Balaji College of Pharmacy,Ananthapuramu

ApprovedbyPCI,NewDelhi&AffiliatedtoJNTUAnantapur

Rudrampeta Bypass, Sanapa Road, Ananthapuramu, Andhra Pradesh -515002

Academic Year: 2020 –

2021Class: II

Program:B.Pharmacy

NameoftheCourse:**MEDICINAL CHEMISTRY-1**

COURSEFILECONTENTS

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VISION

Achievingacademicexcellencebyprovidinggloballyacceptabletechnicaleducation byforecastingtechnologythroughinnovativeresearchanddevelopment,industry institute interactionandempowered manpower.

MISSION

To induce higher planes of learning by imparting technical education withinternationalstandards,appliedresearch,creativeabilityandvalue-basedinstruction.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR, ANANTHAPURAMU

Academic Calendar

B.Tech/B.Pharm II & III Year – II Semester (2020-2021)

I Spell of Instructions:	08.04.2021 to 03.06.2021	(08 weeks)
I Mid-term Examinations: (1st Objective + 1st descriptive)	04.06.2021 to 10.06.2021	(06 days)
II Spell of Instructions:	11.06.2021 to 05.08.2021	(08 weeks)
II Mid-term Examinations: (2nd Objective + 2nd descriptive)	06.08.2021 to 12.08.2021	(06 days)
Preparation and Practicals:	13.08.2021 to 21.08.2021	(06 days)
End Examinations:	23.08.2021 to 04.09.2021	(02 weeks)
Commencement of Class Work for III & IV years B.Tech/B.Pharm I semester for AY 2021-2022	16.09.2021 (Thursday)	

Note:

(i) The Mid-term Examinations should be conducted and completed as per the schedule given.

(ii) All the midterm examinations shall be of both objective and descriptive type as per the academic regulations.

(iii) I semester supplementary examinations will be conducted immediately after II semester end examinations

Date: 07.04.2021

DIRECTOR OF EVALUATION

Balaji College of Pharmacy,Ananthapuramu

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Rudrampeta Bypass, Sanapa Road, Ananthapuramu, Andhra Pradesh -515002

PROGRAM:B.Pharmacy

PROGRAMEDUCATIONALOBJECTIVES(PEO)

FundamentalKnowledge:

- To produce pharmacy graduates with strong fundamental concepts and high technical competence in pharmaceutical sciences and technology, who shall be
  able to use these tools in pharmaceutical industry and/or institutes where ever necessary for success.
- To provide students with a strong and well-defined concept in the various fields of pharmaceutical sciences viz., Pharmaceutics, Pharmaceutical chemistry, Pharmacology and Pharmacognosy according to the requirement of pharmaceutical industries, community and Hospital Pharmacy and also to develop a sense of teamwork and awareness amongst students towards the importance of interdisciplinary approach for developing competence in solving complex problems in the area of Pharmaceutical Sciences.

PracticeandCare:

- To promote the development of trained human resource in Pharmaceutical Sciences for dissemination of quality education with highly professional and ethical attitude, strong communication skills, effective skills to work in a team with a multidisciplinary approach.
- To generate potential knowledge pools with interpersonal and collaborative skills to identify, assess and formulate problems and execute the solution in closely related pharmaceutical industries.
- To train the students to contribute towards health care system and counseling for prophylaxis and prevention of diseases.

LifelongLearningandInnovation:

- To encourage the students to participate in life-long learning process for a highlyproductive career and to relate the concepts of Pharmaceutical Sciences
  towards serving the cause of the society.
- Developinginnovativeideasandapproachestoenhancequalityandovercomeprofessionalbarriers.
- Engagingincreativethinkingtoenvisionbetterwaysofachievingprofessionalgoals.

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PROGRAM:B. Pharmacy

PROGRAMOUTCOMES(POs)

1. **Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.
2. **Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
3. **Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
4. **Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
5. **Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.
6. **Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g., health care professionals, promoters of health, educators, managers, employers, employees).
7. **Pharmaceutical Ethics:** Honor personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes

cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

8. **Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
9. **The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
10. **Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
11. **Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

JAWAHARLALNEHRUTECHNOLOGICALUNIVERSITYANANTAPUR

B. Pharmacy -IIYEAR II SEMESTER

BP 402 T. MEDICINAL CHEMISTRY - 1Theory:3 + 1 Hrs./Week

Objectives of the subject:

Upon completion of the course the student shall be able to

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship (SAR) of different class of drugs
4. Write the chemical synthesis of some drugs.

1. Detailedsyllabusandlecturewiseschedule:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugssuperscripted (*)

UNIT-I **10Hours**

IntroductiontoMedicinalChemistry

History and development of medicinal chemistry

Physicochemicalpropertiesinrelationtobiologicalaction

Ionization,Solubility,PartitionCoefficient,Hydrogenbonding,Protein binding,Chelation,Bioisosterism,OpticalandGeometricalisomerism.

Drug metabolism

Drugmetabolismprinciples-PhaseIandPhase II.

Factorsaffectingdrugmetabolismincludingstereochemicalaspects.

UNIT-II 10Hours

DrugsactingonAutonomicNervousSystem

Adrenergic Neurotransmitters:

Biosynthesisandcatabolismofcatecholamine.

Adrenergicreceptors(Alpha&Beta)andtheirdistribution.

Sympathomimeticagents:SARofSympathomimeticagents

Directacting:Nor-epinephrine,Epinephrine,Phenylephrine*,Dopamine Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

- Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agentswithmixedmechanism:Ephedrine,Metaraminol.

AdrenergicAntagonists:

Alpha adrenergic blockers: Tolazoline*, Phentolamine,Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III 10Hours

Cholinergicneurotransmitters:

Biosynthesisandcatabolismofacetylcholine.

Cholinergicreceptors(Muscarinic&Nicotinic)andtheirdistribution.

Parasympathomimeticagents:SARofParasympathomimeticagents

Direct acting agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion.

Cholinesterasereactivator: Pralidoximechloride.

CholinergicBlockingagents:SARofcholinolyticagents

Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyaminesulphate, Scopolamine hydrobromide, Homatropinehydrobromide, Ipratropium bromide*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate,Methantheline bromide,Propantheline bromide,Benztropinemesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT-IV **08Hours**

DrugsactingonCentralNervousSystem

A. SedativesandHypnotics:

Benzodiazepines: SARof Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

Barbiturtes: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital

Miscelleneous:

Amides&imides:Glutethmide.

Alcohol&theircarbamatederivatives:Meprobomate,Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

Phenothiazeines: SAR of Phenothiazeines - Promazine hydrochloride,

Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

RingAnaloguesofPhenothiazeines: Chlorprothixene,Thiothixene, Loxapine succinate, Clozapine.

Flurobuterophenones: Haloperidol,Droperidol,Risperidone.

Betaaminoketones: Molindonehydrochloride.

Benzamides: Sulpieride.

C. **Anticonvulsants:**SARofAnticonvulsants**,**mechanismofanticonvulsant action

Barbiturates:Phenobarbitone,Methabarbital.**Hydantoins:**

Phenytoin*,Mephenytoin,Ethotoin**Oxazolidinediones:**

Trimethadione,Paramethadione**Succinimides:**

Phensuximide,Methsuximide,Ethosuximide***Ureaand**

monoacylureas: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone,Valproicacid,Gabapentin,Felbamate

UNIT–V **07Hours**

DrugsactingonCentralNervousSystem

General anesthetics:

Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

Ultra short acting barbitutrates: Methohexital sodium*, Thiamylalsodium, Thiopental sodium.

Dissociativeanesthetics: Ketaminehydrochloride.*

Narcoticandnon-narcoticanalgesics

Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanoltartarate.

Narcotic antagonists: Nalorphine hydrochloride, Levallorphantartarate, Naloxone hydrochloride.

Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin,Zomepriac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

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B. Pharmacy–II YEAR II SEM

BP406P. MEDICINAL CHEMISTRY – I (Practical)

-4 Hours/Week

I	**Preparationofdrugs/intermediates**
1	1,3-pyrazole
2	1,3-oxazole
3	Benzimidazole
4	Benztriazole
5	2,3-diphenylquinoxaline
6	Benzocaine
7	Phenytoin
8	Phenothiazine
9	Barbiturate
II	Assayofdrugs
1	Chlorpromazine
2	Phenobarbitone
3	Atropine
4	Ibuprofen
5	Aspirin
6	Furosemide
III	DeterminationofPartitioncoefficientforanytwodrugs

RecommendedBooks(LatestEditions)

1. WilsonandGiswold'sOrganicmedicinalandPharmaceuticalChemistry.
2. Foye'sPrinciplesofMedicinalChemistry.
3. Burger'sMedicinalChemistry,VolItoIV.
4. Introductiontoprinciplesofdrugdesign-SmithandWilliams.
5. Remington'sPharmaceuticalSciences.
6. Martindale'sextrapharmacopoeia.
7. OrganicChemistrybyI.L.Finar,Vol.II.
8. TheOrganicChemistryofDrugSynthesisbyLednicer,Vol.1-5.
9. IndianPharmacopoeia.

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LESSONPLAN

AcademicYear:2020–2021 Class:II Sem: II

Program:B. Pharmacy Duration of the year: 2020 - 2021

NameoftheCourse:**MEDICINAL CHEMISTRY I**

Prescribed Hours: **Theory:**3 + 1 Hrs./Week

Scheduled Date: 08.04.2021 to 04.09.2021

S.No	Chapter name	Topic	No. of hours	Name of thefaculty
1.	Introduction to Medicinal Chemistry	**History and development of medicinal chemistry** **Physicochemical properties in relation to biological action** Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism. **Drug metabolism** Drug metabolism principles- Phase I and Phase II. Factors affecting drug metabolism including stereo chemical aspects	05 03	Mrs.B.VishnuVandana
2.	Drugs acting on Autonomic Nervous System	**Adrenergic Neurotransmitters** Biosynthesis and catabolism of catecholamine. Adrenergic receptors (Alpha & Beta) and their distribution. Sympathomimetic agents: SAR of **Sympathomimetic agent** **Direct acting:** Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline • **Indirect acting agents:** Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine. • Agents with mixed mechanism:	02 01 01	MS.B.VishnuVandana

		Ephedrine, Meta Adrenergic Antagonists **Alpha adrenergic blockers**: Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergid Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol,	01	
3.	Cholinergic neurotransmitters:	Biosynthesis and catabolism of acetylcholine. Cholinergic receptors (Muscarinic & Nicotinic) and their distribution. Parasympathomimetic agents: SAR of **Parasympathomimetic agents** **Direct acting agents:** Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine. **Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible):**Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion. **Cholinesterase reactivator**: Pralidoxime chloride. **Cholinergic Blocking agents**: SAR of cholinolytic agents Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyaminesulphate, Scopolamine hydrobromide,	01 01 08 01 01 01 05	MS.B.VishnuVandana

		Homatropinehydrobromide, Ipratropium bromide*. **Synthetic cholinergic blocking agents**: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropinemesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazinehydrochloride		
4.	Drugs acting on Central Nervous System	A. Sedatives and Hypnotics: Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem Barbiturtes: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital Miscelleneous: Amides & imides: Glutethmide. Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol Aldehyde & their derivatives: Triclofos sodium, Paraldehyde		

		B. Antipsychotics Phenothiazeines: SAR of Phenothiazeines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Trifluprомazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride. RingAnalogues of Phenothiazeines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine. Flurobuterophenones: Haloperidol, Droperidol, Risperidone. Beta amino ketones: Molindone hydrochloride. Benzamides: Sulpieride. C. Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action Barbiturates: Phenobarbitone, Methabarbital. Hydantoins: Phenytoin*, Mephenytoin, EthotoinOxazolidinediones: Trimethadione, ParamethadioneSuccinimides: Phensuximide, Methsuximide, Ethosuximide* Urea and monoacylureas: Phenacemide, Carbamazepine* Benzodiazepines:Clonazepam Miscellaneous: Primidone, Valproic		

		acid , Gabapentin, Felbamate		
5.	Drugs acting on Central Nervous System	Generalanesthetics :Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane. Ultra short acting barbitutrates: Methohexital sodium*, Thiamylal sodium, Thiopental sodium. Dissociativeanesthetics: Ketamine hydrochloride.* Narcotic and non-narcotic analgesics Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylatehydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanoltartarate. Narcotic antagonists: Nalorphine hydrochloride,	08	MS.B.VishnuVandana

		Levallorphantartarate, Naloxone hydrochloride. Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepriac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.		

Medicinal chemistry practical syllabus (BP406P)

S.No	Experiment name	Name of thefaculty
1	**I Preparation of drugs/ intermediates** 1 1,3-pyrazole 2 1,3-oxazole 3 Benzimidazole 4 Benztriazole 5 2,3- diphenyl quinoxaline 6 Benzocaine 7 Phenytoin 8 Phenothiazine 9 Barbiturate	**B.Vishnuvandana**
2	**II Assay of drugs** 1 Chlorpromazine 2 Phenobarbitone 3 Atropine 4 Ibuprofen 5 Aspirin 6 Furosemide	**B.Vishnuvandana**
3	**III Determination of Partition coefficient for any two drugs**	**B.Vishnuvandana**

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COURSE OUTCOMES

AcademicYear:2020–2021 Class:II Sem: II

Program:B. Pharmacy Duration of the year: 2020 - 2021

NameoftheCourse:**MEDICINAL CHEMISTRY I**

Prescribed Hours: **Theory:**3 + 1 Hrs./Week

Scheduled Date: 08.04.2021 to 04.09.2021

Course Outcomes

CO NO.	Course Outcome
CB.402.1	To gain the knowledge about the principles of drug action & physico chemical properties .
CB.402.2	To learn the classification, mechanism of action synthesis and other medicinal chemistry properties of drugs on sympathetic nervous system
CB.402.3	To learn the classification, mechanism of action synthesis and other medicinal chemistry properties of drugs on para sympathetic nervous system .
CB.402.4	To learn the SAR of drugs acting on ANS
CB.402.5	To learn the classification, mechanism of action synthesis and other medicinal chemistry properties of drugs on Central nervous system To learn the classification, mechanism of action synthesis and other medicinal chemistry properties of drugs on para sympathetic nervous system

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COURSE OUTCOMES

AcademicYear:2020–2021 Class:II Sem: II

Program: B. Pharmacy Duration of the year: 2020 - 2021

NameoftheCourse: **MEDICINAL CHEMISTRY IPRACTICAL (BP406P)**

Prescribed Hours: **Theory:**4 Hrs./Week

Scheduled Date: 08.04.2021 to 04.09.2021

Course Outcomes

CO NO.	Course Outcome
CB.406.1	Learn synthesis of medicinally important compounds / drug intermediates with recrystallization and TLC techniques
CB.406.2	Understand purification methods for synthesized compounds using column chromatography
CB.406.3	Study of partition coefficient and ionization constant of drugs
CB.406.4	Analyze experimental data to draw conclusions about the structure-activity relationship (SAR) of drugs.
CB.406.5	Critically assess the efficacy and safety of selected drugs.

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AcademicYear:2020–2021 Class:II Sem: II

Program:B. Pharmacy Duration of the year: 2020 - 2021

NameoftheCourse:**MEDICINAL CHEMISTRY I**

Prescribed Hours: **Theory:**3 + 1 Hrs./Week

Scheduled Date: 08.04.2021 to 04.09.2021

ASSIGNMENTS

ASSIGNMENTTOPIC	Course Outcome	BTL
Assignment1		
History and development of medicinal chemistry	C2.4.1 C2.4.1 C2.4.1	Understanding Applying
Drug metabolism	C2.4.1 C2.4.2 C2.4.4	Understanding Applying
Factors affecting drug metabolism including stereo chemical aspects.	C2.4.1	Analyzing
Assignment2		
Biosynthesis and catabolism of catecholamine.	C2.4.2 C2.4.4 C2.4.5	Remembering Understanding
SAR of cholinolytic agent	C2.4.1	Analyzing

Formatoftheassignment:

1. Minimum& Maximumnumberofpages.
2. Itshallbewrittendraftcopy.
3. Nameandsignatureofthestudent.
4. Assignmentcanbeacombinedseminar presentationattheend of thesemester.
5. Time allocatedforseminarmaybe8+2Mi

BALAJI COLLEGE OF PHARMACY: ANANTAPUR::II Year II Sem
(R19 IV SEM) I Mid Exams JULY 2021 AY- 2020-21
Sub: MEDICINAL CHEMISTRY-I BP402 T (Subjective)
Time: 01hr:30 min Max Marks: 30 M

I	**ANSWER ALL QUESTIONS**	**MARKS**	**CO**	**BTL**
1	What is bioisosterism?	02	01	01
2	Define Protein Binding.	02	01	01
3	Show the structure of catechol .outline the example.	02	02	01&02
4	Name cholinergic receptors.	02	03	01
5	Define partition coefficient	02	01	02

II	**ANSWER ANY ONE QUESTION**	**1X10=10M**		
6	Illustrate the various types of phase-I biotransformation (metabolic) pathway. Explain factors affecting metabolism.	10	01	02
7	Classify sympathomimetic drugs with examples .Define the following with examples a) Sympathomimetic b) Sympatholytics	10	02	02 &1
III	**ANSWER ANY TWO QUESTIONS**	**2X5=10M**		
8	Outline the biosynthesis of adrenergic Neurotransmitters	05	02	02
9	Interpret the synthesis and uses for the following (i) Salbutamol ii) Propranolol iii) Carbachol	05	02 & 3	02
10	Relate hydrogen bonding with biological activity.	05	01	02

BALAJI COLLEGE OF PHARMACY: ANANTAPUR::II Year II Sem
(R19 IV SEM) II Mid Exams JULY/AUG 2021 AY- 2020-21
Sub: Medicinal Chemistry-I BP402 T (Subjective)
Time: 01hr:30 min Max Marks: 30 M

I	**ANSWER ALL QUESTIONS (2X5=10M)**	**MARKS**	**CO**	**BLT**
1	Outline the structure and use of thiopental sodium.	02	04	02
2	Define anticonvulsants with example.	02	04	01
3	What are general anaesthetics? outline the example	02	05	01
4	Illustrate the structure and use of a) Barbital b) Ethosuximide	02	04	02
5	What are Preanaesthetic medicaments?	02	05	01
II	**ANSWER ANY ONE QUESTION (1X10=10M)**			
6	Outline the Classification of NSAIDS at least one example from each class. Explain the synthesis, mode of action and uses of a) Ibuprofen) Mefenamic acid.	10	05	02
7	Explain about SAR of barbiturates b) Classify barbiturates with examples and structures.	10	04	01
III	**ANSWER ANY TWO QUESTIONS (2X5=10M)**			
8	Outline the Classification of general anaesthetics with examples.	05	05	02
9	Explain opiod antagonists.	05	04	02
10	Organise chemistry and biological significance of prostaglandins.	05	04	03

B.PHARMACY – II-YEAR-II-SEM (IV SEM) - AY: 2020-2021 (R19)
MID EXAMINATIONS AVERAGE MARKS AWARD LIST

Name of the Sub:MEDICINAL CHEMISTRY I Sub. CodeBP402T:
(Theory) Lab code:BP406P

Sl No.	H.T.No	Name Of The Student	MID-I		MID-II		Avg (15M)	Continuous Mode (10 M)	Total (25M)
			FOR 30 M	FOR 15 M	FOR 30 M	FOR 15 M			
1.	19T11R0001	S ABDUL ALEEM	21	11	25	13	12	09	21
2.	19T11R0003	SHAIK ANSEERA	25	13	22	11	12	10	22
3.	19T11R0004	THALARI ANUSHA	27	14	24	12	13	10	23
4.	19T11R0006	KUMMARI BASAVARAJU	15	08	27	14	11	09	20
5.	19T11R0007	DUDEKULA BHANU	26	13	27	14	14	10	24
6.	19T11R0008	EEDIGA BHARGAV	16	08	22	11	10	10	20
7.	19T11R0009	PINDIKURI BHARGAVA	10	05	12	06	06	09	15
8.	19T11R0010	GOLLA BHARGAVI	22	11	13	07	09	O9	18
9.	19T11R0011	PAPANNAGARI BLESSI RANI	29	14	28	14	14	10	24
10.	19T11R0012	E CHANDANA	23	12	29	15	14	09	23
11.	19T11R0013	S CHANDANA	23	12	29	15	13	10	23
12.	19T11R0014	VANGAM CHINNA	23	12	29	15	14	10	24
13.	19T11R0015	GOLLA DEEPIKA	26	13	29	15	14	10	24
14.	19T11R0016	CHITTIBOINA DHARANI	27	14	27	14	14	10	24
15.	19T11R0017	S DIVYAMANI	22	11	27	14	13	09	22
16.	19T11R0018	GUJJULA DHIVYASRI	11	06	20	10	08	08	16
17.	19T11R0019	T. DRUVATEJA REDDY	13	07	22	11	09	09	18
18.	19T11R0020	PENUKONDLA GEETHA	22	11	20	10	11	09	20
19.	19T11R0021	S GNANESWARI	28	14	25	13	14	10	24
20.	19T11R0022	PALEM GOVARDHAN BABU	21	11	21	11	12	09	21
21.	19T11R0023	SHAIK GOWHARTAJ	25	13	27	14	14	10	24
22.	19T11R0024	GANDA GOWTHAMI	25	13	22	11	13	11	21
23.	19T11R0025	MANDA HARIKA	21	11	25	13	12	09	21
24.	19T11R0026	MADINENI HARINI	24	12	22	11	12	09	21
25.	19T11R0027	P.Harshavardhan	–	-	-	-	-	—	-
26.	19T11R0028	GUJJALA HEMALATHA	26	13	27	14	14	10	24
27.	19T11R0029	SHAIK INTHIYAZ	15	08	18	09	09	08	17
28.	19T11R0030	Y.JAGADEESWARA REDDY	27	14	29	14	14	10	24
29.	19T11R0031	KAMBADUR JAYANTHI	21	11	29	14	13	09	22
30.	19T11R0033	GOLLA KARISHMA	23	12	29	15	14	09	23
31.	19T11R0034	CHINTHAKUNTA KAVITHA	21	11	28	14	13	09	22
32.	19T11R0035	POTLURU KAVYA	27	14	28	14	14	10	24
33.	19T11R0036	S.Keerthisree	-	-	-	-	-	-	16
34.	19T11R0037	DASARI KISHORE	21	11	28	14	13	09	22
35.	19T11R0038	YERUKALA KOKILA	29	14	29	14	14	10	24
36.	19T11R0039	KUNTA LAKSHMI DEVI	25	13	27	14	14	09	23
37.	19T11R0040	SAKE LALITHA	AB	0	22	11	06	08	16
38.	19T11R0041	KOTAMEEEDA LAVANYA	22	11	23	12	12	09	21

39.	19T11R0043	PADUCHURI LIKITHA	27	14	29	14	14	10	24
40.	19T11R0045	R. MAHALAKSHMI	01	01	02	01	01	08	15
41.	19T11R0046	SHAIK MD. SHAHUL	06	03	26	13	08	10	18
42.	19T11R0047	CHAKKARI MALLESWARI	24	12	22	11	12	09	21
43.	19T11R0048	K MALLIKARJUNA	AB	AB	19	10	05	10	15
44.	19T11R0049	NEERUGANTI MARY	28	14	28	14	14	08	22
45.	19T11R0050	CHAKALI MEGHANA	27	14	23	12	13	10	23
46.	19T11R0051	BOYA MOUNIKA	28	14	27	14	14	10	24
47.	19T11R0052	MAJJIGA MOUNIKA	10	05	09	05	05	08	16
48.	19T11R0053	THOTA NANDEESWARI	22	11	25	13	12	10	22
49.	19T11R0054	KURUBA NANDINI	21	11	23	12	12	09	21
50.	19T11R0055	NANDAVARAM NANDINI	21	11	24	12	12	09	21
51.	19T11R0056	N.NANDISWARI	23	12	27	14	13	09	22
52.	19T11R0057	BURRA NANDITHA	24	12	21	11	12	09	21
53.	19T11R0058	SHAIK NASREEN BANU	23	12	26	13	13	09	22
54.	19T11R0059	MANNALA NAVYA JYOTHI	-	-	-	-	-	-	17
55.	19T11R0060	MOOLA NIRANJAN	13	09	18	09	08	09	17
56.	19T11R0061	POLICE NOORISHA	29	14	28	14	14	10	24
57.	19T11R0062	GOLLA PALLAVI	-	-	-	-	-	-	-
58.	19T11R0063	SHAIK PARVEEN BANU	28	14	28	14	14	10	24
59.	19T11R0064	H. PAVAN	21	11	28	14	13	09	22
60.	19T11R0065	BOYA PAVAN KALYAN	25	13	24	12	13	10	23
61.	19T11R0066	K.PAVAN KALYAN	17	09	28	14	12	10	22
62.	19T11R0067	S.P.PAVAN NAIK	25	13	28	14	14	09	23
63.	19T11R0068	D. PAVITHRA	28	14	26	13	14	10	24
64.	19T11R0069	ATTHOTI PRANUTH	25	13	23	12	13	10	23
65.	19T11R0070	SAKE PRASANTH KUMAR	15	08	21	11	10	10	20
66.	19T11R0071	KURUBA PREETHI SWAPNA	21	11	24	12	12	09	21
67.	19T11R0072	DASARI PUSHPA LATHA	21	11	24	12	12	09	21
68.	19T11R0073	THUMBIGANURU RADHA	21	11	27	14	13	09	22
69.	19T11R0074	YALERU RAJESH	21	11	27	14	13	09	22
70.	19T11R0075	K RAJESWARI	22	11	28	14	13	09	22
71.	19T11R0076	T RANJITH KUMAR	26	13	24	12	13	10	23
72.	19T11R0077	BOCHHU RAVI	22	11	19	10	11	09	20
73.	19T11R0078	DUDEKULA RIZWANA	23	12	25	13	13	09	22
74.	19T11R0079	C. B. SAI KUMAR	25	13	26	13	13	10	23
75.	19T11R0080	P.SAI LIKHITHA	22	11	29	15	13	09	22
76.	19T11R0081	BASAGANI SAI MOHAN	28	14	29	15	14	10	24
77.	19T11R0082	BALA SAI RAKESH YADAV	21	11	21	11	11	10	21
78.	19T11R0083	MALLIBOYENE SAIKUMAR	04	02	05	03	03	07	15
79.	19T11R0084	MADDIMADUGU SAINATH	02	01	05	03	02	07	16
80.	19T11R0085	RASIPOGULA SARALA	24	12	22	11	12	10	22
81.	19T11R0086	SHAIK KOLIMI SHABANA	28	14	27	14	14	10	24

82.	19T11R0087	SHAIK SHAZIA TABASSUM	28	14	24	12	13	10	23
83.	19T11R0088	NAYAKULA SHYAMALA	26	13	24	12	13	10	23
84.	19T11R0089	DASARI SIREESHA	-	-	-	-	-	-	-
85.	19T11R0090	KADUPU SOWJANYA	29	14	28	14	14	10	24
86.	19T11R0091	KONDAPALLI SOWMYA	22	11	25	13	12	09	21
87.	19T11R0092	GAJJELLI SRUTHI	25	13	28	14	14	10	24
88.	19T11R0094	Y K SUKANYA	25	13	29	14	14	10	24
89.	19T11R0095	MALLELA SUMA	25	12	20	10	11	09	20
90.	19T11R0096	RAJULA SUNNY	23	12	28	14	13	09	22
91.	19T11R0097	SRISAILAM SUSMITHA	22	11	18	09	10	10	20
92.	19T11R0098	BUDIMEPALLI SWETHA	27	14	29	14	14	10	24
93.	19T11R0099	THAPPETA VAMSI KRISHNA	17	09	26	13	11	09	20
94.	19T11R00A0	P. VANDHANA	24	12	29	14	13	09	22
95. 13	19T11R00A1	G VENKATESH NAIK	13	07	20	10	09	09	18
96.	19T11R00A2	MARAKA VENNELA	26	13	27	14	14	10	24
97.	19T11R00A3	NALLOLLA VIDHYA SREE	27	14	27	14	14	10	24
98.	19T11R00A4	RAJAPUTRA VISHNU PRIYA	25	13	29	14	14	10	24
99.	19T11R00A5	SHAIK WAHEED BASHA	23	12	28	14	13	09	22
100.	19T11R00A6	NAGARURU YAMUNA	25	13	24	12	13	10	23
101.	19T11R00A7	KOTHWAL ZABEEN	20	10	26	13	12	09	21
102.	**19Z71R0056**	P.RAJKUMAR	-	-	-	-	-	-	-

Unit-I

MEDICINAL CHEMISTRY – I (Theory)

UNIT 1SHORT ESSAY

1.What is phase I biotransformation. Discuss any two oxidative reactions.
2.What is phase II biotransformation? Discuss any two conjugation reactions
3.Write the factors affecting drug metabolism
4.Define biotransformation. What is its importance? Write the sites of biotranformation.
5.Discuss the role of glucouronic acid and glycine in biotransformation.
6.Explain role of Cytochrome P-450 in biotransformation.
7.Write in detail ionization & solubility as an important physico-chemical parameter.
8.Add a note on hydrogen bonding and protein binding.
9. Explain the role of solubility and partition coefficient
10. Explain the role of Chelation and bioisosterism.
11.Explain optical and geometrical isomerism in relation to biological action.
12.Discuss hepatic and extra-hepatic metabolism.
13.Explain the role of solubility and protein binding.
14.Explain the role of hydrogen boding and partition coefficient
15.Explain the role of ionisation and bioisosterism.
16.Explain the role of ionisation and Chelation
17.Discuss reductive and hydrolytic drug metabolism with its importance.
18.Explain the role of solubility and hydrogen boding

SHORT ANSWERS

1.Oxidation reactions in drug metabolism
2.Reduction reactions in drug metabolism
3. Hydrolytic reactions in drug metabolism
4.Write the aim and purpose of drug metabolism
5.Sites of biotransformation
6.First pass effect in hepatic drug metabolism
7.Importance of extra hepatic drug metabolism
8.Write the diagrammatic representation of Cytochrome

9.Importance of hydrogen bonding in drug action
10.Importance of plasma protein binding in drug action
11.Importance of solubility in drug action.
12.Importance of partition coefficient in drug action

UNIT II

LONG ESSAY

1.Define and classify adrenergic agents? Discuss adrenergic blocking agentsindetail And give the synthesis of propranolol.
2.Classify adrenergic antagonists with suitable example in each class

alongwith Structure. Write the synthesis of Tolazoline.
3.Give the biosynthesis and metabolism of nor-adrenaline. Write the synthesisof Salbutamol and phenylephrine.
4.Give the SAR of B-adrenergic blocking agents. Outline the synthesis of propranolol.
5.Write the class, structure ,mechanism and uses of a) Methyldopa b)Ephedrine c)Phenoxy benzamine and d) Metaprolol6.Define, classify and write the SAR of adrenergic agents and give thesynthesis of Phenylephrine.

SHORT ESSAY

1.Write the structure, mechanism ofaction of Oxymetazoline and Clonidinewith Uses.
2.Write a note on alpha adrenergic antagonists and structure and use of anyone.
3.Discuss on different beta receptor antagonists and write the limitations of non- selective beta blockers.
4.Explain the mechanism of action and uses of a)Esmolol b) Xylometazolinec)Prazosin d)Pseudoephedrine.

5.Explain the mechanism of action and uses a)terbutaline b)Ephedrinec)Methysergine d) Atenolol.
6.What are indirect acting sympathomimetic agents? Write the structure anduses of any one drug.

SHORT ANSWERS

1.Write the structure and uses of Propylhexedrine
2.Write the structure and uses of Dobutamine and Metaraminol.
3.Write any two drug structures for asthma
4.Write any two drug structures used for nasal decongestione
5.Write any two drug structures and uses of beta blockers.
6.Write any two drug structures and uses of alpha adrenergic blockers
7.What is catecholamine? Mention any two important neurotransmitterCatacholamines.
8.Write the structure and specific uses of Prazosin and Carvedilol
9.Write a note on alpha receptors
10.Write a note on beta receptors
11.Write any two structures of selective beta 2 agonists
12.Write the structure and uses of Metibranolol.
13.Write the structure and uses of Atenolol
14.Write the structure and uses of Betazolol
15.Write the structure and uses of Bisoprolol
16.Write the structure and uses of Esmolol
17.Write the structure and uses of Metoprolol18.Write the structure and uses

of Carvedilol

UNIT III

SHORT ESSAY

1.Explain the biosynthesis of acetyl choline and its function via variousreceptors

2.Explain the catabolism of acetyl choline. Write the structure and uses of pilocarpine.

3.Discuss the role of reversible and irreversible cholinaetarase inhibitors as medicinal Agents.

4.What are solanatious alkaloids? Write the synthesis and specific use of Ipratropium bromide

5.Classify cholinergic receptors. Write a note on their distribution andfunction.

6.Write the synthesis of dicyclomine hydrochloride. Discuss its mechanism ofaction, uses and possible side effects

.7.Write the synthesis of procyclidine hydrochloride. Discuss its mechanism ofaction, Uses and possible side effects

.8.Discuss SAR of parasympathomimetic agents.

9.Discuss SAR of cholinolytic agents.

10.Write the structure, uses and mechanism of action of pralidoxime chloride.

11.Explain the role of cholinesterase enzyme. Write the Synthesis, mechanismof action And uses of Neostigmine

12.What are How are they useful. Explain the synthesis of Carbachol.

13.Discuss the role of acetylcholine estarase in the body. Classify acetyl cholineInhibitors with two examples each along with its specific uses.

14.Write the structure of atropine. Discuss its mechanism of action, uses andside effects.

15.Write the structure, uses and mechanism of a) scopolamine Hydrobromide b)Propantheline bromide

SHORT ANSWER

1. Write a note on muscarinic receptors
2. Write a note on Nicotinic receptors
3. Write the structure and uses Edrophonium chloride.
4. Write the structure and uses of Tacrine hydrochloride
5. Write the structure and uses of Ambenonium chloride.
6. Write the structure and uses of Isofluorphate.
7. Write the structure and uses of Echothiophate iodide,
8. Write the structure and uses of Parathione
9. Write the structure and uses of Malathion
10. Write a note on Cholinesterase reactivator
11. Write the structure and uses of Atropine sulphate
12. Write the structure and uses of Hyoscyaminesulphate
13. Write the structure and uses of Scopolamine hydrobromide
14. Write the structure and uses of Homatropinehydrobromide
15. Write the structure and uses of Tridihexethyl chloride

16. Write the structure and uses of Isopropamide iodide
17. Write the structure and uses of Ethopropazine hydrochloride.
18. What are cholinolytics. Write one cholinolytic structure and uses

UNIT IV

LONG ESSAY

1.Define sedatives and hypnotics. Explain the SAR of barbiturates. Write thesynthesis of barbital.

.2.Write the SAR of benzodiazepines. Outline the synthesis of diazepam.

3.Explain the SAR of phenothiazines. Outline the synthesis and uses ofchlorpromazine Hydrochloride.

4.What are anticonvulsants? Classify chemically with an example each.Enumerate the Structure, chemical name; synthesis and specific use any one.

5.Define and classify convulsions. Outline the synthesis of phenytoin andCarbamazepine.

6.Differentiate between the term anxiolytics, sedative, hypnotic andtranquiliser. Outline the synthesis of diazepam.

7.Define antipsychotic drugs. Write the structure of any four drugs to treat thesameBelonging to different classes. Outline the synthesis of Chlorpromazine hydrochloride.

SHORT ESSAY

1.Discuss the SAR of Barbiturates. Write the synthesis of barbital.

2.Discuss the SAR of Benzodiazepins. Write the structure and uses ofAlprazolam.

3.Write the structure and uses of sedative and hypnotics from themiscellaneous Category.

4.Write and structure and uses of a) PromazineHydrochloride,Triflupromazine and Trifluperazine.

5.Write the structure and uses of Phenothiazine ring analogues.6.Write the structure and specific uses of Hydantoin and Oxazolidinediones

SHORT ANSWER

1.Write the structure and specific uses of Lorazepam

2.Write the structure and specific uses of Alprazolam

3.Write the structure and uses Beta amino ketones as CNS depressants.

4.Write the structure and specific uses of phenobarbital with possible side effects

5.Write the structure of any one clinically used benzamide as CNS depressant6.Write the mechanism of action of Phenobarbitone

UNIT V

LONG ESSAY

1. What is anaesthesia? Classify general anaesthetics. Give its mechanism ofaction. Outline the synthesis of Halothane and ketamine hydrochloride.
2. Explain the SAR Morphine with respect to peripheral modification. Writethe Synthesis of Fentanyl citrate.
3. Classify NSAIDS with example in each class. Write the synthesis ofIbuprofen.
4. What are narcotic analgesics? Give their mechanism of action withlimitations. Write the synthesis of methadone hydrochloride
5. Differentiate between narcotics and NSAIDS. Outline the synthesis ofmethadone Hydrochloride and mefenemic acid.
6. Define anti-inflammatory drugs. Write the structure and uses of any foursuch drugs. Write the synthesis of Ibuprofen.

SHORT ESSAY

1. Explain inhalation anaesthetics in details with relevant structures andcomparative Clinical merits.
2. What is dissociative anaesthetic ? Write synthesis and uses of ketaminehydrochloride

,3. What are Narcotic antagonists? Write the structure, uses and demerits of anytwo. Narcotic antagonists.

4. Write the nuclear SAR of morphine with respect to nuclear modifications.
5. Write the structure, uses and their serious side effects of a)Indomethacin b)Ketorolac c)Naproxen6. Write the structure, uses and their serious side effects of a) Piroxicam b) Phenylbutazone and c) Aspirin.

SHORT ANSWER

1. Write structure and specific uses of Sulindac
2. Write the structure and specific uses of Tolmetin
3. Write the structure and specific uses of Zomepriac
4. Write any one drug structure of antitussive narcotic drug
5. Write the structure, specific uses and long term side effects of diclofenac
6. Write the structure and specific uses Loperamide hydrochloride

Code: 15R00802

R15

B.Pharm IV Year II Semester (R15) Regular & Supplementary Examinations June/July 2022

INTELLECTUAL PROPERTY RIGHTS

Time: 3 hours Max. Marks: 70

PART – A

(Compulsory Question)

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1		Answer the following: (10 X 02 = 20 Marks)	
	(a)	Define IPR.	2M
	(b)	What are the new developments in IPR?	2M
	(c)	How long is patent from extension?	2M
	(d)	How do patents affect the economy?	2M
	(e)	Write about time period of copyright protection.	2M
	(f)	What are the main functions of trademark?	2M
	(g)	What does industrial design include?	2M
	(h)	How plant varieties are protected?	2M
	(i)	What is licensing of intellectual property?	2M
	(j)	How IPR can protect biotechnology?	2M

PART – B

(Answer all the questions: 05 X 10 = 50 Marks)

2	(a)	Why does intellectual property need to be promoted and protected?	5M
	(b)	Give some examples of IPR.	5M
		OR	
3		Explain about intellectual property rights in India.	10M
4		Explain about the remedies for misappropriation in trade secrets.	10M
		OR	
5		Discuss about know-how and a patent.	10M
6	(a)	What are all well-known marks?	5M
	(b)	How well known marks are protected?	5M
		OR	
7	(a)	Describe various types of marks.	5M
	(b)	What kind of signs can be used as trademark?	5M
8		What are all the essential requirements for the registration of industrial design under design act?	10M
		OR	
9		What is plant variety protection act? Explain it.	10M
10		Explain the role of IPR in biotechnology research.	10M
		OR	
11		Give a brief note on commercialization of biotechnology inventions.	10M

*****

Academic Year 2022 – 2023

Class: IV-I

Program: B. Pharm

NameoftheCourse: **INDUSTRIAL PHARMACY II**

COURSEFILECONTENTS

Vision

To be recognized as an Institute of excellence, imparting quality pharmacy and healthcare education, producing competent professionals with research orientation and entrepreneurial attitude, capable of meeting the demands of the Industry and serving the Society.

Mission

M1: To provide a conducive environment for student centric teaching - learning process to achieve academic excellence.

M2: To foster among students the attitude of research, innovation and entrepreneurship.

M3: To establish effective Industry – Institute interaction with the Pharmaceutical and Healthcare sectors.

M4: To inculcate ethical and moral values among students to make them responsible to meet the needs of the society.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR, ANANTHAPURAMU

ACADEMIC CALENDAR 2022-23

B.Pharm IV Year I & II Semesters

(for 2019 admitted batch)

I Semester		
Industrial Training	10.08.2022 to 03.09.2022	(04 Weeks)
I Spell of Instructions: (include I Mid-term Examinations)	05.09.2022 to 02.11.2022	(50 Days)
II Spell of Instructions: (include II Mid-term Examinations)	03.11.2022 to 27.12.2022	(50 Days)
End laboratory Examinations:	28.12.2022 to 31.12.2022	(04 Days)
End Theory Examinations:	02.01.2023 to 16.01.2023	(12 Days)
Commencement of Class Work for IV Years B.Pharm II semester	23.01.2023 (Monday)	
Declaration of results for IV-I	15.02.2022	

II Semester		
I Spell of Instructions including project work: (include I Mid-term Examinations)	23.01.2023 to 11.03.2023	(50 Days)
II Spell of Instructions including project work: (include II Mid-term Examinations)	13.03.2023 to 29.04.2023	(50 Days)
End Theory Examinations:	01.05.2023 to 03.05.2023	(03 Days)
Project work Viva Voce Examinations:	04.05.2023 to 06.05.2023	(03 Days)
Declaration of results for IV-II	15.05.2023	

Note:

- The Mid-term Examinations should be conducted and completed as per the schedule given.
- For slippage of working days due to any unavoidable reasons, compensation can be made by conducting class work on second Saturdays, Sundays and other holidays, except on National Holidays and important festivals.

Date: 08.08.2022

DIRECTOR OF EVALUATION

PROGRAM: B.Pharmacy

PROGRAMEDUCATIONALOBJECTIVES (PEO)

Fundamental Knowledge:

- To produce pharmacy graduates with strong fundamental concepts and high technical competence in pharmaceutical sciences and technology, who shall be able to use these tools in pharmaceutical industry and/or institutes where ever necessary for success.
- To provide students with a strong and well-defined concept in the various fields of pharmaceutical sciences viz., Pharmaceutics, Pharmaceutical chemistry, Pharmacology and Pharmacognosy according to the requirement of pharmaceutical industries, community and Hospital Pharmacy and also to develop a sense of teamwork and awareness amongst students towards the importance of interdisciplinary approach for developing competence in solving complex problems in the area of Pharmaceutical Sciences.

PracticeandCare:

- To promote the development of trained human resource in Pharmaceutical Sciences for dissemination of quality education with highly professional and ethical attitude, strong communication skills, effective skills to work in a team with a multidisciplinary approach.
- To generate potential knowledge pools with interpersonal and collaborative skills to identify, assess and formulate problems and execute the solution in closely related pharmaceutical industries.
- To train the students to contribute towards health care system and counseling for prophylaxis and prevention of diseases

LifelongLearningandInnovation:

- To encourage the students to participate in life-long learning process for a highly productive career and to relate the concepts of Pharmaceutical Sciences towards serving the cause of the society.
- Developinginnovativeideasandapproachestoenhancequalityandovercomeprofessionalbarriers.
- Engagingincreativethinkingtoenvisionbetterwaysofachievingprofessionalgoals.

PROGRAM: B.Pharmacy

PROGRAM OUTCOMES (POs)

1. Comprehensive Pharmacy and Clinical Knowledge: Demonstrate proficiency in core knowledge and skills related to pharmaceutical, biomedical, clinical, and epidemiological sciences. This includes expertisein areas supporting quality pharmacy practice, such as pharmaceutics, medicinal chemistry, pharmacokinetics, pharmacodynamics, pharmacology, pathophysiology, Pharmacotherapeutics, and pharmaceutical care.

2. Patient-Centered Care: Provide personalized care to diverse patients, incorporating the best available evidence and considering patients' individual circumstances. Develop, modify, implement, document, and monitor pharmacotherapy care plans independently or as part of healthcare teams.

3. Problem Solving and Decision Making: Utilize observational, analytical, and critical thinking skills to identify and address pharmacotherapy problems. Make informed decisions based on evidence-based practice.

4. Social and Cultural Awareness: Recognize the social determinants of health and respect patients' cultural, social, and religious perspectives. Promote safe and appropriate medication use within society. Demonstrate self-awareness and a commitment to lifelong learning, reflecting on personal knowledge, experiences, values, attitudes, biases, and beliefs.

5. Professionalism: Exhibit professional ethics, attitudes, and behaviors, including patient advocacy, altruism, accountability, compassion, Integrity, and respect for others. Understand, analyze, and communicate the value of professional roles in society, such as healthcare professionals, health promoters, educators, managers, employers, and employees.

7. Innovation and Entrepreneurship: Engage in innovative activities, using creative thinking to envision improved ways of achieving professional goals. Apply scientific inquiry and critical thinking in daily practice. Acquire the skills needed to start a community pharmacy or a chain of community pharmacies with patient care services.

8. Confidentiality and Professional Ethics: Practice ethically, maintaining patient confidentiality, addressing errors in care and professional misconduct, and adhering to principles of ethical research. Apply ethical principles when making decisions and take responsibility for the outcomes associated with those decisions.

9. Interpersonal and Communication Skills: Demonstrate effective interpersonal written and verbal communication skills, adapting to socioeconomic, cultural, and situational factors. Educate families, patients, caregivers, and other healthcare professionals. Collaborate effectively within healthcare teams and provide consultation to regulatoryagencies and policy makers.

10. Clinical Pharmacist and Society: Apply contextual knowledge to assess societal healthcare needs and demonstrate effective planning abilities to address healthcare practice issues. Educate and raise awareness among patients regarding health aspects and disease prevention, providing cost-effective drug therapy.

11. Environment and Sustainability: Understand the impact of professional pharmacy solutions in societal and environmental contexts. Demonstrate knowledge of and advocate for sustainable development.

12. Practice-Based Learning and Improvement: Evaluate and improve patient care and pharmacy services. Demonstrate self- assessment skills and a commitment to lifelong learning for high-quality care. Locate, appraise, and integrate evidence from scientific studies to enhance the quality of care and services. Effectively utilize information, informatics, and technology to optimize learning and patient care.

Course objectives

- This course will enable the student to know the process of pilot plant and scale up of pharmaceutical products.
- Upon completion of the course, the students will also get knowledge with respect to the technology transfer from lab scale to commercial batch.
- This course gives complete package of different laws and acts that regulate the operations in pharmaceutical industries.
- This course also gives an idea to the students about the regulatory requirements for new drug approval process and day-to-day operations in the pharmaceutical industries and provides the confidence to the students to take up jobs in industries.

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
C70 2.1	Summarize the scale up process in pharmaceutical Industry.	L1: Remember L2: Understand L3: Apply
C70 2.2	Review the technology transfer.	L3: Apply L4: Analyse L5: Evaluate
C70 2.3	Explain about various laws and acts that regulate Pharmaceutical industry.	L3: Apply L4: Analyse L5: Evaluate
C70 2.4	Implement the regulatory environment by Upholding good regulatory practices.	L3: Apply L4: Analyse L5: Evaluate
C70 2.5	Describe the regulations and approval process in Pharmaceutical industry.	L3: Apply L4: Analyse L5: Evaluate

BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate, L6: Create

How program out comes are assessed:

Program Outcome		Level	Proficiency assessed by
PO1:	Pharmacy Knowledge	3	Assignments/ Internals/Viva
PO2:	Planning Abilities	2	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	2	Assignments/ Internals/ Practicals
PO4:	Problem Analysis	3	Assignments/ Internals
PO5:	Modern Tool Usage	2	Seminars/academic activities
PO6:	Leadership Skills	3	Group discussion / Role play
PO7:	Professional Identity	3	Group discussion
PO8:	Pharmaceutical Ethics	3	Personality development seminars
PO9:	Communication	3	Students' seminars/ student -teacher interaction
PO10:	The Pharmacist and Society	3	Group discussion / Role play
PO11:	Environment And Sustainability	3	Students' seminars
PO12	Life-Long Learning	3	Assignments/ Internals

LEVEL: 1- Slight (Low), 2- Moderate(Medium), 3- Substantial(High)

LESSONPLAN

AcademicYear: 2022–2023 Class: IV SEM: I

Program: B. Pharmacy Duration of the year: 2022 - 2023

NameoftheCourse: **PHARMACEUTICAL MICROBIOLOGY**

Prescribed Hours: **Theory:** 3 + 1 Hrs. /Week

Scheduled Date: 10/08/2022 to 31/012/2022

S.No	Chapter name	Topic	No. of hours	Name of the faculty
1	UNIT 1	Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology	10	Mr. Venkatesh Naik V Assistant Professor
2	UNIT 2	Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation -confidentiality agreement, licensing, MoUs, legal issues	10	Mr. Venkatesh Naik V Assistant Professor

3	**UNIT 3**	Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.	**10**	**Mr. Venkatesh Naik V Assistant Professor**
4	**UNIT 4**	Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP	**8**	**Mr. Venkatesh Naik V Assistant Professor**
5	**UNIT 5**	Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.	**7**	**Mr. Venkatesh Naik V Assistant Professor**

BP 702 T. INDUSTRIAL PHARMACYII (Theory)

45 Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

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

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Course Content:

UNIT-I 10 Hours

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II 10 Hours

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation -confidentiality agreement, licensing, MoUs, legal issues

UNIT-III 10 Hours

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT-IV08 Hours

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V 07 Hours

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.

2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php

3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.

4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.

Program: B. Pharmacy Duration of the year: 2022 - 2023

Name of the Course: **INDUSTRIAL PHARMACY II**

Prescribed Hours: **Theory:** 3 + 1 Hrs./Week

Scheduled Date: 10/04/2023 to 08/09/2023

ASSIGNMENTS

ASSIGNMENTTOPIC	Course Outcome	BTL
Assignment1		
Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation.	**CB405.1**	Remembering
SUPAC guidelines	**CB405.2**	Applying
Assignment2	**CB405.3**	
General considerations of Investigational New Drug (IND) Application	**CB405.4**	Analyzing
Investigator's Brochure (IB) and New Drug Application (NDA).	**CB405.5**	Understanding
Assignment3	**CB405.1**	
Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP	**CB405.2**	Understanding

Format of the assignment:

1. Minimum& Maximum number of pages.
2. It shall be written draft copy.
3. Name and signature of the student.
4. Assignment can be combined seminar presentation at the end of the semester.
5. Time allocatedforseminarmaybe8+2Min.

Balaji College of Pharmacy, Ananthapuramu.

IV Year I sem B.Pharm I Mid Examinations, **MAY–2022**

INDUSTRIAL PHARMACY II

Time: 01:30Hrs **Max. Marks: 30**

S.NO	ANSWER ALL QUESTIONS	MARKS	COURSE OUTCOME	BLOOMS LEVEL
1	Differentiate between acid fast and nonacid fast bacteria	02	CB405.1	Remembering
2	Differentiate between log phase and decline phase?	02	CB405 .1	Remembering
3	What is basal media? Give example	02	CB405.2	Remembering
4	Mention the demerits of ethylene oxide sterilization?	02	CB405.2	Remembering
5	Define sterilization?	02	CB405.3	Remembering
	ANSWER ANY ONE QUESTION			
6	Explain the principle, procedure, applications and demerits of sterilization using autoclave?	10	CB405.1	Understanding
7	Draw an ultra-structure of typical bacteria. Write composition and functions of its organelles?	10	CB405.2	Creating
	ANSWER ANY TWO QUESTIONS			
8	Differentiate between gram positive and Gram negative cell wall?	05	CB405.1	Understanding
9	Give the principle and main characteristic of phase contrast microscopy?	05	CB405.2	Understanding
10	Describe any two methods of total counting?	05	CB405.3	Evaluating

Course Outcome analysis:

CO	Total CO Marks	%CO
C 405.1	19M	42.22%
C 405.2	19M	42.22%

C 405.3	07M	15.56%
C 405.4	0M	0%
C 405.5	0M	0%
TOTAL	45M	100%

Blooms taxonomy analysis for educational objectives:

Taxonomy	Taxonomy Marks	%Taxonomy
Remember	10M	22.22%
Understand	20M	44.45%
Apply	0M	0%
Analyze	0M	0%
Evaluate	05M	0%
Create	10M	11.11%
TOTAL	45M	100%

Balaji College of Pharmacy, Ananthapuramu.

IV Year I sem B.Pharm II Mid Examinations, **July–2022**

INDUSTRIAL PHARMACY-II

Time: 01:30Hrs **Max. Marks: 30**

S.NO	ANSWER ALL QUESTIONS	MARKS	COURSE OUTCOME	BLOOMS LEVEL
1	Name the technology transfer agencies in India?	02	CB405.4	Remembering
2	Mention Two functions of Port Offices of CDSCO?	02	CB405.4	Understanding
3	What are the elements of QbD?	02	CB405 .5	Analyzing
4	Define TQM? What are the key elements of TQM?	02	CB405.5	Understanding
5	Salient features of ISO 9000?	02	CB405.4	Understanding
	ANSWER ANY ONE QUESTION			
6	Explain the concepts of Total Quality Management and Quality by Design (QbD)?	05 05	CB405.4 CB405.4	Remembering Remembering
7	What is technology transfer? Discuss the TT protocol, process, packaging and cleaning?	05 05	CB405.5 CB405.5	Understanding Understanding
	ANSWER ANY TWO QUESTIONS			
8	Describe the Organization of CDSCO with fl diagram?	05	CB405.4	Remembering
9	Explain six sigma concepts for Quality Improvement?	05	CB405.5	Understanding
10	Write a note on Drug Technical Advisory Board (DTAB) and its functions?	05	CB405.3	Evaluating

Course Outcome analysis:

CO	Total CO Marks	%CO
C 405.1	0M	0%
C 405.2	0M	0%
C 405.3	05M	11.11%
C 405.4	21M	46.66%
C 405.5	19M	42.22%
TOTAL	45M	100%

Blooms taxonomy analysis for educational objectives:

Taxonomy	Taxonomy Marks	%Taxonomy
Remember	17M	37.77%
Understand	21M	46.66%
Apply	0M	0%
Analyze	02M	0.044%
Evaluate	05M	11.11%
Create	0M	0%
TOTAL	45M	100%

INDUSTRIAL PHARMACY-II
VII Semester B Pharm

Long Essays-10Marks

1. What is a pilot plant? Explain the factors to be considered in the organization of a pharmaceutical pilot plant.
   Write a note on WHO guidelines for Technology Transfer (TT).
2. Discuss Regulatory requirement of NDA approval process.
3. What is a pilot plant? Explain the factors to be considered in the organization of a pharmaceutical pilot plant.
4. Explain the significance of documentation in BA-BE studies and add a note on outsourcing BA and BE to CRO.
5. Explain how master formula records and batch manufacturing records are developed in pilot plant scale up studies.
6. Discuss the Role of Regulatory affairs department in pharma industry.
7. Explain the protocol for pilot plant scale up for tablets production.
   Discuss the Granularity of TT Process for Active Pharmaceutical Ingredients (API) and excipients.
8. What are the data's to be submitted during New Drug Application (NDA) filing
9. Explain the requirements for pilot plant scale up of Liquid Orals.
   What are the contents of Technology transfer protocol?
10. Explain the Different Phases of drug development.
11. Explain the requirements for pilot plant scale up of Semisolids.
12. Explain the functioning of various Drug Development Teams.
13. What is a pilot plant? Explain the factors to be considered in the organization of a pharmaceutical pilot plant.
14. Describe in detail the process of Investigational New Drug Application.
15. Give Regulatory Requirements for INDA approval process.
    Explain the concepts of Total Quality Management and Quality by Design (QbD).
16. Explain the CDSCO and COPP.
17. Explain in detail Pilot plant scale up considerations for Liquid orals. Write a note on platform technology.
    What is technology transfer? Discuss the TT protocol, process, packaging and cleaning.
18. Discuss regulatory requirement of NDA approval process, modules of CTD.
19. Write a note on platform technology.
    Name the various Approved regulatory bodies and agencies in TT. Explain any two.
20. Explain in detail the process of transfer from R and D to Production.

Short Essays -5Marks

1. Write a note on Platform Technology.
2. Write a note on Technology transfer proto
3. Explain the responsibilities of regulatory affairs professionals.
4. Explain six sigma concepts for Quality Improvement.
5. Define TQM? Discuss in detail the principles of TQM.

6. What is CDSCO? What are the different functions of CDSCO?
7. Explain the requirements for pilot plant scale up of Liquid Orals.
   What are the different reasons of Technology Transfer?
8. Discuss Granularity of TT Process for API.
9. Write a note on investigators brochure.
10. Write a note on QbD concept as per ICH Q8 Guidelines.
11. Discuss the objectives and scope of GLP in Pharmaceutical industry.
12. Discuss how OSS results are handled in pharmaceutical industry.
13. Explain in detail certification of pharmaceutical product.
14. What is a pilot plant? What is the significance of Pilot Plant scale up techniques?
15. Discuss the TT Process of packaging materials.
16. Describe the key elements in managing clinical programs.
17. What are the advantages of Implementing TQM.
18. What are the Benefits of NABL accreditations?
19. Write a note on Central Drugs Testing Laboratories (CDTL).
20. Describe the Organization of CDSCO with flow diagram.
21. Discus the Significance of personnel requirements in pilot Plant scale up.
    Discuss the Documentation process involved in TT.
22. Discuss the Types of studies involved in Pre-clinical Drug Development.
23. Write a note on ICH E6 (R2) Good Clinical Practice guidelines.
24. Write a note on QbD concept as per ICH Q8 Guidelines.
25. Write a note ISO 14000 Guidelines.
26. Write a note on Drug Technical Advisory Board (DTAB) and its functions.
27. Write a note on Drug Approval of New Drugs in India.
28. Discus the space requirements in pilot Plant scale up.
29. What are the various steps involved in Transfer of analytical methods.
    What are the Contents of the Investigator's Brochure?
30. Explain the Responsibility of the Regulatory Affairs Professionals.
31. What are the conditions under which laboratories can be disqualified according to GLP?
32. Explain the procedure of NABL accreditation.
33. Describe the WHO Certification Scheme for a Certificate of Pharmaceutical Product (COPP).
34. Functions of State Drug Regulatory Authorities (SDRAs).
35. Define clinical trials? Why are the clinical trials required?
36. List out Risk management methodology and What are the Equipment requirements during TT?
37. Discuss the Scope and objectives of Regulatory Affairs.
38. What does ICH stands for? Describe the composition of ICH.
39. Discuss the approval and implementation of Change control management System in Pharmaceutical Industry.
40. Write the Functions of Drugs Controller General of India (DCGI).

41. Describe the Process to apply for a COPP.
42. Discuss change in Equipment and process as per SUPAC Guidelines
43. Organization of technology transfer
44. Applications of Biostatistics in Pharmaceutical Product Development.
45. Explain the concepts of six sigma for Quality Improvement.
46. Explain briefly the protocol for conducting Non-clinical lab studies.
47. Describe the Types of COPP and Contents.
48. Describe the Organization of CDSCO with flow diagram.
49. Write a note on scale up process approval changes
50. Discuss the Technology Transfer agencies in India and Explain the significance of documentation in BA – BE studies.
51. Write in detail about Pilot plant scale up considerations for solids.
52. Write a note on documentation of finished products, packaging materials.
53. What is clinical research protocols and data presentation?
54. Write the elements of ISO14000.
55. Discuss the GLP and discuss the same.
56. Write about USFDA guideline for Good laboratory Practices.
57. Write a note on different phases of Clinical trials.

58. Write a note on Total quality management and Quality by design.
59. Discuss the SUPAC guidelines.
60. Explain briefly the handling of out of specification (OOS).
61. Write a note on Certificate of Pharmaceutical Product.
62. Define Documentation, APCTD, FDA, CTD and QbD.
63. Write the general considerations of Pilot plant.
64. Write a note SUPAC Guidelines and List out the responsibilities of Sending Unit in technology transfer.
65. What are information's required in Process Technology Transfer.
66. Explain Investigator's Brochure.
67. Write a note on different philosophies of TQM.
68. Explain the steps involved in ISO 9000 registration.
69. How to obtain COPP.
70. Write a note on Drug Approval of New Drugs in India.

Short Answer-2Marks

1. What is master formula records?
2. Write the principles of quality risk management.
3. Enumerate the objectives of TIFAC.
4. Name the different types of drug applications that can be submitted to FDA.
5. What are the objectives of ICH guidelines?
6. What are the benefits of ISO 9000?
7. List out the significance of NABL accreditation
8. Define medical device. Give two examples.
9. Give two applications of biostatistics in pharmaceutical product development.
10. How equipment's are categorized as per SUPAC guideline.
11. What are the significance pilot plant?

12. Differentiate qualification and calibration of equipment.
13. Write the primary functions of APCTD.
14. What is the purpose of confidential agreement?
15. What are the advantages of implementing TQM.
16. Mention the advantages of QbD.
17. Define clinical trials and write its importance.
18. Define biostatistics.
19. What are the objectives of OOS.
20. Name the technology transfer agencies in India.
21. Enlist the significances of batch formula record.
22. How equipment are categorized as per SUPAC guideline
23. Write the two importance of Technology Transfer in Pharmaceutical Industry.
24. Write the primary objectives NRDC.
25. Write two key elements in managing clinical programs.
26. Write the significance BE study.
27. What is zero-defect product?
28. What are the objectives of GLP.
29. Two functions of Port Offices of CDSCO
30. Write the types of drugs for which COPPs may be issued.
31. What are the different parts of batch manufacturing record?
32. What is platform technology?
33. Write the two reasons for technology transfer in Pharmaceutical Industry.
34. Write the functions of BCIL.
35. List out various Regulatory Authorities.
36. Name the two key elements in managing clinical programs.
37. Write the four reasons for disqualification of testing facilities.
38. Classify Changes and give examples.
39. What is CTD.
40. Difference between assignable and non-assignable causes as per OOS.
41. Significance of Raw material requirements**.**
42. Write the benefits of pilot plant scale up studies
43. Write the two reasons for technology transfer in Pharmaceutical Industry.
44. Write the two functions of TIFAC.
45. Name the two significance of New Drug Application (NDA).
46. List the two key responsibilities of Regulatory Affairs.
47. What are the elements of QbD.
48. Classify Changes and give examples.
49. What are the significances of CTD?
50. What are the Types of COPP.
51. Name the contents of batch manufacturing record.
52. Name any four general requirements for pilot plant construction
53. What are the Steps involved technology transfer
54. Write features of TBSE.
55. Write the two significances of BE Study.

56. What is ADR reporting
57. Define TQM? What are the key elements of TQM.
58. Enlist the benefits of ISO 14000.
59. List out places of Zonal offices and Sub-zonal offices of CDSO.
60. What is the scope of COPP.
61. Write the benefits of pilot plant scale up studies
62. Name any four general requirements for pilot plant construction
63. Enlist the significances of batch formula record
64. Write the primary objectives of NRDC.
65. Write the two reasons for technology transfer in Pharmaceutical Industry.
66. Define validation and qualification.
67. Name types of studies involved in Pre-clinical Drug Development.
68. Name the five ICH efficacy guidelines with number and title.
69. What are the personnel requirements as per GLP.
70. What is zero-defect product?
71. Write the significance of personnel requirements.
72. Write the guidelines for technology transfer (TT).
73. Write the functions of clinical studies.
74. What is State licensing authority?
75. What are the objectives of NRDC.
76. What are MoUs and legal issues?
77. Define qualification and validation.
78. Discuss the Role of Regulatory affairs department.
79. What is six sigma concept and OOS.
80. Salient features of ISO 9000.
81. Elements of TQM.
82. Define clinical research protocol.
83. What is innovation and collaboration?
84. Quality control in Technology transfer.
85. What is CMC and preclinical testing?
86. Prospective validation.
87. Detection limit and Quantitation limit.
88. What is investigators brochure.
89. Write about similarity factors and its significance.
90. Write the principles of total quality management.
91. Write the primary objectives of pilot plant.
92. Enlist the significances of batch formula record.
93. Write two responsibilities the Receiving Unit in technology transfer
94. What are the legal issues in TT.
95. Write two functions of Drug Development Team.
96. Define Bioavailability and bioequivalence.
97. Write two objectives of GLP.
98. Define standard deviation.
99. Write two advantages of the COPP scheme.
100. Write two functions of State Drug Regulatory Authorities (SD

Code: BP702T **R19**

B.Pharm IV Year I Semester (R19) Regular Examinations January 2023
INDUSTRIAL PHARMACY - II

Time: 3 hours Max. Marks: 75

PART – A
(Compulsory Question)
*****

1		Answer the following: (10 X 02 = 20 Marks)	
	(a)	Define pilot and scale up.	2M
	(b)	Give the objectives of pilot plants.	2M
	(c)	Define Drug Master File (DMF)	2M
	(d)	What do you mean by analytical method transfer.	2M
	(e)	Mention the major regulatory bodies in the world.	2M
	(f)	Define clinical trial protocol.	2M
	(g)	Give the purposes of ICH guidelines.	2M
	(h)	Write about ISO 9000 series.	2M
	(i)	Write the functions of RDTL.	2M
	(j)	Where the office of CDL & CDSCO is located.	2M

PART – B
(Answer any two questions: 02 X 10 = 20 Marks)

2		Discuss in details the pilot plant scale up consideration for solid dosage form.	10M
3	(a)	Discuss technology transfer from R & D to production as per WHO guidelines.	6M
	(b)	Describe in short about qualification and validation for TT as per WHO guidelines.	4M
4		Explain regulatory requirement approval for obtaining NDA.	10M

PART – C
(Answer any seven questions: 07 X 05 = 35 Marks)

5	(a)	What is SUPAC means?	1M
	(b)	Enlist the SUPAC guidelines.	4M
6	(a)	Define platform technology.	2M
	(b)	Give its applications.	3M
7	(a)	Explain IQ, DQ, OQ and PQ.	4M
	(b)	Define GMP as per WHO guidelines.	1M
8		Discuss about premises and equipments for TT as per WHO guidelines.	5M
9		Discuss the different phases of clinical trial.	5M
10	(a)	Define regulatory affairs.	1M
	(b)	Discuss the role and responsibilities of RA professional.	4M
11	(a)	Explain QbD.	3M
	(b)	Give its applications.	2M
12		Write a note on six sigma concept.	5M
13		Write about the functions of state regulatory authority.	5M

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BALAJI COLLEGE OF PHARMACY, ANANTAPURAMU

(Approved by AICTE, PCI, New Delhi and affiliated to JNTUA)
Rudrampeta Bypass, Sanapa Road, Anantapuramu, Andhraprades-515002

THEORY MID EXAMINATIONS AVERAGE MARKS AWARD LIST

Name of the Sub: IND.PHARMACY-II Sub. Code:BP702T (LAB) Lab code:NA

(As per I.SYNOPSIS-10M, II.MAJOR EXP. 15M, III. MINOR EXP.10M, IV.VIVA-5M: {Total=40 convert dividing by /4})

Sl No.	H.T.No	Name Of The Student	MID-I		MID-II		AVG MARKS (15M)	Continuous Mode (10 M)	Total (25M)
			FOR 30 M	FOR 15 M	FOR 30 M	FOR 15 M			
1.	19T11R0001	Abdul Aleem S	27	14	27	14	14	9	23
2.	19T11R0002	Anitha B	--	--	---	---	--	--	--
3.	19T11R0003	Anseera Shaik	26	13	26	13	13	9	22
4.	19T11R0004	Anusha T	28	14	28	14	14	10	24
5.	19T11R0005	Aravind Ramesh Gari	--	--	--	--	--	--	--
6.	19T11R0006	Basavaraju Kummari	25	13	25	13	13	8	21
7.	19T11R0007	Bhanu Dudekula	25	13	24	12	13	8	21
8.	19T11R0008	Bhargav E	22	11	26	13	12	8	20
9.	19T11R0009	Bhargava Pindikuri	20	10	20	10	10	9	19
10.	19T11R0010	Bhargavi Golla	20	10	20	10	10	8	18
11.	19T11R0011	Blessi Rani Papannagari	28	14	28	14	14	9	23
12.	19T11R0012	Chandana E	26	13	24	12	13	9	22
13.	19T11R0013	Chandana S	28	14	25	13	13	8	22
14.	19T11R0014	Chinna Vangam	26	13	26	13	13	9	22
15.	19T11R0015	Deepika G	28	14	28	14	14	9	23
16.	19T11R0016	Dharani Chittiboina	26	13	20	10	12	8	20
17.	19T11R0017	Divyamani S	26	13	25	13	13	9	22
18.	19T11R0018	Divyasree G	26	13	26	13	13	9	22
19.	19T11R0019	Druvateja Reddy T	25	13	23	12	12	8	20
20.	19T11R0020	Geetha P	25	13	22	11	12	8	20
21.	19T11R0021	Gnaneswari S	28	14	28	14	14	9	23

22.	19T11R0022	Govardhan Babu Palem	24	12	22	11	12	7	19
23.	19T11R0023	Gowhartaj S	26	13	23	13	13	9	22
24.	19T11R0024	Gowthami Ganda	26	13	24	12	13	9	22
25.	19T11R0025	Harika M	26	13	26	13	13	10	23
26.	19T11R0026	Harini Madineni	24	12	24	12	12	8	20
27.	19T11R0027	Harsha Vardhan P	-	-	-	-	-	-	-
28.	19T11R0028	Hemalatha Gujjala	28	14	28	14	14	10	24
29.	19T11R0029	Inthiyaz S	20	10	20	10	10	8	18
30.	19T11R0030	Jagadeeswara Reddy Yenamala	26	13	28	14	14	8	22
31.	19T11R0031	Jayanthi K	24	12	24	12	12	9	21
32.	19T11R0032	Jeenal Rawal P	-	-	-	-	-	-	-
33.	19T11R0033	Karishma Golla	26	13	26	13	13	10	23
34.	19T11R0034	Kavitha C	26	13	26	13	13	9	22
35.	19T11R0035	Kavya Putluru	26	13	26	13	13	9	22
36.	19T11R0036	Keerthi Sree S	24	12	24	12	12	8	20
37.	19T11R0037	Kishore Dasari	24	12	28	14	13	9	22
38.	19T11R0038	Kokila Yerukala	26	13	26	13	13	8	21
39.	19T11R0039	Lakshmi Devi Kunta	26	13	26	13	13	9	22
40.	19T11R0040	Lalitha S	24	12	22	11	12	8	20
41.	19T11R0041	Lavanya Kotameeda	24	12	24	12	12	9	21
42.	19T11R0042	Likitha Kanekanti	-	-	-	-	-	-	-
43.	19T11R0043	Likitha P	28	14	28	14	14	9	23
44.	19T11R0044	Madhusudan Gampolla	-	-	-	-	-	-	-
45.	19T11R0045	Mahalakshmi R	20	10	24	12	11	9	20
46.	19T11R0046	Mahammad Sahul S	26	13	24	12	13	8	21
47.	19T11R0047	Malleswari Chakkari	24	12	24	12	12	9	21
48.	19T11R0048	Mallikarjuna K	20	10	20	10	10	8	18

49.	19T11R0049	Mary Neeruganti	23	12	20	10	11	8	19
50.	19T11R0050	Meghana C	24	12	24	12	12	7	19
51.	19T11R0051	Mounika Boya	26	13	24	12	13	9	22
52.	19T11R0052	Mounika Majjiga	24	12	22	11	12	8	20
53.	19T11R0053	Nandeeswari Thota	26	13	26	13	13	8	21
54.	19T11R0054	Nandini Kuruba	25	13	24	12	13	8	21
55.	19T11R0055	Nandini Nandhavaram	26	13	26	13	13	8	21
56.	19T11R0056	Nandiswari N	26	13	28	14	14	9	23
57.	19T11R0057	Nanditha Burra	26	13	26	13	13	9	22
58.	19T11R0058	Nasreen Banu Shaik	26	13	26	13	13	9	22
59.	19T11R0059	Navya Jyothi Mannala	-	-	-	-	-	-	-
60.	19T11R0060	Niranjan Moola	22	11	22	11	11	8	19
61.	19T11R0061	Noorisha Police	28	14	28	14	14	9	23
62.	19T11R0062	Pallavi G	-	-	-	-	-	-	-
63.	19T11R0063	Parveen Banu Shaik	26	13	24	12	13	8	21
64.	19T11R0064	Pavan Hanumantharayappa Gari	26	13	24	12	13	7	20
65.	19T11R0065	Pavan Kalyan Boya	24	12	22	11	12	8	20
66.	19T11R0066	Pavan Kalyan Kattakrinda	26	13	24	12	13	7	20
67.	19T11R0067	Pavan Naik Sugali Pithavath	24	12	24	12	12	8	20
68.	19T11R0068	Pavithra D.T	28	14	28	14	14	9	23
69.	19T11R0069	Pranuth Atthoti	24	12	24	12	12	9	21
70.	19T11R0070	Prashanth Kumar S	26	13	24	12	13	7	20
71.	19T11R0071	Preethi Swapna Kuruba	24	12	24	12	12	9	21
72.	19T11R0072	Pushpalatha D	26	13	24	12	13	8	21
73.	19T11R0073	Radha T	26	13	26	13	13	9	22
74.	19T11R0074	Rajesh Y	24	12	24	12	12	8	20
75.	19T11R0075	Rajeswari K	26	13	26	13	13	10	23
76.	19T11R0076	Ranjith Kumar T	26	13	26	13	13	9	22

77.	19T11R0077	Ravi Bochhu	22	11	24	12	12	7	19
78.	19T11R0078	Rizwana Dudekula	27	14	27	14	14	9	23
79.	19T11R0079	Sai Kumar C	22	11	24	12	13	9	22
80.	19T11R0080	Sai Likhitha P	28	14	28	14	14	9	23
81.	19T11R0081	Sai Mohan Basagani	28	14	28	14	14	9	23
82.	19T11R0082	Sai Rakesh Yadav B	22	11	22	11	11	9	20
83.	19T11R0083	Saikumar Malliboyene	20	10	20	10	10	9	19
84.	19T11R0084	Sainath M	20	10	20	10	10	7	17
85.	19T11R0085	Sarala Rasipogula	22	11	20	10	11	8	19
86.	19T11R0086	Shabana Shaik Kolimi	26	13	24	12	13	9	22
87.	19T11R0087	Shazia Tabassum Shaik	26	13	25	13	13	9	22
88.	19T11R0088	Shyamala Nayakula	26	13	26	13	13	9	22
89.	19T11R0089	Sireesha Dasari	20	10	20	10	10	6	16
90.	19T11R0090	Sowjanya Kadupu	28	14	24	12	13	8	21
91.	19T11R0091	Sowmya K	24	12	24	12	12	10	22
92.	19T11R0092	Sruthi Gajjelli	26	13	26	13	13	9	22
93.	19T11R0093	Subramanyam G	-	-	-	-	-	-	-
94.	19T11R0094	Sukanya Y K	22	11	20	10	11	9	20
95.	19T11R0095	Suma Mallela	24	12	20	10	11	9	20
96.	19T11R0096	Sunny Rajula	26	13	24	12	13	7	20
97.	19T11R0097	Susmitha Srisailam	26	13	24	12	13	9	22
98.	19T11R0098	Swetha Budimepalli	26	13	26	13	13	9	22
99.	19T11R0099	Vamsi Krishna Thappeta	22	11	21	11	11	9	20
100.	19T11R00A0	Vandana P	26	13	26	13	13	9	22
101.	19T11R00A1	Venkatesh Naik G	22	11	22	11	11	9	20
102.	19T11R00A2	Vennela M	26	13	26	13	13	9	22
103.	19T11R00A3	Vidhya Sree Nallolla	26	13	26	13	13	9	22
104.	19T11R00A4	Vishnu Priya Rajaputra	28	14	28	14	14	9	23

105.	19T11R00A5	Waheed Basha Shaik	24	12	20	10	11	9	20
106.	19T11R00A6	Yamuna Nagaruru	26	13	24	12	13	9	22
107.	19T11R00A7	Zabeen K	26	13	22	11	12	8	20

Signature of the faculty member

Balaji College of PharmacyAnanthapuramu

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Rudrampeta Bypass, Sanapa Road, Ananthapuramu, Andhra Pradesh -515002

Academic Year: 2021 – 2022

Class: III year II SEM

Program: B. Pharmacy

Name of the Course: Quality Assurance

COURSEFILECONTENTS

S.NO	CONTENT
1.	VISIONAND MISSIONOFINSTITUTE
2.	ACADEMICCALENDER
3.	PROGRAMEDUCATIONALOBJECTIVES
4.	PROGRAMOUTCOMES
5.	SYLLABUSCOPY
6.	LESSONPLAN
7.	COURSEOUTCOMES
8.	CO–POMAPPING,GAPSIDENTIFIEDANDJUSTIFICATION
9.	NOTES
10.	ASSIGNMENTQUESTIONS
11.	MIDQUESTIONPAPERSWITHCOANDBTLANALYSIS
12.	UNITWISEIMPORTANTQUESTIONS
13.	PREVIOUSQUESTIONPAPERS
14.	MID MARKS
15.	ATTENDENCEREGISTER
16.	SLOWLEARNERSANDADVANCELEARNERS

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR, ANANTHAPURAMU

ACADEMIC CALENDAR

B.Tech/B.Pharm III Year – II Semester (2021-2022)

Commenced from	**14.03.2022**	
I Spell of Instructions:	14.03.2022 to 07.05.2022	(08 Weeks)
I Mid-term Examinations: (1^{st} Objective + 1^{st} descriptive)	09.05.2022 to 16.05.2022	(01 Week)
II Spell of Instructions:	17.05.2022 to 08.07.2022	(08 Weeks)
Issue of Examination Notification	**20.06.2022**	
Finalization & submission of attendance to University (considering presumptive attendance for a period of one week)	02.07.2022 (Saturday) (Presumptive week from 02.07.2022 to 08.07.2022)	
II Mid-term Examinations: (2^{nd} Objective + 2^{nd} descriptive)	11.07.2022 to 16.07.2022	(01 Week)
End Laboratory Examinations	18.07.2022 to 23.07.2022	(01 Week)
End Theory Examinations:	25.07.2022 to 06.08.2022	(02 Weeks)

Note:

- The Mid-term Examinations should be conducted and completed as per the schedule given.
- For slippage of working days due to any unavoidable reasons, compensation can be made by conducting class work on second Saturdays, Sundays and other holidays, except on National Holidays and important festivals.

Date: 26.02.2022

DIRECTOR OF EVALUATION

Balaji College of Pharmacy,Ananthapuramu

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Rudrampeta Bypass, Sanapa Road, Ananthapuramu, Andhra Pradesh -515002

VISION

To be recognized as an institute of excellence, imparting quality pharmacy and healthcare education, producing competent professionals with research orientation and entrepreneurial attitude capable of meeting the demands of the industry and serving the society.

Mission

M1: To provide a conducive environment for student centric teaching – learning process to achieve academic excellence.

M2: To foster among students the attitude of research, innovation and entrepreneurship.

M3: To establish effective industry – Institute interaction with the Pharmaceutical and healthcare sectors.

M4: To inculcate ethical and moral values among students to make them responsible to meet the needs of the society.

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Rudrampeta Bypass, Sanapa Road, Ananthapuramu, Andhra Pradesh -515002

PROGRAM: B.Pharmacy

PROGRAMEDUCATIONALOBJECTIVES(PEO)

FundamentalKnowledge:

- To produce pharmacy graduates with strong fundamental concepts and high technical competence in pharmaceutical sciences and technology, who shall be able to use these tools in pharmaceutical industry and/or institutes where ever necessary for success.
- To provide students with a strong and well-defined concept in the various fields of pharmaceutical sciences viz., Pharmaceutics, Pharmaceutical chemistry, Pharmacology and Pharmacognosy according to the requirement of pharmaceutical industries, community and Hospital Pharmacy and also to develop a sense of teamwork and awareness amongst students towards the importance of interdisciplinary approach for developing competence in solving complex problems in the area of Pharmaceutical Sciences.

PracticeandCare:

- To promote the development of trained human resource in Pharmaceutical Sciences for dissemination of quality education with highly professional and ethical attitude, strong communication skills, effective skills to work in a team with a multidisciplinary approach.
- To generate potential knowledge pools with interpersonal and collaborative skills to identify, assess and formulate problems and execute the solution in closely related pharmaceutical industries.
- To train the students to contribute towards health care system and counseling for prophylaxis and prevention of diseases.

LifelongLearningandInnovation:

- To encourage the students to participate in life-long learning process for a highlyproductive career and to relate the concepts of Pharmaceutical Sciences
  towards serving the cause of the society.
- Developinginnovativeideasandapproachestoenhancequalityandovercomeprofessionalbarriers.
- Engaging in creative thinking to envision betterways of achieving professional goals.

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PROGRAM:B. Pharmacy

PROGRAMOUTCOMES(POs)

1. **Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.
2. **Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
3. **Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
4. **Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
5. **Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.
6. **Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g., health care professionals, promoters of health, educators, managers, employers, employees).
7. **Pharmaceutical Ethics:** Honor personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

8. **Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
9. **The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
10. **Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
11. **Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

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

- understand the cGMP aspects in a pharmaceutical industry
- appreciate the importance of documentation
- understand the scope of quality certifications applicable to pharmaceutical industries
- understand the responsibilities of QA & QC departments

Course content:

UNIT – I **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedures

UNIT - II **10 Hours**

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III **10 Hours**

Quality Control: Quality control test for containers, rubber closures and secondary packing

materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT – IV **08 Hours**

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V **07 Hours**

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

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LESSONPLAN

AcademicYear:2021–2022 Class:III Sem:II

Program:B. PharmacyDuration of the year: 2021 - 2022

NameoftheCourse:**Quality Assurance**

Prescribed Hours: **Theory:**3 + 1 Hrs./Week

Scheduled Date: 14/03/2022 to 6/08/2022

ReferenceBooks:

1.Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's– P P Sharma.
6. ISO 9000 and Total QualityManagement– Sadhank G Ghosh
7. The International Pharmacopoeia– Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices– Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

S.No	Chapter name	Topic	No. of hours	Name of thefaculty
1.	Quality Assurance and Quality Management concepts Total Quality Management (TQM) ICH stabilitytesting guidelines Quality by design (QbD)	Definition and concept of Quality control, Quality assurance and GMP Definition, elements, philosophies ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, Definition, overview, elements of QbD program, tools ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration NABL accreditation Principles and procedures	10 hrs	S. Parveen
2.	Organization and personnel: Premises: Equipments and raw materials:	Personnel responsibilities, training, hygiene and personal records. Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials	10	S. Parveen

3.	Quality Control: Good Laboratory Practices	Quality control test for containers, rubber closures and secondary packing 141 materials. General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities	10	S. Parveen
4.	Complaints:	Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal. Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Qualitydocumentation, Reports and documents, distribution records	8	S. Parveen
5.	Calibration and Validation:	Introduction, definition and general principles o calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration o pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. Warehousing: Goo warehousing practice, materials management	7	S. Parveen

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COURSE OUTCOMES

AcademicYear:2021–2022 Class:III SEM: II

Program: B. Pharmacy Duration of the year: 2021 - 2022

Name of the Course: **Quality Assurance**

PrescribedHours:**Theory**: 3 + 1Hrs./Week

ScheduledDate:14/03/2022 to 06/08/2022

Course Outcomes

CO NO.	Course Outcome
CB606.1	Explain significance of quality in pharmaceutical manufacturing
CB606.2	Role of regulatory agencies in deciding Quality standards, significance of validation in quality assurance
CB606.3	Follow cGMP, GLP and GDP while working in pharmaceutical industry
CB606.4	Toexplain the concept of QbD

CO-PO MAPPING

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CO-PO MAPPING

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AcademicYear:2021–2022 Class:III SEM: II

Program: B. Pharmacy Duration of the year: 2021- 2022

Name of the Course: **Quality Assurance**

PrescribedHours:**Theory**: 3 + 1Hrs./Week

ScheduledDate:14/03/2022 to 08/08/2022

ASSIGNMENTS

ASSIGNMENTTOPIC	Course Outcome	BTL
Assignment1		
Write down the various methods for preparation of TLC plates and applications of HPTLC	CB606.1	Understanding Applying
Factors governing the resolution of peaks in the gas chromatogram.	CB606.2	Understanding Applying
Detectors used in GC.	CB606.3	Analyzing
Assignment2		
Discuss the parameters to be checked for method validation of analytical equipment.	CB606.3	Remembering Understanding
Describe the principle, types and procedures of ELISA. Mention its application in diagnosis of disease.	CB606.5	Analyzing Applying

Format of the assignment:

1. Minimum& Maximumnumberofpages.
2. Itshallbewrittendraftcopy.
3. Nameandsignatureofthestudent.
4. Assignmentcanbeacombinedseminar presentationattheend of thesemester.
5. Time allocatedforseminarmaybe8+2Min.

Balaji college of pharmacy, Anantapuramu:
B.Pharm III Year II sem
I Mid exams
MAY- 2022 (AY 2021-2022)

Max time: 1 Hr 30 mins **Max Marks: 30**

Sub: Quality Assurance (BP606T)

S.No.	Questions	Marks	CO	BTL
I 1.	**ANSWER ALL OF THE FOLLOWNG (2X5=10M)** Define NABL accreditation.	2	1	1
2.	Define QC and QA.	2	1	1
3.	What is contamination and cross contamination?	2 2	4 2	4 2
4.	Explain powdered glass test?	2	4	4
5.	Define and classify containers.	5	2	2
6.	**SHORT ESSAYS (ANSWER ANY 2) 2X5=10M)** Write short notes on ISO 9000 and ISO 14000	5	2	2
7.	Explain the elements of QbD.	5	2	2
8.	Discuss the maintenance of raw material stores.			
9.	**LONG ESSAYS (ANSWER ANY 1) (1X10=10M)** Discuss the important and principle of Total Quality Management?	10	2	2
10.	Give a detail account on stability testing of dosage form as per ICH guidelines.	10	4	4

BALAJI COLLEGE OF PHARMACY: ANANTAPUR

B.Pharmacy III Year II Sem (VI SEM)

II Mid Examination

JULY 2022 AY:2021-2022

Time: 1:30 min **Max Marks: 30**

Sub: Quality Assurance (BP606T)

S.No.	Questions	Marks	CO	BTL
I	**ANSWER ALL OF THE FOLLOWNG (2X5=10M)**			
1.	Define GLP?	2	3	1
2.	Enlist the significances of batch formula record	2	4	1
3.	What is Master formula record	2	4	4
4.	Define validation?	2	5	2
5.	Write a note on Good ware house practices	5	5	4
6.	**SHORT ESSAYS (ANSWER ANY 2) 2X5=10M)** What is SOP? And write the protocol for design of SOP with suitable examples.	5	4	2
7.	What is 'Recall' in pharmaceutical industry?	5	4	2
8.	What are the characteristics should be considered for analytical method validation and explain it?		5	2
9.	**LONG ESSAYS (ANSWER ANY 1) (1X10=10M)** Discuss the GLP for a quality control laboratory in detail	10	3	2
10.	a) What are complaints and how they are evaluated? b) Explain the handling of market complaints.	10	4	4

CourseOutcomeanalysis:

CO	TotalCOMarks	%CO
C2.4.1	19M	38%
C2.4.2	14M	28%
C2.4.3	15M	30%
C2.4.4	07M	14%
C2.4.5	0M	0%
TOTAL	50M	100%

Bloomstaxonomyanalysisforeducationalobjectives:

Taxonomy	TaxonomyMarks	%Taxonomy
Remember	25M	50%
Understand	30M	60%
Apply	0M	20%
Analyze	05M	10%
Evaluate	0M	0%
Create	05M	10%
TOTAL	50M	100%

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UNITWISEIMPORTANTQUESTIONS

AcademicYear: 2022–2023 Class: III SEM: II

Program:B. Pharmacy

Name of the Course: **Quality Assurance**

PrescribedHours: **Theory**: 3 + 1Hrs./Week

ScheduledDate:14/03/2022 to 08/08/2022

QUESTIONS
CHAPTER 1
10 Marks Questions 1. Discuss in detail the design, construction, plant layout and requirement of environmental control in sterile manufacturing unit 2. Discuss the objectives and scope of GLP in Pharmaceutical industry 3. Discuss in detail the principles of TQM 4. Explain the facility requirements for maintenance of sterile manufacturing area 5. Discuss the importance of Good Laboratory Practices Explain briefly the protocol content of non-clinical laboratory study 6. List and explain Q series guidelines of ICH 7. Describe the requirements s of organization and personal responsibilities as per schedule M 8. Explain in detail the quality control test for packaging materials. 9. Explain ICH Q1 guidelines for stability testing of drug and drug product 10. Discuss briefly cGMP guidelines for construction, maintenance and sanitation of pharmaceutical unit 11. Explain the objectives and scope of GLP 12. Discuss the important principles of Total Quality Management 13. Describe the requirements for environmental control and layout of sterile manufacturing area 14. Explain the objectives and scope of GLP 15. Describe in-detail the features of ISO 9000 and ISO 14000. 16. Discuss the regulatory requirements for design, construction and plant layout of pharmaceutical manufacturing facility 17. Explain the quality control tests for containers used in pharmaceutical packaging 18. Discuss in detail about the concepts of Quality Assurance and GMP 19. Explain about the quality control tests for containers and rubber closures

20. Describe the design, construction and plant layout of a production unit
21. Explain scope and objectives of GLP.
22. Write in detail about personnel responsibilities, training and hygiene in pharmaceutical industry.
23. Write in detail about NABL accreditation, principles and procedures.
24. Give a detail account on stability testing of dosage form as per the ICH guidelines
25. Discuss in-detail the salient features of Schedule-M
26. Explain the objectives and scope of GLP
27. What is QSEM and discuss in details Q-series guidelines
28. Discuss in detail the design, construction, plant layout and requirement of environmental control in sterile manufacturing

5 Marks Questions

1. Explain the steps involved in ISO 9000 registration
2. What is CTD and explain module -2
3. Write the significance of personnel hygiene in pharmaceutical industry
4. Describe the equipment selection and purchase procedure
5. Explain the protocol for conduct of non-clinical laboratory study
6. Explain the quality control tests for containers and rubber closures
7. Discuss the handling of return goods
8. Explain the importance and scope of validation
9. Explain the concept of QA and QC
10. Enlist ICH Q-series guidelines and explain any one in detail
11. Describe the criteria for equipment selection in pharmaceutical industry
12. How is cross contamination is prevented in dispensing unit
13. Write the reasons for disqualification of testing facilities
14. Describe the procedure for handling of return goods
15. Write a short note on quality audit and quality review
16. Explain the procedure for qualification of pH meter
17. Describe the principle of analytical method validation
18. Explain the principles are of TQM
19. Explain the scope and features of NABL accreditation
20. Discuss the steps involved in the purchase specification.
21. Write a note on maintenance of stores for raw materials
22. Give reasons for disqualification of testing facilities in GLP
23. Explain briefly the protocol for conducting non-clinical lab studies
24. What are complaints and how they are evaluated?
25. How do you handle disposal of waste products in pharmaceutical unit.
26. Write the procedurefor qualification of UV- Visible spectrophotometer
27. Write the elements of ISO 9000
28. Write the procedure for NABL accreditation
29. How is the cross contamination prevented in dispensing and production areas.
30. How do you audit vendor for ensuring purchase specification
31. Discuss the procedure for conducting non clinical laboratory studies.
32. Discuss the SOP for disposal of waste in pharmaceutical unit.
33. Elaborate on master formula record
34. Write the procedurefor qualification of UV- Visible spectrophotometer
35. Write a note on ISO 9000 and ISO 14000
36. Explain briefly about ICH stability testing
37. Discuss the maintenance of raw material stores
38. Describe the SOP for purchase specification
39. Explain the procedure for qualification of UV visible spectrophotometer

40. Write a note on material Management
41. Discuss the QC tests for secondary packing materials
42. Explain briefly CTD and its modules
43. Explain the handling of market complaints
44. Explain the elements of QbD
45. Describe the methods to prevent product contamination in sterile manufacturing unit
46. Write the minimum criteria for selection of pharmaceutical equipments
47. Explain the procedure for NABL accreditation
48. Discuss the SOP for Handling of return goods
49. Explain the guidelines to be followed for waste disposal in pharmaceutical industry
50. Write in brief the material management in industry
51. Describe the protocol for conduct of non-clinical laboratory study
52. Enlist the reasons for disqualification of testing facility
53. Discuss the tools and elements of QbD program
54. Explain the protocol for conduct of non- clinical laboratory study
55. Write a note on NABL Accreditation
56. Describe briefly regarding equipment selection and purchase specification
57. Write briefly about Master Formula Record
58. Describe the maintenance of sterile area facilities
59. Write a note on good ware house practices
60. What is DMF and explain its contents
61. Summarize the reasons for disqualification of testing facility
62. Write in brief on processing of pharmaceutical complaints.
63. Explain the elements of TQM
64. What are the steps involved in validation?

2 Marks Questions

1. What are the benefits of ISO 9000?
2. What are the elements of QbD
3. Enlist the objectives of ICH
4. State the importance of personal records in manufacturing
5. Differentiate between validation and calibration
6. Explain secondary packing material
7. Write the importance of SOP in manufacturing
8. Enlist the significances of batch formula record
9. What the general principles of validation
10. Define accuracy and precision
11. Define QbD
12. Enlist the benefits of ISO 14000
13. Name any four Deming's principles of quality management
14. What are the steps involved in the purchase of raw materials
15. What are the personnel requirements as per GLP
16. Explain the role of SOP in manufacturing unit
17. What is Master formula record
18. What is FIFO and LIFO
19. Name any two parameters for qualification of UV-visible spectrophotometer
20. Write the importance of calibration
21. Write the difference between QA and QC
22. What are the benefits of QbD

23. Write a note on personal hygiene in pharmaceutical unit
24. Name different types of containers used in pharmaceutical industries
25. What is DMF and give its importance.
26. What is quality audit and quality review
27. Write the difference between qualification and validation
28. Explain the concept of FIFO
29. Write the difference between prospective and retrospective validation
30. Write the objective of ISO14000
31. Write any four elements of TQM
32. Define QA and QC
33. What is cross contamination and mix up contamination
34. Name any four types of closures
35. What is DMF? Give its importance
36. What is quality audit and quality review
37. Define calibration,qualification and validation
38. Write briefly the scope of validation.
39. Name the parameters used for analytical method validation.
40. What is the difference between QMS and EMS.
41. Define TQM
42. What are the materials used for secondary packaging?
43. Differentiate calibration and qualification
44. Define MFR
45. What are the objectives of validation
46. Write about quality documentation
47. What are the personal responsibilities in plant layout
48. Enlist Q series of ICH guidelines
49. Define NABL accreditation
50. Name different types of validation
51. What is Batch formula record?
52. Define Qualification and validation
53. Differentiate between quality control and Quality assurance
54. What are secondary packaging materials? Give examples
55. Define TQM
56. Differentiate QMS and EMS
57. Define is BMR and BPR
58. Write the importance of quality documentation
59. Name any four parameters for validation of analytical method
60. What is the significance of calibration
61. What is the difference between Quality Assurance and Quality control
62. Define standard operation procedure (SOP)
63. What is BMR
64. Define calibration and validation
65. Mention the elements of ISO 9000
66. Define QbD
67. What is contamination and cross contamination
68. Define Validation Master Plan.
69. What are secondary packing materials give example.
70. Define accuracy and precision.
71. What is batch formula record?
72. Define calibration.
73. Give the importance of Quality control.

74. What is ISO 14000?
75. Define ICH guidelines
76. What is secondary packing materials? Give two examples.
77. What is Quality review?
78. What is 'Recall' in pharmaceutical industry?
79. What are types of qualifications?
80. Define Validation.
81. What is quality assurance and TQM?
82. Define quality assurance and quality control
83. What is contamination and cross contamination
84. Differentiate ISO 9000 and ISO 14000
85. What is CTD
86. Define and classify containers
87. Differentiate calibration and qualification
88. Write the importance of SOP
89. What is LIFO and FIFO
90. Enlist the merits of warehousing
91. What are the benefits of ISO 9000?
92. What are the elements of QBD
93. Enlist the objectives of ICH
94. State the importance of personal records in manufacturing
95. Describe the design of sterile manufacturing
96. Explain secondary packing material
97. Write the importance of SOP in manufacturing
98. Enlist the significances of batch formula record
99. What the general principles of validation
100. Explain the importance of validation

Code: BP606T

R19

B.Pharm III Year II Semester (R19) Regular Examinations July/August 2022

PHARMACEUTICAL QUALITY ASSURANCE

Time: 3 hours | Max. Marks: 75

PART – A

(Compulsory Question)

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1		Answer the following: (10 X 02 = 20 Marks)	
	(a)	Define quality assurance & explain its importance.	2M
	(b)	Define quality by design & explain its importance.	2M
	(c)	Write about training of personnel in the pharma industry.	2M
	(d)	Write about sanitation of premises in the pharma industry.	2M
	(e)	Write about maintenance of reports in a lab according to GLP.	2M
	(f)	Explain about personnel requirements in a lab according to GLP.	2M
	(g)	Write about distribution records maintenance in a pharma industry.	2M
	(h)	Write about recalling goods in the pharmaceutical industry.	2M
	(i)	Write the importance of validation in a pharmaceutical industry.	2M
	(j)	Write about good warehousing practice in a pharma industry.	2M

PART – B

(Answer any two questions: 02 X 10 = 20 Marks)

2	(a)	Define total quality management & elements of it.	5M
	(b)	Write about NABL accreditation principle & procedure.	5M
3	(a)	Explain about utilities & maintenance of sterile areas in the pharma industry.	5M
	(b)	Explain about equipment selection in the pharma industry.	5M
4	(a)	Write the protocol for conducting nonclinical laboratory study.	5M
	(b)	Explain about disqualification of testing facilities in a lab according to GLP.	5M

PART – C

(Answer any seven questions: 07 X 05 = 35 Marks)

5	Write about ICH guidelines purpose, participants & process of harmonization.	5M
6	Write about tools of the QbD program.	5M
7	Explain about contamination control in the pharmaceutical industry.	5M
8	Write about maintenance of stores for raw materials in the pharmaceutical industry.	5M
9	Explain about records maintenance in a laboratory according to GLP.	5M
10	Write about quality control tests for rubber closures.	5M
11	Write about maintenance of master formula records in the pharmaceutical industry.	5M
12	Explain about handling of return goods in the pharmaceutical industry.	5M
13	Write about qualification of UV-visible spectrophotometer.	5M

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BALAJI COLLEGE OF PHARMACY :: ANANTAPUR
B.PHARMACY – III-YEAR-II-SEM (VI SEM) - AY: 2021-2022 (R19)
MID EXAMINATIONS AVERAGE MARKS AWARD LIST
Name of the Sub:Quality Assurance Sub. Code:BP606T(Theory) Lab code:NA

S.No	Roll No	Name		Mid I	Mid II		Avg (15 M)	Continuous mode(10 M)	Total (25M)
			FOR 30	FOR 15	For 30	For 15			
1	19T11R0001	Abdul Aleem S	21	11	25	13	12	9	21
2	19T11R0002	Anitha B							13
3	19T11R0003	Anseera Shaik	20	10	22	11	11	9	20
4	19T11R0004	Anusha T	22	11	21	11	11	9	20
5	19T11R0005	Aravind Ramesh Gari							12
6	19T11R0006	Basavaraju Kummari	22	11	23	12	12	9	21
7	19T11R0007	Bhanu Dudekula	23	12	21	11	11	9	20
8	19T11R0008	Bhargav E	16	8	22	11	10	9	19
9	19T11R0009	Bhargava Pindikuri	12	6	8	4	6	9	15
10	19T11R0010	Bhargavi Golla	17	9	18	9	9	9	18
11	19T11R0011	Blessi Rani Papannagari	24	12	26	13	13	9	22
12	19T11R0012	Chandana E	19	10	21	11	10	9	19
13	19T11R0013	Chandana S	22	11	26	13	12	9	21
14	19T11R0014	Chinna Vangam	25	13	22	11	12	9	21
15	19T11R0015	Deepika G	21	11	25	13	12	9	21
16	19T11R0016	Dharani Chittiboina	22	11	22	11	11	9	20
17	19T11R0017	Divyamani S	23	12	21	11	11	9	20
18	19T11R0018	Divyasree G	16	8	12	6	7	9	16
19	19T11R0019	Druvateja Reddy T	16	8	17	9	9	9	18
20	19T11R0020	Geetha P	16	8	7	4	6	9	15
21	19T11R0021	Gnaneswari S	20	10	24	12	11	9	20
22	19T11R0022	Govardhan Babu Palem	17	9	21	11	10	9	19
23	19T11R0023	Gowhartaj S	23	12	24	12	12	9	21
24	19T11R0024	Gowthami Ganda	20	10	20	10	10	9	19
25	19T11R0025	Harika M	21	11	12	6	9	9	18
26	19T11R0026	Harini Madineni	21	11	18	9	10	9	19
27	19T11R0027	Harsha Vardhan P							
28	19T11R0028	Hemalatha Gujjala	23	12	23	12	12	9	21
29	19T11R0029	Inthiyaz S			5				
30	19T11R0030	Jagadeeswara Reddy Yenamala	20	10	24	12	11	9	20
31	19T11R0031	Jayanthi K	21	11	19	10	10	9	19
32	19T11R0032	Jeenal Rawal P							11
33	19T11R0033	Karishma Golla	21	11	24	12	12	9	21
34	19T11R0034	Kavitha C	21	11	27	14	12	9	21
35	19T11R0035	Kavya Putluru	25	13	24	12	13	9	22
36	19T11R0036	Keerthi Sree S	17	9	19	10	8	9	18
37	19T11R0037	Kishore Dasari	22	11	23	12	12	9	21
38	19T11R0038	Kokila Yerukala	25	13	26	13	13	9	22

39	19T11R0039	Lakshmi Devi Kunta	26	13	24	12	13	9	22
40	19T11R0040	Lalitha S	16	8	21	11	10	9	19
41	19T11R0041	Lavanya Kotameeda	19	10	24	12	11	9	20
42	19T11R0042	Likitha Kanekanti							12
43	19T11R0043	Likitha P	22	11	25	13	12	9	21
44	19T11R0044	Madhusudan Gampolla							12
45	19T11R0045	Mahalakshmi R	12	6	18	9	9	8	17
46	19T11R0046	Mahammad Sahul S	22	11	22	11	11	9	20
47	19T11R0047	Malleswari Chakkari	23	12	25	13	12	9	21
48	19T11R0048	Mallikarjuna K	4	2	11	6	4	9	13
49	19T11R0049	Mary Neeruganti	16	8	25	13	11	9	20
50	19T11R0050	Meghana C	21	11	19	10	10	9	19
51	19T11R0051	Mounika Boya	21	11	21	11	11	9	20
52	19T11R0052	Mounika Majjiga	20	10	13	7	9	9	18
53	19T11R0053	Nandeeswari Thota	23	12	20	18	11	9	20
54	19T11R0054	Nandini Kuruba	18	9	21	11	11	9	19
55	19T11R0055	Nandini Nandhavaram	18	9	22	11	10	9	19
56	19T11R0056	Nandiswari N	22	11	22	11	11	9	20
57	19T11R0057	Nanditha Burra	21	11	23	12	11	9	20
58	19T11R0058	Nasreen Banu Shaik	18	9	19	10	10	9	19
59	19T11R0059	Navya Jyothi Mannala							12
60	19T11R0060	Niranjan Moola	15	8	18	9	9	9	18
61	19T11R0061	Noorisha Police	24	12	26	13	13	9	22
62	19T11R0062	Pallavi G							12
63	19T11R0063	Parveen Banu Shaik	23	12	27	14	13	9	23
64	19T11R0064	Pavan Hanumantharayappa Gari	20	10	26	13	12	9	21
65	19T11R0065	Pavan Kalyan Boya	18	9	23	12	11	9	20
66	19T11R0066	Pavan Kalyan Kattakrinda	22	11	27	14	13	9	22
67	19T11R0067	Pavan Naik Sugali Pithavath	17	9	25	13	11	9	20
68	19T11R0068	Pavithra D.T	21	11	21	11	11	9	20
69	19T11R0069	Pranuth Atthoti	21	11	23	12	11	9	20
70	19T11R0070	Prashanth Kumar S	12	6	17	9	8	9	17
71	19T11R0071	Preethi Swapna Kuruba	18	9	13	7	8	9	17
72	19T11R0072	Pushpalatha D	23	12	23	12	12	9	21
73	19T11R0073	Radha T	21	11	21	11	11	9	20
74	19T11R0074	Rajesh Y	19	10	15	8	9	9	18
75	19T11R0075	Rajeswari K	22	11	23	12	12	9	21
76	19T11R0076	Ranjith Kumar T	22	11	21	11	11	9	23
77	19T11R0077	Ravi Bochhu	11	6	9	5	5	8	13
78	19T11R0078	Rizwana Dudekula	21	11	27	14	12	10	22
79	19T11R0079	Sai Kumar C	19	10	11	6	8	9	17
80	19T11R0080	Sai Likhitha P	22	11	25	13	12	10	22
81	19T11R0081	Sai Mohan Basagani	26	13	26	13	13	10	23
82	19T11R0082	Sai Rakesh Yadav B	17	9	15	8	8	9	17
83	19T11R0083	Saikumar Malliboyene	10	5	16	8	7	6	16
84	19T11R0084	Sainath M							15
85	19T11R0085	Sarala Rasipogula	17	9	17	9	9	10	19

86	19T11R0086	Shabana Shaik Kolimi	22	11	21	11	11	9	20
87	19T11R0087	Shazia Tabassum Shaik	22	11	23	12	12	10	22
88	19T11R0088	Shyamala Nayakula	19	10	19	10	10	10	20
89	19T11R0089	Sireesha Dasari							11
90	19T11R0090	Sowjanya Kadupu	23	12	26	13	13	9	22
91	19T11R0091	Sowmya K	18	9	25	13	11	9	20
92	19T11R0092	Sruthi Gajjelli	23	12	26	13	13	10	23
93	19T11R0093	Subramanyam G							11
94	19T11R0094	Sukanya Y K	18	9	21	11	10	10	20
95	19T11R0095	Suma Mallela	25	13	22	11	12	10	22
96	19T11R0096	Sunny Rajula	21	11	24	12	12	10	22
97	19T11R0097	Susmitha Srisailam	16	8	17	9	9	9	18
98	19T11R0098	Swetha Budimepalli	21	11	23	12	11	10	21
99	19T11R0099	Vamsi Krishna Thappeta	22	11	22	11	11	9	20
100	19T11R00A0	Vandana P	23	12	25	13	12	10	22
101	19T11R00A1	Venkatesh Naik G	20	10	21	11	11	10	21
102	19T11R00A2	Vennela M	22	11	22	11	11	10	21
103	19T11R00A3	Vidhya Sree Nallolla	21	11	20	10	11	9	20
104	19T11R00A4	Vishnu Priya Rajaputra	24	12	23	12	12	9	21
105	19T11R00A5	Waheed Basha Shaik	21	11	21	11	11	9	20
106	19T11R00A6	Yamuna Nagaruru	17	9	20	10	10	9	19
107	19T11R00A7	Zabeen K	21	11	20	10	11	9	20
108	19Z71R0056	Raj Kumar	16	8	22	11	10	9	19

Balaji College of Pharmacy,Ananthapuramu

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Rudrampeta Bypass, Sanapa Road, Ananthapuramu, Andhra Pradesh -515002

Academic Year: 2022 – 2023

Class: IV-II

Program:B.Pharmacy

Name of the Course: **B-PHARMACY**

COURSE FILE CONTENTS

S.NO	CONTENT
1.	VISIONAND MISSIONOFINSTITUTE
2.	ACADEMIC CALENDER
3.	PROGRAM EDUCATIONAL OBJECTIVES
4.	PROGRAM OUTCOMES
5.	SYLLABUS COPY
6.	LESSON PLAN
7.	COURSE OUT COMES
8.	CO–POMAPPING,GAPSIDENTIFIEDANDJUSTIFICATION
9.	NOTES
10.	ASSIGNMENT QUESTIONS
11.	MID QUESTION PAPERS WITH CO AND BTL ANALYSIS
12.	UNIT WISE IMPORTANT QUESTIONS
13.	PREVIOUS QUESTION PAPERS
14.	MID MARKS
15.	ATTENDENCE REGISTER
16.	SLOW LEARNERS AND ADVANCE LEARNERS

Balaji College of Pharmacy,Ananthapuramu

ApprovedbyPCI,NewDelhi&AffiliatedtoJNTUAnantapur

Rudrampeta Bypass, Sanapa Road, Ananthapuramu, Andhra Pradesh -515002

Vision

To be recognized as an Institute of excellence, imparting quality pharmacy and healthcare education, producing competent professionals with research orientation and entrepreneurial attitude, capable of meeting the demands of the Industry and serving the Society.

Mission

M1: To provide a conducive environment for student centric teaching - learning process to achieve academic excellence.

M2: To foster among students the attitude of research, innovation and entrepreneurship.

M3: To establish effective Industry – Institute interaction with the Pharmaceutical and Healthcare sectors.

M4: To inculcate ethical and moral values among students to make them responsible to meet the needs of the society.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR, ANANTHAPURAMU

ACADEMIC CALENDAR 2022-23

B.Pharm IV Year I & II Semesters

(for 2019 admitted batch)

I Semester		
Industrial Training	10.08.2022 to 03.09.2022	(04 Weeks)
I Spell of Instructions: (include I Mid-term Examinations)	05.09.2022 to 02.11.2022	(50 Days)
II Spell of Instructions: (include II Mid-term Examinations)	03.11.2022 to 27.12.2022	(50 Days)
End laboratory Examinations:	28.12.2022 to 31.12.2022	(04 Days)
End Theory Examinations:	02.01.2023 to 16.01.2023	(12 Days)
Commencement of Class Work for IV Years B.Pharm II semester	**23.01.2023 (Monday)**	
Declaration of results for IV-I	**15.02.2022**	

II Semester		
I Spell of Instructions including project work: (include I Mid-term Examinations)	23.01.2023 to 11.03.2023	(50 Days)
II Spell of Instructions including project work: (include II Mid-term Examinations)	13.03.2023 to 29.04.2023	(50 Days)
End Theory Examinations:	01.05.2023 to 03.05.2023	(03 Days)
Project work Viva Voce Examinations:	04.05.2023 to 06.05.2023	(03 Days)
Declaration of results for IV-II	**15.05.2023**	

Note:

- The Mid-term Examinations should be conducted and completed as per the schedule given.
- For slippage of working days due to any unavoidable reasons, compensation can be made by conducting class work on second Saturdays, Sundays and other holidays, except on National Holidays and important festivals.

Date: 08.08.2022

DIRECTOR OF EVALUATION

Balaji College of Pharmacy,Ananthapuramu

ApprovedbyPCI,NewDelhi&AffiliatedtoJNTUAnantapur

Rudrampeta Bypass, Sanapa Road, Ananthapuramu, Andhra Pradesh -515002

PROGRAM:B.Pharmacy

PROGRAM EDUCATIONAL OBJECTIVES(PEO)

Fundamental Knowledge:

- To produce pharmacy graduates with strong fundamental concepts and high technical competence in pharmaceutical sciences and technology, who shall be
  able to use these tools in pharmaceutical industry and/or institutes where ever necessary for success.
- To provide students with a strong and well-defined concept in the various fields of pharmaceutical sciences viz., Pharmaceutics, Pharmaceutical chemistry, Pharmacology and Pharmacognosy according to the requirement of pharmaceutical industries, community and Hospital Pharmacy and also to develop a sense of teamwork and awareness amongst students towards the importance of interdisciplinary approach for developing competence in solving complex problems in the area of Pharmaceutical Sciences.

Practice and Care:

- To promote the development of trained human resource in Pharmaceutical Sciences for dissemination of quality education with highly professional and ethical attitude, strong communication skills, effective skills to work in a team with a multidisciplinary approach.
- To generate potential knowledge pools with interpersonal and collaborative skills to identify, assess and formulate problems and execute the solution in closely related pharmaceutical industries.
- To train the students to contribute towards health care system and counseling for prophylaxis and prevention of diseases.

Life long Learning and Innovation:

- To encourage the students to participate in life-long learning process for a highlyproductive career and to relate the concepts of Pharmaceutical Sciences
  towards serving the cause of the society.
- Developinginnovativeideasandapproachestoenhancequalityandovercomeprofessionalbarriers.
- Engagingincreativethinkingtoenvisionbetterwaysofachievingprofessionalgoals.

Balaji College of Pharmacy,Ananthapuramu

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Rudrampeta Bypass, Sanapa Road, Ananthapuramu, Andhra Pradesh -515002

PROGRAM:B. Pharmacy

PROGRAM OUTCOMES(POs)

1. **Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.
2. **Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
3. **Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
4. **Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
5. **Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.
6. **Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g., health care professionals, promoters of health, educators, managers, employers, employees).
7. **Pharmaceutical Ethics:** Honor personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

8. **Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
9. **The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
10. **Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
11. **Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

JAWAHARLALNEHRUTECHNOLOGICALUNIVERSITYANANTAPUR

B. Pharmacy -IVYEAR II SEMESTER

BP802T SOCIAL AND PREVENTIVE PHARMACY

Theory:3 + 1 Hrs./Week

Objectives:

After the successful completion of this course, the student shall be able to:

- Acquire high consciousness/realization of current issuesrelated to health and pharmaceutical problems within the country and worldwide.
- Haveacriticalwayof thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related tohealth and pharmaceutical issues

Recommended Books (Latest Edition):

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad Recommended Journals: 1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

Course content:

Unit I: **10 Hours**

Concept of health and disease:

Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick. Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention. Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health Hygiene and health: personal hygiene and health care; avoidable habits

Unit II: **10 Hours**

Preventive medicine:

General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

Unit III: **10 Hours**

National health programs, its objectives, functioning and outcome of the following:
HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV: **08 Hours**

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

Unit V: **07 Hours**

Community services in rural, urban and school health:
Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school

Balaji College of Pharmacy,Ananthapuramu

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Rudrampeta Bypass, Sanapa Road, Ananthapuramu, Andhra Pradesh -515002

LESSON PLAN

Academic Year: 2022–2023 Class: IV Sem: II

Program:B. Pharmacy Duration of the year: 2022 - 2023

Name of the Course: **Social and preventive pharmacy**

Prescribed Hours: **Theory:**3 + 1 Hrs./Week

Scheduled Date: 23/01/2023 to 29/04/2023

1. Recommended Books (Latest Edition):

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications

2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications

3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications

4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications

5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.

6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad Recommended Journals: 1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

S.No	Chapter name	Topic	No. of hours	Name of thefaculty
1.	**Social and preventive pharmacy**	**Concept of health and disease:** Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick. **Social and health education:** Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention. **Sociology and health:** Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health **Hygiene and health:** personal hygiene and health care; avoidable habits	03 03 02 02	MULLA MOHAMMED ASIF
2.	**Social and preventive pharmacy**	**Preventive medicine:** General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse	05 05	MULLA MOHAMMED ASIF

3.	**Social and preventive pharmacy**	National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National 158 programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme	01 01 05 01 01 01	MULLA MOHAMMED ASIF

4.	**Social and preventive pharmacy**	National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program	08	MULLA MOHAMMED ASIF

5.	**Social and preventive pharmacy**	Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.	0	MULLA MOHAMMED ASIF

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Rudrampeta Bypass, Sanapa Road, Ananthapuramu, Andhra Pradesh -515002

COURSE OUTCOMES

AcademicYear:2022–2023 Class:IV SEM: II

Program: B. Pharmacy Duration of the year : 2022 - 2023

Name of the Course: **Social & preventive pharmacy**

Prescribed Hours:**Theory**: 3 + 1Hrs./Week

Scheduled Date: 23/01/2023 to 29/04/2023

Course Outcomes

CO NO.	Course Outcome
CB.802.1	Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
CB.802.2	Have a critical way of thinking based on current healthcare development.
CB.802.3	Evaluate alternative ways of solving problems related to health and pharmaceutical issues
CB.802.4	This course also introduced a number of national health programmes.
CB.802.5	The roles of the pharmacist in these contexts are also discussed.

CO-PO MAPPING

…… o……

Balaji College of Pharmacy,Ananthapuramu

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Rudrampeta Bypass, Sanapa Road, Ananthapuramu, Andhra Pradesh -515002

AcademicYear:2022–2023 Class:IV SEM: II

Program: B. Pharmacy Duration of the year: 2022 - 2023

Name of the Course: **SOCIAL AND PREVENTIVE PHARMACY**

PrescribedHours:**Theory**: 3 + 1Hrs./Week

ScheduledDate: 23/01/2023 to 29/04/2023

ASSIGNMENTS

ASSIGNMENTTOPIC	**Course Outcome**	**BTL**
Assignment1		
General principles of prevention and control of diseases such as cholera, SARS, Ebola virus,	CB.802.1 CB.802.2 CB.802.4	Understanding Applying
National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme,	CB.802.3 CB.802.4 CB.802.5	Remembering Understanding
National health intervention programme for mother and child, National family welfare programme,	CB.802.1	Analyzing
Assignment2		
Functions of PHC, Improvement in rural sanitation,	CB.802.3 CB.802.4 CB.802.5	Remembering Understanding
Role of WHO in Indian national program	CB.802.1	Analyzing

Formatoftheassignment:

1. Minimum& Maximumnumberofpages.
2. Itshallbewrittendraftcopy.
3. Nameandsignatureofthestudent.
4. Assignmentcanbeacombinedseminar presentationattheend of thesemester.

5. Time allocatedforseminarmaybe8+2Min.

CodeNo:BP802T Roll.No:

Balaji College of Pharmacy, Ananthapuramu.

IVYear II semB.PharmI Mid Examinations, **July–2023**

SOCIAL AND PREVENTIVE PHARMACY

Time:01:30HrsMax.Marks: 30

S. NO	ANSWER ALL QUESTIONS	MARKS	COURSE OUTCOME	BLOOMS LEVEL
1	What is balanced diet?	02	CB.802.1	Remembering
2	Define health and explain the types?	02	CB.802.1	Remembering
3	What is nutritional deficiency? Mention the types involved?	02	CB.802.3	Remembering
4	What are infectious disease?	02	CB.802.2	Remembering
5	What is preventive medicine and mention types involved?	02	CB.802..2	Remembering
	ANSWER ANY ONE QUESTION			
6	write general principle, prevention and control of cholera?	10	CB.802..2	Remembering & Understanding
7	Explain in detail about hypertension ?	10	CB.802.2	Understanding
	ANSWER ANY TWO QUESTIONS			
8	Write the evaluation of public health and explain the types involved?	05	CB.802.1	Understanding
9	Explain prevention and control of diabetes mellitus ?	05	CB.802.2	Remembering & Creating
10	Write a note on food in relation to nutrition and health?	05	CB.802.1	Understanding &analyzing

Course Out come analysis:

CO	TotalCOMarks	%CO
CB.802.1	19M	38%
CB.802.2	14M	28%
CB.802.3	15M	30%
CB.802.4	07M	14%
CB.802.5	0M	0%
TOTAL	50M	100%

Blooms taxonomy analysis for educational objectives:

Taxonomy	TaxonomyMarks	%Taxonomy
Remember	25M	50%
Understand	30M	60%
Apply	0M	20%
Analyze	05M	10%
Evaluate	0M	0%
Create	05M	10%
TOTAL	50M	100%

BalajiCollege ofPharmacy, Ananthapuramu.

IVYear II semB.Pharm II Mid Examinations, **July–2023**

SOCIAL AND PREVENTIVE PHARMACY BP802T

Time:01:30HrsMax.Marks: 30

S. NO	ANSWER ALL QUESTIONS	MARKS	COURSE OUTCOME	BLOOMS LEVEL
1	Write a note on national immunization schedule ?	02	CB.802.3	Remembering
2	What is pentavalent vaccine ?	02	CB.802.3	Remembering
3	What is rashtriya Bal swasthya karyakram (R BSK)?	02	CB.802.4	Remembering
4	Enlist functioning of PHC?	02	CB.802.5	Remembering
5	Draw the structure of healthcare system India ?	02	CB.802.5	Remembering
	ANSWER ANY ONE QUESTION			
6	a)Explain in detail national (TB) control program? b)Give the function of WHO?	10	CB.802.3	Remembering & Understanding
7	Write a note on Health promotion & Education in school?	10	CB.802.5	Understanding
	ANSWER ANY TWO QUESTIONS			
8	Discuss the primary health care control ?	05	CB.802.5	Understanding
9	Explain in detail about national tobacco control in India ?	05	CB.802.4	Remembering & Creating
10	(a)Write a note on pulse polio prevention ? (b)explain NP for blindness ?	05	CB.802.3	Understanding &analyzing

Course Out come analysis:

CO	TotalCOMarks	%CO
CB.802.1	19M	38%
CB.802.2	14M	28%
CB.802.3	15M	30%
CB.802.4	07M	14%
CB.802.5	0M	0%
TOTAL	50M	100%

Blooms taxonomy analysis for educational objectives:

Taxonomy	TaxonomyMarks	%Taxonomy
Remember	25M	50%
Understand	30M	60%
Apply	0M	20%
Analyze	05M	10%
Evaluate	0M	0%
Create	05M	10%
TOTAL	50M	100%

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UNIT WISE IMPORTANT QUESTIONS

AcademicYear:2022–2023 Class: IV SEM: II

Program:B. Pharmacy

Name of the Course: **Social and preventive pharmacy**

PrescribedHours: **Theory**: 3 + 1Hrs./Week

ScheduledDate:10/04/2023to08/09/2023

QUESTIONS
CHAPTER 1

LONG ESSAYS (10 Marks)

1. Explain different vitamin deficiency disorders and their prevention.(I)
2. Explain Integrated disease surveillance programme(IDSP).(III)
3. Write a note on national health programme and national AIDS control programme.(III)
4. Explain the evaluation of public health.(I)
5. What are national health programs, write in detail about national AIDS control program.(III)
6. Write general principles of prevention and control of respiratory infections.(II)
7. Explain different vitamin deficiency disorders and their prevention.(I)
8. Write general principles, prevention and control of cholera.(II)
9. Explain about national Tuberculosis health programme.(III)
10. Define malnutrition and write about types & diseases associated with it.(I)
11. Write general principles of prevention and control of diabetes mellitus.(II)
12. Write a note on HIV and AIDS control program.(III)
13. Explain the Evaluation of public health.(I)
14. Describe the general principles for prevention and control of malaria.(II)
15. Explain national leprosy control programme.(III)
16. Write a note on concept of health and disease.(I)
17. Write general principles of prevention and control of acute respiratory infection.(II)
18. Write a note on objectives, functioning and scope of national leprosy control program(III)
19. Write a note on General principles and control of cancer.(II)
20. Write a note on HIV and AIDS control programme.(III)

SHORT ESSAYS (5 Marks)

1. Write a note on food in relation to nutrition and health.(I)
2. Write general principles of prevention and control of cholera.(II)
3. Write the evaluation of public health.(I)
4. What is SARS write its symptoms and prevention?(II)
5. What are the objectives of the national family welfare program?(IV)
6. Objectives and functions of the national leprosy program.(III)
7. What are the functions of Primary Health Centres?(V)
8. Objectives and implementation of the national tobacco control program.(IV)
9. What are the community services in urban areas?(V)
10. Write functions of PHC in the health care system.(V)
11. Role of WHO in Indian national health program.(IV)
12. Explain the concept of diseases.(I)
13. Explain malnutrition and its preventive measures.(I)
14. Explain prevention and control of Dengue.(II)
15. Explain about Integrated disease surveillance program (IDSP).(III)
16. Explain national health intervention programs for mother and child.(IV)
17. Write the objectives in improving rural sanitation.(V)
18. Explain the universal immunization program(III)
19. Write a note on the prevention of vitamin deficiency diseases.(I)
20. Define health, write a note on the evolution of public health.(I)

SHORT ANSWERS

Social and preventive pharmacy (2 Marks)

1. What is Beriberi? (I)
2. Causes of malaria.(II)
3. Objectives of National Tuberculosis Programme.(III)
4. Toxic effects of tobacco.(IV)
5. What is the national urban health mission?(V)
6. Importance of personal hygiene.(I)
7. Lymphatic filariasis.(II)
8. Objectives of national mental health programme.(III)
9. Health care programme for elderly.(IV)
10. Health promotion in schools.(V)
11. What is Night blindness?(III)
12. Social Causes of diseases.(I)
13. Define cholera and its symptoms.(II)
14. Write about drug addiction.(II)
15. What is health care for the elderly?(IV)
16. Prevention and control of deafness.(III)
17. Health education in schools.(V)
18. Urban health mission.(V)
19. Define health.(I)
20. Harmful effects of Tobacco.(IV)
21. What is Marasmus?()
22. Socio-cultural factors to health and diseases.(I)
23. Screening of diabetes mellitus.(II)
24. What is SARS?(II)
25. What is a universal immunization program?(III)
26. Objectives of national mental health program.(III)
27. Intervention programme for children.(IV)
28. Adverse health effects of open defecation.(II)
29. How to improve health education in schools?(V)
30. Health issues of old age.(IV)

BALAJI COLLEGE OF PHARMACY :: ANANTAPUR
B.PHARMACY – IV-YEAR-I-SEM (VII SEM) - AY: 2022-2023 (R19)
MID EXAMINATIONS AVERAGE MARKS AWARD LIST
Name of the Sub: Social and preventive pharmacy Sub. Code:Bp802T
(Theory) Lab code:NA

Sl No.	H.T.No	Name Of The Student	MID-I		MID-II		Avg (15M)	Continuous Mode (10 M)	Total (25M)
			FOR 30 M	FOR 15 M	FOR 30 M	FOR 15 M			
1.	19T11R0001	S ABDUL ALEEM	26	13	26	13	13	10	23
2.	19T11R0003	SHAIK ANSEERA	28	14	28	14	14	09	23
3.	19T11R0004	THALARI ANUSHA	21	14	28	14	14	09	23
4.	19T11R0006	KUMMARI BASAVARAJU	25	13	24	12	13	10	23
5.	19T11R0007	DUDEKULA BHANU	25	13	29	14	14	09	23
6.	19T11R0008	EEDIGA BHARGAV			29	15	08	10	18
7.	19T11R0009	PINDIKURI BHARGAVA	21	11	20	10	10	10	20
8.	19T11R0010	GOLLA BHARGAVI	20	10	22	11	11	09	20
9.	19T11R0011	PAPANNAGARI BLESSI RANI	26	13	28	14	14	09	23
10.	19T11R0012	E CHANDANA	24	12	28	14	13	09	22
11.	19T11R0013	S CHANDANA	25	13	27	14	14	09	23
12.	19T11R0014	VANGAM CHINNA	26	13	26	13	13	10	23
13.	19T11R0015	GOLLA DEEPIKA	27	14	28	14	14	09	23
14.	19T11R0016	CHITTIBOINA DHARANI	26	13	26	13	13	09	22
15.	19T11R0017	S DIVYAMANI	27	14	28	14	14	08	22
16.	19T11R0018	GUJJULA DHIVYASRI	24	12	22	11	12	10	22
17.	19T11R0019	T. DRUVATEJA REDDY	27	13	25	13	13	09	22
18.	19T11R0020	PENUKONDLA GEETHA	20	10	27	14	12	09	21
19.	19T11R0021	S GNANESWARI	23	14	29	15	15	08	23
20.	19T11R0022	PALEM GOVARDHAN BABU	22	11	23	12	12	08	20
21.	19T11R0023	SHAIK GOWHARTAJ	29	14	29	15	14	10	24
22.	19T11R0024	GANDA GOWTHAMI	29	14	28	14	14	10	24
23.	19T11R0025	MANDA HARIKA	28	14	26	13	13	10	23
24.	19T11R0026	MADINENI HARINI	27	14	25	13	13	10	23
25.	19T11R0027	P.Harshavardhan							
26.	19T11R0028	GUJJALA HEMALATHA	27	14	29	15	14	10	24
27.	19T11R0029	SHAIK INTHIYAZ	24	12	26	13	13	08	21
28.	19T11R0030	Y.JAGADEESWARA REDDY	28	14	28	14	14	08	22
29.	19T11R0031	KAMBADUR JAYANTHI	20	10	26	13	12	09	21
30.	19T11R0033	GOLLA KARISHMA	25	13	28	14	14	08	22
31.	19T11R0034	CHINTHAKUNTA KAVITHA	24	12	29	14	13	08	21
32.	19T11R0035	POTLURU KAVYA	27	14				10	23

33.	19T11R0036	S.Keerthi sree	22	11	26	13	12	10	22
34.	19T11R0037	DASARI KISHORE	25	13	28	14	13	10	23
35.	19T11R0038	YERUKALA KOKILA	25	13	28	14	14	09	23
36.	19T11R0039	KUNTA LAKSHMI DEVI	22	11	27	14	13	09	22
37.	19T11R0040	SAKE LALITHA	24	12	28	14	13	10	23
38.	19T11R0041	KOTAMEEEDA LAVANYA	24	12	29	15	13	09	22
39.	19T11R0043	PADUCHURI LIKITHA	24	12	29	15	14	10	24
40.	19T11R0045	R. MAHALAKSHMI	22	11	27	14	13	09	22
41.	19T11R0046	SHAIK MD. SHAHUL	25	13	26	13	13	09	22
42.	19T11R0047	CHAKKARI MALLESWARI	24	12	27	14	13	09	22
43.	19T11R0048	K MALLIKARJUNA					05	09	18
44.	19T11R0049	NEERUGANTI MARY	24	12	28	14	13	09	22
45.	19T11R0050	CHAKALI MEGHANA	29	14	28	14	14	09	23
46.	19T11R0051	BOYA MOUNIKA	28	14	27	14	14	09	23
47.	19T11R0052	MAJJIGA MOUNIKA	24	12	28	14	13	09	22
48.	19T11R0053	THOTA NANDEESWARI	27	14	28	14	14	09	23
49.	19T11R0054	KURUBA NANDINI	24	12	21	11	12	10	22
50.	19T11R0055	NANDAVARAM NANDINI	26	13	24	12	13	09	22
51.	19T11R0056	N.NANDISWARI	24	12	27	14	14	09	23
52.	19T11R0057	BURRA NANDITHA	27	14	25	13	13	09	22
53.	19T11R0058	SHAIK NASREEN BANU	26	13	27	14	13	09	22
54.	19T11R0059	MANNALA NAVYA JYOTHI							
55.	19T11R0060	MOOLA NIRANJAN	26	13	27	14	13	10	23
56.	19T11R0061	POLICE NOORISHA	28	14	29	14	14	09	23
57.	19T11R0062	GOLLA PALLAVI							
58.	19T11R0063	SHAIK PARVEEN BANU	27	13	27	14	14	08	22
59.	19T11R0064	H. PAVAN	26	13	26	13	13	08	21
60.	19T11R0065	BOYA PAVAN KALYAN	27	13	27	14	14	09	23
61.	19T11R0066	K.PAVAN KALYAN	27	13	27	14	14	09	22
62.	19T11R0067	S.P.PAVAN NAIK	27	14	28	14	14	09	23
63.	19T11R0068	D. PAVITHRA	28	14	27	14	14	09	23
64.	19T11R0069	ATTHOTI PRANUTH	26	13	27	14	14	09	23
65.	19T11R0070	SAKE PRASANTH KUMAR	25	13	27	14	13	09	22
66.	19T11R0071	KURUBA PREETHI SWAPNA	26	13	27	14	13	09	22
67.	19T11R0072	DASARI PUSHPA LATHA	27	14	27	14	14	09	23
68.	19T11R0073	THUMBIGANURU RADHA	28	14	27	14	14	09	23
69.	19T11R0074	YALERU RAJESH	24	12	25	13	12	09	21
70.	19T11R0075	K RAJESWARI	23	12	27	14	13	09	22
71.	19T11R0076	T RANJITH KUMAR	29	14	29	15	15	09	24
72.	19T11R0077	BOCHHU RAVI	24	12	21	12	12	09	21
73.	19T11R0078	DUDEKULA RIZWANA	27	14	27	13	14	09	23
74.	19T11R0079	C. B. SAI KUMAR	26	13	23	12	13	08	21

75.	19T11R0080	P.SAI LIKHITHA	28	14	28	14	14	10	24
76.	19T11R0081	BASAGANI SAI MOHAN	29	15	28	14	14	10	24
77.	19T11R0082	BALA SAI RAKESH YADAV	20	10	22	11	11	09	20
78.	19T11R0083	MALLIBOYENE SAIKUMAR			26	13	07	10	17
79.	19T11R0084	MADDIMADUGU SAINATH							
80.	19T11R0085	RASIPOGULA SARALA	27	13	28	14	14	10	24
81.	19T11R0086	SHAIK KOLIMI SHABANA	26	13	28	14	14	09	23
82.	19T11R0087	SHAIK SHAZIA TABASSUM	27	14	28	14	14	09	23
83.	19T11R0088	NAYAKULA SHYAMALA	27	14	29	15	14	09	23
84.	19T11R0089	DASARI SIREESHA							
85.	19T11R0090	KADUPU SOWJANYA	28	14	28	14	14	10	24
86.	19T11R0091	KONDAPALLI SOWMYA	28	14	26	13	13	10	23
87.	19T11R0092	GAJJELLI SRUTHI	28	14	29	15	14	09	23
88.	19T11R0094	Y K SUKANYA	27	14	27	14	14	10	24
89.	19T11R0095	MALLELA SUMA	23	12	20	10	11	09	20
90.	19T11R0096	RAJULA SUNNY	26	13	26	13	13	10	23
91.	19T11R0097	SRISAILAM SUSMITHA	27	13	28	14	14	09	23
92.	19T11R0098	BUDIMEPALLI SWETHA	28	14	28	14	14	08	22
93.	19T11R0099	THAPPETA VAMSI KRISHNA	26	13	27	13	13	09	22
94.	19T11R00A0	P. VANDHANA	28	14	28	14	14	09	23
95.	19T11R00A1	G VENKATESH NAIK	24	12	24	12	12	09	21
96.	19T11R00A2	MARAKA VENNELA	27	14	28	14	14	10	24
97.	19T11R00A3	NALLOLLA VIDHYA SREE	27	14	26	13	13	09	22
98.	19T11R00A4	RAJAPUTRA VISHNU PRIYA	29	15	26	13	14	10	24
99.	19T11R00A5	SHAIK WAHEED BASHA	25	13	24	12	13	09	22
100.	19T11R00A6	NAGARURU YAMUNA	26	13	27	13	13	08	21
101.	19T11R00A7	KOTHWAL ZABEEN	28	14	28	14	14	09	23
102.	**19Z71R0056**	P.RAJKUMAR	24	12	25	12	12	09	21
103.									
104.									

Signature of the faculty member

B.Pharm IV Year II Semester (R19) Regular
Examinations May 2023
SOCIAL & PREVENTIVE PHARMACY(BP802T)
Time: 3 hours Max. Marks: 75

PART – A
(Compulsory Question)

1		Answer the following: (10 X 02 = 20 Marks)	
	(a)	Define health.	2M
	(b)	What are various Socio culture factors responsible for disease?	2M
	(c)	Give the examples of any two viruses and diseases caused by them.	2M
	(d)	Write the names of any two drugs used in treatment of malaria with their MOA.	2M
	(e)	What are primary objectives of National Health Programme?	2M
	(f)	Give a brief account on Pulse polio programme.	2M
	(g)	Write a brief note on National Tobacco control programmes.	2M
	(h)	What are various National family welfare programmes?	2M
	(i)	Define PHC.	2M
	(j)	What are various issues in rural sanitation?	2M

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PART – B
(Answer any two questions: 02 X 10 = 20 Marks)

2	(a)	What do you mean by Balanced diet? Discuss the factors responsible for malnutrition and its prevention.	5M
	(b)	Write a note on "social causes of diseases" and what are various measures to avoid thesocial problems of the sick.	5M
3	(a)	Discuss the general principles of prevention & control of diseases.	5M
	(b)	Write an exhaustive note on diabetes mellitus.	5M
4	(a)	Write an exhaustive note of National Malaria prevention programmes.	5M
	(b)	Discuss the role of WHO in Indian national health programmes.	5M

PART – C
(Answer any seven questions: 07 X 05 = 35 Marks)

5		What do you mean by public health? What are various parameters used to evaluate thepublic health?	5M

6	(a)	Write a note on various National health intervention programme for mother and child.	3M
	(b)	What are various National programmes for the health care for the elderly?	2M
7	(a)	Explain the needs of personal hygiene in health care.	2M
	(b)	Write a note on avoidable habits for prevention of diseases.	3M
8	(a)	What are various schemes/programmes run by Govt. for health promotion and education in schools?	2M
	(b)	What is the present scenario of improvement in rural sanitation?	3M
9		Explain the causes of development of cancer; what are various preventive measures tocombat cancer and give some drug examples used in the treatment.	5M
10		What are objectives of National health programs? Explain with example of HIV & AIDScontrol programme.	5M
11		Explain the relation between sociology and health; discuss the impact of urbanization and/orpoverty on health & diseases.	5M
12	(a)	Write a note on drug substance abuse.	3M
	(b)	Write a note on lymphatic filariasis.	2M
13		Discuss in detail about Integrated disease surveillance programme (IDSP).	5M