 4 | 10+2 / D.Pharma / ITI | 376 | 25 |
| 7949 | 1-3516032228 | Chalapathi Institute Of Pharmaceutical Sciences | Andhra Pradesh | SCRO | Life Sciences | Research Associate - Product Development / Synthesis / Medicinal Chemistry | 5 | Masters in Sciences (Organic Chemistry and relevant discipline) / M.Pharma | 370 | 25 |
| 7950 | 1-3516032228 | Chalapathi Institute Of Pharmaceutical Sciences | Andhra Pradesh | SCRO | Life Sciences | Scientific Medical Writer | 3 | Master's degree in pharmaceutical, biotechnology, nursing or life sciences | 270 | 25 |
| 7951 | 1-3516032628 | Rajeev Gandhi Memorial College Of Engineering & Technology | Andhra Pradesh | SCRO | Telecom | BSS Support Engineer | 6 | Diploma / Bachelor in Technology (Electronics, Computer Science, IT and related field) | 350 | 100 |
| 7952 | 1-3516032628 | Rajeev Gandhi Memorial College Of Engineering & Technology | Andhra Pradesh | SCRO | Telecom | Network Engineer | 4 | Diploma / ITI | 300 | 100 |
| 7953 | 1-3516035725 | Nova College Of Engineering & Technology | Andhra Pradesh | SCRO | Construction | Structural Steel NDT Tester-UT / MPT / DPT | 3 | Preferably 10th standard and ASNT Level 1 qualified | 200 | 25 |
| 7954 | 1-3516035725 | Nova College Of Engineering & Technology | Andhra Pradesh | SCRO | IT/ITeS | Junior Software Developer | 4 | 12th pass with good aptitude | 400 | 50 |
| 7955 | 1-3516035725 | Nova College Of Engineering & Technology | Andhra Pradesh | SCRO | Electronics | Field Technician - Water Purifier Other Home Appliance | 4 | 8th Pass | 360 | 25 |
| 7956 | 1-3516035725 | Nova College Of Engineering & Technology | Andhra Pradesh | SCRO | Electronics | Solar Panel Installation Technician | 4 | 10th Pass | 400 | 25 |
| 7957 | 1-3516035725 | Nova College Of Engineering & Technology | Andhra Pradesh | SCRO | Electronics | Mobile Phone Hardware Repair Technician | 4 | 8th Pass | 360 | 25 |
| 7958 | 1-3516035725 | Nova College Of Engineering & Technology | Andhra Pradesh | SCRO | Power | Lineman Distribution (Multi Skilled) | 4 | 8th | 300 | 50 |
| 7959 | 1-3516035725 | Nova College Of Engineering & Technology | Andhra Pradesh | SCRO | Automotive | Auto Component Assembly Fitter | 4 | Class X | 300 | 25 |


As per the direction of MHRD, Aadhar based Attendance of students is mandatory for institute running PMU - TI scheme from the AY 2018-19.



Chalapati Institute of Pharmaceutical Sciences (Autonomous)
Chalapati Nagar LAM, GUNTUR-34

Principal
Sylabus

Level-3

| | | | |
|---|--------------------------------------|---|-----------------------------|
|  | Sector Skills Council | Life Sciences Sector Skill Development Council | Batch ID |
| | Training Partner Name | CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES | Investigator Name |
| | Centre ID, Location | Chalapathi Nagar, Lam Village, Tedikonda Mandal, Guntur | Investigator Contact Number |
| | Training Partner SPOC Name | Prof. RAMAN RAO MADENIDA | Date of assessment |
| | Training Partner SPOC Contact Number | 9440101685 | Remarks |

| S.No. | Candidate SDMS ID | Learner Name | Gender | NOS Wise - Theory Marks Obtained | | | | | | | | | | NOS Wise | | | | |
|-------|-------------------|------------------------------|--------|----------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | | | | LFS/NOS30_3 | LFS/NOS31_5 | LFS/NOS32_4 | LFS/NOS33_4 | LFS/NOS34_4 | LFS/NOS34_5 | LFS/NOS40_4 | LFS/NOS40_5 | LFS/NOS41_4 | LFS/NOS41_5 | LFS/NOS42_4 | LFS/NOS42_5 | LFS/NOS43_4 | LFS/NOS43_5 | LFS/NOS44_4 |
| 1 | LT_017 | Mr.BULLA ASHOK | MALE | 21.43 | 7.14 | 15.00 | 15.00 | 22.50 | 23.50 | 16.00 | 15.33 | 21.88 | 28.12 | 5.50 | | | | |
| 2 | LT_005 | Mr.CHINKA KOTESWARA RAO | MALE | 50.00 | 21.43 | 22.50 | 30.00 | 30.00 | 30.00 | 40.00 | 30.67 | 28.12 | 28.12 | 0.00 | | | | |
| 3 | LT_022 | Mrs.GERA ARUNA KUMARI | FEMALE | 42.86 | 35.71 | 22.50 | 15.00 | 15.00 | 15.00 | 24.00 | 23.00 | 34.38 | 28.12 | 5.50 | | | | |
| 4 | LT_013 | Mrs.INDIA SARITHA | FEMALE | 21.43 | 28.57 | 22.50 | 30.00 | 15.00 | 31.33 | 24.00 | 15.33 | 34.38 | 31.25 | 34.00 | | | | |
| 5 | LT_024 | Mr.INJUMUKALA BABU | MALE | 21.43 | 14.29 | 15.00 | 22.50 | 37.50 | 15.67 | 16.00 | 30.67 | 28.12 | 31.25 | 38.00 | | | | |
| 6 | LT_018 | Mr.MEDARA MALLESWARA RAO | MALE | 28.57 | 28.57 | 22.50 | 37.50 | 37.50 | 31.33 | 24.00 | 23.00 | 28.12 | 34.38 | 16.50 | | | | |
| 7 | LT_015 | Mr.PATIBANDLA RAMESH BABU | MALE | 28.57 | 35.71 | 15.00 | 30.00 | 45.00 | 23.50 | 24.00 | 30.67 | 25.00 | 28.12 | 5.50 | | | | |
| 8 | LT_008 | Mr.PATIBANDLA VENKATESWARLU | MALE | 21.43 | 28.57 | 30.00 | 30.00 | 22.50 | 15.67 | 40.00 | 23.00 | 6.25 | 15.62 | 43.00 | | | | |
| 9 | LT_025 | Mrs.PERUBOINA GOPAL RAO | FEMALE | 35.71 | 21.43 | 15.00 | 15.00 | 45.00 | 23.50 | 24.00 | 38.33 | 25.00 | 40.62 | 5.50 | | | | |
| 10 | LT_001 | Mrs.PERUBOYINA ANASURYA | FEMALE | 21.43 | 14.29 | 15.00 | 7.50 | 22.50 | 31.33 | 8.00 | 15.33 | 34.38 | 28.12 | 41.00 | | | | |
| 11 | LT_007 | Mr.PERUBOYINA POORNA GOPI | MALE | 14.29 | 21.43 | 15.00 | 30.00 | 22.50 | 23.50 | 16.00 | 23.00 | 31.25 | 31.25 | 22.00 | | | | |
| 12 | LT_019 | Mr.PERUMEENA GOPAL RAO | MALE | 21.43 | 14.29 | 15.00 | 22.50 | 30.00 | 17.00 | 16.00 | 23.00 | 25.00 | 21.88 | 35.00 | | | | |
| 13 | LT_016 | Mr.RAMISETTY CHANDU | MALE | 21.43 | 28.57 | 22.50 | 22.50 | 22.50 | 23.50 | 24.00 | 7.67 | 31.25 | 25.00 | 42.00 | | | | |
| 14 | LT_020 | Mrs.RAVULA NAGAMANI | FEMALE | 21.43 | 7.14 | 22.50 | 30.00 | 22.50 | 31.33 | 16.00 | 7.67 | 37.50 | 31.25 | 48.00 | | | | |
| 15 | LT_004 | Mr.RUDRU ARUN | MALE | 28.57 | 21.43 | 22.50 | 0.00 | 37.50 | 7.83 | 16.00 | 30.67 | 28.12 | 34.38 | 37.00 | | | | |
| 16 | LT_023 | Mr.SAYYAD BAASHEED | MALE | 7.14 | 0.00 | 0.00 | 0.00 | 7.50 | 7.83 | 16.00 | 7.67 | 31.25 | 25.00 | 5.50 | | | | |
| 17 | LT_006 | Miss.SHAIK MUSKAN | FEMALE | 14.29 | 21.43 | 22.50 | 15.00 | 30.00 | 21.00 | 15.00 | 15.33 | 31.25 | 38.00 | 46.00 | | | | |
| 18 | LT_012 | Mrs.SIDDI KUMARI | FEMALE | 42.86 | 28.57 | 22.50 | 30.00 | 22.50 | 15.67 | 32.00 | 23.00 | 18.75 | 18.75 | 11.00 | | | | |
| 19 | LT_009 | Mrs.TELAGATHOTI KRISHNA VENI | FEMALE | 14.29 | 21.43 | 0.00 | 15.00 | 37.50 | 7.83 | 16.00 | 30.67 | 31.25 | 28.12 | 38.00 | | | | |
| 20 | LT_021 | Mrs.THAMISETTY GOWRI | FEMALE | 28.57 | 28.57 | 22.50 | 22.50 | 15.00 | 15.67 | 24.00 | 30.67 | 25.00 | 25.00 | 32.00 | | | | |
| 21 | LT_014 | Mr.THOTA SAI TRINADH | MALE | 14.29 | 14.29 | 15.00 | 15.00 | 15.00 | 15.67 | 16.00 | 0.00 | 0.00 | 0.00 | 5.50 | | | | |
| 22 | LT_002 | Mr.THOTA CHANDRA SEKCHAR | MALE | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | | | | |
| 23 | LT_003 | Mr.THOTA HARI KRISHNA | MALE | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | | | | |
| 24 | LT_010 | Mr.BANDI ANIL KUMAR | MALE | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | | | | |
| 25 | LT_011 | Mr.THUPAKULA VIJAYA KUMAR | MALE | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | | | | |



Handwritten signature

PRINCIPAL
 Chalapati Institute of Pharmaceutical Sciences
 (Autonomous)
 Chalapati Nagar LAM, GUNTUR-34

| 1-4126013-405 | | Job Role / OP | | | | | | | | | | Lab Technician/Assistant | | | | | |
|---------------|--------------|-------------------------------|--------------|--------------|------------|-----------|-----------|-----------|-----------|-----------|-----------|--------------------------|--------------------|-----------------------|-----------------|--------------------|--------------------|
| 15th Dec 2019 | | Batch Size | | | | | | | | | | 25 | | | | | |
| | | Number of Learners Present | | | | | | | | | | 21 | | | | | |
| | | Pass - Fail - Pass % | | | | | | | | | | 4 | | | | | |
| | | 86% | | | | | | | | | | | | | | | |
| Marks | | MOS Wise Total Marks Obtained | | | | | | | | | | Grand Total | | | | | |
| LFS/N0533_55 | LFS/N0534_55 | LFS/N0560_53 | LFS/N0101_52 | LFS/N0101_54 | LFS/N0530/ | LFS/N0531 | LFS/N0532 | LFS/N0533 | LFS/N0534 | LFS/N0560 | LFS/N0101 | LFS/N0103 | Total Theory (376) | Total Practical (424) | Aggregate (800) | Overall Percentage | Final Result (50%) |
| 0.00 | 30.94 | 29.81 | 6.50 | 10.80 | 43 | 35 | 21 | 15 | 53 | 53 | 23 | 26 | 134 | 134 | 418 | 33.68 | PASS |
| 11.00 | 13.75 | 29.81 | 29.25 | 24.30 | 78 | 50 | 23 | 41 | 44 | 45 | 69 | 55 | 160 | 164 | 405 | 50.58 | PASS |
| 16.50 | 27.50 | 29.81 | 29.25 | 32.40 | 77 | 64 | 28 | 32 | 43 | 61 | 53 | 55 | 209 | 201 | 413 | 51.61 | PASS |
| 5.50 | 34.38 | 33.12 | 32.50 | 32.40 | 56 | 60 | 57 | 36 | 49 | 64 | 57 | 48 | 188 | 239 | 426 | 53.21 | PASS |
| 5.50 | 34.38 | 29.81 | 32.50 | 32.40 | 50 | 46 | 53 | 28 | 72 | 45 | 49 | 63 | 173 | 237 | 408 | 50.63 | PASS |
| 22.00 | 30.94 | 29.81 | 26.00 | 35.10 | 57 | 63 | 39 | 43 | 68 | 61 | 50 | 58 | 231 | 206 | 437 | 54.92 | PASS |
| 41.00 | 20.62 | 23.19 | 29.25 | 27.00 | 54 | 64 | 21 | 52 | 76 | 57 | 53 | 58 | 232 | 203 | 435 | 54.17 | PASS |
| 16.50 | 37.81 | 26.50 | 29.25 | 24.30 | 28 | 44 | 73 | 71 | 43 | 39 | 69 | 47 | 211 | 203 | 414 | 51.80 | PASS |
| 39.00 | 34.38 | 26.50 | 32.50 | 32.40 | 61 | 62 | 21 | 32 | 83 | 50 | 53 | 73 | 218 | 216 | 434 | 54.28 | PASS |
| 38.00 | 30.94 | 36.44 | 29.25 | 35.10 | 56 | 42 | 56 | 47 | 57 | 58 | 41 | 48 | 135 | 268 | 404 | 50.46 | PASS |
| 37.00 | 30.94 | 29.81 | 29.25 | 32.40 | 46 | 53 | 30 | 68 | 53 | 60 | 45 | 58 | 158 | 154 | 412 | 51.56 | PASS |
| 42.00 | 13.75 | 29.81 | 29.25 | 29.70 | 46 | 36 | 50 | 60 | 61 | 47 | 45 | 55 | 159 | 241 | 401 | 50.06 | PASS |
| 34.00 | 30.94 | 29.81 | 32.50 | 32.40 | 53 | 54 | 65 | 65 | 36 | 33 | 53 | 37 | 173 | 243 | 416 | 51.93 | PASS |
| 31.00 | 24.06 | 33.12 | 29.25 | 27.00 | 59 | 38 | 71 | 64 | 53 | 61 | 49 | 40 | 159 | 276 | 435 | 54.37 | PASS |
| 11.00 | 34.38 | 26.50 | 29.25 | 29.70 | 57 | 56 | 60 | 54 | 62 | 41 | 45 | 58 | 197 | 244 | 441 | 53.87 | PASS |
| 27.50 | 37.81 | 29.81 | 29.25 | 35.10 | 46 | 59 | 46 | 43 | 42 | 34 | 45 | 37 | 61 | 153 | 258 | 31.72 | PASS |
| 45.00 | 33.00 | 19.88 | 26.00 | 16.20 | 62 | 47 | 34 | 75 | 56 | 36 | 58 | 51 | 134 | 275 | 407 | 50.85 | PASS |
| 44.00 | 34.38 | 29.81 | 26.00 | 32.40 | 46 | 50 | 38 | 59 | 72 | 38 | 42 | 63 | 217 | 189 | 406 | 50.71 | PASS |
| 42.00 | 27.50 | 29.81 | 16.25 | 32.40 | 54 | 54 | 55 | 65 | 65 | 45 | 40 | 63 | 143 | 264 | 407 | 50.84 | PASS |
| 5.50 | 30.94 | 23.19 | 26.00 | 32.40 | 49 | 39 | 21 | 21 | 46 | 39 | 42 | 63 | 216 | 189 | 405 | 54.99 | PASS |
| 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 136 | 183 | 319 | 39.85 | PASS |
| 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.00 | Absent |
| 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.00 | Absent |
| 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.00 | Absent |
| 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.00 | Absent |



Level-4

| | |
|---|--|
| LSSDC | LSSDC Chalapaty Institute of Pharmaceutical Sciences (Autonomous) Guntur-34 |
| Training Partner Name Chalapaty Institute of Pharmaceutical Sciences Guntur-34, Andhra Pradesh | Job role / up Batch No. 25 |
| Training Partner EPIC Name Chalapaty Institute of Pharmaceutical Sciences Guntur-34, Andhra Pradesh | Progression/Marking Scheme Life Sciences 25 |
| Training Partner EPIC Contact Number 9849111111 | Number of Life Sciences Present 25 |
| MOS Wise Marks (Batch ID - 1-4126100301) | Number of Life Sciences Absent 0 |
| Remarks Pass % - 100% | Pass % |

| S.No. | Candidate ID | Learner Name | Theory | | | | | | | | | | | | | | | Grand Total | |
|-------|-----------------|--------------------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|---------------------|------------------------|-------------------|--------------|--|
| | | | LFS/NO213 (50) | LFS/NO214 (48) | LFS/NO103 (46) | LFS/NO102 (49) | LFS/NO215 (49) | LFS/NO101 (48) | LFS/NO213 (50) | LFS/NO214 (52) | LFS/NO103 (54) | LFS/NO102 (51) | LFS/NO215 (51) | LFS/NO101 (51) | Yrth - Theory (P30) | Yrth - Practical (P30) | Aggregate % (60%) | Final Result | |
| 1 | 1-4126100301-2 | ALLADI SWAROOPA RANI | 20 | 38.4 | 46 | 49 | 24.5 | 48 | 50 | 54 | 51 | 51 | 47.67 | 225.9 | 105.17 | 331.07 | Pass | | |
| 2 | 1-4126100301-3 | ANGOTHU TANISHA | 25 | 38.4 | 46 | 49 | 24.5 | 48 | 50 | 54 | 51 | 51 | 52 | 230.9 | 110 | 340.9 | Pass | | |
| 3 | 1-4126100301-4 | ANNE SWETHA | 25 | 38.4 | 46 | 49 | 24.5 | 48 | 50 | 54 | 51 | 51 | 52 | 230.9 | 110 | 340.9 | Pass | | |
| 4 | 1-4126100301-5 | ATTALURI LAUTHA PRATHYUSHA | 35 | 30.4 | 46 | 36.75 | 24.5 | 48 | 50 | 54 | 51 | 51 | 52 | 228.65 | 110 | 338.65 | Pass | | |
| 5 | 1-4126100301-13 | AVUTHU SAIKIRIL REDDY | 35 | 28.8 | 30.67 | 49 | 0 | 48 | 47 | 54 | 51 | 51 | 52 | 191.47 | 110 | 301.47 | Pass | | |
| 6 | 1-4126100301-6 | BALLA HEMA SAI NAGA SUDHEESHNA | 30 | 19.2 | 46 | 49 | 24.5 | 48 | 47 | 54 | 51 | 51 | 52 | 216.7 | 110 | 326.7 | Pass | | |
| 7 | 1-4126100301-7 | BANDLA BHAVANI PRASAD | 30 | 48 | 46 | 36.75 | 12.25 | 48 | 50 | 54 | 51 | 51 | 52 | 221 | 110 | 331 | Pass | | |
| 8 | 1-4126100301-8 | BANDLA BHAVANI PRASAD | 30 | 28.8 | 38.33 | 49 | 12.25 | 48 | 50 | 54 | 51 | 51 | 52 | 206.38 | 110 | 316.38 | Pass | | |
| 9 | 1-4126100301-9 | BARLA VENKATA SIVA SAI | 25 | 28.8 | 38.33 | 36.75 | 24.5 | 48 | 50 | 54 | 51 | 51 | 52 | 201.38 | 110 | 311.38 | Pass | | |
| 10 | 1-4126100301-10 | BATTUJA MANIKANTA | 30 | 28.8 | 38.33 | 49 | 24.5 | 48 | 50 | 54 | 51 | 51 | 52 | 218.63 | 110 | 328.63 | Pass | | |
| 11 | 1-4126100301-11 | BHASKHAYAM SAI BHARGAVI | 25 | 9.6 | 38.33 | 36.75 | 0 | 40 | 50 | 54 | 51 | 51 | 52 | 149.88 | 110 | 259.88 | Pass | | |
| 12 | 1-4126100301-15 | BURLA GANESH | 35 | 19.2 | 46 | 36.75 | 24.5 | 40 | 50 | 54 | 51 | 51 | 52 | 201.45 | 110 | 311.45 | Pass | | |
| 13 | 1-4126100301-12 | CHANNAMALLU KRISHNA SAI | 35 | 9.6 | 38.33 | 24.5 | 24.5 | 40 | 50 | 54 | 51 | 51 | 52 | 171.89 | 110 | 281.89 | Pass | | |
| 14 | 1-4126100301-19 | CHATTU SAI VENKATA TULASIRAM | 25 | 38.4 | 38.33 | 24.5 | 24.5 | 40 | 50 | 54 | 51 | 51 | 52 | 210.45 | 110 | 320.45 | Pass | | |
| 15 | 1-4126100301-20 | CHEJULA VENKATA SAI MANISHA | 30 | 38.4 | 38.33 | 36.75 | 24.5 | 48 | 50 | 54 | 51 | 51 | 52 | 171.89 | 110 | 281.89 | Pass | | |
| 16 | 1-4126100301-21 | CHIKARAJA KORTHEK SAI BABU | 25 | 38.4 | 46 | 49 | 24.5 | 48 | 50 | 54 | 51 | 51 | 52 | 235.9 | 110 | 345.9 | Pass | | |
| 17 | 1-4126100301-23 | CHINKA GAYATHRI | 35 | 19.2 | 30.67 | 49 | 24.5 | 48 | 50 | 54 | 51 | 51 | 52 | 196.37 | 110 | 306.37 | Pass | | |
| 18 | 1-4126100301-22 | CHINTAGUNTLA THIRUPATHANAMA | 25 | 28.8 | 46 | 36.75 | 12.25 | 48 | 50 | 54 | 51 | 51 | 52 | 208.8 | 110 | 318.8 | Pass | | |
| 19 | 1-4126100301-24 | CHUNDU BHARGAVI | 30 | 9.6 | 38.33 | 24.5 | 12.25 | 48 | 50 | 54 | 51 | 51 | 52 | 141.68 | 110 | 251.68 | Pass | | |
| 20 | 1-4126100301-14 | EDA PURNA KANTH REDDY | 20 | 38.4 | 38.33 | 49 | 24.5 | 40 | 50 | 54 | 51 | 51 | 52 | 221.23 | 110 | 331.23 | Pass | | |
| 21 | 1-4126100301-16 | KUMMARI GOPI | 35 | 38.4 | 30.67 | 36.75 | 12.25 | 40 | 50 | 54 | 51 | 51 | 52 | 188.33 | 110 | 298.33 | Pass | | |
| 22 | 1-4126100301-17 | MASHADA MANIKANTA | 30 | 19.2 | 46 | 49 | 24.5 | 48 | 50 | 54 | 51 | 51 | 52 | 188.33 | 110 | 298.33 | Pass | | |
| 23 | 1-4126100301-18 | MADIMPALLI NAGA LAKSHMI | 25 | 38.4 | 46 | 36.75 | 12.25 | 48 | 50 | 54 | 51 | 51 | 52 | 208.4 | 110 | 318.4 | Pass | | |
| 24 | 1-4126100301-25 | SHAIK BABBANI | 30 | 38.4 | 38.33 | 36.75 | 24.5 | 48 | 50 | 54 | 51 | 51 | 52 | 215.98 | 110 | 325.98 | Pass | | |
| 25 | 1-4126100301-1 | SRIPALASETTI SRI LATHA | 15 | 28.8 | 30.67 | 49 | 12.25 | 8 | 50 | 54 | 51 | 51 | 52 | 106.97 | 110 | 216.97 | Pass | | |



PRINCIPAL
 Chalapaty Institute of Pharmaceutical Sciences
 (Autonomous)
 Chalapaty Nagar LAM, GUNTUR-34

Level-5

| S.No. | Candidate ID | Learner Name | Theory | | | | | | | | | | Total - Theory (386) | Theory Marks (201) | Aggregate 70% (400) | Final Result |
|-------|-----------------|----------------------------------|--|----------------|----------------|----------------|----------------|----------------|----------------|----------------|------|-------|----------------------|--------------------|---------------------|---------------|
| | | | LFS/N0501 (45) | LFS/N0503 (48) | LFS/N0502 (47) | LFS/N0105 (46) | LFS/N0501 (55) | LFS/N0503 (52) | LFS/N0502 (53) | LFS/N0105 (54) | Pass | Fail | | | | |
| 1 | 1-4123502513_9 | ADURTHI JAYA SRI DURGA | 35 | 34.25 | 32.25 | 32.88 | 30.56 | 45 | 42 | 45.66 | 42 | 42 | 134.36 | 159.56 | 201.02 | Pass |
| 2 | 1-4123502513_10 | AMILINENI SIRESHA | 38.55 | 40 | 42 | 38 | 45.66 | 42 | 45.3 | 45.66 | 42 | 45.3 | 158.55 | 150.96 | 209.51 | Pass |
| 3 | 1-4123502513_11 | BANDARU NAYASRI | 36 | 35 | 40.3 | 35.66 | 36.67 | 40 | 48.32 | 40 | 40 | 40 | 146.96 | 164.89 | 212.85 | Pass |
| 4 | 1-4123502513_12 | DOPPALAPUDI CHARITHA | 40 | 30 | 26.88 | 40.3 | 30.56 | 38 | 44.33 | 38 | 38 | 44.33 | 154.89 | 152.09 | 205.74 | Pass |
| 5 | 1-4123502513_15 | DURGAM PRASANNA | 35 | 38.3 | 26.88 | 42 | 42.78 | 30 | 25.33 | 30 | 30 | 30 | 142.18 | 143.56 | 205.74 | Pass |
| 6 | 1-4123502513_16 | GOGULAPATI NEEHARIKA | 33.75 | 17.25 | 21.5 | 19.71 | 42.78 | 42 | 41.67 | 42 | 42 | 41.67 | 122.11 | 122.11 | 214.33 | Fail |
| 7 | 1-4123502513_12 | GUDAPATI THILUKA LAKSHMI | 35.25 | 35.66 | 26.88 | 38 | 36.67 | 42 | 41.67 | 42 | 42 | 41.67 | 135.79 | 150.64 | 208.43 | Pass |
| 8 | 1-4123502513_4 | LAKSHMIPURAM SNEHA | 35 | 34.25 | 32.25 | 35 | 36.67 | 30 | 38 | 36.67 | 30 | 38 | 136.5 | 146.67 | 203.17 | Pass |
| 9 | 1-4123502513_13 | MATTA PALLAVI | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Not Appointed |
| 10 | 1-4123502513_21 | NALLAMI SARAJA | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Not Appointed |
| 11 | 1-4123502513_14 | NELLURI DILIP KUMAR | 40 | 30.3 | 26.88 | 39.3 | 40.56 | 39.22 | 49 | 40.56 | 42 | 49 | 136.48 | 158.78 | 235.26 | Pass |
| 12 | 1-4123502513_17 | NEPPALA YAMINI | 35 | 37.56 | 31.5 | 30.3 | 45.66 | 42 | 38 | 45.66 | 42 | 38 | 134.36 | 161.66 | 216.02 | Pass |
| 13 | 1-4123502513_1 | NIMINA SAI SREE | 35 | 35 | 36.88 | 34.32 | 24.44 | 45 | 42 | 24.44 | 45 | 42 | 147.44 | 147.44 | 208.04 | Pass |
| 14 | 1-4123502513_18 | OGURI VINEELA DEEPTHI | 32.3 | 34.25 | 32.25 | 40 | 30.56 | 42 | 38 | 30.56 | 42 | 38 | 138.8 | 146.56 | 205.96 | Pass |
| 15 | 1-4123502513_19 | PALLABOTHULA SIVA RAMA KRISHNA | 28.13 | 23 | 16.13 | 6.57 | 30.56 | 24 | 19 | 30.56 | 24 | 19 | 73.83 | 109.56 | 177.30 | Fail |
| 16 | 1-4123502513_2 | POLURI SAI SINDHU | 30.2 | 38 | 26.88 | 35 | 36.67 | 45 | 38 | 36.67 | 45 | 38 | 130.08 | 161.67 | 201.75 | Pass |
| 17 | 1-4123502513_24 | RACHAMETTI VIJAYALAKSHMI | 40 | 35.66 | 26.88 | 32.3 | 30.56 | 46 | 44.33 | 30.56 | 46 | 44.33 | 134.84 | 162.89 | 207.71 | Pass |
| 18 | 1-4123502513_3 | RAVI VENKATA NAGA LAKSHMI PRASUN | 28.13 | 28.75 | 21.5 | 6.57 | 18.33 | 24 | 38 | 18.33 | 24 | 38 | 84.95 | 98.33 | 183.20 | Fail |
| 19 | 1-4123502513_25 | RAYA ANJI REDDY | 38.3 | 40 | 36.13 | 39.43 | 45.2 | 42 | 25.33 | 45.2 | 42 | 25.33 | 153.63 | 148.53 | 202.33 | Pass |
| 20 | 1-4123502513_5 | SAMINENI VINAYASRIKALA | 40 | 34.25 | 32.25 | 40 | 24.44 | 39 | 44.33 | 24.44 | 39 | 44.33 | 146.5 | 155.77 | 201.27 | Pass |
| 21 | 1-4123502513_6 | SHAIK HANEEHA | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Not Appointed |
| 22 | 1-4123502513_7 | SHAIK SAJID ALI | 22.5 | 23 | 10.75 | 6.57 | 18.33 | 30 | 19 | 18.33 | 30 | 19 | 62.82 | 103.33 | 168.33 | Fail |
| 23 | 1-4123502513_20 | VAJINEPALLI MOHINI KUMARI | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Not Appointed |
| 24 | 1-4123502513_22 | YARUKALA SUMALATHA | 22.5 | 11.5 | 10.75 | 13.14 | 24.44 | 24 | 25.33 | 24.44 | 24 | 25.33 | 57.89 | 103.77 | 161.08 | Fail |
| 25 | 1-4123502513_8 | YENEDI PRUDHVI | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Not Appointed |
| | | | Grand Total | | | | | | | | | | | | | |
| | | | Theory | | | | | | | | | | | | | |
| | | | Practical - VIVA | | | | | | | | | | | | | |
| | | | NOS Wise Marks (Batch ID - 1-4123502513) | | | | | | | | | | | | | |
| | | | Imparks | | | | | | | | | | | | | |
| | | | Pass - Fail - Pass % | | | | | | | | | | | | | |
| | | | 75.00% | | | | | | | | | | | | | |

LSSSDC
 Sector Skills Council
 Training Partner Name
 Centre ID, Location
 Training Partner SPOC Name
 Training Partner SPOC Contact Number

Life Sciences Sector Skill Development Council
 CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
 Chalapaty Nagar, Lam Village, Tallamamandala, Guntur
 Batch ID
 In-charge
 Date of assessment
 Number of Learners Present
 Number of Learners Absent

Job Role / OP
 Batch Site
 25
 35
 5

Drug Regulatory Affairs Chemist



Principal
 Chalapati Institute of Pharmaceutical Sciences
 (Autonomous)
 Chalapaty Nagar LAM, GUNTUR-34

QUALIFICATIONS PACK - OCCUPATIONAL STANDARDS FOR LIFE SCIENCES INDUSTRY

What are Occupational Standards (OS)?

- OS describe what individuals need to do, know and understand in order to carry out a particular job role or function.
- OS are performance standards that individuals must achieve when carrying out functions in the workplace, together with specifications of the underpinning knowledge and understanding.

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Contents

1. Introduction and Contacts.....P.1
2. Qualifications Pack.....P.2
3. Glossary of Key TermsP.4
4. NOS Units.....P.6
5. Annexure: Nomenclature for QP & OS....P.37
6. Assessment Criteria.....P.39

Introduction

Qualifications Pack-Production/Machine Operator – Life Sciences

SECTOR: LIFE SCIENCES

SUB-SECTOR: PHARMACEUTICAL, BIOPHARMACEUTICAL

OCCUPATION: MANUFACTURING

REFERENCE ID: LFS/Q0207

ALIGNED TO: NCO-2004/ NIL

Machine operator also known as production operator is responsible for preparing the machines before the manufacturing process, perform manufacturing activities and carry out post manufacturing activities.

Brief Job Description: Machine operator is responsible for monitoring the events of a manufacturing of drugs/medicines. They verify materials and products to ensure that a perfect mixture is used and may perform superficial quality checks to ensure total quality management.

Personal Attributes: The individual should have good knowledge of the activities in the manufacturing process. The role holder should be aware of good manufacturing practices and importance of maintaining sterility in the production environment. He/she should also be aware of the basics of housekeeping and hygiene.

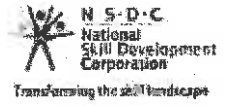



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Qualifications Pack For Production/Machine Operator-Life Sciences


| | | | | |
|--|---|--|------------------|----------|
| Job Details | Qualifications Pack Code | LFS/Q0207 | | |
| | Job Role | Production/Machine Operator – Life Sciences | | |
| | Credits(NSQF) | TBD | Version number | 1.0 |
| | Sector | Life Sciences | Drafted on | 15/12/14 |
| | Sub-sector | Pharmaceutical and Biopharmaceutical | Last reviewed on | 26/03/15 |
| | | Manufacturing | Next review date | 01/06/17 |
| | NSQC Clearance on | 20/07/2015 | | |
| | Job Role | Production/Machine Operator – Life Sciences | | |
| | Role Description | Responsible for <u>preparing the machines before the manufacturing process, perform manufacturing activities and carry out post manufacturing activities</u> | | |
| | NSQF level | 4 | | |
| Minimum Educational Qualifications | 10+2 | | | |
| Maximum Educational Qualifications | Diploma/ D.Pharma/ ITI/ B.Sc (chemistry specialization preferable for Pharmaceutical) | | | |
| Training (Suggested but not mandatory) | On the job training for GMP and EHS | | | |
| Minimum Job Entry Age | 18 Years | | | |
| Experience | 0-2 years | | | |
| Applicable National Occupational Standards (NOS) | <p>Compulsory:</p> <ol style="list-style-type: none"> 1. <u>LFS/N0213: Prepare machines and accessories for the manufacturing process</u> 2. <u>LFS/N0214: Perform manufacturing operations</u> 3. <u>LFS/N0103: Ensure cleanliness in the work area</u> 4. <u>LFS/N0102: carry out reporting and documentation</u> 5. <u>LFS/N0215: Carry out broad level quality checks before, in-process and post manufacturing</u> 6. <u>LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility</u> | | | |



Qualifications Pack For Production/Machine Operator-Life Sciences

| | |
|-----------------------------|---------------------------------------|
| | Optional: N.A. |
| Performance Criteria | As described in the relevant OS units |




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Qualifications Pack For Production/Machine Operator-Life Sciences

| Definitions | Keywords /Terms | Description |
|--------------------------|---|--|
| | Core Skills/Generic Skills | Core Skills or Generic Skills are a group of skills that are key to learning and working in today's world. These skills are typically needed in any work environment. In the context of the NOS, these include communication related skills that are applicable to most job roles. |
| | Description | Description gives a short summary of the unit content. This would be helpful to anyone searching on a database to verify that this is the appropriate NOS they are looking for. |
| | Function | Function is an activity necessary for achieving the key purpose of the sector, occupation, or area of work, which can be carried out by a person or a group of persons. Functions are identified through functional analysis and form the basis of NOS. |
| | Job role | Job role defines a unique set of functions that together form a unique employment opportunity in an organisation. |
| | Knowledge and Understanding | Knowledge and Understanding are statements which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard. |
| | National Occupational Standards (NOS) | NOS are Occupational Standards which apply uniquely in the Indian context. |
| | Occupation | Occupation is a set of job roles, which perform similar/related set of functions in an industry. |
| | Organisational Context | Organisational Context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility. |
| | Performance Criteria | Performance Criteria are statements that together specify the standard of performance required when carrying out a task. |
| Qualifications Pack(QP) | Qualifications Pack comprises the set of NOS, together with the educational, training and other criteria required to perform a job role. A Qualifications Pack is assigned a unique qualification pack code. | |
| Qualifications Pack Code | Qualifications Pack Code is a unique reference code that identifies a qualifications pack. | |
| Scope | Scope is the set of statements specifying the range of variables that an individual may have to deal with in carrying out the function which have a critical impact on the quality of performance required. | |
| Sector | Sector is a conglomeration of different business operations having similar businesses and interests. It may also be defined as a distinct subset of the economy whose components share similar characteristics and interests. | |




Qualifications Pack For Production/Machine Operator-Life Sciences

| Sub-Sector | Sub-sector is derived from a further breakdown based on the characteristics and interests of its components. |
|---------------------|--|
| Sub-functions | Sub-functions are sub-activities essential to fulfil the achieving the objectives of the function. |
| Technical Knowledge | Technical Knowledge is the specific knowledge needed to accomplish specific designated responsibilities. |
| Unit Code | Unit Code is a unique identifier for an NOS unit, which can be denoted with an 'N'. |
| Unit Title | Unit Title gives a clear overall statement about what the incumbent should be able to do. |
| Keywords /Terms | Description |
| NOS | National Occupational Standard(s) |
| NSQF | National Skill Qualifications Framework |
| NCO-2004 | National Classification of Occupations-2004 |
| OS | Occupational Standard(s) |
| QP | Qualifications Pack |
| SOP | Standard Operating Procedures |
| FIFO | First in First Out |
| GMP | Good Manufacturing Practices |

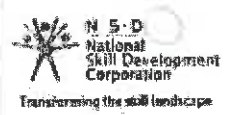
Acronyms




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NOS
National Occupational Standards



LFS/N0213 :

Prepare machines and accessories for the manufacturing process


National Occupational Standards



Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Machine Operator to prepare machines and accessories for the manufacturing process.




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LFS/N0213 : **Prepare machines and accessories for the manufacturing process**

| | | |
|--------------------------------|--|---|
| National Occupational Standard | Unit Code | LFS/N0213 |
| | Unit Title (Task) | Prepare machines and accessories for the manufacturing process |
| | Description | This NOS is about a Machine Operator ensuring housekeeping and safety in the manufacturing area, preparing the machine by managing settings, carrying out tests and regulating it to ensure that it runs flawlessly throughout the procedure and setting parameters on the set-up machine. |
| | Scope | The unit/task covers the following: <ul style="list-style-type: none"> • Equipment Readiness • Raw material/material appropriateness • Health & Safety |
| | Performance Criteria (PC) w.r.t. the Scope | |
| | Element | Performance Criteria |
| | Equipment Readiness | To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> PC1. Take handover from the colleague in previous shift and ensure that the machine, surrounding areas and classified areas are clean, dry, sterilised (wherever required) and fit for use as per the SOP to avoid contamination and highlight the risk if any PC2. set up machines at the beginning of the batch processing to ensure proper working order and refer to the machine history received from the supervisor/colleague at the time of handover PC3. perform testing procedures to ensure that machines work optimally to carry out production activities PC4. ensure that the approach path from the input storage area to storage area for output is free of obstructions to transportation PC5. select the correct raw materials to be loaded PC6. ensure that the material is from a respective batch and is checked by the concerned supervisor and approved by the QA team PC7. assemble the machinery properly PC8. set critical parameters for the machinery (cycle time, temperature, pressure, ampere load, spray rate, etc.) as per the company's SOP PC9. keep all the accessories like cleaning brush, levers, release agent, etc. ready PC10. monitor machines during every procedure to ensure optimum performance PC11. perform random tests to ensure accuracy and maintain online documentation for the same along with justifications for any wrong entries, if any PC12. coordinate with maintenance teams for preventive maintenance |
| | Raw material / material appropriateness | <ul style="list-style-type: none"> PC13. ensure stocks of required materials are ready and available at all times PC14. ensure that the compound/material to be fed is approved by the laboratory as per SOP and record the receipt details like product name, batch name and operator name PC15. match the batch code/item code , Authorized Return (AR) No of each compound/material with the batch code on the job schedule given by the |

LFS/N0213 :

Prepare machines and accessories for the manufacturing process

| | |
|--|--|
| | <p>planning department, ensuring FIFO (First in First Out) and further record the name, shelf life and quantities during documentation</p> <p>PC16. measure/weigh the raw material/compound as per the desired specifications (shape, size and weight) and return the unused material to warehouse with the appropriate label</p> <p>PC17. ensure, by visual inspection, that the compound is of desired quality (free of contamination/bloom), and reach out to the supervisor for rejection control if disparities exist</p> |
| <p>Health & Safety</p> | <p>PC18. ensure housekeeping/safety in the manufacturing area as per the SOP</p> <p>PC19. maintain and clean the machines before and after batch processing</p> <p>PC20. use lifting equipment such as forklift/trolleys while lifting heavy materials to avoid physical injury</p> <p>PC21. ensure that the lift/ejection/slide/pneumatic valve mechanism of the machinery is properly functioning</p> <p>PC22. ensure that signs indicating hot surfaces are put up wherever necessary</p> <p>PC23. adhere to all safety norms (like wearing protective gloves, shoes)</p> <p>PC24. comply with health, safety, environment guidelines, regulations in accordance with international/national standards or organizational SOP</p> |
| <p>Knowledge and Understanding (K)</p> | |
| <p>A. Organisational Context (Knowledge of the Company/ Organisation and its processes)</p> | <p>The user/ individual on the job needs to know and understand :</p> <p>KA1. organizational coding system of finished materials, compounds and the company manual</p> <p>KA2. different quality management systems (ISO-9000, ISO-14001, OHSAS-18000) and tools, good laboratory and manufacturing practices</p> <p>KA3. importance of identifying non-conforming products and storage of the same</p> <p>KA4. importance of FIFO</p> <p>KA5. handover/ takeover procedures and production workflow sequences to be followed and materials required</p> <p>KA6. organization's vision and strategy</p> |
| <p>B. Technical Knowledge</p> | <p>The user/ individual on the job needs to know and understand:</p> <p>KB1. standard measuring units and methods of performing simple calculations</p> <p>KB2. different standard reference material</p> <p>KB3. operation of machinery and functioning of different types of machines like rapid mixer granulator, spray coating machine, strip packing machine, blister packaging machine. Knowledge of working of the machines used for the manufacture of specified products listed below is expected: Liquid - Filter Press, Inline Homogeniser Cum Mixer, Preparation vessel, reactor & Storage Tank, Dispo Homogenizer, Skid CIP-WIP System, Colloid Mill, Automatic Filling Machine, Semi-Automatic Cap Sealing Machine, Induction machine, Washing Machine, On Line Inspection, Turn Table, Labelling machine; Ointment - Planetary, Preparation vessel, reactor & Storage Tank, Vacuum Homogenizer Mixer, Agitator- Stirrer, Colloid Mill, Inline Homogenizer, Skid CIP-WIP System, Tube Filling and Sealong Machines For Laminated / Plastic Tubes</p> |

LFS/N0213 :

Prepare machines and accessories for the manufacturing process

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| | <p>Injection – Multicolumn, Rectangular Steriliser, D.M. storage Tank, Dry Heat Sterilizer, Filling / Pressure Vessel, Automatic Filling Machine, Monoblock Rotary Dry Powder Filling & Sealing Machine, Semi-Automatic Cap Sealing Machine, Semi-Automatic Ropp Cap Sealing Machine & Screw Capping Machine, Automatic Single Head Ropp Cap Sealing Machine, Washing Machine, On Line Inspection, Automatic Self Adhesive Vertical Labelling Machine</p> <p>KB4. operational characteristics of the materials, equipment and processes, sufficient enough to recognize deviation from standard products and processes</p> <p>KB5. usage of appropriate equipment, materials, processes and procedures</p> <p>KB6. potential effects of variations in raw materials and equipment operation on the quality of products</p> <p>KB7. preventive measures to ensure proper working of machines</p> <p>KB8. details of machine history, efficiency, and output time and must possess the aptitude to analyze this information</p> <p>KB9. methods to identify breakdown of machinery</p> |
| Skills (S) | |
| A. Core Skills/ Generic Skills | <p>Writing skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. maintain proper records as per given format</p> <p>Reading and Understanding Skills</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA2. read and interpret images, graphs, diagrams for typical product specifications, job sheets, procedures, basic machine control panels, material labels and safety information as provided</p> <p>Oral Communication (Listening and Speaking skills)</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA3. communicate with upstream teams</p> <p>SA4. work in a team and possess other behavioural skills required to support small group activities</p> <p>SA5. communicate confidential and sensitive information discretely to authorized person as per the SOP</p> |
| B. Professional Skills | <p>Analytical Thinking</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. pay attention to detail</p> <p>SB2. suggest improvements(if any) in current ways of working</p> |

LFS/N0213 :

Prepare machines and accessories for the manufacturing process

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|--|--|
| | SB3. spot process disruptions and delays and report to supervisor |
| | Plan & Organize |
| | The user/individual on the job needs to know and understand how to: |
| | SB4. plan and organize their assigned work in order to achieve specified deadlines |
| | SB5. meet the desired work specifications |
| | Decision Making |
| | The user/individual on the job needs to know and understand how to: |
| | SB6. appropriately use the escalation matrix for complex decisions |
| | Problem Solving |
| | The user/individual on the job needs to know and understand how to: |
| | SB7. solve problems faced in day-to-day work |
| | Critical Thinking |
| | Not Applicable |
| | Customer Centricity |
| | Not Applicable |

NOS Version Control

| NOS Code | LFS/N0213 | | |
|---------------------|--|------------------|----------|
| Credits(NSQF) | TBD | Version number | 1.0 |
| Industry | Life Sciences | Drafted on | 15/12/14 |
| Industry Sub-sector | Pharmaceuticals, Biopharmaceuticals | Last reviewed on | 26/03/15 |
| Occupation | Manufacturing | Next review date | 01/06/17 |

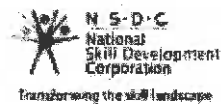


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NOS
National Occupational Standards



LFS/N0214 :

Perform manufacturing operations

National Occupational Standard

Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Machine Operator to perform manufacturing operations.



LFS/N0214 :

Perform manufacturing operations

| | | |
|--------------------------------|--|---|
| National Occupational Standard | Unit Code | LFS/N0214 |
| | Unit Title (Task) | Perform manufacturing operations |
| | Description | This NOS unit is about a Machine Operator operating the machine, feeding raw materials which needs to be processed into the machine, inspecting and resolving any defaults in running of machinery and reporting any unresolved problems and also inspect any defected material or products and report it. |
| | Scope | The unit/ task covers the following: <ul style="list-style-type: none"> Raw material/ material appropriateness Operation |
| | Performance Criteria (PC) w.r.t the Scope | |
| | Element | Performance Criteria |
| | Raw material/ material appropriateness | To be competent, the user/individual on the job must be able to: <p>PC1. handle the chemicals, materials and compounds appropriately to avoid contamination</p> |
| | Operation | <p>PC2. complete takeover of work and equipment and conduct pre-start checks</p> <p>PC3. start the equipment safely and perform 'dry runs' to warm hydraulics and components to operating temperature before production, as required</p> <p>PC4. load the identified material in the correct pattern as per the SOP to minimize material overflow/wastage/excess flash</p> <p>PC5. ensure smooth running of machines and the pressure and temperature is maintained in the machines as per the specifications and adhere to the production timelines</p> <p>PC6. adhere to the SOPs and guidelines for maintaining quality</p> <p>PC7. maintain both online and offline records in the log books and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, etc.</p> <p>PC8. take appropriate safety steps while carrying out manufacturing operations</p> <p>PC9. carry out status labelling and segregation of material/ intermediate/ finished goods as per SOPs</p> <p>PC10. provide support for line clearance before the next batch is produced and handover the work/ equipment to colleague in next shift in adherence of the shift schedule</p> <p>PC11. perform broad level in process checks and report results to supervisor</p> <p>PC12. ensure and confirm correctness of online process parameters</p> <p>PC13. minimize waste during entire production operations</p> <p>PC14. coordinate and work with supervisor, team members in own department and cross functions to achieve the production targets and to ensure efficient workflow</p> <p>PC15. take necessary steps as per SOP and escalation matrix in case of any disagreement with colleagues or in other conflict</p> |

LFS/N0214 :

Perform manufacturing operations

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|---|--|
| | PC16. discuss with supervisor on own performance and receive support and feedback from supervisor or any other appropriate authority |
| Knowledge and Understanding (K) | |
| A. Organisational Context (Knowledge of the Company/ Organisation and its processes) | <p>The user/individual on the job needs to know and understand:</p> <p>KA1. impact of various practices on cost, quality, productivity, delivery and safety</p> <p>KA2. chemicals used in the industry and their functions, material segregation and labelling procedures</p> <p>KA3. risk and impact of not following defined procedures/work instructions</p> <p>KA4. characteristics of the product/material</p> <p>KA5. methods of handover/takeover the equipment/work area as per company's SOP</p> |
| B. Technical Knowledge | <p>The user/individual on the job needs to know and understand:</p> <p>KB1. influence of different process parameters (e.g. time, temperature, pressure) on manufacturing and product performance</p> <p>KB2. good practices to be followed while working on machines</p> <p>KB3. basics of GMP</p> <p>KB4. purpose and requirements of 'dry running' before starting production</p> <p>KB5. potential effects of variations in raw materials and equipment operation on the quality of products</p> <p>KB6. factors which may affect product quality or production output and must be aware of appropriate remedies</p> |
| Skills (S) | |
| A. Core Skills/ Generic Skills | Writing Skills |
| | The user/ individual on the job needs to know and understand how to: |
| | SA1. record and communicate details of work done to appropriate people using written/typed report |
| | Reading skills |
| The user/individual on the job needs to know and understand how to: | |
| SA2. read and interpret images, graphs, diagrams for typical product specifications, job sheets, procedures, basic machine control panels, material labels and safety information as provided | |
| SA3. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc. | |
| | Oral Communication (Listening and Speaking skills) |
| | The user/individual on the job needs to know and understand how to: |

LFS/N0214 :

Perform manufacturing operations

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| | <p>SA4. disclose information only to those who have the right and need to know it</p> <p>SA5. communicate confidential and sensitive information discretely to authorized person as per the SOP</p> <p>SA6. share in a precise manner information about machine's previous history</p> <p>SA7. share in a precise manner the information about critical machine parameters</p> |
| B. Professional Skills | <p>Analytical Thinking</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. pay attention to detail</p> <p>SB2. suggest improvements(if any) in current ways of working</p> <p>SB3. spot equipment/process disruptions and delays and report to supervisor</p> <p>Plan & Organize</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB4. plan and organize assigned work in order to achieve specified deadlines as per the schedule provided</p> <p>SB5. meet the desired work specifications.</p> <p>Decision Making</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB6. appropriately use the escalation matrix for complex decisions</p> <p>Problem Solving</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB7. solve problems faced in day-to-day work</p> <p>Critical Thinking</p> <p>Not Applicable</p> <p>Customer Centricity</p> <p>Not Applicable</p> |



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LFS/N0214 : Perform manufacturing operations
NOS Version Control

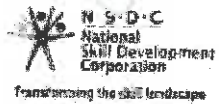
| NOS Code | LFS/N0214 | | |
|---------------------|--|------------------|----------|
| Credits(NSQF) | TBD | Version number | 1.0 |
| Industry | Life Sciences | Drafted on | 15/12/14 |
| Industry Sub-sector | Pharmaceuticals, Biopharmaceuticals | Last reviewed on | 26/03/15 |
| Occupation | Manufacturing | Next review date | 01/06/17 |



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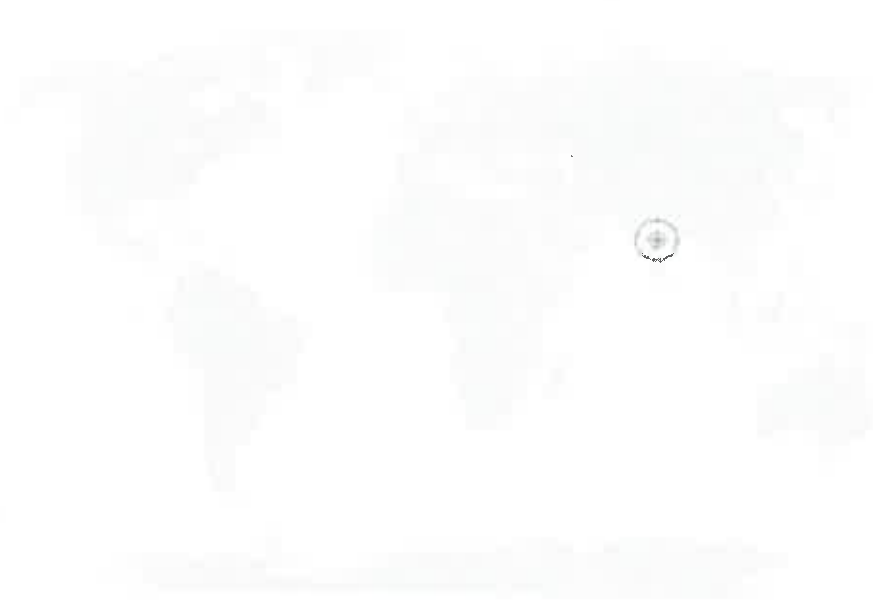
NOS
National Occupational Standards



LFS/N0103 :

Ensure cleanliness in the work area

National Occupational Standard




Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Machine Operator to ensure cleanliness in the work area by carrying out housekeeping of their respective area.

16 | Page




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LFS/N0103 : Ensure cleanliness in the work area

| | | |
|--------------------------------|---|--|
| National Occupational Standard | Unit Code | LFS/N0103 |
| | Unit Title (Task) | Ensure cleanliness in the work area |
| | Description | This NOS unit is about the Machine Operator to carry out housekeeping activities for respective area |
| | Scope | This unit/task covers the following: <ul style="list-style-type: none"> • Pre housekeeping activities • Operations • Post housekeeping activities |
| | Performance Criteria (PC) w.r.t. the Scope | |
| | Element | Performance Criteria |
| | Pre housekeeping activities | To be competent, the user/individual on the job must be able to: <p>PC1. inspect the area while taking into account various surfaces</p> <p>PC2. identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain</p> <p>PC3. ensure that the cleaning equipment is in proper working condition</p> <p>PC4. select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person</p> <p>PC5. plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces</p> <p>PC6. inform the affected people about the cleaning activity</p> <p>PC7. display the appropriate signage for the work being conducted</p> <p>PC8. ensure that there is adequate ventilation for the work being carried out</p> <p>PC9. wear the personal protective equipment required for the cleaning method and materials being used</p> |
| | Operations | PC10. use the correct cleaning method for the work area, type of soiling and surface PC11. deal with accidental damage, if any, caused while carrying out the work PC12. report to the appropriate person any difficulties in carrying out work PC13. identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill |
| | Post housekeeping activities | PC14. ensure that there is no oily substance on the floor to avoid slippage PC15. ensure that no scrap material is lying around PC16. maintain and store housekeeping equipment and supplies PC17. follow workplace procedures to deal with any accidental damage caused during the cleaning process PC18. ensure that, on completion of the work, the area is left clean and dry and meets requirements PC19. return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored |

LFS/N0103 :

Ensure cleanliness in the work area

| | |
|---|--|
| | <p>PC20. dispose the waste garnered from the activity in an appropriate manner</p> <p>PC21. dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly</p> <p>PC22. maintain schedules and records for housekeeping duty</p> <p>PC23. replenish any necessary supplies or consumables</p> |
| Knowledge and Understanding (K) | |
| A. Organisational Context (Knowledge of the Company/Organisation and its processes) | <p>The user/individual on the job needs to know and understand:</p> <p>KA1. levels of hygiene required by storage area and importance of maintaining the same</p> <p>KA2. methodology for storage area inspection with methods and materials required for cleaning variety of surfaces and equipment</p> <p>KA3. the method to check the treated surface and equipment on completion of cleaning</p> <p>KA4. procedures for reporting any unidentified soiling</p> <p>KA5. escalation procedures for soils or stains that could not be removed</p> |
| B. Technical Knowledge | <p>The user/individual on the job needs to know and understand:</p> <p>KB1. role of different materials, chemicals and equipment</p> <p>KB2. Good Laboratory Practices and Good Manufacturing Practices guidelines</p> |
| Skills (S) | |
| A. Core Skills/ Generic Skills | <p>Writing Skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail</p> |
| | <p>Reading and Understanding Skills</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA2. understand the various coding systems as per company norms</p> |
| | <p>Oral Communication (Listening and Speaking skills)</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA3. communicate with upstream and downstream teams</p> <p>SA4. disclose information only to those who have the right and need to know it.</p> |
| | <p>Critical Thinking</p> <p>The user/individual on the job needs to know and understand how to:</p> |
| B. Professional Skills | <p>Critical Thinking</p> <p>The user/individual on the job needs to know and understand how to:</p> |

LFS/N0103 :


Ensure cleanliness in the work area

| | |
|--|--|
| | SB1. suggest improvements(if any) in process based on experience |
| | Decision Making |
| | SB2. make decisions to maintain cleanliness in the area of work |
| | Analytical Thinking |
| | Not Applicable |
| | Decision Making |
| | Not Applicable |
| | Plan and Organize |
| | Not Applicable |
| | Customer Centricity |
| | Not Applicable |

NOS Version Control

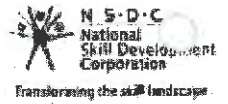
| NOS Code | LFS/N0103 | | |
|---------------------|---|------------------|----------|
| Credits(NSQF) | TBD | Version number | 1.0 |
| Industry | Life Sciences | Drafted on | 22/12/14 |
| Industry Sub-sector | Pharmaceuticals and Bio Pharmaceuticals | Last reviewed on | 15/05/15 |
| Occupation | Manufacturing, Quality, Supply Chain, R&D | Next review date | 01/06/16 |




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NOS
National Occupational Standards



LFS/N0102 :

Carry out reporting and documentation

National Occupational Standard




Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Machine Operator to carry out reporting and documentation.

20 | Page




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LFS/N0102 : Carry out reporting and documentation

National Occupational Standard

| | |
|---|--|
| Unit Code | LFS/N0102 |
| Unit Title (Task) | Carry out reporting and documentation |
| Description | This NOS is about a Machine Operator for reporting ,recording and documentation of data/problem/incidents etc. and to maintain information security |
| Scope | The unit/task covers the following: <ul style="list-style-type: none"> • Reporting. • Recording and documentation • Information security |
| Performance Criteria (PC) w.r.t. the Scope | |
| Element | Performance Criteria |
| Reporting | To be competent, the user/individual on the job must be able to: PC1. report data/problems/incidents as applicable in a timely manner PC2. report to the appropriate authority as laid down by the company PC3. follow reporting procedures as prescribed by the company. |
| Recording and documentation | PC4. identify documentation to be completed relating to one's role PC5. record details accurately in an appropriate format PC6. complete all documentation within stipulated time according to company procedure PC7. ensure that the final document meets regulatory and compliance requirements PC8. make sure documents are available to all appropriate authorities to inspect |
| Information Security | PC9. respond to requests for information in an appropriate manner whilst following organizational procedures PC10. inform the appropriate authority of requests for information received |
| Knowledge and Understanding (K) | |
| A. Organisational Context (Knowledge of the Company/ Organisation and its processes) | The user/individual on the job needs to know and understand: KA1. types of documentation in organization, importance of maintaining the same and different methods of recording information KA2. the importance of reporting incidents where standard operating procedures are not followed KA3. the importance of complete and accurate documentation KA4. production workflow sequences and materials demand KA5. escalation matrix for reporting identified issues, hazards and breakage |
| B. Technical Knowledge | The user/individual on the job needs to know and understand: KB1. methods of obtaining and interpreting records, charts, specifications, equipment manuals, history/technical support reports and other documents |

LFS/N0102 :

Carry out reporting and documentation

| Skills (S) | |
|---|---|
| A. Core Skills/ Generic Skills | Writing skills The user/ individual on the job needs to know and understand how to: SA1. record and communicate details of work done to appropriate people using written/typed report SA2. maintain proper records as per given format |
| | Reading skills The user/individual on the job needs to know and understand how to: SA3. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc. SA4. read and interpret images, graphs, diagrams for typical product specifications, job sheets, procedures, basic machine control panels, material labels and safety information as provided SA5. use and interpret the various coding systems as per company norms |
| | Oral Communication (Listening and Speaking skills) The user/individual on the job needs to know and understand how to: SA6. disclose information only to those who have the right and need to know it SA7. communicate confidential and sensitive information discretely to authorized person as per SOP SA8. communicate with people in a proper form and manner and use language that is open and respectful |
| | B. Professional Skills |
| | Analytical Thinking The user/individual on the job needs to know and understand how to: SB1. pay attention to detail SB2. use automated report writing and documentation technologies |
| | Critical Thinking The user/individual on the job needs to know and understand how to: SB3. suggest improvements(if any) in process based on experience |
| | Plan and Organise The user/individual on the job needs to know and understand how to: SB4. learn from experience in a range of settings and scenarios and the capacity to reflect on and analyse one's learning |
| | Problem Solving |

LFS/N0102 :

Carry out reporting and documentation

| | |
|--|--|
| | The user/individual on the job needs to know and understand how to: |
| | SB5. act objectively, rather than impulsively or emotionally when faced with difficult/stressful or emotional situations |
| | Decision Making |
| | Not Applicable |
| | Customer Centricity |
| | Not Applicable |

NOS Version Control

| NOS Code | LFS/N0102 | | |
|---------------------|---|------------------|----------|
| Credits(NSQF) | TBD | Version number | 1.0 |
| Industry | Life Sciences | Drafted on | 15/12/14 |
| Industry Sub-sector | Pharmaceuticals, Biopharmaceuticals | Last reviewed on | 26/03/15 |
| Occupation | Manufacturing, Quality, Supply Chain, R&D | Next review date | 01/06/17 |



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LFS/N0215 : Carry out broad level quality checks before, in-process and post manufacturing

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Machine Operator to carry out broad level quality checks before, in-process and post manufacturing.

LFS/N0215 : Carry out broad level quality checks before, in-process and post manufacturing

| | | |
|--------------------------------|--|--|
| National Occupational Standard | Unit Code | LFS/N0215 |
| | Unit Title (Task) | Carry out broad level quality checks before, in-process and post manufacturing |
| | Description | This NOS unit is about a Machine Operator carrying out quality checks to identify problems through inspection and analysis activities |
| | Scope | The unit/ task covers the following: <ul style="list-style-type: none"> • Inspection • Analysis Activities |
| | Performance Criteria (PC) w.r.t. the Scope | |
| | Element | Performance Criteria |
| | Inspection | To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> PC1. ensure that the total range of checks are regularly and consistently performed PC2. check that the products, materials and equipment meet the requirements for production PC3. use appropriate measuring instruments, equipment, tools, accessories etc. as required |
| | Analysis | <ul style="list-style-type: none"> PC4. identify non-conformities to quality assurance standards PC5. identify potential causes of non-conformities to quality assurance standards PC6. identify impact on final product due to non-conformance to company standards PC7. evaluate the need for action to ensure that problems do not recur PC8. suggest corrective action to address problems PC9. review effectiveness of corrective action |
| | Knowledge and Understanding (K) | |
| | A. Organisational Context (Knowledge of the Company/ Organisation and its processes) | The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> KA1. risk and impact of not following defined procedures/work instructions KA2. escalation matrix for reporting identified issues, hazards and breakage KA3. implications of inaccurate measurements and testing equipment KA4. implications (impact on internal/external customers) of defective products, materials or components KA5. reason and impact of problems affecting the equipment KA6. measures, steps and possible solutions that have been identified/taken to address previous problems KA7. the correct method for sampling, identification of non-conforming products and carrying out corrective actions outlined for each problem KA8. importance of identifying non-conforming products and labelling and storage of the same |

LFS/N0215 : Carry out broad level quality checks before, in-process and post manufacturing

| | |
|--|---|
| <p>B. Technical Knowledge</p> | <p>The user/individual on the job needs to know and understand:</p> <p>KB1. implications of delays in the preparation process</p> <p>KB2. possible causes of common machinery problems and their remedies</p> <p>KB3. influence of different process parameters (e.g. time, temperature, pressure) on manufacturing and product performance</p> <p>KB4. good practices for working on machines</p> <p>KB5. factors which may affect product quality or production output and appropriate remedies</p> <p>KB6. correct method / procedure for processing samples</p> <p>KB7. how to interpret the sample quality check results</p> |
| <p>Skills (S)</p> | |
| <p>A. Core Skills/ Generic Skills</p> | <p>Writing skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. record and communicate details of work done to appropriate people using written/typed report</p> <hr/> <p>Reading skills</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA2. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc.</p> <p>SA3. read and interpret images, graphs, diagrams for typical product specifications, job sheets, procedures, basic machine control panels, material labels and safety information as provided</p> <p>SA4. use and interpret the various coding systems as per company norms</p> <hr/> <p>Oral Communication (Listening and Speaking skills)</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA5. communicate with other teams</p> <p>SA6. disclose information only to those who have the right and need to know it.</p> <p>SA7. communicate confidential and sensitive information discretely to authorized person as per SOP</p> <p>SA8. communicate with people in an appropriate form and manner and use language that is open and respectful</p> |
| <p>B. Professional Skills</p> | <p>Analytical Thinking</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. pay attention to detail</p> <p>SB2. diagnose common quality issues/non-conformities etc.</p> <p>SB3. suggest improvements(if any) in current ways of working</p> |

LFS/N0215 : Carry out broad level quality checks before, in-process and post manufacturing


| | |
|----------------------------|---|
| | Decision Making |
| | The user/individual on the job needs to know and understand how to: |
| | SB4. appropriately use the escalation matrix for complex decisions |
| | SB5. appropriately highlight and escalate identified issues |
| | Critical Thinking |
| | Not Applicable |
| | Plan and Organize |
| | Not Applicable |
| | Problem Solving |
| | Not Applicable |
| Customer Centricity | |
| Not Applicable | |



NOS Version Control

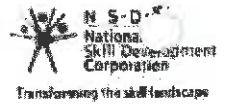
| NOS Code | LFS/N0215 | | |
|---------------------|--|------------------|----------|
| Credits(NSQF) | TBD | Version number | 1.0 |
| Industry | Life Sciences | Drafted on | 15/12/14 |
| Industry Sub-sector | Pharmaceuticals, Biopharmaceuticals | Last reviewed on | 26/03/15 |
| Occupation | Manufacturing | Next review date | 01/06/17 |




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NOS
National Occupational Standards



LFS/N0101 : Maintain a healthy, safe and secure working environment in the life sciences facility

National Occupational Standard

Overview

This Occupational Standard is about the knowledge, understanding and skills required by a Machine Operator to ensure healthy, safe and secure working environment in the life sciences facility



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LFS/N0101 : Maintain a healthy, safe and secure working environment in the life sciences facility

| | | |
|--|---|---|
| National Occupational Standard | Unit Code | LFS /N0101 |
| | Unit Title (Task) | Maintain a healthy, safe and secure working environment in the life sciences facility |
| | Description | This NOS unit is about a Machine Operator monitoring the working environment and making sure that it meets the requirements for health, safety and security in the pharmaceutical/contract research/biopharmaceutical facility/ manufacturing/ testing/ analysis/ research laboratory. |
| | Scope | <p>This unit / task covers the following:</p> <p>Ensuring healthy, safe and secure working environment:</p> <ul style="list-style-type: none"> self monitor and adhere to safety principles and standards ensure behavioural safety by workmen to cGMP and applicable safety standards on the shop floor/ laboratory report any identified breaches in health, safety, and security policies and procedures to the designated person <p>Managing emergency procedures:</p> <ul style="list-style-type: none"> illness accidents fires other reasons to evacuate the premises breaches of security |
| Performance Criteria (PC) wrt the Scope | | |
| Element | Performance Criteria | |
| Ensuring healthy, safe and secure working environment | <p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. observe and comply with the company's current health, safety and security policies and procedures</p> <p>PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines</p> <p>PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person</p> <p>PC4. responsible for maintaining discipline at the shop-floor/ production area</p> <p>PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority</p> <p>PC6. adhere and comply to storage and handling guidelines for hazardous material</p> <p>PC7. identify and recommend opportunities for improving health, safety, and security to the designated person</p> <p>PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately</p> | |
| Managing emergency procedures | <p>PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected</p> <p>PC10. follow the company's emergency procedures promptly, calmly, and efficiently</p> | |
| Knowledge and Understanding (K) | | |

LFS/N0101 : Maintain a healthy, safe and secure working environment in the life sciences facility

| | |
|--|---|
| <p>B. Organisational Context (Knowledge of the Company/ Organisation and its processes)</p> | <p>The user/ individual on the job needs to know and understand:</p> <p>KA1. legislative requirements and company's procedures for health, safety and security and individual's role and responsibilities in relation to this</p> <p>KA2. what is meant by a hazard, including the different types of health and safety hazards that can be found in the workplace</p> <p>KA3. how and when to report hazards</p> <p>KA4. limits of individual responsibility for dealing with hazards</p> <p>KA5. the organization's emergency procedures for different emergency situations and the importance of following these</p> <p>KA6. the importance of maintaining high standards of health, safety and security</p> <p>KA7. implications that any non-compliance with health, safety and security may have on individuals and the organization</p> <p>KA8. health hazards and its implications if any in the production process</p> |
| <p>B Technical Knowledge</p> | <p>The user/ individual on the job needs to know and understand:</p> <p>KB1. different types of breaches in health, safety and security and how and when to report these</p> <p>KB2. evacuation procedures for workers and visitors</p> <p>KB3. how to summon medical assistance and the emergency services, where necessary</p> <p>KB4. how to use the health, safety and accident reporting procedures and the importance of these</p> <p>KB5. different types of occupational health hazards</p> <p>KB6. knowledge of chemical substances, their characteristics and required precaution and safety measures</p> |
| <p>Skills (S)</p> | |
| <p>C. Core Skills/ Generic Skills</p> | <p>Writing skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. complete accurate, well written work with attention to detail</p> |
| | <p>Reading skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA2. read instructions, guidelines, procedures, rules and service level agreements</p> |
| | <p>Oral Communication (Listening and Speaking skills)</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA3. listen effectively and orally communicate information accurately</p> |

LFS/N0101 : Maintain a healthy, safe and secure working environment in the life sciences facility

| | |
|--|--|
| D. Professional Skills | Decision making |
| | The user/ individual on the job needs to know and understand how to: |
| | SB1. make decisions on suitable courses of action |
| | Plan and Organise |
| | The user/ individual on the job needs to know and understand how to: |
| | SB2. plan and organize work to meet health, safety and security requirements |
| | Problem solving |
| | The user/ individual on the job needs to know and understand how to: |
| | SB3. apply problem solving approaches in different situations |
| | Analytical thinking |
| The user/ individual on the job needs to know and understand how to: | |
| SB4. analyse data and activities | |
| Critical thinking | |
| The user/ individual on the job needs to know and understand how to: | |
| SB5. apply balanced judgments to different situations | |
| Customer Centricity | |
| Not Applicable | |

NOS Version Control

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|----------------------------|--|-------------------------|-----------------|
| NOS Code | LFS/N0101 | | |
| Credits(NSQF) | TBD | Version number | 1.0 |
| Industry | Life Sciences | Drafted on | 26/06/14 |
| Industry Sub-sector | Pharmaceuticals and Bio Pharmaceuticals | Last reviewed on | 15/05/15 |
| Occupation | Manufacturing, Quality, Supply Chain, R&D | Next review date | 01/06/16 |



K. Srinivas

Qualifications Pack For Production/Machine Operator –Life Sciences

Annexure

Nomenclature for QP and NOS

Qualifications Pack

9 characters

LFS / Q 0101

LFS



QP Number (2 numbers)

Q denoting Qualification Pack

Occupation (2 numbers)

Occupational Standard

An example of NOS with 'N'

9 characters

LFS / N 0101

LFS



OS Number (2 numbers)

N denoting National Occupational Standard

Occupation (2 numbers)



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Qualifications Pack For Production/Machine Operator –Life Sciences

The following acronyms/codes have been used in the nomenclature above:

| Sub-Sector | Range of Occupation Numbers |
|--|-----------------------------|
| Pharmaceutical and Biopharmaceutical and Contract Research | 01-10 |
| Pharmaceutical | 11-20 |
| Biopharmaceutical | 21-30 |
| Contract Research | 31-40 |

| Sequence | Description | Example |
|------------------|-------------------|---------|
| Three letters | Industry name | LFS |
| Slash | / | / |
| Next letter | Whether QP or NOS | Q/N |
| Next two numbers | Occupation code | 01 |
| Next two numbers | OS number | 01 |



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Qualifications Pack For Production/Machine Operator –Life Sciences
CRITERIA FOR ASSESSMENT OF TRAINEES

Job Role Production/Machine Operator – Life Sciences
Qualification Pack LFS/Q0207
Sector Skill Council Life Sciences Sector Skill Development Council

Guidelines for Assessment:

1. Criteria for assessment for each Qualification Pack will be created by the Sector Skill Council. Each Performance Criteria (PC) will be assigned marks proportional to its importance in NOS. SSC will also lay down proportion of marks for Theory and Skills Practical for each PC.
2. The assessment for the theory part will be based on knowledge bank of questions created by the SSC.
3. Individual assessment agencies will create *unique question papers for theory part for each candidate at each examination/training center* (as per assessment criteria below)
4. Individual assessment agencies will create *unique evaluations for skill practical for every student at each examination/training center* based on this criteria
5. To pass the Qualification Pack, every trainee should score a minimum of 70% in every NOS
6. In case of successfully passing only certain number of NOS's, the trainee is eligible to take subsequent assessment on the balance NOS's to pass the Qualification Pack.

| Assessment Outcome | Assessment Criteria of Outcomes | Total Marks (600) | Marks Allocation | | |
|---|--|-------------------|------------------|--------|------------------|
| | | | Out Of | Theory | Skills Practical |
| LFS/N0213 (Prepare machines and accessories for the manufacturing process) | PC1. Take handover from the colleague in previous shift and ensure that the machine, surrounding areas and classified areas are clean, dry, sterilised (wherever required) and fit for use as per the SOP to avoid contamination and highlight the risk if any | 100 | 4 | 2 | 2 |
| | PC2. set up machines at the beginning of the batch processing to ensure proper working order and refer to the machine history received from the supervisor/colleague at the time of handover | | 4 | 2 | 2 |
| | PC3. perform testing procedures to ensure that machines work optimally to carry out production activities | | 4 | 2 | 2 |
| | PC4. ensure that the approach path from the input storage area to storage area for output is free | | 4 | 2 | 2 |

Qualifications Pack For Production/Machine Operator –Life Sciences

| | | | | | |
|--|--|--|---|---|---|
| | of obstructions to transportation | | | | |
| | PC5.select the correct material to be loaded | | 4 | 2 | 2 |
| | PC6. ensure that the material is from a respective batch and is checked by the concerned supervisor and approved by the QA team | | 4 | 2 | 2 |
| | PC7.assemble the machinery properly | | 4 | 2 | 2 |
| | PC8. set critical parameters for the machinery (cycle time, temperature, pressure, ampere load, spray rate, etc.) as per the company's SOP | | 4 | 2 | 2 |
| | PC9. keep all the accessories like cleaning brush, levers, release agent, etc. ready | | 4 | 2 | 2 |
| | PC10. monitor machines during every procedure to ensure optimum performance | | 4 | 2 | 2 |
| | PC11. perform random tests to ensure accuracy and maintain online documentation for the same along with justifications for any wrong entries, if any | | 4 | 2 | 2 |
| | PC12. coordinate with maintenance teams for preventive maintenance | | 4 | 2 | 2 |
| | PC13. ensure stocks of required materials are ready and available at all times | | 4 | 2 | 2 |
| | PC14. ensure that the compound/material to be fed is approved by the laboratory as per SOP and record the receipt details like product name, batch name and operator name | | 4 | 2 | 2 |
| | PC15. match the batch code/item code , authorized return (AR) No. of each compound/material with the batch code on the job schedule given by the planning department, ensuring FIFO and further record the name, shelf | | 4 | 2 | 2 |

Qualifications Pack For Production/Machine Operator –Life Sciences

| | | | | | |
|---|---|-----|------------|-----------|-----------|
| | life and quantities during documentation | | | | |
| | PC16. measure/weigh the raw material/compound as per the desired specifications (shape, size and weight) and return the unused material to warehouse with the appropriate label | | 4 | 2 | 2 |
| | PC17. ensure, by visual inspection, that the compound is of desired quality (free of contamination/bloom), and reach out to the supervisor for rejection control if disparities exist | | 4 | 3 | 3 |
| | PC18. ensure housekeeping/safety in the manufacturing area as per the SOP | | 4 | 2 | 2 |
| | PC19. maintain and clean the machines before and after batch processing | | 4 | 2 | 2 |
| | PC20. use lifting equipment such as forklift/trolleys while lifting heavy materials to avoid physical injury | | 4 | 2 | 2 |
| | PC21. ensure that the lift/ejection/slide/pneumatic valve mechanism of the machinery is properly functioning | | 4 | 2 | 2 |
| | PC22. ensure that signs indicating hot surfaces are put up wherever necessary | | 4 | 2 | 2 |
| | PC23. adhere to all safety norms (like wearing protective gloves, shoes) | | 4 | 2 | 2 |
| | PC24. comply with health, safety, environment guidelines, regulations in accordance with international/national standards or organizational SOP | | 4 | 3 | 3 |
| | Total | | 100 | 50 | 50 |
| LFS/N0214 (Perform manufacturing operations) | PC1. handle the chemicals, materials and compounds appropriately to avoid contamination | 100 | 8 | 4 | 4 |
| | PC2. conduct pre-start checks | | 12 | 6 | 6 |

Qualifications Pack For Production/Machine Operator –Life Sciences

| | | | |
|---|----|---|---|
| PC3. start the equipment safely and perform 'dry runs' to warm hydraulics and components to operating temperature before production, as required | 10 | 5 | 5 |
| PC4. load the identified material in the correct pattern as per the SOP to minimize material overflow/wastage/excess flash | 8 | 4 | 4 |
| PC5. ensure smooth running of machines and the pressure and temperature is maintained in the machines as per the specifications and adhere to the production timelines | 8 | 4 | 4 |
| PC6. adhere to the SOPs and guidelines for maintaining quality | 6 | 3 | 3 |
| PC7. maintain both online and offline records in the log books and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, etc | 6 | 3 | 3 |
| PC8. take appropriate safety steps while carrying out manufacturing operations | 5 | 2 | 3 |
| PC9. carry out status labelling and segregation of material/ intermediate/ finished goods as per SOPs | 4 | 2 | 2 |
| PC10. provide support for line clearance before the next batch is produced and handover the work / equipment to colleague in next shift in adherence of the shift schedule | 4 | 2 | 2 |
| PC 11. perform broad level in-process checks and report results to supervisor | 4 | 2 | 2 |
| PC 12. ensure and confirm correctness of online process parameters | 6 | 3 | 3 |
| PC 13. minimize waste during entire production operations | 4 | 2 | 2 |

Qualifications Pack For Production/Machine Operator –Life Sciences

| | | | | | |
|--|--|-----|------------|-----------|-----------|
| | PC14. coordinate and work with supervisor, team members in own department and cross functions to achieve the production targets and to ensure efficient workflow | | 6 | 2 | 4 |
| | PC15. take necessary steps as per SOP and escalation matrix in case of any disagreement with colleagues or in other conflict | | 5 | 2 | 3 |
| | PC16. discuss with supervisor on own performance and receive support and feedback from supervisor or any other appropriate authority | | 4 | 2 | 2 |
| | Total | | 100 | 48 | 52 |
| LFS/N0103 (Ensure cleanliness in the work area) | PC1.inspect the area while taking into account various surfaces | 100 | 4 | 2 | 2 |
| | PC2.identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain | | 5 | 2 | 3 |
| | PC3.ensure that the cleaning equipment is in proper working condition | | 5 | 2 | 3 |
| | PC4.select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person | | 4 | 2 | 2 |
| | PC5.plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces | | 4 | 2 | 2 |
| | PC6.inform the affected people about the cleaning activity | | 4 | 2 | 2 |
| | PC7.display the appropriate signage for the work being conducted | | 4 | 2 | 2 |
| | PC8.ensure that there is adequate ventilation for the work being carried out | | 5 | 2 | 3 |
| | PC9.wear the personal protective equipment required for the cleaning method and materials being used | | 4 | 2 | 2 |



Qualifications Pack For Production/Machine Operator –Life Sciences

| | | | |
|--|---|---|---|
| PC10.use the correct cleaning method for the work area, type of soiling and surface | 4 | 2 | 2 |
| PC11.deal with accidental damage, if any, caused while carrying out the work | 4 | 2 | 2 |
| PC12.report to the appropriate person any difficulties in carrying out work | 4 | 2 | 2 |
| PC13.identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill | 4 | 2 | 2 |
| PC14.ensure that there is no oily substance on the floor to avoid slippage | 4 | 2 | 2 |
| PC15.ensure that no scrap material is lying around | 4 | 2 | 2 |
| PC16.maintain and store housekeeping equipment and supplies | 4 | 2 | 2 |
| PC17.follow workplace procedures to deal with any accidental damage caused during the cleaning process | 4 | 2 | 2 |
| PC18.ensure that, on completion of the work, the area is left clean and dry and meets requirements | 4 | 2 | 2 |
| PC19.return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored | 5 | 2 | 3 |
| PC20.dispose the waste garnered from the activity in an appropriate manner | 5 | 2 | 3 |
| PC21.dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly | 5 | 2 | 3 |
| PC22.maintain schedules and records for housekeeping duty | 5 | 2 | 3 |

Qualifications Pack For Production/Machine Operator –Life Sciences

| | | | | | |
|---|---|-----|------------|-----------|-----------|
| | PC23.replenish any necessary supplies or consumables | | 5 | 2 | 3 |
| | Total | | 100 | 46 | 54 |
| LFS/N0102 (Carry out reporting and documentation) | PC1.report data/problems/incidents as applicable in a timely manner | 100 | 10 | 5 | 5 |
| | PC2.report to the appropriate authority as laid down by the company | | 10 | 5 | 5 |
| | PC3.follow reporting procedures as prescribed by the company | | 10 | 5 | 5 |
| | PC4.identify documentation to be completed relating to one's role | | 10 | 5 | 5 |
| | PC5.record details accurately in an appropriate format | | 10 | 5 | 5 |
| | PC6.complete all documentation within stipulated time according to company procedure | | 10 | 5 | 5 |
| | PC7.ensure that the final document meets regulatory and compliance requirements | | 10 | 5 | 5 |
| | PC8.make sure documents are available to all appropriate authorities to inspect | | 10 | 5 | 5 |
| | PC9.respond to requests for information in an appropriate manner whilst following organizational procedures | | 10 | 5 | 5 |
| | PC10.inform the appropriate authority of requests for information received | | 10 | 4 | 6 |
| | Total | | 100 | 49 | 51 |
| LFS/N0215 (Carry out broad level quality checks before, in-process and post manufacturing) | PC1.ensure that total range of checks are regularly and consistently performed | 100 | 10 | 5 | 5 |
| | PC2.check that the products, materials and equipment meet the requirements for production | | 10 | 5 | 5 |
| | PC3.use appropriate measuring instruments, equipment, tools, accessories etc. as required | | 10 | 5 | 5 |
| | PC4.identify non-conformities to quality assurance standards | | 10 | 5 | 5 |



Qualifications Pack For Production/Machine Operator –Life Sciences

| | | | | | |
|--|--|-----|-----|----|----|
| | PC5.identify potential causes of non-conformities to quality assurance standards | | 10 | 5 | 5 |
| | PC6.identify impact on final product due to non-conformance to company standards | | 15 | 7 | 8 |
| | PC7.evaluate the need for action to ensure that problems do not recur | | 10 | 5 | 5 |
| | PC8.suggest corrective action to address problems | | 12 | 6 | 6 |
| | PC9.review effectiveness of corrective action | | 13 | 6 | 7 |
| | Total | | 100 | 49 | 51 |
| LFS/N0101 (Maintain a healthy, safe and secure working environment in the life sciences facility) | PC1.observe and comply with the company's current health, safety and security policies and procedures | 100 | 10 | 5 | 5 |
| | PC2.while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines | | 10 | 5 | 5 |
| | PC3.report any identified breaches in health, safety, and security policies and procedures to the designated person | | 10 | 5 | 5 |
| | PC4. responsible for maintaining discipline at the shop-floor/ production area | | 10 | 5 | 5 |
| | PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority | | 10 | 5 | 5 |
| | PC6.adhere and comply to storage and handling guidelines for hazardous material | | 10 | 5 | 5 |
| | PC7.identify and recommend opportunities for improving health, safety, and security to the designated person | | 10 | 5 | 5 |
| | PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately | | 10 | 4 | 6 |

Qualifications Pack For Production/Machine Operator –Life Sciences

| | | | | | |
|--|---|--|------------|-----------|-----------|
| | PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected | | 10 | 4 | 6 |
| | PC10. follow the company's emergency procedures promptly, calmly, and efficiently | | 10 | 5 | 5 |
| | Total | | 100 | 48 | 52 |





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**1.3.2 & 1.3.3 Value-added courses
For the year 2017-2018**

CB205T

**I/IV B. PHARMACY-2nd SEMESTER
PROFESSIONAL ETHICS AND HUMAN VALUES
[THEORY -50Hours]**

Scope of the subject:

1. To bring awareness among pharmacy graduates on ethics and human values.
2. To understand the ethical theories and their application to work ethics.
3. To know various codes of ethics used by professional bodies.
4. To understand the concepts of corruption and its measures.
5. To learn about professional responsibility as a pharmacist.

Outcomes of the subject:

The student will be able to:

- a) Develop awareness on ethics and human values
- b) Become morally and socially responsible.
- c) Motivate others on moral values.

| Unit No. | Topic | Duration (Hours) | References |
|----------|--|------------------|---|
| 01 | Human Values: Morals, Values and ethics - Integrity - Work ethics - Service learning, Civic virtue, Respect for others, Living peacefully - Caring, Sharing, Honesty, Courage, Valuing time, Co-operations, Commitment, Empathy, Self confidence, Character and Spirituality. | 06 hrs | R.S.Naagarazan Professional ethics and Human values Edition I, New Age International Pvt.Ltd., Edition -1, Chapter - 1 |
| 02 | Introduction to professional ethics, corruption and its measures: Need of ethics in pharmacy, changing times, RPSGB guidance, ethical norms, moral relativism, facts and values, ethical theories and concepts. Corruption in public life, economic impact of corruption, payments that equate supply and demand; bribes as incentive payments, bribes to reduce costs, organized crime and corruption. Anti-corruption measures - Anti Corruption Bureau (ACB), Central Vigilance Commission (CVC), | 07 hrs | Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceutical press, Edition I, Chapter - 1. |

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|----|--|--------|---|
| | Central Bureau of Investigation (CBI), lok-adalats, Ombudsman, Comptroller and auditor general (CAG) and Right to information. | | |
| 03 | <p>Moral concepts and reasoning in pharmacy: Moral issues, rational inquires, moral autonomy, moral reasoning and pharmacist, moral development theories, justice and human rights, trust and truthfulness and moral dilemmas.</p> | 07 hrs | <p>1.R.S.Naagarazan Professional ethics and Human values Edition I, New Age International Pvt.Ltd., Edition -1, Chapter - 2 2.Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceurical press, Edition I, Chapter - 4.</p> |
| 04 | <p>Professionalism and Industrial ethics: Pharmacy and professionalism, ethical basis in professionalism and accountability, industrial ethics, Pharmacist in different clusters with different ethical issues - ethical issues in clinical pharmacy practice, community pharmacy and manufacturing of pharmaceutical products.</p> | 07 hrs | <p>1. Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceurical press, Edition I, Chapter - 4. 2. R.S.Naagarazan Professional ethics and Human values Edition I, New Age International Pvt.Ltd., Edition - 1Chapter - 2</p> |
| 05 | <p>Professional societies and various pharmaceutical associations: Indian Pharmaceutical Congress Association, Indian Pharmaceutical Association, Indian Hospital Pharmacists Association, Indian Pharmacy Graduates Association, Association of Pharmaceutical Teachers of India, The All India Drug Control Officers Confederation, Indian Society for Technical Education, National Pharmaceutical Pricing Authority and Other allied professional societies/ associations</p> | 06 hrs | <p>1. Professional Pharmacy - M.L. Schroff 2. Harikishan singh: History of Pharmacy in India and related aspects, volume I, II and III Pharmacopoeias and formularies, 1st edition, Vallbh Prakashan, 2005.</p> |

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| | | | |
|----|--|--------|--|
| 06 | Social pharmacy and code of pharmaceutical ethics: The Concept and context of social pharmacy, principles of ethics, Morality, ethical codes, Pharmaceutical Ethics in relation to job, trade, profession and medical profession. Pharmacist oath. | 07 hrs | 1. N.K.Jain, Forensic Pharmacy, Eight edition, 2014, 484-492. 2. B.M.Mithal, A Text book of Forensic Pharmacy, Valla prakasan, 10 th Edition. Chapter-14 |
|----|--|--------|--|

Further Readings:

1. NK Jain, Health Education and Community Pharmacy by, CBS, Publ. And Distributors New Delhi.
2. R.M Metha, Dispensing Pharmacy
3. Pharmacoethics: A problem based approach by G. Vidya Sagar
4. Gupta AK, Health Education and Community Pharmacy, CBS, Publ. and Distributors, New Delhi.



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II/IV B.PHARMACY FOR THE ACADEMIC YEAR 2014-2015 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To create awareness of communication skills and human refinement ideologies to a student in the right perspective.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.

COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English | 3 hours |
| 2 | Importance of Communication Skills | 2 hours |
| 3 | Qualities of a speaker / listener | 2 hours |
| 4 | How to speak without fear-Mock practice | 10 hours |
| 5 | Importance of soft skills | 3 hours |
| 6 | Qualities / Duties of a student | 2 hours |
| 7 | Social Etiquette | 2 hours |
| 8 | Telephone Etiquette | 2 hours |
| 9 | Successful tips for exams | 2 hours |
| 10 | Behavioural approach and attitude | 2 hours |

Name of the Faculty

C. Anthony Reddy, Asst. Professor in English



10/12/2014
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I/IV B.PHARMACY FROM THE ACADEMIC YEAR 2015-2016 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To create awareness of communication skills and human refinement ideologies to a student in the right perspective.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.

COURSE OUTCOMES: On completion of the course, student will be able to


| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English | 2 hours |
| 2 | Importance of Communication Skills | 2 hours |
| 3 | Qualities of a speaker / listener | 2 hours |
| 4 | How to speak without fear-Mock practice | 10 hours |
| 5 | Importance of soft skills | 4 hours |
| 6 | Qualities / Duties of a student | 2 hours |
| 7 | Social Etiquette | 2 hours |
| 8 | Telephone Etiquette | 2 hours |
| 9 | Successful tips for exams | 2 hours |
| 10 | Behavioural approach and attitude | 2 hours |

Name of the Faculty

C. Anthony Reddy, Asst. Professor in English




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III/IV B.PHARMACY FOR THE ACADEMIC YEAR 2016-2017 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To enhance communication skills, value of group discussions and global exposure.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.


COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English and Communication Skills | 2 hours |
| 2 | Qualities of a speaker / listener | 2 hours |
| 3 | Importance of Soft skills | 2 hours |
| 4 | Importance of Viva voce skills | 2 hours |
| 5 | Speaking / Writing tasks | 6 hours |
| 6 | Human Refinement tips | 2 hours |
| 7 | Mnemonics (memory tips) | 2 hours |
| 8 | Group discussions | 4 hours |
| 9 | Extempore practice | 4 hours |
| 10 | Presentation skills | 4 hours |

| | |
|---------------------|--|
| Name of the Faculty | C. Anthony Reddy, Asst. Professor in English |
|---------------------|--|




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2017-2018
2018-2019

**CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
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**DEPARTMENT OF PHARMACOLOGY
SYLLABUS FOR SKILL DEVELOPMENT COURSE ON**

“RECENT TRENDS IN EXPERIMENTAL PHARMACOLOGY”

Department : Pharmacology

Participants : IV/IV B.Pharmacy and III/VI Pharm D students

Duration : 30 Hrs

| COURSE OUTCOMES | |
|-----------------|--|
| CO-1 | To demonstrate the significance of CPCSEA guidelines and to demonstrate various routes of drug administration and blood collection techniques for laboratory animals |
| CO-2 | To summarize screening models for Psychotropic/neurotropic, learning and memory activities. |
| CO-3 | To interpret the advanced methods of screening for Learning and Memory activity |
| CO-4 | To compile various preclinical models for drugs acting on CVS and PNS |

- 1. CPCSEA Guidelines** **4 hrs**
Goal and Objectives, Composition, activities, IAEC – Functioning, Requirements for animal house, Maintenance of Records.
- 2. Laboratory Animals** **4 hrs**
Identification of animal species, sex, strain and breeding. Handling of animals, routes of administration, dosing and blood collection techniques.
- 3. Animal House Facility** **4 hrs**
Environment, Physical Facilities, Animal procurement, Quarantine, Stabilization, Separation, Breeding, Housing, Maintenance of Laboratory animals, Surveillance, Diagnosis, Treatment and control of disease, Personal Hygiene.
- 4. Psychotropic and neurotropic activity:** **5 hrs**
Anti-epileptic activity (electroconvulsimeter), anti-aggressive activity (agressometer), behavior (Locomotor activity –actophotometer, hole board test), anxiolytic activity (elevated plus maze, open field test), antipsychotic activity (CAR).
- 5. Nootropic or learning and memory activity:** **5 hrs**
Spatial long term memory (Elevated Plus Maze), Working memory (8 Arm Radial Maze), Spatial working memory (Y Maze, Rectangular Maze), Learning, memory & reasoning (Hebbs William Maze & Labyrinth Maze).
- 6. Cardiovascular activity:** **5 hrs**
Anti- hypertensive activity by non-invasive blood pressure measurement technique [NIBP]/Invasive blood pressure measurement (2-channel physiograph), anti-hyper lipidemic activity (high fat diet induced/streptozotocin).
- 7. Analgesic activity (Eddy’s hot plate/ tail-flick analgesiometer) / anti-inflammatory activity (digital plethysmometer) / Anti-diabetic activity (alloxan/streptozotocin)/ Diuretic activity** **3 hrs**




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Department of Pharmaceutics

Skill oriented program

On

ADVANCES IN MANUFACTURING AND QUALITY CONTROL TECHNIQUES OF ORAL SOLIDS

Scope:

A short-term skill-oriented certificate program on Advances in oral solids manufacturing and Quality Control Techniques shall provide practical training in formulation and evaluation of oral solid dosage forms for III/IV B. Pharmacy students. The objective is to impart competency in students for bridging the gap between academic and industrial environment.

Module:

- Demonstration and handling of various equipment and instrument.
- Formulation of oral solid dosage forms
- Evaluation of oral solid dosage forms.

Duration: 30 hours

| S. No. | Course Content | Didactic | Duration 30 (Hrs) |
|--------|---|---------------------|-------------------|
| 1. | Formulation and Evaluation of Tablets (Conventional and Novel) | Theory Practical | 6 hrs |
| 2. | Tablet coating methodology using R & D coater (Film Coating and Sugar Coating) | Theory Practical | 4 hrs |
| 3. | In process quality control tests for tablets and capsules | Theory Practical | 2 hrs |
| 4. | Fluidized bed coating by using Fluidized Bed Processor | Theory Practical | 4 hrs |
| 5. | Palletization and Granulation by using Kalweka all-purpose equipment | Theory Practical | 2 hrs |
| 6. | Drying of materials using Spray drier | Theory Practical | 2 hrs |
| 7. | Dissolution rate testing of pharmaceutical dosage forms <ul style="list-style-type: none">• Dissolution testing methodology- Compendial methods.• Dissolution data handling, Kinetics and Modelling. | Theory | 6hrs |
| 8. | PCP Disso software: Dissolution data handling and kinetics- Graphs and interpretation. | Practical | |
| 9. | In Vitro release testing and flux determination of pharmaceutical dosage forms (ointments, Gels, Transdermal Patches) | Theory Practical | 4 hrs |



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Program out comes:

By the end of this skill development program, students will be expertise in the following

1. Understand the concepts and principles involved in the manufacturing of oral solids.
2. Identify the various unit operations involved in the manufacturing of oral solids.
3. Enlighten the role of quality control tests to ensure the product quality and performance.
4. Acquire the ability to handle various equipment and instruments.
5. Gain the knowing about process variables and their impact on the product quality.

Training on following list of equipment:

| S. No | Equipment Name |
|-------|---------------------------------------|
| 1. | 16 station Rotary Compression Machine |
| 2. | Fluidized Bed Processor (FBP) |
| 3. | Spray drier |
| 4. | R and D Coater |
| 5. | Planetary Mixer |
| 6. | 48 plate- Tray drier |
| 7. | Kalweka wet granulator |
| 8. | Kalweka pelletizer |
| 9. | Double cone blender |
| 10. | Disintegration test apparatus |
| 11. | Tablet friability tester |
| 12. | USP Dissolution rate test apparatus |
| 13. | Automatic tablet hardness tester |
| 14. | 8 stage diffusion cell apparatus |



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2017-18

2017-2018 only



CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR.
DEPARTMENT OF PHARMACY PRACTICE
PG DIPLOMA CERTIFICATE PROGRAMME IN CLINICAL DATA MANAGEMENT

Duration – 50 Hrs

Scope of the course:

This course will help students acquire a basic understanding of the concepts and practices in the field of clinical data management. This course is intended to sensitize students and equip them with knowledge on clinical data practices globally as well as Indian scenario in detail. This course is intended to enrich the knowledge regarding generation of superior quality, dependable and statistically well informed data from clinical trials. The ultimate goal of clinical data management is to assure a well maintained data support conclusions drawn from research and thus achieving this goal protects public health and creates confidence in the world of therapeutics.

Objectives:

1. To provide basic understanding on clinical data management.
2. To gain understanding in the flow process of clinical data management.
3. To understand the scenario of clinical data management in the global market.
4. To manage the discrepancies in data validation and issues raised regarding queries.

Programme Outcomes:

1. To generate the high-quality, reliable, and statistically sound data from clinical trials
2. To produce a drastic reduction in time from drug development to marketing
3. Acquiring the skills to Controlling data entry, storage, and transmission
4. Enabling better patient experiences and outcomes by reducing the drug development time
5. To analyse the clinical data management system reduces the duration of the study and cost of drug development
6. To have adequate process knowledge that helps to maintain the quality standards of CDM processes





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COURSE CONTENT

| S. NO | CONTENTS | HOURS |
|--------------|---|---------------|
| 1. | Data – Definition & Types | 1 hr |
| 2. | CRF Design for Clinical Trial | 1 hr |
| 3. | Query Resolution | 1 hr |
| 4. | Database update, drug safety and database locking | 2 hrs |
| 5. | EDC System and 21CFR Part 11 compliance | 2 hrs |
| 6. | Data Privacy: Implications for Clinical Operations | 1 hr |
| 7. | Data Management in Epidemiology & Pharmacoeconomics | 2 hrs |
| 8. | Data management plan | 1 hr |
| 9. | Project management for the clinical data manager | 2 hrs |
| 10. | Vendor selection and management | 1 hr |
| 11. | Data management standards in clinical research | 1 hr |
| 12. | Design and development of data collection | 1 hr |
| 13. | Edit check design principles | 2 hrs |
| 14. | Electronic data capture-Concepts and study start up | 2 hrs |
| 15. | Electronic data capture-Study conduct & Study close out | 2 hrs |
| 16. | CRF Completion Guidelines | 1 hr |
| 17. | CRF printing and vendor selection | 1 hr |
| 18. | Data validation, programming and standards | 2 hrs |
| 19. | Laboratory data handling | 1 hr |
| 20. | External data transfer | 2 hrs |
| 21. | Patient-reported outcomes | 1 hr |
| 22. | CDM presentation at investigator meetings | 1 hr |
| 23. | Training Metrics for clinical trials | 2 hrs |
| 24. | Computer Systems | 1 hr |
| 25. | Systems Software Validation Issues – Clinical Trials Database Environment | 1 hr |
| 26. | Data Quality and Data Integrity | 1 hr |
| 27. | Measuring, Assuring data quality | 1 hr |
| 28. | Data storage, Data entry process | 1 hr |
| 29. | Medical coding dictionary management and maintenance | 1 hr |
| 30. | Safety data management and reporting | 2 hrs |
| 31. | Serious adverse event data reconciliation | 1 hr |
| 32. | Database closure | 2 hrs |
| 33. | Clinical data archiving | 2 hrs |
| 34. | Overview all topics and Interview Panel | 2 hrs |
| 35. | Mock Interviews, written test and Feed Back | 2 hrs |
| Total | | 50 hrs |




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**1.3.2 & 1.3.3 Value-added courses
For the year 2016-2017**

2016-17



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II/IV B.PHARMACY FOR THE ACADEMIC YEAR 2014-2015 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To create awareness of communication skills and human refinement ideologies to a student in the right perspective.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.

COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
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| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English | 3 hours |
| 2 | Importance of Communication Skills | 2 hours |
| 3 | Qualities of a speaker / listener | 2 hours |
| 4 | How to speak without fear-Mock practice | 10 hours |
| 5 | Importance of soft skills | 3 hours |
| 6 | Qualities / Duties of a student | 2 hours |
| 7 | Social Etiquette | 2 hours |
| 8 | Telephone Etiquette | 2 hours |
| 9 | Successful tips for exams | 2 hours |
| 10 | Behavioural approach and attitude | 2 hours |

Name of the Faculty

C. Anthony Reddy, Asst. Professor in English



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I/IV B.PHARMACY FROM THE ACADEMIC YEAR 2015-2016 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

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COURSE OUTCOMES: On completion of the course, student will be able to

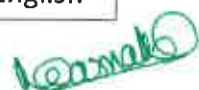
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|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English | 2 hours |
| 2 | Importance of Communication Skills | 2 hours |
| 3 | Qualities of a speaker / listener | 2 hours |
| 4 | How to speak without fear-Mock practice | 10 hours |
| 5 | Importance of soft skills | 4 hours |
| 6 | Qualities / Duties of a student | 2 hours |
| 7 | Social Etiquette | 2 hours |
| 8 | Telephone Etiquette | 2 hours |
| 9 | Successful tips for exams | 2 hours |
| 10 | Behavioural approach and attitude | 2 hours |

Name of the Faculty

C. Anthony Reddy, Asst. Professor in English




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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

CHALAPATHI NAGAR, LAM, GUNTUR - 522034

III/IV B.PHARMACY FOR THE ACADEMIC YEAR 2016-2017 ONWARDS

TITLE : COMMUNICATION SKILLS AND SOFT SKILLS

No. of Hours : 30

OBJECTIVE : To enhance communication skills, value of group discussions and global exposure.

The objective of the course is to impart the English language skills to communicate better and create awareness in soft skills to meet the corporate challenges. A handful of theoretical and practical knowledge in all aspects of social etiquette, planning strategy and to speak and write confidently will add value to the budding pharmacists.

COURSE OUTCOMES: On completion of the course, student will be able to

| | |
|---|--|
| 1 | Effectively communicate through verbal /oral communication and improve the listening skills. |
| 2 | Write precise briefs or reports and technical documents. |
| 3 | Actively participate in group discussion / meetings / interviews and prepare and deliver presentations. |
| 4 | Become more effective individual through goal / target, self motivation and practicing creative thinking. |
| 5 | Function effectively in multidisciplinary and heterogenous teams through the knowledge of team work, interpersonal relationships and leadership quality. |
| 6 | Effectively apply active listening skills. |

| S.No. | Contents | Prescribed hours |
|-------|---|------------------|
| 1 | Value of English and Communication Skills | 2 hours |
| 2 | Qualities of a speaker / listener | 2 hours |
| 3 | Importance of Soft skills | 2 hours |
| 4 | Importance of Viva voce skills | 2 hours |
| 5 | Speaking / Writing tasks | 6 hours |
| 6 | Human Refinement tips | 2 hours |
| 7 | Mnemonics (memory tips) | 2 hours |
| 8 | Group discussions | 4 hours |
| 9 | Extempore practice | 4 hours |
| 10 | Presentation skills | 4 hours |

Name of the Faculty

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2016-17

2016-2017 — 100/100
2017-2018
2019-2020



CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR.

(AUTONOMOUS)

DEPARTMENT OF PHARMACY PRACTICE

CERTIFICATE COURSE IN PHARMACOVIGILANCE – 50 Hrs

Scope of the course:

This course will help students acquire a basic understanding of the concepts and practices in the field of Pharmacovigilance. This course is intended to sensitize students and equip them with knowledge on Pharmacovigilance practices worldwide and on the Indian scenario in detail. This course is intended to enrich the knowledge of Pharmacovigilance among students. This course will enable the students to better understand the requirements within the Pharmacovigilance industry and government organization in India in the aspects of patient safety.

Objectives:

1. To provide the basic knowledge of pharmacovigilance.
2. To understand risk assessment and type of events being collected.
3. To become familiar in pharmacovigilance and risk management systems, risk management plans, inspections.
4. To understand the utility of Argus software.
5. To understand pharmacovigilance inspections and audits quality assessment.

Programme outcomes:

1. To benefit the patient care and safety in relation to the use of medicines and their interventions.
2. Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public and health care professionals.
3. Contribute to the assessment of risk, benefit and effectiveness medicines.
4. To detect problems related to the use of medicines and communicate the findings in a timely manner.
5. Encourage the safe rational and more effective medicines to improve public health.




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COURSE CONTENT

| S. No | TOPIC | Hrs |
|-------|--|-------|
| 1. | Pharmacovigilance Basics 1.1 Introduction To Pharmacovigilance (History, Need and Scope) 1.2 Terminologies used in Pharmacovigilance | 3 hrs |
| 2. | Fundamental Clinical Aspects of ADRs 2.1 Types and mechanisms of ADRs 2.2 Clinical management of ADRs. | 3 hrs |
| 3. | Current perspective of Pharmacovigilance 3.1 Pharmacovigilance Programme of India (PvPI) 3.2 Global scenario of Pharmacovigilance | 1 hr |
| 4. | ICSR's 4.1 Guidelines for Detecting and Reporting ICSR's 4.2 Content, structure and validity of reports and reporting procedures 4.3 Case Assessment 4.4 Repots related to Vaccines herbals and specific situations | 6 hrs |
| 5. | PV in Clinical Trials 5.1 Characteristics of Pharmacovigilance in Clinical Trials 5.2 Collection of Safety Data (Safety Plan, Complaint Plan) 5.3 Guidance and regulatory Framework 5.4 Risk Assessment and type of events being collected 5.5 Expedited Reporting 5.6 Role of DSMB | 5 hrs |
| 6. | Aggregate Reporting 6.1 Purpose and General Principles 6.2 Sources of Information 6.3 Types of aggregate reports across all phases of the product lifecycle 6.4 Line listings and/or Summary Tabulations 6.5 Format and contents of Aggregate reports, Template 6.6 Reporting Timelines | 5 hrs |
| 7. | Regulations and Guidelines in PV 7.1 ICH guidelines for Pharmacovigilance 7.2 Mandatory tasks and procedures from legislation at industry Expedited reporting and post approval expedited reporting, Study reports, Periodic Safety Update Reports (PSURs), Periodic Benefit Risk Evaluation Reports (PBRERs), Other documents: DSUR; RMP, REMS; renewal dossiers; reports on request 7.3 Facilities at regulatory authorities Pharmacovigilance system and SOPs, crisis management plan 7.4 Mandatory tasks and procedures from legislation at regulatory authorities ADR collection and storing in an electronic database, signal detection and management | 6 hrs |




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| 8. | Signal Detection and Management 8.1 Definition of a signal; sources, potentials, detection by non-statistical medical means 8.2 Disproportionality statistics for signal detection in spontaneous ISCR databases 8.3 Special issues in disproportionality approaches 8.4 Prioritization | 3 hrs |
| 9. | Benefit-Risk Assessment and Risk Management Planning 9.1 'Benefit-risk': definitions, methodological approaches; disease as criterion of benefit 9.2 Drug-related risks (ADRs): analyzing, weighting and combining their components 9.3 Pharmacovigilance and Risk Management Systems, Risk Management Plans (RMPs), Inspections | 3 hrs |
| 10. | Pharmacovigilance Inspections and Audits, Quality Assessment 10.1 Purpose, frequency and actors 10.2 Indicators of capacity and performance of the pharmacovigilance system 10.3 External Inspections by competitive authorities 10.4 Internal Audits in companies and regulatory authorities 10.5 Quality Assurance and benchmarking processes 10.6 Legislation and guidelines | 3 hrs |
| 11. | Tools used in Pharmacovigilance 11.1 Argus tool and its utility | 2 hrs |
| 12. | Drug Product Recalls and Field Alert Reports 12.1 Drug product recalls due to safety and efficacy reasons and other than safety and efficacy reasons. 12.2 Field alert reports. 12.3 Submission of field alert reports to drug regulatory agency | 5 hrs |
| 13. | Case Handling Activities 13.1 Causality assessment of adverse drug reactions 13.2 Case narratives 13.3 Signal detection and risk management 13.4 Argus software | 5 hrs |
| | Total Hours | 50 hrs |

REFERENCES:

1. World Health Organization, the Uppsala Centre for International Drug Monitoring. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva: World Health Organization; 2002.

2. The Uppsala Monitoring Centre. UMC Pharmacovigilance Training Course. Available from: <http://www.who-umc.org/>.



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CB205T

I/IV B. PHARMACY-2nd SEMESTER
PROFESSIONAL ETHICS AND HUMAN VALUES
[THEORY -50Hours]

Scope of the subject:

1. To bring awareness among pharmacy graduates on ethics and human values.
2. To understand the ethical theories and their application to work ethics.
3. To know various codes of ethics used by professional bodies.
4. To understand the concepts of corruption and its measures.
5. To learn about professional responsibility as a pharmacist.

Outcomes of the subject:

The student will be able to:

- a) Develop awareness on ethics and human values
- b) Become morally and socially responsible.
- c) Motivate others on moral values.

| Unit No. | Topic | Duration (Hours) | References |
|----------|--|------------------|---|
| 01 | Human Values: Morals, Values and ethics - Integrity - Work ethics - Service learning, Civic virtue, Respect for others, Living peacefully - Caring, Sharing, Honesty, Courage, Valuing time, Co-operations, Commitment, Empathy, Self confidence, Character and Spirituality. | 06 hrs | R.S.Naagarazan Professional ethics and Human values Edition I, New Age International Pvt.Ltd., Edition -1, Chapter - 1 |
| 02 | Introduction to professional ethics, corruption and its measures: Need of ethics in pharmacy, changing times, RPSGB guidance, ethical norms, moral relativism, facts and values, ethical theories and concepts. Corruption in public life, economic impact of corruption, payments that equate supply and demand; bribes as incentive payments, bribes to reduce costs, organized crime and corruption. Anti-corruption measures - Anti Corruption Bureau (ACB), Central Vigilance Commission (CVC), | 07 hrs | Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceutical press, Edition I, Chapter - 1. |


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| | Central Bureau of Investigation (CBI), lok-adalats, Ombudsman, Comptroller and auditor general (CAG) and Right to information. | | |
| 03 | Moral concepts and reasoning in pharmacy: Moral issues, rational inquires, moral autonomy, moral reasoning and pharmacist, moral development theories, justice and human rights, trust and truthfulness and moral dilemmas. | 07 hrs | 1.R.S.Naagarazan Professional ethics and Human values Edition I, New Age International Pvt.Ltd., Edition -1, Chapter - 2 2.Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceutical press, Edition I, Chapter - 4. |
| 04 | Professionalism and Industrial ethics: Pharmacy and professionalism, ethical basis in professionalism and accountability, industrial ethics, Pharmacist in different clusters with different ethical issues - ethical issues in clinical pharmacy practice, community pharmacy and manufacturing of pharmaceutical products. | 07 hrs | 1. Joy Wingfield and David Badcott, Pharmacy ethics and decision making, Pharmaceutical press, Edition I, Chapter - 4. 2. R.S.Naagarazan Professional ethics and Human values Edition I, New Age International Pvt.Ltd., Edition - 1 Chapter - 2 |
| 05 | Professional societies and various pharmaceutical associations: Indian Pharmaceutical Congress Association, Indian Pharmaceutical Association, Indian Hospital Pharmacists Association, Indian Pharmacy Graduates Association, Association of Pharmaceutical Teachers of India, The All India Drug Control Officers Confederation, Indian Society for Technical Education, National Pharmaceutical Pricing Authority and Other allied professional societies/ associations | 06 hrs | 1. Professional Pharmacy - M.L. Schroff 2. Harikishan singh: History of Pharmacy in India and related aspects, volume I, II and III Pharmacopoeias and formularies, 1st edition, Vallbh Prakashan, 2005. |



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06

Social pharmacy and code of pharmaceutical ethics:

The Concept and context of social pharmacy, principles of ethics, Morality, ethical codes, Pharmaceutical Ethics in relation to job, trade, profession and medical profession. Pharmacist oath.

07 hrs

1. N.K.Jain, Forensic Pharmacy, Eight edition, 2014, 484-492.
2. B.M.Mithal, A Text book of Forensic Pharmacy, Valla prakasan, 10th Edition. Chapter-14

Further Readings:

1. NK Jain, Health Education and Community Pharmacy by, CBS, Publ. And Distributors New Delhi.
2. R.M Metha, Dispensing Pharmacy
3. Pharmacoethics: A problem based approach by G. Vidya Sagar
4. Gupta AK, Health Education and Community Pharmacy, CBS, Publ. and Distributors, New Delhi.



K. Ramaiah
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