DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

Supplementary Examination – Winter 2023

Date : 02/01/2024

Course	**:**	**B. Pharmacy**	**Sem : VIII**		
Subject Name	**:**	**Biostatistics & Research Methodology**	**Subject Code**	**:**	**BP801T**
Max Marks	**:**	**75**	**Duration**	**:**	**3 Hr.**

Instructions:

1. **All questions are compulsory**
2. **Draw diagrams / figures wherever necessary**
3. **Figures to right indicate full marks**

Q. 1. Objective Type Questions (Answer all the questions) **(10 x 2) = 20**

i) Define Mean, Median and Mode.

ii) Give need of research

iii) Enumerate different graphs used for representing quantitative data

iv) Enlist methods of sample size calculation in research study

v) Give advantages and disadvantages of Pie chart.

vi) Define bias in clinical studies.

vii) Write formula for calculation of standard deviation and coefficient of correlation

viii) Differentiate between type -I & type -II errors.

ix) Enlist various online statistical software used in clinical trials

x) Define a) Biostatistics b) Frequency distribution

Q. 2. Long Answers (Answer 2 out of 3) **(2 x 10) = 20**

i) Discuss in detail Parametric tests.

ii) Explain in detail about how statistical analysis is conducted by using Excel, SPSS & MINITAB.

iii) Write a note on Response surface methodology.

Q. 3. Short Answers (Answer 7 out of 9) **(7 x 5) = 35**

i) Define hypothesis. Explain different types of hypothesis.

ii) Explain Plagiarism? Give method to avoid Plagiarism.

iii) Explain Multiple correlation with examples.

iv) Explain in detail about Normal distribution, Poisson's distribution.

v) Explain in short Mann - Whitney U test.

vi) What do you mean by cohort studies? Write some advantages and disadvantages of cohort studies.

vii) Describe design and analysis of experiments

viii) Explain significance of measures of dispersion with suitable examples.

ix) Write a short note on Factorial design.

------END OF THE PAPER------

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

Supplementary Examination – Winter 2023

Date: 04/01/2024

Course:	**B. Pharmacy**	**Sem: VIII**	
Subject Name:	Social and Preventive Pharmacy	**Subject Code:**	BP802T
Max Marks:	75	**Duration:**	3 Hr.

Instructions:

1. **All questions are compulsory**
2. **Draw diagrams / figures wherever necessary**
3. **Figures to right indicate full marks**

Q. 1. Objective Type Questions (Answer all the questions) **(10 x 2) = 20**

i) Name the causative agent of Malaria

ii) Who are ASHA workers?

iii) Write a short note on Drug addiction- drug substance abuse

iv) Give treatment for Narcotics and Hallucinogene.

v) Write a short note on Kwashiorkor disease

vi) Define acute respiratory infection. Name the vaccines used to immune the children from pneumonia

vii) How counseling helps in preventing drug abuse.

viii) State objectives of nutrition.

ix) What is the full form NACP? When did it launched in India

x) Write the Importance of health promotion in schools

Q. 2. Long Answers (Answer 2 out of 3) **(2 x 10) = 20**

i) Classify vitamins. Write the importance , daily requirements & sources of it

ii) What are the functions of PHC? Elaborate community services in rural with improvement in sanitation with health promotion activities in school

iii) Write a Short note on Dengue and Pneumonia.

Q. 3. Short Answers (Answer 7 out of 9) **(7 x 5) = 35**

i) Define public health. Explain the types & designs used to evaluate the public health

ii) Write a note on Tobacco control programme

iii) Explain national health intervention programme for mother and child

iv) Write a note on Ebola virus

v) Explain the objectives and functions of national leprosy programme

vi) What do you mean by safe period or calendar method?

vii) Briefly explain Diabetes Mellitus

viii) Write a note on food in relation to nutrition and health

ix) What are the community services in urban areas?

------END OF THE PAPER------

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE
Supplementary Semester Examination – Winter 2023

Date: 06/01/2024 Saturday | **Time: - 10.00 AM to 1.00PM**
Course: B. Pharmacy | **Sem: VIII**
Subject Name: Pharma Marketing Management | **Subject code: BP803ET**
Max Marks: 75 | **Duration: 3 Hr.**

Instructions:

1. **All questions are compulsory**
2. **Draw diagrams / figures wherever necessary**
3. **Figures to right indicate full marks**

Q. 1. Objective Type Questions **(Answer all the questions)** **(10x2)= 20**

i. Define public relation and OTC products.
ii. State the advantages of digital marketing.
iii. Define channel of distribution and enlist its types.
iv. What do you mean by pharmaceutical detailing? Write its importance.
v. List the different members in pharmaceutical distribution channels.
vi. Differentiate between marketing and selling.
vii. What is role of NPPA?
viii. What are the advantages of medical exhibition.
ix. List out four functions of Wholesaler.
x. Write the objective and scope of industrial Marketing

Q.2. Long answers **(Answers 2 out of 3)** **(2x10)= 20**

i. Define Pharmaceutical marketing and give an account of consumer buying behavior. Discuss the various marketing environments.
ii. Define professional sales representatives (PSR). Describe the duties and responsibilities of PSR. Explain in detail selection and training of sales representatives.
iii. Define pricing, explain its objectives and describe in detail different methods of pricing.

Q.3 Short answers **(Answers 7 out of 9)** **(7x5)=35**

i. Write an overview of DPCO (Drug Price Control Order).
ii. Discuss in detail the different stages involved in product life cycle.
iii. Give an overview of Personal selling and Advertisement.
iv. Why is physical distribution management important for sales productivity? Discuss the tasks in physical distribution management.
v. What is promotional mix? Discuss the various determinants of promotional mix.
vi. Add a note on conflicts in channel.
vii. Discuss in detail market segmentation.
viii. Write a note on vertical and horizontal marketing in detail.
ix. Give an overview of product line and product mix decision.

-----END OF THE PAPER------

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

Supplementary Winter Examination – 2023

Course: B. Pharmacy | **Semester : VIII**

Subject Name: Pharmaceutical Regulatory Science | **Subject Code: BP804ET**

Max. Marks: 75 | **Date: 06/01/2024** | **Duration: 3 Hr.**

Instructions to the Students:

1. **All questions are compulsory**
2. **Draw diagrams / figures wherever necessary**
3. **Figures to right indicate full marks**

Q.1.	**Objective Type Questions (Answer all the questions)**	**(10X2) =20**
i)	Define NDA and ANDA.	
ii)	Define IND and BLA.	
iii)	Which is the regulatory authority of Australia and Japan?	
iv)	Define DMF.	
v)	Distinguish between CTD and eCTD.	
vi)	Define IRB.	
vii)	Distinguish between orange book and purple book.	
viii)	Give the role of CDSCO in India.	
ix)	Define clinical trial protocol.	
x)	What is the role of ACTD in research?	
Q. 2.	**Long Questions (Answer 2 out of 3)**	**(2X10) =20**
i)	Elaborate in detail approval processes and timelines involved in NDA and ANDA.	
ii)	Explain in detail stages of drug discovery, and drug development process.	
iii)	Describe developing of clinical trial protocols, and Institutional Review Board.	
Q. 3.	**Short Questions (Answer 7 out of 9)**	**(7 X 5) = 35**
i)	Explain Concept of generics, and generic drug product development.	
ii)	Write an overview of regulatory authorities of India, and United States.	
iii)	Describe CTD and eCTD.	
iv)	Write a note on GCP obligations of Investigators, sponsors & Monitors.	
v)	Discuss Pharmacovigilance – safety monitoring in clinical trials.	
vi)	Write a note on Federal Register, and Code of Federal Regulatory.	
vii)	Explain organization structure and types of applications Japan, and Canada.	
viii)	Explain in detail IND.	
ix)	Write a note on procedure for export of pharmaceutical products, Technical documentation, and DMF.	

***** END OF THE PAPER *****

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Examination – Regular Winter 2023

Date: 06/01/2024

Course	**:**	**B. Pharmacy**	**Sem:**		**VIII**
Subject Name	**:**	**Pharmacovigilance**	**Subject Code**	**:**	**BP805ET**
Max Marks	**:**	**75**	**Duration**	**:**	**3 Hr.**

Instructions:

1. **All questions are compulsory**
2. **Draw diagrams / figures wherever necessary**
3. **Figures to right indicate full marks**

Q. 1. Objective Type Questions (Answer all the questions) **(10 x 2) =20**

i) Enlist any four reasons of vaccine failure.

ii) Define Data mining and mention its importance in pharmacovigilance.

iii) Role of CDSCO in pharmacovigilance.

iv) Write a short note on daily defined dose in pharmacovigilance.

v) Importance of Pharmacogenomics.

vi) Goals of CDSCO (India).

vii) Classify ADRs according to severity.

viii) Short note on CIOMS form

ix) Write a short note on individual case study reports (ICSR).

x) Write a note on Eudravigilance.

Q. 2. Long Answers (Answer 2 out of 3) **(2 x 10) = 20**

i) What is vaccine safety surveillance? Explain in detail different types of pharmacovigilance methods used for passive and active surveillance.

ii) What are the objectives of pharmacovigilance programme of India? .Explain in details various methods of monitoring, detecting and reporting of ADRs

iii) Discuss the different method of causality and severity assessment of ADR and explain the WHO scale.

Q. 3. Short Answers (Answer 7 out of 9) **(7 x 5) = 35**

i) Write a note on ICH.

ii) Discuss the role and responsibilities of CDSCO in Pharmacovigilance

iii) Scope of MedDRA and Clinical research organization.

iv) Describe Safety monitoring of medicine.

v) Explain drug safety evaluation guidelines in pregnancy and lactation.

vi) Discuss in details clinical trials for drug safety data generation.

vii) Drug safety evaluation in geriatric and pediatric populations.

viii) Discuss Naranjo's and WHO causality assessment scales.

ix) Explain Pre- marketing and Post marketing clinical trials.

——END OF THE PAPER——

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

Regular/Supplementary Winter Examination – 2023

Course: B. Pharmacy IV Semester: VIII

Subject Name: Quality Control and Standardization of Herbals

Subject Code: BP 806 ET

Max Marks: 75 **Date: 06.01.2024** **Duration: 3 Hr.**

Instructions to the Students:

1. All questions are compulsory

2. Draw diagrams / figures wherever necessary

3. Figures to right indicate full marks

Q.1.	**Objective Type Questions (Answer All the Questions)**	**(10X2) =20**
i)	Enlist various basic test methods for herbal raw materials.	
ii)	Define Quality in terms of Herbal Drugs.	
iii)	Briefly state the difference between cGMP and GMP.	
iv)	Write the test procedures for Alkaloidal Phytochemicals.	
v)	What do you mean by safety and efficacy of herbals?	
vi)	Write parameters tested in control of starting materials as per EU guidelines.	
vii)	Write the basic identification tests for Tannins	
viii)	Discuss briefly about Chemical markers.	
ix)	Enlist various Herbal Pharmacopoeias.	
x)	List down components of GMP Guidelines for Herbal Medicine.	
Q.2.	**Long Answers (Answer 2 out of 3)**	**(10X2) =20**
i)	Explain in detail WHO guidelines for quality control of herbal drugs.	
ii)	Explain GMP guidelines for Herbal Medicinal Products.	
iii)	Write a detail note on applications of various chromatographic techniques in standardization of herbal products.	
Q.3.	**Short Answers (Answer 7 out of 9)**	**(5 X 7) = 35**
i)	Describe GAP guidelines for Herbal Raw Material.	
ii)	Illustrate on evaluation of commercial crude drugs.	
iii)	Discuss on preparation of documents for new drug application and export registration.	
iv)	Explain GACP guidelines for Herbal Raw Materials.	
v)	Discuss stability studies for herbal medicines.	
vi)	Discuss the role of chemical and biological markers in standardization of herbal products.	
vii)	Discuss the Research guidelines for evaluating the safety and efficacy of Herbal Medicines.	

viii)	Elaborate the Regulatory requirements for herbal medicines.
ix)	Outline Good Laboratory Practices for Herbal Drug Industry.
	*** END OF THE PAPER ***

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DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE
End Semester Examination – Winter 2023

Course: B. Pharmacy
Subject Name: Cosmetic Science
Max Marks: 75

Date: 06/01/24
Sem: VIII
Subject Code: BP809ET
Duration: 3 Hr

Instructions:
1. **All questions are compulsory**
2. **Draw diagrams / figures wherever necessary**
3. **Figures to right indicate full marks**

Q. 1. Objective Type Questions (Answer all the questions) **(10 x 2) = 20**

1. Write the advantages and disadvantages of cold creams.
2. Define tensile strength of a hair.
3. Differentiate between cosmetic and cosmeceutical preparations.
4. What are Sunscreens? Give its examples.
5. Write any four applications of Turmeric as cosmetic.
6. Define the terms Anagen and Catagen.
7. Draw a well labelled diagram of typical structure of skin.
8. Define preservatives. Give any two examples of preservatives used in cosmetics.
9. What is Sebumeter? Give its importance.
10. Define antidandruff shampoos. Give any two examples of it.

Q. 2. Long Answers (Answer 2 out of 3) **(2 x 10) = 20**

1. Define herbal cosmetics. Discuss the role of Henna and Amla in hair care formulations.
2. Discuss in details about various cosmetic excipients
3. Describe the principle building blocks in the formulation of oral care formulations such as toothpaste for bleeding gums, Teeth whitening, Mouthwash .

Q. 3. Short Answers (Answer 7 out of 9) **(7 x 5) = 35**

1. What is quasi drug? Explain cosmetic as OTC drugs.
2. Describe BIS specifications for toothpaste.
3. Explain the chemistry and formulation of Para-phylene diamine based hair dye.
4. What are the important causes of body odour?
5. Elaborate the steps involved in the manufacturing of soaps.
6. Write a short note on corneometer?
7. Detailed out the methods of preparation for Vanishing cream.
8. Write a short note on face wash formulation.
4. write a note on cosmetic problems associated with Hair and scalp.

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

Supplementary Winter Examination: 2023-24

Course: B. Pharmacy **Semester: VIII**

Subject Name: Instrumental Methods of Analysis **Subject Code: BP811ET**

Max Marks: 75 **Date: 06/01/2024** **Duration: 10.00 am to 01.00 pm**

Instructions to the Students:

1. All questions are compulsory

2. Draw diagrams / figures wherever necessary

3. Figures to right indicate full marks

Q.1.	**Objective Type Questions (Answer All the Questions)**	**(10X2) =20**
i)	Write the difference between Accuracy and Precision?	
ii)	Which is used in calibration of IR instrument? Why?	
iii)	Enlist any 4 types of Immunoassays.	
iv)	Define extraction techniques? Enlist its types.	
v)	What is role of interface in hyphenated techniques of analysis?	
vi)	In which analytical technique photographic detectors are used? Why?	
vii)	In NMR spectrum of 1, 1, 2-Trichloroethane, the signal from $-CH_2$ appears as doublet. Why?	
viii)	Bragg's equation is associated with which analytical technique? Write the equation.	
ix)	When substance is bombarded with electrons of energy 9 to 15 eV, by the loss of one electron which ion is produced in Mass spectrometry?	
x)	Change in weight is measured in which thermal method of analysis? Why?	
Q.2.	**Long Answers (Answer 2 out of 3)**	**(10X2) =20**
i)	What is RIA? Discuss principle, working and limitations of RIA.	
ii)	Explain MALDI mass analyzer. Write any five fragmentation rules of Mass Spectrometry.	
iii)	Explain the term chemical shift and enlist the factors influencing it. Write brief note on spin- spin splitting in NMR.	
Q.3.	**Short Answers (Answer 7 out of 9)**	**(5 X 7) = 35**
i)	Describe the flow rate accuracy checking parameter in HPLC calibration.	
ii)	Explain procedure involved in solid phase extraction.	
iii)	Comment on principle of HPTLC-MS.	
iv)	Explain the principle of TGA.	
v)	Explain the rotating crystal method of XRD.	
vi)	What is calibration? Why it is important to calibrate equipments frequently.	
vii)	Write in short on LC-MS/MS.	
viii)	Explain instrumentation of GC-MS/MS.	
ix)	Write the difference between DTA and DSC.	

***** END OF THE PAPER *****

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DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Examination – Winter 2023

Date: 06 January 2024

Course:	**B. Pharmacy**	**Sem: VIII**	
Subject Name :	Pharmaceutical Product Development	**Subject Code: BP814ET**	
Max Marks :	**75**	**Duration :**	**3 Hr.**

Instructions:

1. **All questions are compulsory**
2. **Draw diagrams / figures wherever necessary**
3. **Figures to right indicate full marks**

Q. 1. Objective Type Questions (Answer all the questions) **(10 x 2) = 20**

i) Enlist various excipients used in the preparation of tablets.
ii) Write different coating materials in formulation development.
iii) Enlist quality control tests for plastic packaging material.
iv) What are the objectives of pharmaceutical product development.
v) List the quality control tests for capsule dosage form.
vi) Write the semisolid excipients employed in pharmaceutical product development.
vii) Which are the quality control tests for glass?
viii) Give the applications of factorial design.
ix) State the solvents used in the formulation development.
x) Give the applications of PEGs in formulation development.

Q. 2. Long Answers (Answer 2 out of 3) **(2 x 10) = 20**

i) Define optimization and classify different techniques of optimization. Describe factorial design along with its applications.
ii) Give detailed account of cyclodextrins and their applications in pharmaceutical product development.
iii) Define pharmaceutical product development and give its objectives. Discuss guidelines for stability assessment.

Q. 3. Short Answers (Answer 7 out of 9) **(7 x 5) = 35**

i) Enumerate various semisolid excipients.
ii) Give detailed account of sorbitol.
iii) Explain QbD and its applications in pharmaceutical product development.
iv) Explain glass as a packaging material.
v) Write a note on excipients in parenteral and aerosol products.
vi) Give in detail about non-ionic surfactants in the design of pharmaceutical product.
vii) Describe quality control testing of plastic products.
viii) Discuss various directly compressible vehicles.
ix) Write in brief about regulatory requirements for stability assessment of pharmaceutical product.

------END OF THE PAPER------