

VIII SEMESTER B PHARMACY

PHARMACOLOGICAL SCREENING METHODS

QUESTION BANK

BP810 ET. PHARMACOLOGICAL SCREENING METHODS

45 Hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objectives

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

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and research methodology
- Design and execute a research hypothesis independently

Unit –I	08 Hours
<p>Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.</p>	
Unit –II	10 Hours
<p>Preclinical screening models a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. b. Study of screening animal models for Diuretics, nootropics, anti-Parkinson's, antiasthmatics, Preclinical screening models: for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease</p>	

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<p>Unit –III</p> <p>Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics</p>	
<p>Unit –IV</p> <p>Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants</p> <p>Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.</p>	
<p>Research methodology and Bio-statistics</p> <p>Selection of research topic, review of literature, research hypothesis and study design</p> <p>Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data</p>	05Hours

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

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UNIT-I		Hours: 10	Weightage: 22 Marks
Learning content distribution	Topics		
	Introduction to Pharmacovigilance, Introduction to adverse drug reactions, Basic terminologies used in pharmacovigilance		
Must know	Pharmacovigilance Program of India(PvPI)		
	Definitions and classification of ADRs • Detection and reporting • Methods in Causality assessment • Severity and seriousness assessment, Management of adverse drug reactions		
Desirable to know	Importance of safety monitoring of Medicine ,WHO international drug monitoring programme		
	Predictability and preventability assessment		
	Terminologies of adverse medication related events		
Nice to know	History and development of Pharmacovigilance		
	Regulatory terminologies		

UNIT-II		Hours: 10	Weightage: 22 Marks
Learning content distribution	Topics		
	Drug and disease classification, Drug dictionaries and coding in pharmacovigilance, Information resources in pharmacovigilance, Establishing pharmacovigilance programme		
Mustknow	MedDRA and Standardised MedDRA queries		
	Basic drug information resources , Specialised resources for ADRs		
	Establishing in a hospital , Establishment & operation of drug		

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	safety department in industry , Contract Research Organisations (CROs) , Establishing a national programme
Desirable to know	International classification of diseases,Daily defined doses
	WHO adverse reaction terminologies,WHO drug dictionary
Nice to know	Anatomical, therapeutic and chemical classification of drugs,International Non proprietary Names for drugs
	Eudravigilance medicinal product dictionary

UNIT-III	Hours: 10	Weightage: 21 Marks
Learning content distribution	Topics	
	Vaccine safety surveillance,Pharmacovigilance methods,Communication in pharmacovigilance,	
Must know	Passive surveillance – Spontaneous reports and case series • Stimulated reporting • Active surveillance – Sentinel sites, drug event monitoring and registries • Comparative observational studies – Cross sectional study, case control study and cohort stud	
Desirable to know	Vaccine Pharmacovigilance,Adverse events following immunization	
	Effective communication in Pharmacovigilance • Communication in Drug Safety Crisis management • Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media	

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Nice to know	Vaccination failure
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UNIT-IV		Hours: 8	Weightage: 19 Marks
Learning content distribution	Topics		
	Safety data generation,ICH Guidelines for Pharmacovigilance		
Must Know	Pre clinical phase • Clinical phase • Post approval phase (PMS)		
	Expedited reporting,Individual case safety reports • Periodic safety update reports		
Desirable to know	Organization and objectives of ICH, Good clinical practice in pharmacovigilance studies		
Nice to know	Pharmacovigilance planning		

UNIT-V		Hours: 7	Weightage: 11 Marks
Learning content distribution	Topics		
	Pharmacogenomics of adverse drug reactions,Drug safety evaluation in special population,CIOMS,CDSCO (India) and Pharmacovigilance		
Must know	Drug safety evaluation in special population - Paediatrics, Pregnancy and lactation, Geriatrics		
	CDSCO (India) and Pharmacovigilance - D&C Act and Schedule Y		
Desirable to know	Pharmacogenomics of adverse drug reactions • Genetics related ADR with example focusing PK parameters		

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	CIOMS Working Groups, CIOMS Form
	Differences in Indian and global pharmacovigilance requirements
Nice to know	-----

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.

BLUE PRINT OF MODEL QUESTION PAPER

BP805T. PHARMACOVIGILANCE

TIME: 3 HOURS

MAX. MARKS: 75

Unit No	Hours	Must know			Desirable to know			Weightage of marks
		LE (10X3)	SE (5X6)	SA (2X3)	LE (10X0)	SE (5X3)	SA (2X7)	
Unit-I	10	1	1	-	-	1	1	22
Unit-II	10	1	1	-	-	1	1	22
Unit-III	10	1	1	1	-	-	2	21
Unit-IV	08	-	2	1	-	1	1	19

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LONG ESSAY

1. Enumerate methods to evaluate antidepressant activity of an agent. Discuss two in vivo methods.
2. Enlist methods to evaluate anti-diabetic activity of an agent. Discuss two in vivo method.
3. Enumerate methods to evaluate nootropics activity of an agent. Discuss one in vivo method.
4. Explain any two in-vivo screening methods for sympatholytic agents.
5. Enumerate methods to evaluate analgesic activity of an agent. Discuss two in vivo method
6. Describe two in-vivo methods to screen central analgesic activity
7. Describe any two methods to screen antiarrhythmic drugs.
8. Enumerate methods to evaluate anti-inflammatory activity of an agent. Discuss one in vivo method
9. List the various methods used in preclinical evaluation of sympathomimetic agents. Discuss two in-vivo methods.
10. Enumerate various methods to evaluate a compound for anti-diabetic activity. Explain two in-vitro methods and the chemically induced diabetes in rat.
11. List the various methods used in preclinical evaluation of anti-cancer agents. Discuss two in-vivo methods.
12. Enlist the methods to evaluate skeletal muscle relaxant activity. Discuss two in vivo method
13. List out the various screening methods for Antihypertensive drugs. Discuss one In-vitro & One In-vivo method.
14. Enlist methods to evaluate Parasympatholytics activity of an agent. Discuss two screening methods.
15. Explain any three in-vivo screening methods for anti-hypertensive agents.
16. Explain two in-vivo Preclinical Screening methods for Anti-pyretic drugs
17. Enlist various Preclinical Screening methods for Anti-inflammatory drugs. Explain two in-vivo methods.
18. Describe two various screening methods for Parasympathomimetics drugs.
19. Explain the any three Pre clinical Screening methods for Anti-cancer drugs
20. Describe three in-vivo screening methods for Sympathomimetic drugs.
21. Enlist methods to evaluate antihypertensive activity of an agent. Discuss two in vivo methods
22. Enumerate and explain various Preclinical Screening methods for Antipsychotic drugs.
23. Describe various screening methods for Sympathomimetic drugs. Explain on model in detail.
24. Enlist methods to evaluate anti-arrhythmic activity of an agent. Discuss two in vivo methods.
25. Explain any two in-vivo screening methods for skeletal muscle relaxants agents.

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26. Enlist various methods to evaluate a compound for anti-cancer activity. Explain two in vivo methods
27. Describe any three screening models for Parasympatholytics drugs.
28. List the methods to screen antipsychotic activity. Discuss two in-vivo methods.
29. List the commonly used methods to screen an agent for skeletal muscle relaxants agents. Discuss two in-vivo methods.
30. List out various methods to evaluate a compound for anti-inflammatory activity. Explain two in-vivo methods.

SHORT ESSAY

1. Explain different methods for collection of blood in laboratory animals.
2. Describe the use to transgenic animals in preclinical screening.
3. Explain on method for screening local anesthetics.
4. Describe the two different screening methods for Antidiabetic activity.
5. In brief describe research hypothesis. Explain any two screening methods for coagulants
6. Explain any two screening methods for analgesics.
7. Explain significance of statistical analysis of one way ANOVA.
8. Explain constitution of IAEC and mention their role.
9. Discuss any two preclinical screening methods for nootropics models
10. Describe various blood collection methods of laboratory animals.
11. Explain any two preclinical screening methods for Parasympatholytics activity.
12. Explain any two preclinical screening methods for Antiulcer activity.
13. Enlist the various screening methods for Anti-arrhythmic drugs. Explain any one model.
14. Enlist the various screening methods for Anti-diabetic drugs. Explain any one model.
15. Explain the Significance of Statistical analysis of Student t test.
16. Mention the objectives of CPCSEA. Write the composition and responsibilities of IAEC.
17. Enlist different screening methods for coagulants. Explain any one in vivo method.
18. Explain one screening method for anti-arrhythmic agents.
19. Explain one screening method for anti-inflammatory activity.
20. Explain one screening method for anti-depressant
21. Describe one screening model for anticoagulants.
22. Explain the use of mutant animals in preclinical screening.
23. Describe the techniques of anaesthesia in laboratory animals.
24. Explain one screening method for sympathomimetic.
25. Explain one method to screen anti-ulcer activity.
26. What is the difference between student t test and one way ANOVA?
27. What are the commonly used methods to screen an agent for skeletal muscle relaxation?
28. Describe the significance of laboratory animals in pharmacological screening methods.
29. Describe any two screening methods for anti-ulcer activity.
30. Describe one in-vivo screening model for anti-epileptic drug.
31. Describe one in-vivo screening model for local anaesthetics.
32. Explain the high fat diet model for screening of anti-atherosclerotic agents.
33. Describe one way ANOVA.
34. Briefly explain breeding methods of laboratory animals.

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35. Describe one screening method for anti-aggregatory activity.
36. Describe techniques of anaesthesia in laboratory animals.
37. Explain research hypothesis.
38. Discuss one screening method for anticoagulants
39. Explain one in vivo screening method for anti-hyperlipidemics.
40. In brief explain maintenance of laboratory animals as per CPCSEA guidelines?
41. What are the techniques used for anaesthesia in laboratory animals?
42. Explain any one screening method for anti-arrhythmic agents.
43. Explain one method to screen antipyretic activity.
44. Explain the applications of transgenic animals in pharmacology research.
45. Describe one in-vivo screening model for anti-asthmatics.
46. List various in-vivo methods to screen analgesic agents and discuss any one method
47. Explain the significance of statistical analysis of student T test.
48. What is Euthanasia? Describe different methods of Euthanasia.
49. Explain any one screening method for anti-cancer agents.
50. Explain significance of statistical analysis of student't' test
51. Explain any two preclinical screening methods for Antidepressant activity.
52. Describe any one preclinical screening method for diuretic activity.
53. Describe different routes of drug administration in lab animals.
54. Describe different routes of drug administration in laboratory animals
55. What are the functions of institutions animal ethics committee?
56. Explain one screening methods for anti-asthmatic activity.
57. Describe one in-vivo screening method for sympathomimetic activity.
58. Discuss one in-vivo method for Screening antiulcer activity. In brief explain ANOVA.
59. Explain techniques for collection of blood in laboratory animals.
60. What are screening methods for parasympathomimetics?
61. Explain significance of sham negative and positive control group.
62. Explain different screening methods for anti-coagulants. Explain any one in vivo method.
63. Write a brief note on Maintenance of Laboratory Animals.
64. Describe any two preclinical screening methods for anti-aggregatory drugs.
65. Describe the use of Transgenic animals in Preclinical screening methods
66. Explain any two preclinical screening methods for Anti-Parkinsonism activity.
67. Application of mice as laboratory animal.
68. Explain any one screening method for anti-dyslipidemic activity.
69. Explain one screening method for anti-asthmatic activity
70. Enlist and explain any two preclinical screening methods for antiepileptic activity.
71. Enumerate any two preclinical screening methods for local anaesthetics.
72. Explain any two preclinical screening methods for anti-hyperlipidemia activity.
73. Describe two screening methods for anti-asthmatic activity.
74. Explain any two preclinical screening methods for coagulant activity.
75. Describe student-t-test and its significance.
76. Write a brief note on Maintenance of Laboratory Animals.
77. Explain two preclinical screening methods for Alzheimer's disease.
78. Explain any one preclinical screening methods for Skeletal muscle relaxants.
79. Describe any two preclinical screening methods for analgesic activity.
80. Discuss one screening method on nootropics
81. Describe one in vivo preclinical method on local anaesthetics.
82. Explain one screening method for antipyretic activity.
83. Explain the different methods involved in breeding of laboratory animals
84. Discuss one screening method for anti-diabetic activity.
85. Explain rationale in selection of animal species and sex in experimental study.
86. Explain any one screening method anti-epileptic agents.

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87. Explain one screening method for coagulants.

SHORT ANSWERS

1. What is the significance of sham negative group?
2. What are the methods used for preparations of drugs suspension.
3. Enlist the methods for screening anti-ulcer activity.
4. Application of mutant animals.
5. What are the methods for screening of analgesic activity?
6. Mention the screening methods for anti-asthmatics.
7. List the screening methods for drugs acting on eye.
8. Application of transgenic animals.
9. What is one way ANOVA?
10. Mention screening methods for sedative agents.
11. What are the techniques for collection of blood samples in laboratory animals.
12. What are different techniques for euthanasia?
13. Different methods for screening analgesics
14. What are the rationales for selection of animal species?
15. Briefly explain the on the study designs involved in pre-clinical experiments.
16. Define research hypothesis.
17. Define hypothesis with example.
18. What are pharmacological uses of rat as laboratory animals?
19. List out different routes of drug administration in laboratory animals?
20. Mention the different species and strains of animals used in laboratory?
21. What method used for preparations of drugs suspension with examples.
22. Application of transgenic animals.
23. List out different methods for screening of anti-inflammatory activity.
24. Define Sedative and hypnotics.
25. Explain the preparation of drug solution regarding to various solvents used.
26. Enlist preclinical screening methods for anti-inflammatory activity.
27. Enlist preclinical screening methods for skeletal muscle relaxants.
28. Mention the screening methods for diuretics.
29. Mention the list of screening methods for anti-ulcer activity.
30. What different method used for screening anti-epileptic activity.
31. Write a short note on ANOVA.
32. Explain Graphical representation of data
33. Mention the screening methods for hypnotic activity.
34. Short note on review of literature.
35. List out different techniques for euthanasia?
36. List the screening methods for drugs acting on eye.
37. Enlist various techniques for collection of Blood Sample.
38. What is OECD? Briefly describe breeding techniques.
39. List out the screening models for analgesic activity.
40. Explain the preparation of drug solution in regard with various solvents used.
41. Explain the mechanism of chemical induced convulsions for screening of Anti-epileptic drugs.
42. Mention the screening methods for anti-ulcer drugs.
43. Mention the list of screening methods for sedatives and hypnotic activity.
44. Enlist methods to screen anti-hypertensive activity
45. Enlist the various screening methods for Anti-inflammatory drugs.

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46. Enlist the various screening methods for Ant-asthmatic activity.
47. Explain the Possible ways of Graphical representation of a data.
48. Enumerate the different screening methods for Parasympatholytics.
49. What are Parametric and nonparametric tests?
50. Mention the screening methods for drugs acting on eye.
51. Enlist different methods for screening of type-2 Anti-diabetic activity.
52. What is research hypotheses?
53. Enumerate different techniques for anaesthesia in laboratory animals.
54. Enlist models used to screen for hypnotic activity.
55. What are different routes of drug administration in laboratory animals?
56. Application of transgenic animals.
57. Mention different methods for screening anti- Alzheimer's activity?
58. What are the rationales for selection of animal species?
59. What is review of literatures?
60. Examples for mydriatics and miotics.
61. What is student t test?
62. What are the methods for review of literatures?
63. What are different techniques for euthanasia in laboratory animals?
64. Give full form of CPCSEA and OECD?
65. Enlist different methods for screening nootropics?
66. What are the rationales for selection of animal species?
67. Write the full form of IAEC and OECD.
68. What are pharmacological uses of guinea pig as laboratory animal?
69. What are the rationales for selection of animal species?
70. Mention the composition of IAEC.
71. Mention the different species and strains of animals used in laboratory?
72. What are different routes of drug administration in laboratory animals?
73. Mention the screening methods for hypnotics.
74. Rationale for selection of animal species in preclinical studies.
75. Uses of rabbit in experimental pharmacology.
76. What is the significance of sham negative group?
77. How do you screen the analgesic agents?
78. Mention screening methods for sedative agent
79. What are the objectives of OECD guidelines?
80. Enlist preclinical screening methods for diuretics
81. Explain the possible ways of Graphical representation of data
82. What are parametric and non-parametric tests?
83. Enlist preclinical screening methods for diuretics
84. Explain the possible ways of Graphical representation of data.
85. What are parametric and non-parametric tests?
86. Mention the screening methods for anti-diabetic drugs.
87. Mention the list of screening methods for hypnotic activity.
88. What different models used for screening glaucoma activity?
89. Significance of Student –t-test.
90. Explain study design.
91. What are pharmacological uses of mice as laboratory animal?
92. What are experimental uses of rabbit?
93. Name the different methods used for screening of Parasympatholytics?
94. What are different techniques for euthanasia in laboratory animals?

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95. What are the techniques for collection of blood samples?
96. Mention the screening methods for anti-asthmatics.
97. List out the methods to screen anti-epileptic agents?
98. Mention different species and strains of animals used in laboratory.