Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block Jayanagar, Bengaluru

Curriculum delivery design of B. Pharm. course of
Semester VIII w.e.f Academic year 2020-21

SEMESTER- VIII
BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY

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

A. Learning Objectives:

Upon completion of this course the student should be able to

a. To understand the applied statistical principles in drug development and clinical pharmacy.
b. Understand the applications of descriptive statistics, statistical graphics, statistical thinking and decision making with the aid of, probability theory, sampling size, parametric and non-parametric tests, correlations and regressions.
c. Equip with the application of Design of Experiments and its application in drug development.
d. Discern and understand the requirements of Clinical testing of drugs, and testing of hypothesis
e. To gain operational experience in data analysis software - JMP®, MINITAB®, EXCEL® and R- Project.

1. 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.

UNIT-I	Hours: 10	Weightage: 22 Marks
Learning content distribution	**Topics**	
	Introduction to statistical applications in Pharmacy, Measures of Central Tendency and Dispersion, Correlation	
Must know	Statistical topics most relevant to those in the pharmaceutical industry and pharmacy practice, fundamentals required to understand descriptive and inferential statistics for problem solving in drug development and clinical testing.	
	Descriptive statistics for the observed results of a continuous variable 1) the center of that distribution (mode, median, and mean) and 2) how the observations are dispersed within the distribution (range, variance, and standard deviation).	
	Correlation of two or more variables compared to determine if there is a relationship and to measure the strength of that relationship.	
Desirable to know	Centres of a Continuous Distribution, Population versus Sample Measures of Central Tendency, Measurements Related to the Sample Standard Deviation	
	Comparison between two or more variables to determine if there is a relationship and to measure the strength of that relationship to describe the degree to which two or more variables show interrelationships within a given population. Positive or negative correlation, correlation coefficient (*r*), Pearson r. Degrees of freedom, Relative Standard Deviation, Standard Error of Mean.	
Nice to know	Sample mode, modal value, bimodal distribution, percentile, sample range, Degrees of freedom, Probability Distribution, inter quartile range, skewness, kurtosis.	
	Bivariate scatter, unit of association, inverse correlation, quadrants, Covariance, product-moment correlation coefficient	

UNIT-II	Hours: 10	Weightage: 22 Marks
Learning content distribution	**Topics**	
	Regression, Probability theory in statistics, Sampling, Parametric testing methods	
Mustknow	Regression - how one or more independent (predictor) variables influence outcomes for one continuous dependent (response) variable, ANOVA table for linear regression, Application of regression in stability testing of pharmaceutical products	
	Probability - Scope of probability in statistical inference, Conditional Probability, Probability Distribution,	
	Sampling - Samples from a population and represent the best estimate of the true parameters of that population, Confidence Intervals and Tolerance Limits	

	Parametric Testing - parametric procedures t-tests, analysis of variance (ANOVAs or F-tests)
Desirable to know	Regression: Coefficient of Determination, ANOVA Table, Confidence Intervals and Hypothesis Testing for the Population Slope (β), Confidence Intervals and Hypothesis Testing for the Population Intercept (α)Factorials, Permutations, Combinations
	Sampling: Random Sampling, Sample size estimation, Power, Probability Sampling Procedures, probability sample, Selective sampling, Systematic sampling, stratified sampling, cluster sampling
	Parametric Testing: t-Distribution, *Student t-test*, One-Tailed versus Two-Tailed Tests, One-Sample t-Tests, Two-Sample t-Tests; how the F-test or one-way analysis of variance provides an extension to *k* levels of the independent variable, Hypothesis Testing with the *One-Way ANOVA*, F-Distribution, *One-way Analysis of Variances (ANOVA)*
Nice to know	Probability: linear function, abscissa, ordinate, regression coefficient (β), coefficient of determination, residuals, residual sum of squares, Probability MatrixBinomial Distribution, Poisson Distribution.
	Sampling: Sample size estimation using Excel®
	Parametric Testing: homogeneity of variance, homoscedasticity, Type I error (α), Type II error (β), *post-hoc* tests for parametric testing

UNIT-III	**Hours: 10**	**Weightage: 19 Marks**
Learning content distribution	**Topics**	
	Non-parametric test methods, statistical graphing, ntroduction to research, Protocol writing & report compilation	
Must know	Non-parametric test methods – *Z test*comparisonsmade between proportions or percentages for one or two levels of a discrete independent variable; *Chi square tests* are used when only discrete variables are involved. *Measures of association* require that at least one of the variables is presented in a nominal or ordinal scale and can be applied only to data from a contingency table reporting frequencies (or counts).	
	Statistical graphing - graphic representation of data beneficial for describing and/or explaining research data Visualizing data useful when reviewing preliminary data, for interpreting the results of inferential statistics, and for detecting possible extreme or erroneous data (outliers). Variety of graphic displays in use.	
	Protocol writing & report compilation –Importance of protocol, writing the statistical analysis plan of a protocol, compiling the salient findings of a study, report writing and data presentation,	

	observational and experimental study designs and clinical trial phases
Desirable to know	*z*-Test of Proportions – One-Sample, *z*-Test of Proportions – Two-Sample, Power and Sample Size for *z*-Test of Proportions, Chi Square Goodness-of-Fit, Chi Square for One Discrete Dependent Variable, Chi Square Goodness-of-Fit Test for Distributions; *Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test*
	Tabulation of Data, Visual Displays for Discrete Variables (histograms, bar, block, line charts, Pictograms, Pie charts); Visual Displays for Continuous Variables (stem & leaf plot, box-and-whisker plot)
	Hypothesis testing is the process of inferring from a sample whether to reject acertain statement about a population or populations. Hypotheses are establishedand two errors can occur, rejection of a true hypothesis or failing to reject a false hypothesis.
Nice to know	Application of non-parametric tests in clinical pharmacy, and survey studies
	Interpretation of a hypothesis result by parametric or non-parametric methods (one each)

UNIT-IV	**Hours: 8**	**Weightage: 16 Marks**
Learning content distribution	**Topics**	
	Hands-on use of data analysis software, factorial designs, regression models	
Must Know	Data analytics software used in statistical analysis – SAS JMP®, Microsoft Excel®, Minitab® - features and data output	
	Application of factorial design in pharmaceutical Product development	
	Application of regression models in stability testing and shelf -life estimation of pharmaceutical products	
Desirable to know	Hands-on use of SAS JMP®, Microsoft Excel®, Minitab® for descriptive and inferential statistical applications	
	ICH stability testing Q1E – interpretation of stability test data for shelf-life determination and pharmacokinetic applications of regression.	
Nice to know	Case study for use of JMP® and Excel® for inferential statistics	
	Case study for factorial and fractional factorial design for pharmaceutical formulation development	
	Application of JMP® and Minitab® for shelf-life estimation and JMP® for estimating non compartmental pharmacokineticsparameters using curve fitting function	

UNIT-V	Hours: 7	Weightage: 16 Marks
Learning content distribution	**Topics**	
	Design of Experiments (DoE)	
Must know	Application of DoE in pharmaceutical development and QbD	
Desirable to know	Types of DoE applied in formulation development, factorial designs - used for factor screening and response optimization, 2^2 2^3design. Advantage of factorial design Response Surface methodology, Central composite design. QbD and factorial design in screening the effects and optimization of pharmaceutical formulations	
Nice to know	DoE Case study for effects screening & responses optimalization using JMP®, Minitab® or DesignXpert®.	

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

BP801T. BIOSTATISITCS ANDRESEARCHMETHODOLOGY

TIME: 3 HOURS MAX. MARKS: 75

Unit No	Hours	Must know			Desirable to know			Weightage of marks
		LE (10X3)	SE (5X8)	SA (2X5)	LE (10X0)	SE (5X1)	SA (2X5)	
Unit-I	10	1	2	1	_		2	22
Unit-II	10	1	2	2	_	1	1	22
Unit-III	10	1	2		_		1	19
Unit-IV	08	-	1	1	_		1	16
Unit-V	07	-	1	1	_	-		16
Total	**45**	**30**	**40**	**10**	**-**	**5**	**10**	**95**
		80			**15**			**95**

Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block Jayanagar, Bengaluru

Curriculum delivery design of B. Pharm. course of Semester VIII System
w.e.f Academic year 2020-21

SEMESTER-VIII

BP802T SOCIAL AND PREVENTIVE PHARMACY

Scope:
The purpose of this course is to introduce to students a number of health issues and their challenges. This course also gives the knowledge of number of national health programmes and the roles of the pharmacist in these contexts are also discussed

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

- **a.** Acquire high consciousness/realization of current issues related to health and Pharmaceutical problems within the country and worldwide.
- **b.** Have a critical way of thinking based on current healthcare development
- **c.** Evaluate alternative ways of solving problems related to health and
- **d.** Pharmaceutical issues

2. 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 of marks.

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.

UNIT-I	**Hours: 10**	**Weightage: 24 Marks**
Learning content distribution	**Topics**	
	Concept of health and disease, Social and health education, Sociology and health, Hygiene and health	
Must to know	Definition and concept of health and Disease, Evaluation of public health, concept of prevention of disease, concept of control of disease, food in relation to nutrition and health, balanced diet, nutritional deficiencies, Vitamin deficiencies, malnutrition and its prevention,	
Desirable to know	Social causes of disease, and social problems of sick, socio cultural factors related to health and diseases, impact of urbanization on health and disease, poverty and health, Personal hygiene and health care, avoidable habits.	
Nice to know	Responsibility for health.	

UNIT-II	Hours: 10	Weightage: 24 Marks
Learning content distribution	**Topics**	
	Preventive medicine	
Must to know	General principles of prevention and control of diseases such as cholera, acute respiratory infections, malaria, chicken guinea, dengue, pneumonia, hypertension, diabetes mellitus, cancer	
Desirable to know	General principles of prevention and control of diseases such as SARS, Ebola virus, influenza, lymphatic filariasis, drug addiction-drug substance abuse.	
Nice to know	Principles of preventive medicine for Paediatrics and Geriatrics.	

UNIT-III	Hours: 10	Weightage: 19 Marks
Learning content distribution	**Topics**	
	National health programs, its objectives, functioning and outcome of the following.	
Must to know	HIV and AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, Universal immunization programme,.	
Desirable to know	Pulse polio programme, National mental health program, National programme for prevention and control of deafness	
Nice to know	Introduction to national health programmes in India.	

UNIT-IV	Hours: 8	Weightage: 14 Marks
Learning content distribution	**Topics**	
	National health programmes and role of WHO	
Must to know	National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, role of WHO in Indian national program	
Desirable to know	National programme for the health care for the elderly, Social health programme.	
Nice to know	Reproductive and child health programme.	

UNIT-V	Hours: 7	Weightage: 14 Marks
Learning content distribution	**Topics**	
	Community services,	
Must to know	Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national	

	urban health mission.
Desirable to know	Health promotion and education in school.
Nice to know	Administrative pattern of Community services in the country.

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

BP 802T SOCIAL AND PREVENTIVE PHARMACY

TIME: 3 HOURS MAX. MARKS: 75

Unit No	**Hours**	**Must know**			**Desirable to know**			**Weightage of marks**
		LE (10X3)	**SE (5X8)**	**SA (2X5)**	**LE (10X0)**	**SE (5X1)**	**SA (2X5)**	
Unit-I	10	1	2	1	_	-	1	24
Unit-II	10	1	1	1	_	1	1	24
Unit-III	10	1	1	1	_	-	1	19
Unit-IV	08	-	2	1	_	-	1	14
Unit-V	07	-	2	1	_	-	1	14
Total	**45**	**30**	**40**	**10**	**-**	**05**	**10**	**95**
		80			**15**			**95**

BP803ET. PHARMAMARKETINGMANAGEMENT (Theory)

Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block Jayanagar, Bengaluru

Curriculum delivery design of B. Pharm course of
Semester VIII w.e.f Academic year 2020-21

SEMESTER-VIII

BP803ET. Pharma Marketing Management (Theory)

Scope:

- The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry.
- The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Course Objective:

- The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.
- Explains the marketing concepts and techniques, their applications in pharmaceutical industry and various aspects of pharmaceutical market.
- Various techniques for product branding, Discuss techniques for product promotion. To know about pharmaceutical marketing channels and role of professional sales representative. Enumerate pharmaceutical marketing channels and role of professional sales representative
- 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.

Semester VIII- BP803ET. Pharma Marketing Management (Theory) Blue Print

Sl No`	Topic	Hours	Learning content distribution			Weightage
			Must know	Desirable to know	Nice to know	
UNIT-I	Marketing, Pharmaceutical market	10	Definition, general concepts and scope of marketing; Distinction between marketing & selling; Analyzing consumer buying behavior; industrial buying behavior. Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Analyzing the Market; Role of market research.	Marketing environment; Industry and competitive analysis. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist	Pharmaceutical Market overview with respect to industry and consumer	22
UNIT-II	Product decision	10	Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions.	Product management in pharmaceutical industry	Product differentiation	19
UNIT-III	Promotion	07	Methods, determinants of promotional mix, promotional budget; An overview	Online promotional techniques for OTC	Online promotional techniques for	17

			of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations	Products	cosmetics	
UNIT-IV	Pharmaceutical marketing channels, Professional sales representative (PSR)	10	Physical distribution management: Strategic importance, tasks in physical distribution management. Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.	Designing channel, channel members, selecting the appropriate channel, conflict in channels.	C&F agents, distributors and retailers	21
UNIT-V	Pricing, Emerging concepts in marketing:	08	Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority)	Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.	Latest knowledge about DPCO and NPPA, Digital marketing	16

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

BP803ET. Pharma Marketing Management

TIME: 3 HOURS MAX. MARKS: 75

Unit No	Hours	Must know			Desirable to know			Weightage of marks
		LE (10X3)	SE (5X8)	SA (2X5)	LE (10X0)	SE (5X1)	SA (2X5)	
Unit-I	10	1	2	1	-	-	0	22
Unit-II	10	1	1	1	-	-	1	19
Unit-III	08		2	1	-	1	0	17
Unit-IV	10	1	1	1	-	-	2	21
Unit-V	07		2	1	-	-	2	16
Total	**45**	**30**	**40**	**10**	**-**	**5**	**10**	**95**
		80			**15**			**95**

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal andMichael Levy:Marketing, Tata MC Graw Hill
4. Arun Kumar and NMenakshi:MarketingManagement, Vikas Publishing, India
5. Rajan Saxena:MarketingManagement; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective,

   IndianContext,Macmilan India, New Delhi.
7. Shanker, Ravi: ServiceMarketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

xxxxx

Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block Jayanagar, Bengaluru

Curriculum delivery design of B. Pharm. course of Semester VIII System
w.e.f Academic year 2020-21

SEMESTER-VIII

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE

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

   A. Learning Objectives:

   Upon completion of this course the student should be able to

   a. Explain the process of drug discovery and approval.
   b. Know different regulatory bodies and their function
   c. Regulatory approval process for registration in regulated market
   d. Clinical trial process and Pharmacovigilance

3. 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.

UNIT-I	**Hours: 10**	**Weightage: 17 Marks**
Learning content distribution	**Topics**	
	New Drug Discovery and Development	
Must to know	Stage of drug discovery and drug development.	
Desirable to know	Pre-clinical, non-clinical and clinical studies	
Nice to know	Innovator and concept of generics, generic drug product development	

UNIT-II	Hours: 10	Weightage: 26 Marks
Learning content distribution	**Topics**	
	Regulatory Approval Process	
Must to know	Approval process involved in IND, NDA and ANDA. Overview of regulatory authorities – Organization structures, hierarchy and functions of India and US	
Desirable to know	Changes to NDA/ANDA Overview of regulatory authorities – Organization structures, hierarchy and functions EU and Australia	
Nice to know	Timelines involved in IND/ NDA/ANDA Overview of regulatory authorities – Organization structures, hierarchy and functions Japan and Canada Types of applications	

UNIT-III	Hours: 10	Weightage: 24 Marks
Learning content distribution	**Topics**	
	Registration of Indian drug products in overseas market	
Must to know	Overview and different modules of DMF, CTD and eCTD. Open and closed parts of DMF.	
Desirable to know	Overview and different modules of ACTD.	
Nice to know	Procedure for the export of pharmaceutical products	

UNIT-IV	Hours: 08	Weightage: 16 Marks
Learning content distribution	**Topics**	
	Clinical Trials	
Must to know	Institution review board/ Independent ethics committee- Formation and working procedures, informed consent process.	
Desirable to know	Pharmacovigilance – safety monitoring in clinical trials	
Nice to know	GCP -obligations of investigators, sponsors, monitors, managing and monitoring clinical trials	

UNIT-V	Hours: 07	Weightage: 12 Marks
Learning content distribution	**Topics**	
	Regulatory concepts	
Must to know	Orange book and Purple book	
Desirable to know	Code of Federal Regulation – Part 21 CFR	
Nice to know	Basic terminology of regulatory concepts, guidance and guidelines. Laws and acts.	

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

BP804FT: Pharmaceutical Regulatory Sciences

TIME: 3 HOURS MAX. MARKS: 75

Unit No	Hours	Must know			Desirable to know			Weightage of marks
		LE (10X3)	SE (5X4)	SA (2X5)	LE (10X0)	SE (5X5)	SA (2X5)	
Unit-I	10	1	-	-	_	1	1	17
Unit-II	10	1	1	2	_	1	1	26
Unit-III	10	1	1	1	-	1	1	24
Unit-IV	08	-	1	2	-	1	1	16
Unit-V	07	-	1	-	-	1	1	12
Total	**45**	**30**	**20**	**10**	**-**	**25**	**10**	**95**
		60			**35**			**95**

Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block Jayanagar, Bengaluru

Curriculum delivery design of B. Pharm course of
Semester VIII w.e.f Academic year 2017-18

SEMESTER- VIII

BP805T. PHARMACOVIGILANCE (Theory)

Scope: This paper will provide an opportunity for the student to learn about development of Pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Learning Objectives: At completion of this paper it is expected that students will be able to (know, do, and appreciate):

1. Why drug safety monitoring is important?
2. History and development of Pharmacovigilance
3. National and international scenario of Pharmacovigilance
4. Dictionaries, coding and terminologies used in Pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in Pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
11. ICH guidelines for ICSR, PSUR, expedited reporting, Pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

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.

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 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	
Nice to know	Vaccination failure	

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	
	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
Unit-V	07	-	1	1	_	-	2	11
Total	**45**	**30**	**30**	**6**	**-**	**15**	**14**	**95**
		66			**29**			**95**

Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block Jayanagar, Bengaluru

Curriculum delivery design of B. Pharm course of
Semester VIII w.e.f Academic year 2020-21

SEMESTER-VIII

BP806ET: QUALITYCONTROLANDSTANDARDIZATIONOF ERBALS

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

   A. **Learning Objectives:**

   Upon completion of this course the student should be able to

   a. Know WHO guidelines for quality control of herbal drugs
   b. Know Quality assurance in herbal drug industry
   c. Know the regulatory approval process and their registration in Indian and international markets
   d. Appreciate EU and ICH guidelines for quality control of herbal drugs

5. 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.

UNIT-I	**Hours: 10**	**Weightage: 24 Marks**
Learning content distribution	**Topics**	
	Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use	
Must to know	Objectives of WHO guidelines for quality control of herbal drugs. Botanical, Physicochemical, Pharmacological and toxicological evaluation. Advanced analytical evaluation.	
Desirable to know	Evaluation of commercial crude drugs intended for use. Basic tests for drugs–Pharmaceutical substances, Medicinal plants materials. WHO Guidelines for safety and toxicity of herbal drugs	
Nice to know	Definition, Need and significance of evaluation. Basic tests for dosage forms	

UNIT-II	Hours: 10	Weightage: 19 Marks
Learning content distribution	**Topics**	
	Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine. WHO guidelines on GACP for medicinal plants.	
Must to know	Objectives of quality assurance in herbal Industry, WHO Guidelines on current good manufacturing practices (cGMP) for herbal medicines.	
Desirable to know	WHO guidelines on GACP for medicinal plants. GLP requirement in traditional system of medicine	
Nice to know	Factors relating to quality of herbal drugs, quality standards of herbal products	
UNIT-III	**Hours: 10**	**Weightage: 14 Marks**
Learning content distribution	**Topics**	
	EU and ICH guidelines for quality control of herbal drugs. Research guidelines for evaluating the safety and efficacy of herbal medicines	
Must to know	Importance of European medicine Agency-Guideline on quality of herbal medicinal products /traditional herbal medicinal products. Role of the Committee on Herbal Medicinal Products (HMPC) of European Medicines Agency's (EMA) committee for compiling and assessing scientific data on herbal substances, preparations and combinations, to support the harmonisation of the European market. ICHguidelinesforqualitycontrolofherbaldrugs.	
Desirable to know	Research guidelines for evaluating the safety and efficacy of herbal medicines.	
Nice to know	EU Standards and EU Monographs for herbal drugs	
UNIT-IV	**Hours: 8**	**Weightage: 24 Marks**
Learning content distribution	**Topics**	
	Stability testing of herbal medicines, application of various chromatographic techniques in standardization of herbal products. GMP requirements and Drugs & Cosmetics Act provisions for herbal and traditional drugs.	
Must to know	Types of stability, different stability testing methods and conditions, protocol for stability testing. Applicationsof TLC, HPLC & HPTLC techniques in standardiztion of herbal products.	
Desirable to know	Predictable changes in herbal medicinal products during storage. Challenges in stability testing of herbal drugs. GMP requirements of herbal drugs and provisions of herbal drug in Drugs and Cosmetic Act.	
Nice to know	Difficulties in conducting shelf-life studies in herbal medicinal products and formulations, stability testing conditions as per ICH and WHO guidelines. Preparation of documents for new drug application and export registration	

UNIT-V	Hours: 7	Weightage: 14 Marks
Learning content distribution	**Topics**	
	Regulatory requirements for herbal medicines & WHO guidelines on safety monitoring of herbal medicines in Pharmacovigilance. Comparison of various herbal pharmacopoeias. Role of chemical and biological markers in standardization of herbal products	
Must to know	Importance of Pharmacovigilance. Regulatory requirements for herbal medicines & WHO guidelines on safety monitoring of herbal medicines in Pharmacovigilance.	
Desirable to know	Definition, types and role of chemical and biological markers in standardization of herbal products	
Nice to know	Challenges in monitoring the safety of herbal medicines. Comparison of Monographs of herbal drugs as per Indian Pharmacopeia, Ayurvedic Pharmacopeia & British herbal Pharmacopeia	

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

BP806ET: QUALITY CONTROL AND STANDARDIZATION OF HERBALS

TIME: 3 HOURS MAX. MARKS: 75

Unit No	Hours	Must know			Desirable to know			Weightage of marks
		LE (10X3)	SE (5X8)	SA (2X5)	LE (10X0)	SE (5X1)	SA (2X5)	
Unit-I	10	01	01	01	-	01	01	24
Unit-II	10	01	01	01	-	-	01	19
Unit-III	10	-	02	01	-	-	01	14
Unit-IV	08	01	02	01	-	-	01	24
Unit-V	07	-	02	01	-	-	01	14
Total	**45**	**30**	**40**	**10**	**-**	**05**	**10**	**95**
		80			**15**			**95**

Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block,Jayanagar, Bengaluru

Curriculum delivery design of B. Pharm. course of Semester VII&VIII System
w.e.f Academic year 2020-21

SEMESTER-VIII

BP807ET: COMPUTER AIDED DRUG DESIGN (Theory)

6. Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.
7. Objectives:

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

A. Learning Objectives:

Upon completion of this course the student should be able to

- Understand the fundamental concepts, advances and modern applications of drug design and discovery
- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking and advance aspects like 3D-QSAR
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modelling software.

Course Outcomes:

- To recall the approaches in drug discovery, drug development and lead discovery based on metabolism and clinical observation and also analog based drug design.
- To explain the development, approaches of QSAR, importance and determination of physicochemical parameters.
- To make use of molecular modelling and virtual screening techniques.
- To apply the molecular docking techniques to examine the binding interactions of ligand with molecular targets.
- To explain the applications of bioinformatics, chemo informatics, ADME databases, chemical, biochemical and pharmaceutical databases relevant to drug design.
- To discuss the conformational analysis of molecules using molecular and quantum mechanics approach and also to determine the global conformational minima.

8. 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.

UNIT-I	**Hours: 10**	**Weightage: 19 Marks**
	Topics	
Learning content distribution	**Introduction to Drug Discovery and Development** Stages of drug discovery and development **Lead discovery and Analog Based Drug Design** Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation. **Analog Based Drug Design**: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies	
Must to know	**Introduction to Drug Discovery and Development** Introduction to drug discovery, phases of drug development, Definition of lead, The examples of drug discovery without a lead, Stages of drug discovery **Lead discovery and Analog Based Drug Design** Types of Lead discovery, Rational approaches to lead discovery based on traditional medicine with examples and structures, Lead discovery by random screening, Lead discovery by Non-random screening, serendipitous discovered drugs with examples and structures, lead discovery based on drug metabolism with examples and structures, lead discovery based on clinical observation with examples and structures. **Analog Based Drug Design** Definition and objectives of analog design, Categories of Analogs, Definition of Bioisosterism, Classification of Bioisosterism, Bioisosteric replacement strategies, Three case studies for the discovery of new analogs using bioisosteric replacement strategy.	
Desirable to know	Lead optimization and methods	
Nice to know	Structure based drug design approaches	

UNIT-II	Hours: 10	Weightage: 21 Marks
Learning content distribution	**Topics**	
	Quantitative Structure Activity Relationship (QSAR) SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches likeCOMFA and COMSIA	
Must to know	Basic concepts of QSAR, Recall history and development of QSAR, Types of Physicochemical parameters with emphasis on their effect on drug action, Determination of Partition coefficient, Electronic parameters, Steric parameters, Hansch analysis, Free Wilson analysis,	
Desirable to know	Types of 3D-QSAR studies like COMFA and COMSIA	
Nice to know	Type of QSAR, GQSAR, 2D-QSAR concepts, Software based QSAR calculations and interpretations	

UNIT-III	Hours: 10	Weightage: 22 Marks
Learning content distribution	**Topics**	
	Molecular Modeling and virtual screening techniques **Virtual Screening techniques:** Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening. **Molecular docking:** Rigid docking, flexible docking, manual docking, Docking based screening. De novo drug design.	
Must to know	**Virtual Screening techniques** Introduction to virtual screening, Recent developed techniques used in VS,Definition and Concept of Pharmacophore, pharmacophore mapping and its applications. Introduction to pharmacophore-based virtual screening, steps involved and applications. **Molecular docking** Definition of Molecular modelling, Types of docking like rigid docking, flexible docking, manual docking, Docking based screening. Approaches of docking, requirements for Molecular modelling, Applications of Molecular modelling, Introduction to *De novo* drug design, Approaches for *De novo* drug design.	
Desirable to know	Principles in drug likeliness prediction	
Nice to know	Steps involved in molecular docking studies, Interpretation of docking results.	

UNIT-IV	Hours: 8	Weightage: 16 Marks
Learning content distribution	**Topics**	
	Informatics & Methods in drug design Introduction to Bioinformatics, Chemoinformatics. ADMEdatabases, Chemical, biochemical and pharmaceutical databases.	
Must to know	Definition and applications of Bioinformatics, Definition of Chemoinformatics and its steps involved in chemical data curation, ADME databases, and How the ADME databases are obtained?	
Desirable to know	Introduction and applications of chemical, biochemical and pharmaceutical databases.	
Nice to know	Study of ADMET properties of drugs using software.	

UNIT-V	Hours: 7	Weightage: 17 Marks
Learning content distribution	**Topics**	
	Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis,global conformational minima determination.	
Must to know	Theory of Molecular and Quantam mechanics in drug design. Various parameters of molecular mechanics, Conformational Analysis,process of global conformational minima determination,	
Desirable to know	Different methods in determination of energy minimization.	
Nice to know	Introduction and importance of Molecular dynamic studies	

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

BP 807 ET. COMPUTER AIDED DRUG DESIGN

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

Unit No	Hours	Must know			Desirable to know			Weightage of marks
		LE (10X3)	SE (5X8)	SA (2X5)	LE (10X0)	SE (5X1)	SA (2X5)	
Unit-I	10	1	1	1	_		1	19
Unit-II	10	1	1	2	_		1	21
Unit-III	10	1	2		_		1	22
Unit-IV	08		2	1	_		2	16
Unit-V	07		2	1	_	1		17
Total	**45**	**30**	**40**	**10**	**-**	**5**	**10**	**95**
		80			**15**			**95**

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

   A. Learning Objectives:

   Upon completion of this course the student should be able to

   e. Summarize the developments in the field of cell and molecular biology.
   f. Identify the various cellular components.
   g. Describe the structure and functions of cellular components.
   h. Explain the chemical foundations of cell biology.
   i. Describe the structure and function of proteins.
   j. Describe the process and regulation of basic genetic molecular mechanisms including replication, transcription and translation.
   k. Explain the cell cycle and its regulation.
   l. Explain the types of cell signaling pathways.
   m. Apply the knowledge of cell and genetic processes in the field of drug discovery.

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.

UNIT-I	Hours: 10	Weightage: 16 Marks
Learning content distribution	**Topics**	
	Introduction: a) Cell and Molecular Biology: Definitions theory and basics and Applications. b) Cell and Molecular Biology: History and Summation. c) Properties of cells and cell membrane. d) Prokaryotic versus Eukaryotic e) Cellular Reproduction f) Chemical Foundations – an Introduction and Reactions (Types)	
Must know	Prokaryotic and eukaryotic cells – properties, examples, differences between the two Cell doctrine Structure and functions of cell and its components Cell membrane – structure, functions, transport processes across membranes (diffusion, active transport, osmosis, exo and endocytosis, phagocytosis etc) Types of reactions in cells (exergonic, endergonic), free energy, high energy compounds, respiratory chain (ETC), oxidative phosphorylation.	
Desirable to know	Protoplasm theory, organismal theory. Introduction to carbohydrates, proteins, lipids – definition, classification, functions. Cellular reproduction – asexual and sexual methods History of cell biology and developments	
Nice to know	--------	

UNIT-II	Hours: 10	Weightage: 21Marks
Learning content distribution	**Topics**	
	Organization and sequences of cellular genomes a) DNA and the Flow of Molecular Information b) DNA Functioning c) DNA and RNA d) Types of RNA e) Transcription and Translation	
Mustknow	Definition of DNA & RNA Chemical structure and composition, functions of DNA & RNA Types of RNA DNA replication Transcription Translation	

Desirable to know	Enzymes involved in replication, transcription and translation processes Regulation of replication, transcription and translation Genetic code definition and characteristics DNA repair mechanisms Mutations
Nice to know	----------

UNIT-III	**Hours: 10**	**Weightage: 16 Marks**
Learning content distribution	**Topics**	
	Protein synthesis, processing and regulation a) Proteins: Defined and Amino Acids b) Protein Structure c) Regularities in Protein Pathways d) Cellular Processes e) Positive Control and significance of Protein Synthesis	
Must know	Definition of amino acids and proteins Structure of protein at primary, secondary, tertiary and quarternary levels Protein biosynthesis – process, significance, regulation by positive control mechanism (lac operon, tryptophan operon)	
Desirable to know	Intracellular protein traffic and targeting Classification of proteins and amino acids, chemical tests for proteins and amino acids	
Nice to know	----------	

UNIT-IV	**Hours: 8**	**Weightage: 22 Marks**
Learning content distribution	**Topics**	
	The Cell cycle a) Science of Genetics b) Transgenics and Genomic Analysis c) Cell Cycle analysis d) Mitosis and Meiosis e) Cellular Activities and Checkpoints	
Must know	Chromosomal theory of inheritance Concept of gene Cell cycle phases Cell division and reproduction - mitosis, meiosis, gametogenesis, fertilization Cell cycle checkpoints	

Desirable to know	Control of phases of cell cycle Transgenesis and its applications Introduction to genomic analysis techniques History and development of genetics
Nice to know	----------

UNIT-V	**Hours: 7**	**Weightage: 20 Marks**
Learning content distribution	**Topics**	
	Cell signaling a) Cell Signals: Introduction b) Receptors for Cell Signals c) Signaling Pathways: Overview d) Misregulation of Signaling Pathways e) Protein-Kinases: Functioning	
Mustknow	1. Definition, steps and importance of cell signaling pathways 2. Detail study onsignaling devices 3. Detail study onsignaling receptors 4. Explanation of protein kinases	
Desirable to know	Misregulation of signalling pathways Phosphoinositide cascade (lipid signalling)	
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
BP808ET: Cell and Molecular Biology

TIME: 3 HOURS MAX. MARKS: 75

Unit No	**Hours**	**Must know**			**Desirable to know**			**Weightage of marks**
		LE (10X3)	**SE (5X8)**	**SA (2X5)**	**LE (10X0)**	**SE (5X1)**	**SA (2X5)**	
Unit-I	10	-	2	1	-		2	16
Unit-II	10	1	1	2	-	-	1	21
Unit-III	10	-	2	1	-	-	2	16
Unit-IV	08	1	1	1	-	1	-	22
Unit-V	07	1	1		-	1	-	20
Total	**45**	**30**	**35**	**10**		**10**	**10**	**95**
		75			**20**			**95**

BP809ET. COSMETIC SCIENCE (Theory)

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

Learning Objectives:Upon completion of this course, the student should be able to,

n. Define and classify Cosmetics and Cosmeceuticals, Cosmetics as quasi and OTC drugs.
o. Explain the role of basic excipients used in the formulation and development of cosmetics and cosmeceuticals.
p. Explain basic structure and functions of Skin, types of skin, Common problems associated with skin. Role of building block agents in cosmeticand cosmeceutical formulations in skin beautification, treating problems associated with skin.
q. Explain basic structure and functions of Hair, Hair growth cycle, Common problems associated with hair and scalp.Role of building block agents in cosmetic and cosmeceutical formulations in hair conditioning, treating problems associated with hair.
r. Explain common problems associated with oral cavity.Role of building block agents cosmetic and cosmeceutical formulations in oral hygiene, treating problems associated with oral cavity.
s. Explain Actives and its mechanism of action in body care and personnel care cosmetic and cosmeceutical formulations.
t. Explain role of herbs incorporation in cosmetics and cosmeceuticals in treating and beautifying problems associated with skin, hair and oral cavity.
u. Explain BIS specification and analytical methods for selected skin care, hair care and oral care cosmetic formulations.
v. Explain the various instruments and methods used to evaluate the skin and hair properties.

12. 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.

UNIT-I	**Hours: 10**	**Weightage: 19 Marks**
Learning content distribution	**Topics** ❖ Classification of Cosmetic and Cosmeceutical products. ❖ Definition of Cosmetics as per Indian and EU regulations. ❖ Evolution of Cosmeceuticals from cosmetics. ❖ Cosmetics as Quasi and OTC drugs ❖ Cosmetic excipients-Surfactants, Rheology modifiers, Humectants, Emollients, Preservatives. Classification and applications. ❖ Skin- Basic structure and function of skin. ❖ Hair- Basic structure of hair. Hair growth cycle. ❖ Oral Cavity- Common problem associated with teeth and gums.	
Must to know	❖ Cosmetic excipients-Surfactants, Rheology modifiers, Humectants, Emollients, Preservatives. Classification and applications. ❖ Skin- Basic structure and function of skin. ❖ Hair- Basic structure of hair. Hair growth cycle. ❖ Oral Cavity- Common problem associated with teeth and gums.	
Desirable to know	❖ Definition of Cosmetics as per Indian and EU regulations. ❖ Classification of Cosmetic and Cosmeceutical products. ❖ Cosmetics as Quasi and OTC drugs	
Nice to know	❖ Evolution of Cosmeceuticals from cosmetics.	

UNIT-II	**Hours: 10**	**Weightage: 22 Marks**
Learning content distribution	**Topics** ❖ **Principles of formulation and building blocks of skin care products-** Face wash, Moisturizing creams, Cold creams and vanishing creams. Their advantages and disadvantages. Application of skin care products in the formulation of cosmeceuticals ❖ **Antiperspirants and Deodourants-** Actives and Mechanism of action ❖ **Principles of formulation and building blocks of Hair care products-** Conditioning shampoos, Hair conditioners, Anti-dandruff shampoo, Hair oils,	

	Chemistry and formulation of Para-phylene diamine based hair dye ❖ **Principles of formulation and building blocks of Oral care products-** Toothpaste for bleeding gums and Sensitive teeth, Teeth whitening, Mouthwash
Must to know	❖ **Principles of formulation and building blocks of skin care products-** Face wash, Moisturizing creams, Cold creams and vanishing creams. Their advantages and disadvantages, Application of skin care products in the formulation of cosmeceuticals. ❖ **Principles of formulation and building blocks of Hair care products-** Conditioning shampoos, Hair conditioners, Anti-dandruff shampoo, Hair oils, Chemistry and formulation of Para-phylene diamine based hair dye. ❖ **Principles of formulation and building blocks of Oral care products-** Toothpaste for bleeding gums and Sensitive teeth, Teeth whitening, Mouthwash.
Desirable to know	❖ **Antiperspirants and Deodourants-** Actives and Mechanism of action
Nice to know	❖ Examples of Formulation of skin care, hair care and oral care cosmetic and cosmeceutical products

UNIT-III	**Hours: 10**	**Weightage: 19 Marks**
Learning content distribution	**Topics**	
	❖ **Sun protection. Classification of Sunscreens and SPF.** ❖ **Role of Herbs in cosmetics-** Skin Care- Aloe and Turmeric; Hair care- Henna and Amla; Oral care- Neem and Clove ❖ **Analytical cosmetics-** BIS Specification and analytical methods for Shampoo, Skin cream and Tooth paste	
Must to know	❖ **Role of Herbs in cosmetics-** Skin Care- Aloe and Turmeric; Hair care- Henna and Amla; Oral care- Neem and Clove ❖ **Analytical cosmetics-** BIS Specification and analytical methods for Shampoo, Skin cream and Tooth paste	
Desirable to know	❖ **Sun protection. Classification of Sunscreens and SPF.**	
Nice to know	❖ Examples of Formulation of sun protection and sunscreen cosmetic and cosmeceutical products	

UNIT-IV	Hours: 8	Weightage: 16 Marks
Learning content distribution	**Topics**	
	❖ Principles of Cosmetic evaluation- Principles of Sebumeter, Corneometer ❖ Measurement of TEWL ❖ Hair tensile strength ❖ Hair combing properties ❖ Soaps and Syndet bars ❖ Evolution and skin benefits	
Must to know	❖ Principles of Cosmetic evaluation- Principles of Sebumeter, Corneometer ❖ Measurement of TEWL ❖ Hair tensile strength	
Desirable to know	❖ Soaps and Syndet bars	
Nice to know	❖ Hair combing properties ❖ Evolution and skin benefits	

UNIT-V	Hours: 7	Weightage: 19 Marks
Learning content distribution	**Topics**	
	❖ Oily and dry skin causes leading to dry skin in moisturization. ❖ Basic understanding of Comedogenic, Dermatitis. ❖ Cosmetic problems associated with hair and scalp- Dandruff, Hair fall causes ❖ Cosmetic problems associated with skin- Blemishes, Wrinkles, Acne, Prickly heat and body odour ❖ Antiperspirants and Deodourants-Actives and Mechanism of action (Repeated heading)	
Must to know	❖ Cosmetic problems associated with hair and scalp- Dandruff, Hair fall causes ❖ Cosmetic problems associated with skin- Blemishes, Wrinkles, Acne, Prickly heat and body odour	
Desirable to know	❖ Oily and dry skin causes leading to dry skin in moisturization. ❖ Basic understanding of Comedogenic, Dermatitis.	
Nice to know	❖ Antiperspirants and Deodourants-Definition, mechanism of action and its formulation examples.	

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 represented by learning objectives under each chapter.

BLUE PRINT OF MODEL QUESTION PAPER **BP809ET. COSMETIC SCIENCE (Theory)** **TIME: 3 HOURS** **MAX. MARKS: 75**								
Unit No	**Hours**	**Must know**			**Desirable/Nice to know**			**Weightage of marks**
		LE (10X3)	**SE (5X8)**	**SA (2X5)**	**LE (10X0)**	**SE (5X1)**	**SA (2X5)**	
Unit-I	10	1	1	1	-	-	1	19
Unit-II	10	1	1	1	-	1	-	22
Unit-III	10	1	1	-	-	-	2	19
Unit-IV	08	-	2	2	--	-	1	16
Unit-V	07	-	3	1		-	1	19
Total	**45**	**30**	**40**	**10**	**-**	**5**	**10**	**95**
Marks distribution		**80**			**15**			**95**

Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block Jayanagar, Bengaluru

Curriculum delivery design of B. Pharm. course of
Semester VIII System w.e.f Academic year 2020-21

SEMESTER-VIII

BP810ET. PHARMACOLOGICAL SCREENING METHODS (Theory)

45 Hours

Scope:

This subject is designed to impart the basic knowledge of preclinical studies inexperimental 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 researchmethodology.
- Design and execute a research hypothesis independently.

Unit-I	Hours: 08	Weightage of marks: 16
Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common laboratory 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 anaesthesia and euthanasia.		
Unit-II	**Hours: 10**	**Weightage of marks: 26**
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 CNS activity:** Analgesic, antipyretic,anti-inflammatory,Sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, anti-parkinsonism, alzheimer's disease and nootropics.		

Unit-III	Hours: 09	Weightage of marks: 17
Preclinical screening models: a. For ANS activity:sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye. Forlocal anesthetics.		
Unit-IV	**Hours: 13**	**Weightage of marks: 27**
Preclinical screening models: a. For CVS activity- anti-hypertensives, antiarrhythmic, anti-dyslepidemic, anti-aggregatory, coagulants, and anticoagulants. Preclinical screening models for other important drugs like antiulcer, anti-diabetic, anticancer, anti-asthmatics and diuretics.		
Unit-V	**Hours: 05**	**Weightage of marks: 09**
Research methodology and Bio-statistics a. Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data		

Recommended Books (latest edition):

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

UNIT-I	Hours: 08	Weightage: 15 Marks
Learning content distribution	**Topics**	
	Laboratory Animals	
Must know	• Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common. • Laboratory animals: Description and applications of different species and strains of animals. • Techniques for collection of blood and common routes of drug administration in laboratory animals. Techniques of anesthesia and euthanasia	
Desirable to know	• Popular transgenic and mutant animals	
Nice to know	----	

UNIT-II	Hours: 10	Weightage: 27 Marks
Learning content distribution	**Topics**	
	• **Preclinical screening models**	
Must know	• **Introduction**: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. • **Study of screening animal models for CNS activity:** Analgesic, antipyretic, anti-inflammatory, antipsychotic, antidepressant, antiepileptic, anti-parkinsonism, alzheimer's disease and nootropics.	
Desirable to know	• Rationale for selection of animal species and sex for the study. • Sedative and hypnotics.	
Nice to know	• Alternatives to animal experiments.	

UNIT-III	Hours: 09	Weightage: 15 Marks
Learning content distribution	**Topics**	
	• **Preclinical screening models**	
Must know	• For ANS activity: sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, • For local anesthetics.	
Desirable to know	• Drugs acting on eye.	
Nice to know	----	

UNIT-IV	Hours: 13	Weightage: 27 Marks
Learning content distribution	**Topics**	
	• **Preclinical screening models:**	
Must know	• For CVS activity- anti-hypertensives, antiarrhythmic, anti-dyslepidemic, • Preclinical screening models for other important drugs like antiulcer, anti-diabetic, anticancer, anti-asthmatics.	
Desirable to know	• Coagulants, and anticoagulants, anti-aggregatory. • Diuretics.	
Nice to know	----	

UNIT-V	Hours: 05	Weightage: 11 Marks
Learning content distribution	**Topics**	
	Research methodology and Bio-statistics	
Must know	• Selection of research topic, review of literature. • Pre-clinical data analysis and interpretation using Students 't' test and	

	One-way ANOVA. Graphical representation of data
Desirable to know	• Research hypothesis and study design.
Nice to know	----

BLUE PRINT OF MODEL QUESTION PAPER

BP 810ET.PHARMACOLOGICAL SCREENINGMETHODS

TIME: 3 HOURS MAX. MARKS: 75

Unit No	**Hours**	**Must know**			**Desirable to know**			**Weightage of marks**
		LE (10X3)	**SE (5X8)**	**SA (2X5)**	**LE (10X0)**	**SE (5X1)**	**SA (2X5)**	
Unit-I	08		2	2	-	-	1	**16**
Unit-II	10	1	2	1	-	-	2	**26**
Unit-III	09	1	1	-	-	-	1	**17**
Unit-IV	13	1	2	1	-	1	-	**27**
Unit-V	05	-	1	1	-	-	1	**09**
Total	**45**	**30**	**40**	**10**	**-**	**5**	**10**	
		80			**15**			**95**

Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block Jayanagar, Bengaluru

Curriculum design, continuous and formative assessment evaluation of B. Pharm Semester VIII w.e.f Academic year 2020-2021

SEMESTER-VIII

BP811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

OBJECTIVES

Upon completion of the course the student shall be able to

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
- understand the calibration of various analytical instruments
- know analysis of drugs using various analytical instruments.

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.

UNIT-I	**Hours: 10**	**Weightage: 10 Marks**
Learning content distribution	**Topics**	
	NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY Principles of H-NMR and C-NMR, chemical shift, factors affecting chemicalshift, coupling constant, Spin - spin coupling, relaxation and instrumentation and applications **Mass Spectrometry**- Principles, Fragmentation, Ionization techniques Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time offlight	

	and Quadrupole and instrumentation applications
Must know	Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation and instrumentation **Mass Spectrometry**- Principles, Fragmentation, Ionization techniques Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time offlight and Quadrupole and instrumentation.
Desirable to know	Application of ^{1}H-NMR,^{13}C-NMR and Mass Spectrometry
Nice to know	Recent advances in^{1}H-NMR,^{13}C-NMR of NMR and Mass Spectroscopy.

UNIT-II	**Hours: 10**	**Weightage: 10 Marks**
Learning content distribution	**Topics**	
	THERMAL METHODS OF ANALYSIS X-RAY DIFFRACTION METHODS: **Thermal Methods of Analysis**: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC). **X-Ray Diffraction Methods:** Origin of X-rays, basic aspects of crystals, Xray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications	
Must know	**Thermal Methods of Analysis**: Principles, instrumentation and applications ofThermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), DifferentialScanning Calorimetry (DSC).	
	X-Ray Diffraction Methods:	
	Origin of X-rays, basic aspects of crystals, Xray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications	
Desirable to know	Applications of Thermal Methods of Analysis and X-Ray Diffraction Methods.	
Nice to know	New techniquesof Thermal Methods of Analysis and X-Ray Diffraction Methods	

UNIT-III	Hours: 10	Weightage: 10Marks
Learning content distribution	**Topics**	
	CALIBRATION AND VALIDATION ICH and USFDA guidelines **Calibration of following Instruments** Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC	
Must know	ICH and USFDA guidelines **Calibration of following Instruments** Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC	
Desirable to know	Validation Parameter (Accuracy precession LoD, LoQ Robustness)	
Nice to know	Calibration SOP for the above instruments	

UNIT-IV	Hours: 8	Weightage: 8Marks
Learning content distribution	**Topics**	
	RADIO IMMUNE ASSAY Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay **Extraction techniques**: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction	
Must know	**RADIO IMMUNE ASSAY** Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay. **Extraction techniques**: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction	
Desirable to know	Limitation and Applications of Assay by using the Radio isotopes	
Nice to know	Latest development in the radio immuno assay and extraction methods	

UNIT-V	Hours: 7	Weightage: 7 Marks
Learning content distribution	**Topics**	
	HYPHENATED TECHNIQUES: LC-MS/MS, GC-MS/MS, HPTLC-MS.	
	Basic Principle, Instrumentation and sampling techniques of LC-MS/MS, GC-	

Must know	MS/MS, HPTLC-MS
Desirable to know	Importance and Application of LC-MS/MS, GC-MS/MS, HPTLC-MS techniques
Nice to know	Basic aspects of chromatographic techniques.

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

BP811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

TIME: 3 HOURS MAX. MARKS: 45

Unit No	**Hours**	**Must know**			**Desirable to know**			**Weightage of marks**
		LE (10X3)	**SE (5X7)**	**SA (2X5)**	**LE (10X0)**	**SE (5X2)**	**SA (2X5)**	
Unit-I	10	1	2	1	-	-	1	24
Unit-II	10	1	1	1	_	1	1	24
Unit-III	10	1	1	1	_	-	1	19
Unit-IV	08	-	1	1	_	1	1	14
Unit-V	07	-	2	1	_	-	1	14
Total	**45**	**30**	**35**	**10**	**-**	**10**	**10**	**95**
		75			**20**			**95**

Project work

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The internal and external examiner appointed by the University shall evaluate the project

at the time of the Practical examinations of other semester(s). Students shall be evaluated

in groups for four hours (i.e., about half an hour for a group of five students).

The projects shall be evaluated as per the criteria given below.

Evaluation of Project Work Book:

Objective(s) of the work done 15 Marks

Methodology adopted 20 Marks

Results and Discussions 20 Marks

Conclusions and Outcomes 20 Marks

Total 75 Marks

Evaluation of Presentation:

Presentation of work 25 Marks

Communication skills 20 Marks

Question and answer skills 30 Marks

Total 75 Marks

Explanation: The 75 marks assigned to the project work book shall be same for all the students in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.

Template

for submission of project work

Rajiv Gandhi University of Health Sciences, Karnataka

Instructions to Candidates

Although your project work may be prepared on a computer, consider the following requirements for meeting the standards.

Page

Use only A4 size word format in portrait orientation with normal margins for all text contents.

Type Size and Print

Select fonts type Times New Roman and size of 12 characters. The size of the titles should be 14 and Bold, the size of subtitles should be 12 and bold. Print should be with dark black characters that are consistently clear and dense. Use the same type of print and print size throughout the document.

Pagination

Number all of the pages of your document, including not only the principal text, but also all plates, tables, diagrams, maps, and so on. Roman numerals are used on the preliminary pages (pages up to the first page of text) and Arabic numerals are used on the text pages. The numbers themselves can be placed anywhere on the page, however they should be consistent.

Spacing

Use double spacing except for long quotations, footnotes, and endnotes, which are single-spaced.

Margins

The left-hand margin must be 1.5”. Other margins should be 1.0”. Diagrams, photographs, or facsimiles in any form should be a standard page size only.

Photographs

Please submit digital images with minimum resolution.

Tables and figures

- Do not repeat tables and graphs
- Actual numbers from which graphs are drawn must be provided
- Table and figure numbers in Arabic letters (not Roman)
- Table legends should go above the body of the Table and Figure legends should go below the Figure or Graph.

Cover Page of Dissertation

<----------Title of Project Work Topic----------

by

Name of the Candidate
(Maximum Five Students)

Project Work Submitted to the
Rajiv Gandhi University of Health Sciences, Karnataka, Bengaluru

In partial fulfillment
of the requirements for the degree of

Degree Name

in

Subject Name
(Elective subjects)

Under the guidance of
Name of the Supervisor

Name of the Department
Name of the College
Place

Year

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation/thesis entitled ***"<----------Title----------"*** is a bonafide and genuine research work carried out by me under the guidance of ***Name & designationof the Guide.***

Date :

Signature of the Candidate
Name

Place:

CERTIFICATE BY THE GUIDE

This is to certify that the project work entitled *"<----------Title----------"* is a bonafide research work done by ***Name of the Candidate*** in partial fulfillment of the requirement for the degree of ***Degree Name***.

Date :

Place:

Signature of the Supervisor

Name

ENDORSEMENT BY THE HOD,PRINCIPAL/HEAD OF THE INSTITUTION

This is to certify that the project work entitled *"<----------Title----------"* is a bonafide research work done by ***Name of the Candidate*** under the guidance of ***Name & designation of the*** **Supervisor** .

Seal & Signature of the HOD

Name

Date :

Place:

Seal & Signature of the Principal

Name

Date :

Place:

COPYRIGHT

Declaration by the Candidate

I ------*Name of the Candidate* ----------**of** ----------*Name of the Institution* ----------hereby declare that the Rajiv Gandhi University of Health Sciences, Karnataka shall have the perpetual rights to preserve, use and disseminate this project work in print or electronic format for academic / research purpose.

Date :

Signature of the Candidate
Name

Place:

ACKNOWLEDGMENT

Not lengthy.

Date :

Place:

Signature of the Candidate

Name

LIST OF ABBREVIATIONS USED
(in alphabetical order)

LIST OF TABLES

Sl.No **Tables** **Pages**

LIST OF FIGURES

Sl.No **Figures** **Pages**

TABLE OF CONTENTS

Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block Jayanagar, Bengaluru

Curriculum delivery design of B. Pharm. course of
Semester VIII w.e.f Academic year 2020-21

SEMESTER-VIII

BP 812 ET: DIETARY SUPPLEMENTS AND NUTRACEUTICALS

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

A. Learning Objectives:

Upon completion of this course the student should be able to

a. Understand the need of supplements by the different group of people to maintainhealthy life.
b. Understand the outcome of deficiencies in dietary supplements.
c. Appreciate the components in dietary supplements and their usage for prevention of chronic health ailments.
d. Appreciate the regulatory and commercial aspects of dietary supplements includinghealth claims.

14. Content distribution as per the list of topics, time allotted for each topic, distribution for 'Must to 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.

UNIT-I	**Hours: 07**	**Weightage: 17 Marks**
Learning content distribution	**Topics**	
	Functional foods, Nutraceuticals and Dietary supplements	
Must toknow	Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classificationof Nutraceuticals. Health problems and diseases that can be prevented or cured by nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc. Source, active phyto-constituents and their chemical nature, Medicinal	

	uses and health benefits of following used as nutraceuticals/functional foods: Spirulina,Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds.
Desirable to know	Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.
Nice to know	Study of other natural products like shilajit, cod liver oil and other fish oils.

UNIT-II	**Hours: 15**	**Weightage: 26 Marks**
Learning content distribution	**Topics**	
	Phytochemicals as nutraceuticals	
Must toknow	Occurrence and characteristic featuresof Carotenoids, Sulfides, Polyphenolics, Flavonoidsas functional foods. Occurrence and characteristic features of Prebiotics / Probiotics, Tocopherols, phytoestrogens.	
Desirable to know	Certain proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods.	
Nice to know	Study of various millets, their use in control and prevention of chronic diseases.	

UNIT-III	**Hours: 07**	**Weightage: 14 Marks**
Learning content distribution	**Topics**	
	Free radicals, Dietary fibres and complex carbohydrates	
Must toknow	Free radicals, reactive oxygen species, production of free radicals in cells. Concept of oxidative stress, Oxidative damage to protein and DNA, Lipid peroxidation.	
Desirable to know	Dietary fibres and complex carbohydrates as functional food ingredients.	
Nice to know	Preparation of various smoothie recipes and their health benefits.	

UNIT-IV	**Hours: 10**	**Weightage: 22 Marks**
Learning content distribution	**Topics**	
	Role of Free radicals in lifestyle diseases, Antioxidants and functional foods	
Must toknow	Antioxidants: Enzymatic Endogenous antioxidants –Antioxidant defense system, Mechanism of action of antioxidants, Levels of antioxidant action, Types of antioxidants. Nonenzymatic- Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin.	

	Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage. Free radicals theory ofageing.
Desirable to know	Functional foods for chronic disease prevention.
Nice to know	Free radicals involvement in muscle damage and other disorders.

UNIT-V	**Hours: 06**	**Weightage: 16 Marks**
Learning content distribution	**Topics**	
	Processing, storage, interactions, Regulatory aspects and Pharmacopoeial Specifications of Dietary supplements and nutraceuticals.	
Must toknow	Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on food safety.Adulteration of foods. Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.	
Desirable to know	Pharmacopoeial Specifications for dietary supplements and nutraceuticals	
Nice to know	Factors contributing to improving potency and shelf life of nutraceuticals.	

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

BP812ET: Dietary Supplements And Nutraceuticals

TIME: 3 HOURS MAX. MARKS: 75

Unit No	**Hours**	**Must know**			**Desirable to know**			**Weightage of marks**
		LE (10X3)	**SE (5X8)**	**SA (2X7)**	**LE (10X0)**	**SE (5X1)**	**SA (2X3)**	
Unit-I	07	1	1	-	_	-	1	17
Unit-II	15	1	2	2	_	-	1	26
Unit-III	07	-	2	2	_	-	-	14
Unit-IV	10	1	1	1	_	1	-	22
Unit-V	06	-	2	2	_	-	1	16
Total	**45**	**30**	**40**	**14**	**-**	**5**	**6**	**95**
		84			**11**			**95**