RAJIV GANDHI UNIVERISTY OF HEALTH SCIENCES

KARNATAKA BENGALURU-560041

CURRICULUM DESIGNING

B. PHARMA SEMESTER-VI

1. Name of subject (as per RGUHS): **MEDICINAL CHEMISTRY- III (BP601T)**
2. Departmental objectives (what the learners will be able to perform after completing the subject):

Course Description:

This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Deparmental objectives: Upon completion of the course the student shall be able to

- Understand the importance of drug design and different techniques of drug design.
- Understand the chemistry of drugs with respect to their biological activity.
- Know the metabolism, adverse effects and therapeutic value of drugs.
- Know the importance of SAR of drugs.

3. **Annual objectives (for each year, if the subject is spread over different years)**: **Not applicable**

4. Content distribution as per the list of topics, time allotted for each topic, distribution for 'Must know', 'Desirable to know' and 'Nice to know' and the probable weightage. The following table can also be a reference frame for continuous and formative assessment of learning. If the curriculum management is scheduled as per the tabulation, there can be clarity for both learners and teachers to take stock of the mastery achieved in each objective. This will also help for professional excellence that goes beyond the examination process.

Note: Please refer Annexure-I for teaching sequence.

Unit `	Topic	Hours	Learning content distribution			Wt'age (Marks)
			Must know	Desirable to know	Nice to know	
I	**Antibiotics;** Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. **β-Lactam antibiotics:** Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams **Aminoglycosides:** Streptomycin, Neomycin, Kanamycin **Tetracyclines:** Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline,Doxycycline	10	**β-lactam antibiotics:** History, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation, classification and Mechanism of action of Penicillins and Cepholosporins. **Aminoglycosides:** Nomenclature, chemistry, structures and MOA of aminoglycosides. **Tetracyclines:** History, Nomenclature, Stereochemistry, Structure activity relationship and Mechanism of action of Tetracyclines.	Nomenclature, structures and MOA of β-Lactamase inhibitors & Monobactams.	Bacterial resistance to antibiotics	**22**
II	**Antibiotics:** Historical background, Nomenclature, Stereochemistry, Structure	10	**Macrolide:** History, Structures, Nomenclature, Stereochemistry, degradation, classification and Mechanism of	Structure, MOA and therapeutic uses of Clindamycin. **Prodrugs:** Basic concepts and application	-	**22**

	activity relationship, Chemical degradation classification and important products of the following classes. **Macrolide:** Erythromycin Clarithromycin, Azithromycin. **Miscellaneous:** Chloramphenicol*, Clindamycin. **Prodrugs:** Basic concepts and application of prodrugs design. **Antimalarials:** Etiology of malaria. **Quinolines:** SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine. **Biguanides and dihydrotriazines:** Cycloguanil pamoate, Proguanil. **Miscellaneous:** Pyrimethamine, Artesunete, Artemether, Atovoquone.		action and specific uses of Erythromycin Clarithromycin, Azithromycin **Miscellaneous:** Structure, chemistry, synthesis, MOA, SAR, degradation, synthesis and therapeutic uses of Chloramphenicol. **Antimalarials:** Life cycle of malarial parasite, Structures, Nomenclature, Structure activity relationships, classification and Mechanism of action of Quinolines, Biguanides, dihydrotriazines and Synthesis of Chloroquine and Pamaquine.	of prodrugs design. Structure and therapeutic uses of Pyrimethamine, Artesunete, Artemether, Atovoquone		
III	**Anti-tubercularAgents** **Synthetic anti tubercular**	10	**Anti-tubercularAgents** Structure, classification, MOA, and	Structures and therapeutic uses		**18**

	agents: Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylicacid.* **Anti tubercular antibiotics:** Rifampicin, Rifabutin, Cycloserine, Streptomycine, Capreomycin sulphate. **Urinary tract anti-infective agents** **Quinolones:** SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin **Miscellaneous:** Furazolidine, Nitrofurantoin*, Methanamine. **Antiviral agents:** Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridinetrifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.		therapeutic uses of synthetic and antibiotic antitubercular agents. SAR of Isoniazid, Ethambutol. Synthesis of Isoniozid and Para amino salicylic acid. **Urinary tract anti-infective agents** Structure, classification, MOA, SAR and therapeutic uses of quinolones. Synthesis of Ciprofloxacin and Nitrofurantoin. **Antiviral agents:** Classification, MOA and therapeutic uses of Antiviral agents. Synthesis of Acyclovir.	Rifampicin, Cycloserine, Streptomycin. Structures and therapeutic uses Nalidixic Acid, Norfloxacin, Enoxacin, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin, Furazolidine, Methanamine. Structures and therapeutic uses Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.	Classification of virus and viral diseases.	

IV	**Antifungal agents:** **Antifungal antibiotics:** Amphotericin-B, Nystatin, Natamycin, Griseofulvin. **Synthetic Antifungal agents:** Clotrimazole, Econazole, Butoconazole, OxiconazoleTioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*. **Anti-protozoalAgents:** Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine. **Anthelmintics:** Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin. **Sulphonamides and Sulfones** Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine,	8	**Antifungal agents:** Classification, MOA and therapeutic uses of Antifungal antibiotics and synthetic Antifungal agents. Synthesis of Miconazole and Tolnaftate. **Anti-protozoal Agents:** Classification, MOA and therapeutic uses of Anti-protozoal Agents. Synthesis of Metronidazole. **Anthelmintics:** Classification, MOA and therapeutic uses of Anthelmintics. Synthesis of Diethylcarbamazine citrate and Mebendazole. **Sulphonamides and Sulfones** Classification, MOA, Chemistry, SAR and therapeutic uses of Sulphonamides. Synthesis of Sulfacetamide, Sulfamethoxaole, Trimethoprim and Dapsone. Synergestic effects of	Structures and therapeutic uses of Griseofulvin, Clotrimazole, Econazole, Butoconazole, Oxiconazole, Tioconozole, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride. Structures and therapeutic uses of Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine. Structures and therapeutic uses of Thiabendazole, Albendazole, Niclosamide, Oxamniquine, Praziquantal. Structures and therapeutic uses of Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide, Sulphapyridine, Sulfamethoxaole, Sulphadiazine, Mefenide acetate, Sulfasalazine, Trimethoprim.	Classification of protozoa and protozoal diseases. Classification of Helimenths Causes of Crystalluria.	**26**

	Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine. **Folate reductase inhibitors:** Trimethoprim*, Cotrimoxazole. **Sulfones:** Dapsone*.		Trimethoprim and sulfamethoxazole.			
V	**Introduction to Drug Design:** Various approaches used in drug design. Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis. Pharmacophore modeling and docking techniques. **Combinatorial Chemistry:** Concept and applications chemistry: solid phase and solution phase synthesis. of combinatorial chemistry	7	**Introduction to Drug Design:** Various approaches used in drug design. Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as Hammet's electronic parameter, Tafts steric parameter and Hansch analysis. Pharmacophore modeling and different docking techniques. Concept and applications of Combinatorial Chemistry. Methods used in Combinatorial Chemistry.	Determination of partition coefficient. Definition and equation of Hansch analysis, Free Wilson analysis, Tafts analysis.		**7**

Annexure-I

5. Teaching sequence

Sl NO	Topic	Hours
I	**Unit V**	**8**
	Introduction to Drug Design: Various approaches used in drug design. Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis. Pharmacophore modeling and docking techniques. **Combinatorial Chemistry:** Concept and applications chemistry: solid phase and solution phase synthesis. of combinatorial chemistry **Prodrugs:** Basic concepts and application of prodrugs design.	1 4 2 1
II	**Unit III**	**10**
	Anti-tubercularAgents Synthetic anti tubercular agents: Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylicacid.* **Anti tubercular antibiotics:** Rifampicin, Rifabutin, Cycloserine, Streptomycine, Capreomycin sulphate. **Urinary tract anti-infective agents** **Quinolones:** SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin **Miscellaneous:** Furazolidine, Nitrofurantoin*, Methanamine. **Antiviral agents:** Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridinetrifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.	3 3 4
III	**Unit IV**	**8**
	Antifungal agents: Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin. **Synthetic Antifungal agents:** Clotrimazole, Econazole, Butoconazole, OxiconazoleTioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*. **Anti-protozoalAgents:** Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine. **Anthelmintics:** Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin. **Sulphonamides and Sulfones** Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine. **Folate reductase inhibitors:** Trimethoprim*, Cotrimoxazole. **Sulfones:** Dapsone*.	2 1 1 4

IV	**Unit I**	**10**
	Antibiotics; Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. **β-Lactam antibiotics:** Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams **Aminoglycosides:** Streptomycin, Neomycin, Kanamycin **Tetracyclines:** Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline,Doxycycline	5 2 3
V	**Unit II**	**9**
	Antibiotics: Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. **Macrolide:** Erythromycin Clarithromycin,Azithromycin. **Miscellaneous:** Chloramphenicol*,Clindamycin. **Antimalarials:** Etiology of malaria. **Quinolines:** SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine. **Biguanides and dihydrotriazines:** Cycloguanil pamoate, Proguanil. **Miscellaneous:** Pyrimethamine, Artesunete, Artemether, Atovoquone.	2 1

SIXTH SEMESTER B PHARM- MEDICINAL CHEMISTRY-III

BLUE PRINT OF MODEL QUASTION PAPER

TIME: 3 HOURS **MAX. MARKS: 75**

Unit No.	TOPIC TITLE	HOURS	Must Know			Desirable to Know			WEIGHTAGE OF MARKS
			LONG ESSAYS	SHORT ESSAYS	SHORT ANSWERS	LONG ESSAYS	SHORT ESSAYS	SHORT ANSWERS	
			(10x3)	(5x8)	(2x4)	(10x0)	(5x1)	(2x6)	
Unit-I	**Antibiotics and its derivatives**	10	01	02	---	--	--	01	**22**
Unit-II	**Antibiotics, Antimalarials classification and its derivatives**	10	01	02	---	--	--	01	**22**
Unit-III	**Anti-tubercularAgents and Urinary tract anti-infective agents**	10	--	02	02	--	---	02	**18**
Unit-IV	**Antifungal agents and Anti-protozoal agents, Anthelmentics, Sulphonamides and sulfones**	8	01	02	02	--	--	01	**26**
Unit-V	**Introduction to Drug Design**	7	---	01	---	--	--	01	**07**
	TOTAL MARKS	**45**	**30**	**45**	**08**	**--**	**---**	**12**	**95**
			83			**12**			**95**

NOTE: 1) the question paper must be prepared based on the individual blue print which is based on the weightage of marks fixed for each chapter/unit

Template for curriculum designing

6. Name of subject (as per Apex Council gazette): **BP602 T. PHARMACOLOGY-III**

7. Departmental objectives (what the learners will be able to perform after completing the subject):

a. Understand the mechanism of action various antimicrobial agent and its relevance in the treatment of different infectious diseases.

b. Comprehend the principles of toxicology and treatment of various poisonings.

c. Appreciate correlation of pharmacology with related medical sciences.

d. Understand every minute pharmacological details and salient features of most widely used drugs for treatment of various diseases.

8. Annual objectives (for each year, if the subject is spread over different years):

a. Student should be able choose the most appropriate chemotherapeutic regimen for treatment of infectious diseases.

b. Student should be able to design strategy to prevent antimicrobial resistance.

c. Student should be able to identify drugs' ADR or drug resistance sensibly and should be capable of choosing alternative chemotherapeutic agent.

d. Student should be able to identify toxicity of xenobiotics and should suggest effective measures to prevent or treat the same, rationally.

9. Content distribution as per the list of topics, time allotted for each topic, distribution for 'Must know', 'Desirable to know' and 'Nice to know' and the probable weightage.

The following table can also be a reference frame for continuous and formative assessment of learning. If the curriculum management is scheduled as per the tabulation, there can be clarity for both learners and teachers to take stock of the mastery achieved in each objective. This will also help for professional excellence that goes beyond the examination process.

Sl No`	Topic	Hours	Learning content distribution			Weightage
			Must know	Desirable to know	Nice to know	
1	Drugs acting on respiratory system	5	Definition and classification of : Anti- asthmatics drugs. Drugs Used in Management of COPD. Pharmacology of β_2-agonists and Xanthine	Difference between asthma and COPD. MOA of bromohexine and guaifenesin. Uses of respiratory stimulants. MOA and ADR of	Aerosol preparations used for asthma. Herbal expectorants. Role of	21 Marks

			derivatives. Expectorants and Antitussives. Nasal Decongestants. Respiratory stimulants.	nasal decongestants.	leukotriene and PAF antagonists in asthma. Causes of nasal congestion.	
	Drugs acting on gastrointestinal tract	5	Classification of antiulcer agents, pharmacology of PPIs and H_2 blockers. Classification of drugs used for Constipation, MOA , adverse effects and uses of bulk laxatives, irritant purgatives and saline cathertics. Classification of Anti-emetics and pharmacology of domperidone and ondansetron.	Drugs used to eradicate H.pylori. Sucralfate. Lactulose. Docusate salts. Definition, examples and uses of: Antacids, Appetite Stimulants and Suppressants, Emetics, Digestants and Carminatives. Classification of types of diarrhoea and drugs used in their treatment.	Ulcer healing agents, Study of campylobacter species and their control. Herbal medicines for GI disorders. Racecadotril.	
2	General principles of chemotherapy	3	Introduction to chemotherapy, antibiotics, classification of AMA on the basis of MOA, concept of microbial resistance to antibiotics and its prevention, rationale behind combined use of antibiotics.	Chemotherapeutic index, Chemoprophylaxis, Sources of antibiotics, probiotics, pre probiotics.	Classification of pathogenic microbes.	22 Marks
	Antibiotics and Antimicrobial agents	7	Source , MOA, antimicrobial spectrum, adverse effects and therapeutic uses of Penicillins , Cephalosporins , Chloramphenicol,	Classification of Penicillins , Cephalosporins , Macrolides, tetracyclines and aminoglycosides. Sulfonamides ,	Mechanism microbial development of microbi	

			Macrolides, tetracycline and aminoglycosides. Sulfonamides , Clotrimaxole ,Quinolones, Fluoroquinolones.	Fluoroquinolones. Salient features of different generations of Cephalosporins , Macrolides, Tetracyclines, Fluoroquinolones.	al resistance to individual agents and newer antibiotics.	
3	Chemotherapy of diseases	10	Classification of Antitubercular , Antileprotic, Antimalarial , Antiamoebic agents. Antifungal agents. Antiviral agents Antihelmintics. Source , MOA, antimicrobial spectrum, adverse effects and therapeutic uses of INH, Rifampicin, pyrazinamide, ethambutol, dapsone,chloroquine, artemisinin, metronidazole, amphotericin B, triazoles, Acyclovir, Zidovudin, benzimidazoles.	DOTS, types of leprosy, life cycles of amoeba and malarial parasites, types of helminths. Classification of anti HIV agents.	Treatment of drug resistant tuberculosis, amoebiasis and malaria. HAART therapy for HIV.	22 Marks
4	Chemotherapy of UTI, STD and Cancer	5	Classification of drugs used for treatment of UTI, STD and Cancer. MOA, adverse effects and uses of alkylating agents, antimetabolites and hormonal anticancer agents.	Cell cycle based classification of anticancer agents and their importance in chemotherapy.	Recently introduced anticancer agents.	14 Marks
	Immunopharmacology	5	Classification of Immunostimulants	Uses of Immunostimulants.	Application of	

			and Immunosuppressants. MOA, adverse effects and therapeutic uses of cyclosporin, corticosteroids.		monoclonal antibodies in treating autoimmune diseases.	
5	Principles of Toxicology	6	Genral Principles of treatment of poisoning. Clinical symptoms and management of barbiturates, morphine organ phosphorous compound and lead, mercury and arsenic poisoning.	Definitions of acute, sub acute and chronic toxicity. Genotoxicity, Carcinogenicity, Teratogenicity and Mutagenicity.	Recent advances in eliminating poison from systemic circulation like plasmapheresis, hemodialysis etc.	16 Marks
	Chronopharmacology	1	Definition of rhythm and cycles. Biological clock and their Significance leading to chronotherapy.	----	----	

10. Blueprint of question paper, for each QP. This shows the weightage given to each chapter in the summative assessment. This improves the content validity by distributing the assessment of learners in the competencies that are represented by learning objectives under each chapter.

State the number of QPs for the subject.

The following template demonstrates how each QP Blueprint would look like:

Unit	Chapter	Marks distribution					Total Marks
		Must Know	**Desirable to Know**	**Long Essay**	**Short Essay**	**Short Answer**	

I	**Drugs acting on respiratory system**	7Marks	2Marks	-	5	2×2	**21**
	Drugs acting on gastrointestinal tract	10Marks	2Marks	10	-	2	
II	**General principles of chemotherapy**	5Marks	2Marks	-	5	2	**22**
	Antibiotics and Antimicrobial agents	10Marks	5Marks	10	5	-	
III	**Chemotherapy of diseases**	17Marks	5Marks	10	5×2	2	**22**
IV	**Chemotherapy of UTI, STD and Cancer**	5Marks	2Marks		5	2	**14**
	Immunopharmacology	7Marks	-		5	2	
V	**Principles of Toxicology**	7Marks	2Marks		5×2	2	**16**
	Chronopharmacology	7Marks	-		---	2×2	
Total		**75Marks**	**20Marks**	**10×3=30**	**5×9=45**	**2×10=20**	**95**

* 80 % of the questions shall be from the Must Know area and 20 % shall be from the Desirable to know area of the Curriculum.

11. Question paper layout to show which question number will represent which chapter (s)

	LONG ESSAYS (Any Two)	**2 X 10 = 20 Marks**
1.	Drugs acting on gastrointestinal tract	
2.	Antibiotics and Antimicrobial agents	
3.	Chemotherapy of diseases	
	SHORT ESSAYS (Any Seven)	**7 X 05 = 35 Marks**
4.	Drugs acting on respiratory system	
5.	General principles of chemotherapy	
6.	Antibiotics and Antimicrobial agents	
7.	Chemotherapy of diseases	
8.	Chemotherapy of diseases	
9.	Chemotherapy of UTI, STD and Cancer	
10.	Immunopharmacology	
11.	Principles of Toxicology	
12.	Principles of Toxicology	
	SHORT ANSWERS (Answer All)	**10 X 02 = 20 Marks**
13.	Drugs acting on gastrointestinal tract	
14.	Drugs acting on respiratory system	
15.	Drugs acting on respiratory system	
16.	General principles of chemotherapy	
17.	Chemotherapy of diseases	
18.	Chemotherapy of UTI, STD and Cancer	
19.	Immunopharmacology	
20.	Principles of Toxicology	
21.	Chronopharmacology	
22.	Chronopharmacology	

12. Scheme of Practical / Clinical Teaching and Assessment:

List the expected practical / clinical competencies.

State the objectives for each competencies.

Assign content for the objectives.

Describe the teaching – learning processes.

Sl No	Practical	Duration	Skills /Learning methods
01	Dose calculation in pharmacological experiments	4hrs	All or most of the experiments are performed through computer simulated experiments. So, practicals involves processing of given data and interpretation of results or Demonstration & Presentation of practical skills.
02	Antiallergic activity by mast cell stabilization assay		
03	Study of antiulcer activity of a drug using pylorus ligand (SHAY)rat model and NSAIDsinduced ulcer model.		
04	Study of effect of drugs on gastrointestinal motility		
05	Effect of agonist and antagonists on guinea pig ileum.		
06	Estimation of serum biochemical parameters by using semi - autoanalyser		
07	Effect of saline purgative on frog intestine		
08	Insulin hypoglycaemic effect in rabbit		
09	Test for pyrogens by rabbit method		
10	Determination of acute oral toxicity (LD50)of a drug from given data.		
11	Determination of acute skin irritation of a test substance		
12	Determination of acute eye irritation of a test substance		
13	Calculation of pharmacokinetic parameters from a given data		
14	Biostatistical analysis of given data by Student's t test		
15	Biostatistical analysis of given data by Chi square test		
16	Biostatistical analysis of given data by Wilcoxon signed Rank test.		

Scheme of examination with the distribution of marks as per the prioritisation of competencies.

Sl No	Competency	Assessment criteria	Marks
A	Knowledge	Synopsis	10
B	Cognitive and intellectual skills		
C	Subject specific practical / Cognitive skills	One Major & One Minor Experiment	15+10
D	Transferable professional skills	Viva-voce	05

13. Suggested references (as per APA style):

- Basic references
- Advanced references (may also include journals / web / other electronic sources)

	LONG ESSAYS (Any Two) 2 X 10 = 20 Marks
1.	Classify drugs used for treatment of peptic ulcer. Write mechanism of action, adverse effects and uses of omeprazole.
2.	Classify penicillins with examples. Explain mechanism of action, adverse effects and spectrum of activity of ampicillin.
3.	Name causative organisms of malaria, classify antimalarials with examples. Describe the mechanism of action of Chloroquine.
	SHORT ESSAYS (Any Seven) 7 X 05 = 35 Marks
4.	Write pharmacology of salbutamol.
5.	Classify antimicrobial agents on the basis mechanism of action
6.	Classify anti viral agents. Write mechanism of action of acyclovir.
7.	Describe life cycle of amoeba parasite.
8.	Classify anti leprotic agents. Write a note on types of leprosy.
9.	Write the pharmacology of alkyllating agent.
10.	Write mechanism of action, adverse effects and uses of cyclosporine.
11.	Describe the procedure used for removal of orally ingested poisons.
12.	Outline steps involved in barbiturate poisoning.
	SHORT ANSWERS (Answer All) 10 X 02 = 20 Marks
13.	What are carminatives? Give two examples.
14.	Define expectorants and antitussive.
15.	Enlist respiratory stimulants.
16.	What is chemoprophylaxis? Give an example
17.	Name the causative organisms of tuberculosis.
18.	Mention four urinary antiseptics.
19.	What are monoclonal antibodies?
20.	Explain the term teratogenecity.
21.	What is circadian rhythm?
22.	Define chronopharmacology.

BP 603T HERBAL DRUG TECHNOLOGY

Units	Topic	Hours	Learning content distribution			Weightage
			Must know	Desirable to know	Nice to know	
Unit-I	**Herbs as raw materials** Definition of herb, herbalmedicine, herbal medicinal product, herbal drug preparation Source of Herbs Selection, identification and authentication of herbal materials Processing of herbal raw material **Biodynamic Agriculture** Good agricultural practices in cultivation ofmedicinal plants including Organic farming. Pest and Pestmanagement in medicinal plants: Biopesticides/Bioinsecticides. **Indian Systems ofMedicine** a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.	11	**Indian Systems ofMedicine** a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma. **Herbs as raw materials** Processing of herbal raw material	Definition of herb, herbalmedicine, herbal medicinal product, herbal drug preparation Source of Herbs Selection, identification and authentication of herbal materials. **Biodynamic Agriculture** Good agricultural practices in cultivation ofmedicinal plants including Organic farming. Pest and Pestmanagement in medicinal plants: Biopesticides/Bioinsecticides.	Visit to medicinal plant garden and preparation of herbarium	19
Unit-II	**Nutraceuticals** General aspects, Market, growth, scope and types	07	**Nutraceuticals** General aspects, Market, growth, scope and types	**Herbal-Drug and Herb-Food Interactions:** General	Marketed product study of	19

	of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases. Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina **Herbal-Drug and Herb-Food Interactions:** General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper &Ephedra.		of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases. Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina	introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper &Ephedra.	neutraceuticals	
Unit -III	**Herbal cosmetics**: Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products. **Herbal excipients:** Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors &perfumes. **Herbal formulations :**	10	**Herbal cosmetics**: Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products. **Herbal excipients:** Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants,	**Herbal formulations :** Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes	Study of available herbal formulations in the market	26

	Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes		flavors &perfumes.			
Unit-IV	**Evaluation of Drugs** WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs. **Patenting and Regulatory requirements of natural products:** a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma &Neem. **Regulatory Issues** - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.	10	**Evaluation of Drugs** WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs. **Patenting and Regulatory requirements of natural products:** a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma &Neem.	**Regulatory Issues** - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs	Regulation aspects of herbal drugs in international scenario.	24
Unit-V	**General Introduction toHerbal Industry** Herbal drugs industry: Present scope and future prospects. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India. S**chedule T – GoodManufacturing Practice of Indian systems of medicine** Components of GMP (Schedule – T) and its objectives Infrastructural requirements,	07	**General Introduction toHerbal Industry** Herbal drugs industry: Present scope and future prospects. S**chedule T – GoodManufacturing Practice of Indian systems of medicine** Components of GMP (Schedule – T) and its objectives Infrastructural requirements, working space, storage area,	A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.	Visit to herbal drug industry and research institute	07

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, BANGALORE

SIXTH SEMESTER

BP 604T. BIO PHARMACEUTICS AND PHARMACOKINETICS

Learning objectives: Upon completion of the course student shall be able to:

1. To understand the basic concepts in bio-pharmaceutics and pharmacokinetics and their significance
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion and elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. To Understand various pharmacokinetic parameters, their significance and applications

BP 604T. BIO PHARMACEUTICS AND PHARMACOKINETICS (BLUE PRINT)

	working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.		machinery and equipments, standard operating procedures, health and hygiene, documentation and records.			

Sl.No	Chapter	Marks Distribution					Total
		Must Know	Desirable to know	Long essay	Short essay	Short Answer	
Unit-I	**Introduction to Bio pharmaceutics** **Absorption**; Mechanism of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution:** Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs	**Absorption:** Mechanism of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from **Distribution:** Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding.	Non per oral extra-vascular routes, Kinetics of protein binding, Clinical Significance of protein binding of drugs extra-vascular routes, Protein binding of drugs	**10**	**5+5**	**2+2**	**24M**

Unit-II	**Elimination:** Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs **Bioavailability and Bioequivalence:** Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.	**Elimination:** Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs. **Bioavailability and Bioequivalence:** Absolute and relative bioavailability, measurement of bioavailability, Methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.	Renal clearance, Non renal routes of drug excretion of drugs. *In-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, Poorly soluble drugs	**10**	**5+5**	**2+2**	**24M**
Unit-III	**Pharmacokinetics:** Definition and introduction to Pharmacokinetics, Compartment models, Non compartment	**Pharmacokinetics** Definition, Introduction to Pharmacokinetics, Compartment models, Non	Pharmacokinetics parameters- KE , t1/2, Vd, AUC, Ka, Clt and CL_R- definitions Methods	**10**	**5+5**	**2+2**	**24M**

	models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters- KE , t1/2, Vd, AUC, Ka, Clt and CL_R- definitions methods of eliminations, understanding of their significance and application	compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations.	of eliminations, understanding of their significance and application Understanding significance of pharmacokinetics and application				
Unit-IV	***Multicompartment models:*** Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical setting.	***Multi Compartment Models:*** Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels,	Calculation of loading and maintenance doses Significance in clinical setting.	**---**	**5**	**2+2**	**09M**
Unit-V	**Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with	**Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton	Method of estimating parameters. Explanation with example of drugs.	**---**	**5+5**	**2+2**	**14M**

	example of drugs.						
Total				**30**	**45**	**20**	**95M**

Rajiv Gandhi University of Health Sciences, Bengaluru

SIXTH SEMESTER

BP 604T. Bio pharmaceutics and Pharmacokinetics

MODEL QUESTION PAPER

Long essay (Answer any Two)

2x10=20M

1. Explain physicochemical and physiological factors influencing drug absorption through GIT.
2. Define bioavailability. List out various methods for measurement of bioavailability and explain any one method.
3. Define and classify compartment model. Deduce pharmacokinetic parameters of drug administered by one compartment open model by method of residuals.

Short essay (Answer any Seven)

7x5=35M

4. Explain various factors affecting protein drug binding.
5. Define absorption. Differentiate between active and passive diffusion.
6. Define clearance. Write a note on renal clearance.
7. Explain methods to enhance the dissolution of poorly soluble drugs.
8. Write a note on pharmacokinetic parameters.
9. Explain non compartmental models.
10. Explain drug accumulation during multiple dosing.
11. Explain Michaelis-Menton equation.
12. Estimate K_m and V_{max}.

Short Answers (Answer all)

10x2=20M

13. Define apparent volume of distribution.
14. Write any two clinical significance of protein binding.
15. Define therapeutic and chemical equivalence.
16. List out non renal routes of drug excretion.
17. Define mammillary and caternary model.
18. Define Biological half-life.

19. Define dosage regimen.
20. Enlist factors causing non-linearity.
21. Define loading and maintenance dosing.
22. Define mixed order kinetics.

RGUHS WorkShop on Curriculum Design for B Pharma VI Semester

Subject: BP605 Pharmaceutical Biotechnology (Theory)

Template for curriculum designing

14. Name of subject (as per Apex Council gazette): **Pharmaceutical Biotechnology**

15. Departmental objectives (what the learners will be able to perform after completing the subject):

Upon completion of the subject student shall be able to;

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

16. Annual objectives (for each year, if the subject is spread over different years) **Not applicable**

17. Content distribution as per the list of topics, time allotted for each topic, distribution for 'Must know', 'Desirable to know' and 'Nice to know' and the probable weightage.

The following table can also be a reference frame for continuous and formative assessment of learning. If the curriculum management is scheduled as per the tabulation, there can be clarity for both learners and teachers to take stock of the mastery achieved in each objective. This will also help for professional excellence that goes beyond the examination process.

Sl No	Topic	Hours	Learning content distribution			Weightage
			Must know (80%)	**Desirable to know (20%)**	**Nice to know (Extra)**	
1	Unit 1	10	b) Methods of enzyme immobilization and applications c) Biosensors-Working and applications of biosensors in Pharmaceutical Industries e) Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase. f) Basic principles of genetic engineering.	a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences d) Brief introduction to Protein Engineering.		19
2	Unit	2	a) Study of cloning vectors, restriction endonucleases and DNA ligase. b) Recombinant DNA technology. Application of genetic engineering in medicine. c) Application of r DNA technology and genetic engineering in the production of: i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin. d) Brief introduction to PCR		Transgenic animals and plants; edible vaccines	22

3	Unit	3	Types of immunity- humoral immunity, cellular immunity a) Structure of Immunoglobulins d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity. e) Storage conditions and stability of official vaccines f) Hybridoma technology- Production, Purification and Applications g) Blood Products-Collection, Processing and Storage of whole human blood, dried human plasma and Plasma Substitutes	b) Structure and Function of MHC c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.		21
4	Unit	4	a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting. c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons. d) Introduction to Microbial biotransformation and applications. e) Mutation: Types of mutation/mutants.	b) Genetic organization of Eukaryotes and Prokaryotes		16
5	Unit	5	a) Fermentation methods and general requirements, study of media, equipment's, sterilization methods, aeration process, stirring. b) Large scale production fermenter design and its various controls. c) Study of the production of - penicillin, citric acid, Vitamin B12, Glutamic acid, Griseofulvin, d) Topic repeated and placed in Unit 3 (Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes).			17

18. Blueprint of question paper, for each QP. This shows the weightage given to each chapter in the summative assessment. This improves the content validity by distributing the assessment of learners in the competencies that are represented by learning objectives under each chapter.

State the number of QPs for the subject.

The following template demonstrates how each QP Blueprint would look like:

Sl No	Chapter	Marks distribution					Total Marks
		Must Know	Desirable to Know	Long Essay	Short Essay	Short Answer	
1	Unit 1	-	-	1	1	2	19
2	Unit 2	-	-	1	2	1	22
3	Unit 3	-	-	-	3	3	21
4	Unit 4	-	-	-	2	3	16
5	Unit 5	-	-	1	1	1	17

* 80 % of the questions shall be from the Must Know area and 20 % shall be from the Desirable to Know area of the Curriculum.

19. Question paper layout to show which question number will represent which chapter (s)

Long Essay: **2X 10 = 20**

1	Explain the different methods of enzyme immobilization with advantages and disadvantages.
2	Describe the general method of recombinant DNA technology.
3	Describe the construction and working of a fermenter with a neat labelled diagram.

Short Essays: **7x 5 = 35**

4	Describe the production and uses of amylase.
5	Explain the production of insulin by rDNA technology.
6	Describe the technique of polymerase chain reaction (PCR).
7	Explain the production of vitamin B_{12} by fermentation technology.
8	Describe the production of monoclonal antibodies by hybridoma technology.
9	Outline the general method for the preparation of live attenuated bacterial vaccines.
10	Describe the structure of an immunoglobulin with a neat labelled diagram.
11	Describe ELISA with its applications.
12	Explain microbial biotransformation with examples.

Short Answers: **2X10 = 20**

13	List out any two pharmaceutical applications of biosensors.
14	Write any four pharmaceutical applications of biotechnology.
15	Enlist the different types of vectors.
16	Write the source and uses of griseofulvin.
17	What are toxoids? Give an example.
18	Write any two functions of MHC.
19	What are plasma substitutes?
20	What is western blotting?
21	What are mutagenic agents? Give two examples.
22	What do you mean by conjugation and transduction?

Scheme of Practical / Clinical Teaching and Assessment: **Not applicable**

List the expected practical / clinical competencies.
State the objectives for each competencies.
Assign content for the objectives.
Describe the teaching – learning processes.

Sl No	Skills	Duration	Learning methods

Scheme of examination with the distribution of marks as per the prioritisation of competencies.

Sl No	Competency	Assessment criteria	Marks

20. Suggested references (as per APA style):

- Basic references

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press, Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding:Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi
8. Sambamurthy K, Kar A; Pharmaceutical Biotechnology; New Age international Pvt Ltd. New Delhi,

- Advanced references (may also include journals / web / other electronic sources)

6th Semester B.Pharm

(BP606T) Pharmaceutical Quality Assurance (Theory)

Template for curriculum designing

21. Name of subject (as per Apex Council gazette): Pharmaceutical Quality Assurance.

22. Departmental objectives (what the learners will be able to perform after completing the subject):

1. To understand the cGMP aspects in a Pharmaceutical Industry.
2. To understand ISO 9000 and ISO 14000.
3. To understand the requirement of training and plant layout.
4. To understand the requirement of equipment and vendor qualification.
5. To appreciate importance of good Laboratory and documentation practices.
6. To study the importance of calibration and validation.
7. To understand the responsibilities of QA and QC departments
8. To understand the scope of quality certification in pharmaceutical industry
9. Annual objectives (for each year, if the subject is spread over different years)
10. Content distribution as per the list of topics, time allotted for each topic, distribution for ‘Must know’, ‘Desirable to know’ and ‘Nice to know’ and the probable weightage.

The following table can also be a reference frame for continuous and formative assessment of learning. If the curriculum management is scheduled as per the tabulation, there can be clarity for both learners and teachers to take stock of the mastery achieved in each objective. This will also help for professional excellence that goes beyond the examination process.

Sl No`	Topic	Hours	Learning content distribution			Weightage
			Must know	Desirable to know	Nice to know	
Unit I	QA TQM ICH Guidelines QBD ISO	10	Definition and concept of quality control, quality assurance and GMP TQM Definition, elements and philosophies ICH guidelines, Purpose Brief overview QSEM with special emphasis on Q-series guidelines ICH stability testing guidelines ISO 9000 and ISO 14000, overview, benefits, elements, steps for registration	ICH participants, Process of harmonisation, QBD Definition, overview, elements of QBD program NABL accreditation, principles and procedures	QBD tools	26 Marks (10*1+5*2+3*2)
UNIT-II	Organinization and personne Equipments and raw materials	10	Personnel responsibilities, training, Premises, design, construction and plant layout, maintenance sanitisation, environmental control, utilities and maintenance of sterile areas, control of contamination Equipment selection, purchase specification, maintenance, of stores for raw materials	Hygiene and personal records		26 Marks (10*1+5*2+3*2)
Unit-III	Quality control Good laboratory practices	10	Quality control tests for containers, Rubber closures and secondary packing General provisions, organisation and personnel, facilities, equipments, testing facilities, operations			21 Marks (5*3+3*2)
Unit –IV	Complaints Document maintenanc	8	Complaints and evaluation of complaints, Handling of return goods, recalling and waste disposal Batch formula record, Master formula record, SOP, Quality			14 Marks (5*1+3*3)

	e in pharmaceutical industry		audit, Quality review, and quality documentation, reports, documents, distribution record			
Unit-V	Calibration and Validation Warehousing	7	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, General principles of analytical method validation Good ware house practice and Material management			13 Marks (5*2+3*1)

11. Blueprint of question paper, for each QP. This shows the weightage given to each chapter in the summative assessment. This improves the content validity by distributing the assessment of learners in the competencies that are represented by learning objectives under each chapter.

State the number of QPs for the subject.

The following template demonstrates how each QP Blueprint would look like:

Sl No	Chapter	Marks distribution					Total Marks
		Must Know	Desirable to Know	Long Essay	Short Essay	Short Answer	
		77	23	20	50	30	100
Total		77	23	20	50	30	100

* 80 % of the questions shall be from the Must Know area and 20 % shall be from the Desirable to Know area of the Curriculum.

12. Question paper layout to show which question number will represent which chapter (s)

Long Essay: **2X 10 = 20**

1	List out ICH Q-series guidelines and explain any two in detail
2	Discuss the facility requirements for maintenance of sterile area

Short Essays: **5x 10 = 50**

3	Define QbD and write the elements of QbD program
4	Discuss the principles of TQM
5	How do you maintain raw material store in pharmaceutical Industry
6	Describe the significance of training and personnel hygiene in pharmaceutical industry
7	Discuss the objectives of GLP
8	Discuss in-detail the content of protocol for non-clinical laboratory study
9	Explain briefly the QC tests for containers
10	Discuss the handling of waste product disposal in manufacturing area
11	Discuss the principle of analytical method validation
12	Discuss the parameters for qualification of UV-visible spectroscope

Short Answers: **3X10 = 30**

13	Distinguish between QA and QC departments
14	Describe the principle of NABL accreditation
15	Distinguish between contamination and cross contamination
16	Explain the criteria for equipment selection
17	Describe secondary packing material
18	Explain criteria for disqualification of testing facility
19	Summarise the procedure for handling of return goods
20	Define SOP and give its scope
21	Describe batch formula record
22	Explain the calibration procedure for pH meter

13. Scheme of Practical / Clinical Teaching and Assessment:

List the expected practical / clinical competencies.

State the objectives for each competencies.

Assign content for the objectives.

Describe the teaching – learning processes.

Sl No	Skills	Duration	Learning methods

Scheme of examination with the distribution of marks as per the prioritisation of competencies.

Sl No	Competency	Assessment criteria	Marks

14. Suggested references (as per APA style):

- Basic references
- Advanced references (may also include journals / web / other electronic sources)