Estd. 1962
"A++" Accredited by NAAC(2021)
With CGPA 3.52

SHIVAJI UNIVERSITY, KOLHAPUR - 416 004, MAHARASHTRA
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शिवाजी विद्यापीठ, कोल्हापूर - ४१६ ००४,महाराष्ट्र
दूरध्वनी - ईपीएबीएक्स - २६०९०००, अभ्यासमंडळे विभाग दुरध्वनी ०२३१—२६०९०९३/९४

SU/BOS/Science/497 **Date: 10/07/2023**

To,

The Principal, All Concerned Affiliated Colleges/Institutions Shivaji University, Kolhapur	The Head/Co-ordinator/Director All Concerned Department (Science) Shivaji University, Kolhapur.

Subject: Regarding syllabi of M.Sc. Part-II (Sem. III & IV) as per NEP-2020 degree programme under the Faculty of Science and Technology.

Sir/Madam,

With reference to the subject mentioned above, I am directed to inform you that the university authorities have accepted and granted approval to the revised syllabi, nature of question paper and equivalence of M.Sc. Part-II (Sem. III & IV) as per NEP-2020 degree programme under the Faculty of Science and Technology.

M.Sc.Part-II (Sem. III & IV) as per NEP-2020			
1.	Microbiology (HM)	8.	Food Science & Nutrition
2.	Pharmaceutical Microbiology (HM)	9.	Food Science & Technology
3.	Microbiology	10.	Biochemistry
4.	Computer Science	11.	Biotechnology
5.	Computer Science (Online Mode)	12.	Medical Information Management
6.	Data Science	13.	Environmental Science
7.	Information Technology (Entire)	14.	Physics

This syllabus, nature of question and equivalence shall be implemented from the academic year 2023-2024 onwards. A soft copy containing the syllabus is attached herewith and it is also available on university website **www.unishivaji.ac.in**)

The question papers on the pre-revised syllabi of above-mentioned course will be set for the examinations to be held in October /November 2023 & March/April 2024. These chances are available for repeater students, if any.

You are, therefore, requested to bring this to the notice of all students and teachers concerned.

Thanking you,

Dy Registrar
Dr. S. M. Kubal

Copy to:

1	The Dean, Faculty of Science & Technology	8	P.G. Admission/Seminar Section
2	Director, Board of Examinations and Evaluation	9	Computer Centre/ Eligibility Section
3	The Chairman, Respective Board of Studies	10	Affiliation Section (U.G.) (P.G.)
4	B.Sc. Exam/ Appointment Section	11	Centre for Distance Education

Shivaji University, Kolhapur

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Syllabus for

Master of Science (M.Sc.)

In

Medical Information Management (NEP-2020)

(Under Faculty of Science and Technology)

M.Sc. Part II

(Subject to modifications to be made time to time)

Syllabus to be implemented from 2023-2024

Choice Based Credit System with Multiple Entry and Multiple Exit Option (NEP-2020)
M.Sc. Medical Information Management
M.Sc. Part-II (Level-9)

SEMESTER-III (Duration- Six month)											
	Sr. No.	Course code	Teaching Scheme			Examination Scheme					
			Theory and Practical			University Assessment (UA)			Internal Assessment (IA)		
			Lectures (per week)	Hours (per week)	Credit	Maximum Marks	Minimum Marks	Exam. Hours	Maximum Marks	Minimum Marks	Exam. Hours
CGPA	1	**CC-301:** Clinical Data Management-II	4	4	4	80	32	3	20	8	1
	2	**CC-302:**Clinical Quality Management-II	4	4	4	80	32	3	20	8	1
	3	**CCS-303:** Project Management and Project Presentation	4	4	4	80	32	3	20	8	1
	4	**DSE-304A:** Module to deepen knowledge: Clinical Research, Biostatistics, Epidemiology OR **DSE-304B:** Next Generation Sequencing	4	4	4	80	32	3	20	8	1
	5	**CCPR-305:** Laboratory Course	16	16	08	200*	80	-	-	-	#
Total (C)			-	-	**24**	**520**	-	-	**80**	-	-
Non-CGPA	1	AEC-306	2	2	2	-	-	-	50	20	2
	2	EC (SWMMOOC)-307:	Number of Lectures and credits shall be as specified on SWAYA MOOC								
SEMESTER-IV (Duration- Six month)											
CGPA	1	**CCS 401:** Phase I: Research problem identification and review of literature	-	-	4	-	-	-	100	40	-
	2	**CCS 402:** Phase II: Synopsis submission, and presentation.	-	-	4	-	-	-	100	40	-
	3	**DSE 403:** Phase III: Mid-term evaluation by presentation	-	-	8	-	-	-	200	80	-
	4	**CCS 404 :** Phase IV: Hard bound submission and presentation	-	-	4	-	-	-	100	40	-
	5	**CCPR 405:** Phase V: Viva voce	-	-	**4**	-	-	-	100	40	-
Total (D)			-	-	**24**	-	-	-	**600*#**	**240**	-
Non-CGPA	1	SEC-406	2	2	2	-	-	-	50	20	2
	2	GE-407:	2	2	2	-	-	-	50	20	2
Total (C + D)			-	-	**48**	**520**	-	-	**680**	-	-

* Practical examination will be Internal/External as per department choice.

$ Question no. 1 of each question paper will be subjective (short answer question/objective questions)

Duration of practical/research project examination will be five days (1 Inspection day & 4 Practical days).

• Student contact hours per week : **32** Hours (Min.)	• Total Marks for M.Sc.-II : **1200**
• Theory and Practical Lectures : **60** Minutes Each	• Total Credits for M.Sc.-II (Semester III & IV) : **48**
• CC-Core Course • CCS- Core Course Specialization • CCPR-Core Course Practical and Project • DSE-Discipline Specific Elective • AEC-Mandatory Non-CGPA compulsory Ability Enhancement Course • SEC- Mandatory Non-CGPA compulsory Skill Enhancement Course • EC (SWM MOOC) - Non-CGPA Elective Course • GE- Multidisciplinary Generic Elective	• Practical Examination is annual. • Examination for CCPR-305 shall be based on Semester III Practicals. • Examination for CCPR-405 shall be based on Semester IV Practicals/Research Project. • ***Duration of Practical Examination as per respective BOS guidelines • ***Separate passing is mandatory for Theory, Internal and Practical Examination***
• **Requirement for Entry at Level 9:** **Completed all requirements of the relevant Post Graduate Diploma (Level 8) in Medical Information Management**	
• **Exit at Level 9:** Students will exit after Level 9 with **Master's Degree in Medical Information Management** if he/she completes the courses equivalent to minimum of 96 credits.	

	M.Sc.-I	**M.Sc.-II**	**Total**
Marks	**1200**	**1200**	**2400**
Credits	**48**	**48**	**96**

I. CGPA course:

1. There shall be 10 Core Courses (CC) per programme.
2. There shall be 04 Core Course Specialization (CCS) of 16 credits per programme.
3. There shall be 02 Discipline Specific Elective (DSE) courses of 08 credits per programme
4. Total credits for CGPA courses shall be of 96 credits per programme

II. Mandatory Non-CGPA Courses:

1. There shall be 02 Mandatory Non-CGPA compulsory Ability Enhancement Courses (AEC) of 02 credits each per programme.
2. There shall be 01 Mandatory Non-CGPA compulsory Skill Enhancement Course (SEC) of 02 credits per programme.
3. There shall be one Elective Course (EC) (SWAYAM MOOC). The credits of this course shall be as specified on SWAYAM MOOC.
4. There shall be one Generic Elective (GE) course of 02 credits per programme. Each student has to take generic elective from the department other than parent department.
5. The total credits for Non-CGPA course shall be of 08 credits + 2-4 credits of EC as per availability.

6. The credits assigned to the course and the programme are to be earned by the students and shall not have any relevance with the work load of the teacher.

Scheme of teaching and examination

(Applicable to University Department and University affiliated college centers)

The semester examination will be conducted at the end of each term (theory examination only)

Theory paper will be of 80 marks each and 20 marks for internal evaluation test conducted in the mid of the term. Sem III practical of 200 marks will be conducted annually. However, M.Sc. Dissertation (Research Project) will be continuously internally evaluated throughout the semester IV.

Question papers will be set in the view of the entire syllabus and preferably covering each unit of the syllabus.

Standard of Passing

As per rules and regulations of M.Sc. course.

Nature of Question Paper and Scheme of Marking

Theory question paper Maximum marks – 80

Total No. Of question -7

All questions are of equal marks. Out of these seven questions five questions are to be attempted.

Question No.1 is compulsory.

Remaining 6 questions are divided into two sections, namely section-I and Section-II. Four questions are to be attempted for these two sections such that not more than two questions from any of the section. Both sections are to be written in the same answer book.

M.Sc. Dissertation (Research Project) of 600 marks will be continuously internally evaluated throughout the semester IV.

Department of Biochemistry

Shivaji University, Kolhapur

Syllabus of Choice Based Credit System with Multiple Entry and Multiple Exit Option (NEP-2020)

M.Sc. Medical Information Management

M.Sc. Part-II

	SEMESTER III	**600 Marks**
CC 301	**: Clinical Data Management II**	
CC 302	**: Clinical Quality Management-II**	
CCS 303	**: Project Management and Project Presentation**	
DSE 304 A **DSE 304 B**	**: Module to deepen Knowledge** **Clinical Research, Biostatistics, Epidemiology** **OR** **Next Generation Sequencing**	
CCPR 305	**: Laboratory Course**	
AEC 306	**: Mandatory Non-CGPA Compulsory Ability Enhancement Course (AEC)**	
EC 307	**: (SWMMOOC) Intellectual Property**	
	SEMESTER IV	**600 Marks**
	: M.Sc. Dissertation (Research Project)	
CCS 401	**Phase I:** Research problem identification and review of literature	
CCS 402	**Phase II:** Synopsis submission, and presentation.	
DSE 403	**Phase III:** Mid-term evaluation by presentation	
CCS 404	**Phase IV:** Hard-bound submission and presentation	
CCPR 405	**Phase V:** Viva voce	
SEC 406	**: Mandatory Non-CGPA Compulsory Skill Enhancement Course**	
GE 407	**: Research Methodology and Entrepreneurship**	

SEMESTER III

	CC 301: Clinical Data Management II	**Total Hours: 60**
Unit I	**Study Startup** i. Data Management Plan ii. Case Report Form (CRF) design consideration iii. Database design considerations iv. Edit checks v. Preparing to receive data	15
Unit II	**Study Conduct** i. Receiving data on paper, overseeing data collection ii. Cleaning data, iii. Managing lab data and Non-CRF data iv. Collecting adverse event data v. Creating reports and transferring data	15
Unit III	**Study Closeout and infrastructure** i. Study database lock ii. After database lock iii. Standard Operating Procedures iv. Training, Control access and security v. Working with Clinical Research Organizations (CROs)	15
Unit IV	**Clinical Data Management Systems** i. EDC systems ii. Choosing vendor products iii. Implementation and validation of new systems iv. Test procedure and change control v. Migrating and Archiving Data	15

Reference Books

Practical guide to Clinical Data Management. 3rd Edition. 2012 by Taylor & Francis Group, LLC, USA.

	CC 302: Clinical Quality Management-II	Total Hours: 60
Unit I	**Before and After Good Laboratory Practices (GLP) and Good Clinical Practices (GCP)** i. Quality system ii. Standard Operating Procedure (SOP) iii. Quality Control (QC) ,Quality Assurance (QA) iv. Quality system evolution v. Clinical protocol audits	15
Unit II	**Training and computing in regulated environment** i. Training of staff ii. QA inspection iii. 21 CFR Part 11 iv. Validation and risk assessment v. Biometrics	15
Unit III	**Quality assurance (QA) activities and beyond compliance** i. Inspections ii. Quality Metrics iii. Audit procedures iv. Other quality systems v. Sampling for quality	15
Unit IV	**Business improvement and Audits** i. Managing quality ii. Responsibilities: QA and Management iii. Qualified person iv. Business continuity plan v. Good Quality System	15

Reference Books

A practical guide to quality management in clinical trial research. Graham D. Ogg. CRC Press, Taylor & Francis Group. USA.

	CCS 303: Project Management and Project Presentation	Total Hours: 60
Unit I	**Setting Up the Project Management Operation** i. Project management introduction ii. Project Initiation techniques, milestones iii. Implementing a computer-based project management capability iv. Project life cycles, critical Path, critical chain, and uncertainty v. Exploring concepts of shared resource and workforce management	15
Unit II	**Elements of Resource Management, budgeting and risk management** i. Resource leveling and games of chance ii. Concepts and issues of project budgeting and cost control iii. Software support for cost management iv. Risk management and contingency v. Making project management work	15
Unit III	**Clinical studies project management** i. Drug development and industry trends ii. Contract research organizations iii. Role of clinical study project manager iv. Goals and standards v. Managing clinical trial activities and processes	15
Unit IV	**Clinical Project management Resources** i. Budgets, time, resources ii. Measurements, communications iii. Clinical project management training iv. Surviving quality assurance audits v. Troubleshooting in project management	15

Reference Books

1. Practical Project Management Tips, Tactics, and Tools. Harvey A. Levine. John Wiley & Sons, Inc. 2002. Published by John Wiley & Sons, Inc., USA.
2. Clinical research manual practical tools and templates for managing clinical research. R. Jennifer Cavalieri, Mark E. Rupp. 2013. Sigma Theta Tau International. USA.
3. Clinical studies management a practical guide to success. 2004. Simon Cook Interpharm /CRC.

	DSE 304: Module to deepen Knowledge Clinical Research, Biostatistics, Epidemiology	**Total Hours: 60**
Unit I	**Clinical Trials and outcome measures** i. Clinical trials as research ii. Context for clinical trials iii. Clinical trials as experimental designs iv. Random errors and bias v. Types of outcome measures	15
Unit II	**Clinical Research and CADD** i. Process of CADD in pharmaceutical industry ii. Design and analysis of phase I, II, III trials iii. Randomization iv. Systematic reviews and meta-analysis v. Setting up, conducting and reporting trials vi. Health related quality of life and health economic evaluation	15
Unit III	**Biostatistics** i. Sampling for community health surveys ii. Scales of measurement iii. Constructing a survey questionnaire iv. Validity and reliability of survey questionnaires v. Scales of measurement and methods of data collection	15
Unit IV	**Epidemiology** i. Introduction to Epidemiology ii. Measuring health and disease iii. Types of study iv. Causation and prevention in epidemiology v. Communicable disease epidemiology	15

Reference Books:

1. Clinical trials a methodologic perspective. 2nd edition. 2005. Steven Piantadosi. A John Wiley & Sons, Inc., Publication. UK
2. A concise guide to clinical trials. Allan Hackshaw. 2009. A John Wiley & Sons, Ltd., Publication. UK.
3. Biostatistics. A foundation for analysis in the health sciences. Wayne W. Daniel. 9th Edition. 2009. John Wiley & Sons, Inc. USA.
4. Handbook of health survey methods edited by Timothy P. Johnson. John Wiley & Sons, Inc. 2015. USA.
5. Research methods in community medicine. Surveys, epidemiological research, Programme evaluation, clinical trials. J. H. Abramson. 2008. John Wiley & Sons Ltd. UK.
6. Basic epidemiology, 2nd ed. Bonita, Ruth, Beaglehole, Robert, Kjellström, Tord & World Health Organization. 2006.

7. An introduction to Computational Biochemistry. (C. Stain Tsai, A John Wiley and Sons, Inc., publications).
8. Bioinformatics Methods and Applications Genomics, Proteomics and Drug Discovery. (Rastogi S. C. Mendiratta, and Rastogi P.)

	OR **DSE 304B: Next Generation Sequencing**	**Total Hours: 60**
Unit I	**History & evolution of NGS and types of NGS:** i) First-generation technologies – Sanger dideoxy sequencing, Maxam-Gilbert sequencing.Technologies used in Human Genome Project, Shotgun sequencing, ii) Next (second)-generation and Third-generation sequencing sequencing, NGS platforms, NGS technologies: DNA-seq, RNA-seq, ChIP-seq, Hi-C, Metagenomics, Single cell sequencing. iii) Different sample preparation methods for different type of NGS *(DNASeq, RNASeq,* ChIPSeq, Metagenomics, Single cell), Adaptors, Index, Barcode. iv) Library preparation methods - Bridge amplification, Emulsion PCR. Sequencing methods –sequencing by synthesis, ion semiconductor, SMRT, nanopore.	15
Unit II	**NGS Data formats, Pre-processing and Data Analysis:** i) Data formats overview – FASTQ, subreads,nanopore data, single cell data. Single-end, Paired-end, Mate-pair. ii) NGS Data sources – NCBI SRA, EBI-ENA, DDBJ-SRA, GEO; Retrieving data from data sources - SRA toolkit; Aspera connect. iii) Sequence quality measures – Phred quality score. Quality check *tool* FASTQC, Pre-processing: Trimmomatic, Fastx-toolkit. iv) Introduction to NGS Data Analysis: Assembly principles, output file formats, contigs, scaffolds, assembly quality assessment. v) Mapping Principles, tools – BWA, Bowtie, SAMtools, output file formats – BAM, SAM, mapping alignment assessment – number of reads mapped, concordantreads; Visualisation tools-IGV.	**15**
Unit III	**Introduction to genome assembly:** i) Introduction to DNA assembly, K-mer, repeats, contig, scaffold, denovo assembly, reference based assembly, ii) Applications of DNA assembly-whole genome assembly, hybrid assembly, transcriptome assembly, metagenome genome study. iii) Assembly algorithms and assembly assessment: Mapping-based method, OLC- based method, DBG-based method and greedy based-algorithms, Tools – Velvet	**15**
Unit IV	**Transcriptome assembly and repeat annotations:** i) RNA-seq overview, workflow, Mapping RNA-seq reads, denovo vs	**15**

	referenced based transcriptome assembly, splice variants, Trinity (de novo), functional annotation. ii) Repeat annotation: Repeats – types & classification-tandem repeats, satellite DNA microsatellite/SSR, Direct repeats, inverted repeats, palindromic repeats, interspersed repeats, transposable elements, iii) Genetic and evolutionary significance of repeats, application of repeats, repeat databases – Rpbase, iv) Methods of repeat identification-*Ab-initio* and homology based methods. v) NGS solution for human health diseases: Differential expression profile analysis of onco- and tumor suppressor genes from cancer, precision medicine derived treatment for cancer, multidrug resistance analysis for biofilm-mediated infections, and diagnostic of viral infections.	

References:

1. Arthur M. Lesk, (2007). Introduction to Genomics. Oxford University Press.
2. Sandy B. Primrose and Richard Twyman (2008). Principles of Genome Analysis andGenomics (Third Edition). Blackwell Publishing.
3. Sara El-Metwally, Osama M. Ouda, Mohamed Helmy (2014). Next Generation Sequencing Technologies and challenges in sequence assembly. Springer-Verlag New York.
4. Ali Masoudi-Nejad, Zahra Narimani, Nazanin Hosseinkhan (2013). Next Generation Sequencing and Sequence Assembly:Methodologies and Algorithms. Springer New York.
5. Adam Voshall (2018). Next-Generation Transcriptome Assembly: Strategies andPerformance Analysis. IntechOpen.
6. Michael Chandler, Martin Gellert (2020). Mobile DNA III. Wiley.

CCPR 305: Laboratory Course (120 hrs) 200 Marks

Part A:

Project study: Data Management in Clinical Research. (Various projects related to the topics mentioned below will be given to the students.)

i. Data Management Plan
ii. Clinical Data Management SOPs
iii. CRO-Sponsor Responsibility Matrix
iv. Implementation Plan
v. Validation Plan
vi. Analysis of docking complex
vii. Analysis of MD trajectory
viii. Energy calculation of drug molecules for CADD

Part B:

Project study: Quality Management in Clinical Research and Drug Safety (Various projects related to the topics mentioned below will be given to the students.)

i. Quality systems
ii. Audit preparation
iii. Being ready for regulatory inspections
iv. Pharmacovigilance Medical Writing
v. Real world issues in Pharmacovigilance
vi. Pharmacophore designing in CADD
vii. Molecular modeling for drug designing

Reference Books:

1. Practical guide to Clinical Data Management. 3rd Edition. 2012 by Taylor & Francis Group, LLC, USA.
2. An introduction to pharmacovigilance. Patrick Waller. 2010. John Wiley & Sons.
3. Pharmacovigilance. 2nd Edition. Ronald Mann. 2007. John Wiley & Sons Ltd
4. Cobert's Manual of Drug Safety and Pharmacovigilance. 2nd Edition. 2012. Jones & Bartlett Learning.
5. Pharmacovigilance Medical Writing. A Good Practice Guide. Justina Orleans-Lindsay. 2012. John Wiley & Sons.
6. AutoDock user manual.
7. SPARTAN user manual by Wavefunction, Inc., USA

	AEC 306 : Mandatory Non-CGPA compulsory Ability Enhancement Course	**30 Hrs**
Unit I	Syllabus and nature of paper will be opted as per committee decision.	**15 Hrs**
Unit II		**15 Hrs**

	EC 307 (SWMMOOC): Non-CGPA Elective Course **Intellectual Property**	
Unit I	Syllabus and nature of paper will be opted as per swayam portal.	
Unit II		

SEMESTER IV

Course Code	M.Sc. Dissertation (Research Project) (360 Hrs. Total 600 Marks)
CCS 401	**Phase I:** Research problem identification and review of literature.
CCS 402	**Phase II:** Synopsis submission, and presentation.
DSE 403	**Phase III:** Mid-term evaluation by presentation
CCS 404	**Phase IV:** Hard-bound submission and presentation
CCPR 405	**Phase V:** Viva voce
	Total

	M.Sc. Dissertation (Research Project) from following broad areas for the whole Sem IV)
	• Clinical research • Data management • Quality Management in clinical research • Drug safety • Computer-Aided Drug designing, development and Analysis • Molecular modeling in drug designing **(**Specific topic for each student will be decided based on student's interest in the above mentioned areas and / or supervisor suggestion**)**

	SEC 406 : Skill Enhancement Course	**30 Hrs**
Unit I	Syllabus and nature of paper will be opted as per committee decision.	**15**
Unit II		**15**

	GE 407 :Generic Elective: Research Methodology and Entrepreneurship	**30 Hrs**
Unit I	**Research methodology** Aims and objectives of research, Types of research – basic, novel and applied research. Tools for searching research topic – books, journals, internet, discussions etc. Research hypothesis, Steps in research design. Research Aptitude, Qualities of a researcher, Ethics in research – plagiarism **Intellectual Property Rights** Copyright, Trademark, geographical indicators, design, Patent**,** Role of patent in R & D, Criteria for patentability, Indian patent act, Provisional and final patent filing, writing claims, procedure for patent granting	**15 Hrs**
Unit II	**Entrepreneurship Development** Definitions, types, characteristics of Entrepreneur, Basics of Start-Ups, Definition of micro, small and medium scale industries, government facilities and subsidies/financial institutes supporting Start-Ups, Steps in setting up a business, selecting a business idea, market survey, information, market segmentation, market trends, SWOT analysis, **Preparation of a Project Report** Executive summary, Project description, Marketing plan, Capital structure and operating cost, Management/Financial/Technical plan, Project implementation.	**15 Hrs**

Theory question paper format

M. Sc. II Medical Information Management

(MEME NEP CBCS Common Pattern)

Total marks: 80

Instructions: 1) Question no.1 is compulsory and carries 16 marks
2) Attempt any two questions from each section
3) All questions carry equal marks

Q.1 Objective/multiple choice/one line sentence type 16 questions (16 Marks)

i)

ii)

iii)

iv)

v)

vi)

vii)

viii)

ix

x)

xi)

xii)

xiii)

xiv)

xv)

xvi)

Section-I

Q.2 Long answer question (16 Marks)

Q.3 long answer question (16 Marks)

Q.4 long answer question (16 Marks)

Section-II

Q.5 Short answer questions (16 Marks)

i)

ii)

Q.6 Short note answer questions (16 Marks)

i)

ii)

iii)

iv)

Q.7 Short note answer questions (16 Marks)

i)

ii)

iii)

iv)

For Sem IV: M.Sc. Dissertation (Research Project) (600 Marks)

M.Sc. Dissertation (Research Project) will be submitted by students and will be evaluated internally by department faculty members. The process of dissertation submission and evaluation will be as follows;

Course Code	**Process of Dissertation (Research Project) submission and evaluation**	**Credits**	**Marks distribution**
CCS 401	**Phase I:** Research problem identification and review of literature.	04	100 Marks
CCS 402	**Phase II:** Synopsis submission, and presentation.	04	100 Marks
DSE 403	**Phase III:** Mid-term evaluation by presentation	04	100 Marks
CCS 404	**Phase IV:** Hard-bound submission and presentation	08	200 Marks
CCPR 405	**Phase V:** Viva voce	04	100 Marks
	Total	**24**	**600 Marks**