

Maulana Abul Kalam Azad University of Technology, West Bengal
(Formerly West Bengal University of Technology)
Syllabus for B. Tech in Biomedical Engineering
(Applicable from the academic session 2018-2019)

SEMESTER-VIII

Name of the Course	HOME MEDICARE TECHNOLOGY
Course Code: PE-BME801	Semester: Eighth
L-T-P-C: 3-0-0-3	Contact: 3 hrs/week
Objectives:	
1	To provide basic knowledge of home medicare system and various clinical application.
2	To understand the various aspects that influence safety, quality and effective home medicare.
3	To gain in-depth knowledge about the advances in healthcare technologies and wireless technology related to healthcare system.
Pre-Requisite: Engineering Physiology & Anatomy (PCBME302), Biomedical Instrumentation (PCBME402), Telehealth Technology (PEBME501)/Communication Engineering & Bio-Telemetry (PEBME502).	

M #	Content	Hrs
1	Introduction to Home Medicare: Home healthcare, purpose, legal and ethical aspects, organization of home care system, historical development of home care, environmental influences on home care, home care organization, home care nursing practice, role of home care nurse and orientation strategies, infection control in home, patient education in home.	8
2	Working with Clients: Basic human needs, communication and interpersonal skills, caregiver observation, recording and reporting, confidentiality, working with elderly-aging and body systems, working with children-need for home care, mobility-transfers and ambulation, range of motion exercises, skin care and comfort measures.	8
3	Home Medical Devices: Medical devices at home, user centered design and implementation, co-design with old users, device types, user issues, ethical and legal issues, infant monitors, medical alert services, activity monitors.	7
4	Advancement in Medical Technologies: Advances and trends in health care technologies, driver impacting the growth of medical technologies, impact of Moore's law of medical imaging, e-health and personal healthcare, defining the future of health technology, inventing the future, tools for self-health, future of nano-fabrication molecular scale devices, future of telemedicine, future of medical computing.	10
5	Wireless Technology: Wireless communication basics, types of wireless network, body area network, emergency rescue, remote recovery, general health assessment technology in medical information processing, future trends in health care technology.	7

COURSE OUTCOMES

At the end of the course, students should be able to:

1. Demonstrate the understanding about basics of home medicare system.
2. Identify the critical elements for providing effective integrated health care at home.
3. Evaluate home medicare devices and their clinical applications.

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4. Illustrate the various aspects that influence safety, quality and effective home medicare.
5. Anticipate advances in healthcare technologies and wireless technology related to healthcare system.
6. Plan and design cost effective quality home care devices with proper patent safety.

Text/Reference Books:

1. Robyn Rice, "Home care nursing practice: Concepts and Application", 4th edition, Elsevier, 2006.
2. LodewijkBos, "Handbook of Digital Homecare: Successes and Failures", Springer, 2011.
3. Yadin David, Wolf W. von Maltzahn, Michael R. Neuman, Joseph D. Bronzino, "Clinical Engineering", CRC Press, 2010.
4. Kenneth J. Turner, "Advances in Home Care Technologies: Results of the match Project", Springer, 2011.

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Name of the Course	BIOMEDICAL HAZARDS & SAFETY
Course Code: PE-BME802	Semester: Eighth
L-T-P-C: 3-0-0-3	Contact: 3 hrs/week
Objectives:	
1	To understand the hazardous materials used in hospital and its impact on health.
2	To know various waste disposal procedures and management.
3	To impart sufficient information on the various hazards, medical wastes and relevant precautionary control measures for patient safety in healthcare system.
Pre-Requisite: Biomedical Instrumentation (PCBME402), Hospital Engineering & Management (PEBME701)/Hospital Safety & Management (PEBME702).	

M #	Content	Hrs
1	Hazardous Materials: Hazardous Substances, OSHA hazard communication standard, DOT hazardous material regulations, healthcare hazardous materials, medical gas systems, hazardous waste operations and emergency response standard, respiratory protection.	6
2	Healthcare Hazard Control: Introduction, hazard control, hazard control management, hazard control responsibilities, addressing behaviors, hazard control practice, hazard analysis, hazard control and correction, personal protective equipment, hazard control committees, hazard control evaluation, systems safety, ergonomics, understanding accidents: accident causation theories, human factors, accident deviation models, accident reporting, accident investigations, accident analysis, accident prevention, workers' compensation, orientation, education and training.	10
3	Biomedical Waste Management: Types of wastes, major and minor sources of biomedical waste, categories and classification of biomedical waste, hazard of biomedical waste, need for disposal of biomedical waste, waste minimization, waste segregation and labeling, waste handling, collection, storage and transportation, treatment and disposal.	8
4	Infection Control, Prevention & Patient Safety: Healthcare immunizations, centers for disease control and prevention, disinfectants, sterilants, and antiseptics, OSHA bloodborne pathogens standard, tuberculosis, healthcare opportunistic infections, patient safety: organizational function, errors and adverse events, safety cultures, quality improvement tools and strategies.	8
5	Facility Safety: Introduction, administrative area safety, slip, trip, and fall prevention, safety signs, colors and marking requirements, scaffolding, fall protection, machine guarding, compressed air safety, electrical safety, control of hazardous energy, OSHA hearing conservation standard, ventilating and air-conditioning systems, assessing IAQ, landscape and grounds maintenance, fleet and vehicle safety.	8

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COURSE OUTCOMES

At the end of the course, students should be able to:

1. Demonstrate the types of hazards, planning, organization and training needed to work safely with hazardous materials.
2. Explain the different types of hazardous exposure and its biological effects, exposure guidelines and basic workplace monitoring.
3. Analyze various hazards, infection, accidents and its control.
4. Categorize biowastes and design efficient waste disposal procedures.
5. Design different safety facility and control measures in hospitals.
6. Propose and adopt mandatory regulations and safety norms for improving healthcare delivery.

Text/Reference Books:

1. Tweedy, James T., "Healthcare Hazard Control and Safety Management", CRC Press_Taylor and Francis (2014).
2. Anantpreet Singh, Sukhjit Kaur, "Biomedical Waste Disposal", Jaypee Brothers Medical Publishers (P) Ltd (2012).
3. R.C. Goyal, "Hospital Administration and Human Resource Management", PHI, Fourth Edition, 2006
4. V.J. Landrum, "Medical Waste Management and Disposal", Elsevier, 1991

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Name of the Course	BIOINFORMATICS & EXPERT SYSTEM
Course Code: PE-BME803	Semester: Eighth
L-T-P-C: 3-0-0-3	Contact: 3 hrs/week
Objectives:	
1	To get introduced to the basic concepts of bioinformatics and its significance in biological data analysis.
2	To acquaint with bioinformatics tools, biological database and recent advances in genomics technology.
3	To trained in the basic theory and application of programs used for database searching, protein and DNA sequence analysis, and prediction of protein function.
4	To impart concepts of expert systems and its application in medical field.
Pre-Requisite: Knowledge of Biochemistry, Mathematics, Statistics, Computational theory, Analysis and Algorithm Design.	

M #	Content	Hrs
1	Introduction to Bioinformatics: Definition and history, applications of bioinformatics, internet resources, various databases and bioinformatics tools, organization of databases.	2
2	Sequence Alignment: Sequence analysis: protein and nucleic acids, analysis tools for sequences, data bank, pairwise and multiple sequence alignment, secondary structure predictions, fold recognition, FASTA-BLAST-amino acid substitution matrices.	8
3	Projects & Databases: Structural comparisons, genome projects, biological information, database location and organization, access to database, software, database searching, locating specific entries, identity searches, similarity searches.	8
4	Information Theory & Biology: Entropy, Shannon's formula, divergences from equiprobability and independence, Markov chains, ergodic processes, redundancy, application to DNA and protein sequences.	8
5	DNA Mapping & Sequencing: Map alignment, large scale sequencing and alignment, shotgun-DNA sequencing, sequence assembly, gene predictions and molecular predictions with DNA strings.	8
6	Experts Systems: Overview of an expert system, structure of an expert systems, different types of expert systems-rule based, model based, case based and hybrid expert systems, knowledge acquisition and validation techniques, a case study: MYCIN.	6

COURSE OUTCOMES

At the end of the course, students should be able to:

1. Demonstrate the most important bioinformatics databases, perform text and sequence-based searches, and analyze the results.
2. Carry out gene and protein expression patterns and modeling cellular interactions and processes.
3. Apply bioinformatics and biological databases to solve in real research problems.

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4. Choose biological data, submission and retrieval it from databases and design databases to store the information.
5. Illustrate the impact of bioinformatics in a global, economic, environmental, and societal context.
6. Design and develop expert system for real world problems.

Text/Reference Books:

1. Sillince JA, Sillince M, "Molecular databases for protein sequence and structure studies", springer Verlag, 1991.
2. M. Gribskov, J. Devereux, "Sequence Analysis primer "Stockton Press, 1989.
3. S.L.Seizberg, DB Searls,S.Kasif, "Computational Methods in Mol.Biol./Now Comprehensive Biochemistry", Vol.32. Elsevier 1998.
4. R.F.Doolittle, "Computer methods for macromolecular analysis-Methods in Enzymology", Vol.266, Academic Press 1996.
5. L.I. Garfield, "Information theory&living systems" Columbia UniversityPress,1992.
6. Dan Gusfield, "Algorithms on Strings Trees and Sequences", CambridgeUniversity Press, 1997.
7. P.Baldi,SBrunak, Bioinformatics; "A Machine Learning Approach", MIT Press, 1998.

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Name of the Course	QUALITY CONTROL & REGULATORY ASPECTS OF MEDICAL DEVICES
Course Code: OE-BME801	Semester: Eighth
L-T-P-C: 3-0-0-3	Contact: 3 hrs/week
Objectives:	
1	To know the various quality standards and regulatory guidance used in healthcare.
2	To impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices.
3	To make them understand the regulations of Food and Drug Administration.
4	To give sufficient knowledge about the legal and regulatory requirements for medical devices.
5	To know the regulatory requirements for approval of medical devices in regulated countries.
Pre-Requisite: Biomedical Instrumentation, Analytical & Diagnostic Equipment, Therapeutic Equipment & Implants, Imaging Instruments, Principles of management.	

M #	Content	Hrs
1	Quality Management & Assurance System: Need for ISO 9000 and other quality systems, ISO 9000:2000 quality system-elements, implementation of quality system, quality auditing, need for accreditation of hospitals, NABH, NABL.	6
2	Classification of Medical Devices: Introduction, definition, risk based classification and essential principles of medical devices and IVDs, differentiating medical devices IVDs and combination products from that of pharmaceuticals, product lifecycle of medical devices and classification of medical devices.	7
3	Regulation of Medical Devices: FDA regulations, history of medical device regulation, regulatory approval process for medical devices (Medical Device Directive, Active Implantable Medical Device Directive) and in-vitro diagnostics (In Vitro Diagnostics Directive), CE certification process, basics of in-vitro diagnostics, classification and approval process.	8
4	Quality System Regulation & Ethics: Quality system regulations of medical devices: ISO 13485, quality risk management of medical devices: ISO 14971, validation and verification of medical device, adverse event reporting of medical device, clinical investigation of medical devices, clinical investigation plan for medical devices, good clinical practice for clinical investigation of medical devices (ISO 14155:2011).	9
5	Regulation in Emerging Market & Regulated Market: Applicable regulations, regulatory registration procedure, guidelines and standards for regulatory filing of medical devices, data requirement for market authorization, advertising, labeling and packaging.	4
6	IMDRF/GHTF: Introduction, organizational structure, purpose and functions, regulatory guidelines, working groups, summary technical document (STED),	6

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	global medical device nomenclature (GMDN).	
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COURSE OUTCOMES

At the end of the course, students should be able to:

1. Examine the broad scope of the medical device industry and its quality assurance practices.
2. Explain the basics of medical devices and process of development.
3. Demonstrate the regulatory requirements for approval of medical devices.
4. Harmonize the initiatives for quality and ethical considerations for medical devices.
5. Conduct clinical evaluation and investigation for medical devices.
6. Propose procedures for approval and marketing of medical devices.

Text/Reference Books:

1. Douglas J. Pisano, David Mantus, "FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics".
2. Jonathan S. Kahan, "Medical Device Development: A Regulatory Overview".
3. John J. Tobin, Gary Walsh, "Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, and Medical Devices".
4. Carmen Medina, "Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics".
5. Webster J.G, Albert M. Cook, "Clinical Engineering, Principles & Practices", Prentice Hall Inc., Englewoodcliffs, New Jersey, 1979.
6. S. Amato, B. Ezzell, "Regulatory Affairs for Biomaterials and Medical Devices", Woodhead Publishing
7. Shayne C. Gad, "Safety Evaluation of Pharmaceuticals and Medical Devices: International Regulatory Guidelines", Springer.
8. Country Specific Guidelines from official websites.

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Name of the Course	DESIGN CONCEPT & MAINTENANCE OF BIOMEDICAL INSTRUMENTS
Course Code: OE-BME802	Semester: Eighth
L-T-P-C: 3-0-0-3	Contact: 3 hrs/week
Objectives:	
1	To understand about basic design processes of medical device.
2	To introduce with basics of design, construction and development devices.
3	To familiarize with the application and troubleshooting, maintenance and repairing of medical instruments.
Pre-Requisite: Biomedical Instrumentation, Medical Equipment & Imaging Instruments, Knowledge of biomaterials and Management.	

M #	Content	Hrs
1	Introduction to Design Process: Needs finding, problem identification, prior art searches, strategy and concept generation, estimation, sketching, sketch modeling, machine elements, ergonomics and prototyping.	4
2	Design of Medical Devices & System: Medical device classification, bioethics and privacy, biocompatibility and sterilization techniques, design of clinical trials, design control and regulatory requirements, introduction to specific medical technologies: biopotentials measurement (EMG, EOG, ECG, EEG), medical diagnostics (In-vitro diagnostics), medical diagnostics (Imaging), minimally invasive devices, surgical tools and implants.	10
3	Medical Instruments Troubleshooting & Testing: AC, DC power supply, grounding, shielding, guarding, insulation testing, insulation resistance measurement, testing of electronic components, troubleshooting of PCB boards, calibration of analog and digital sensor probe, display interface, safe electrical practice, cables and standard, fuse, transformer testing, CT and PT, Panel wiring, troubleshooting of X-ray machines, troubleshooting of ECG recorders.,	10
4	Maintenance of Medical Instruments: BP apparatus, suction machine, microscope, ECG machines, pulse oximeter, patient monitor, X-ray machine, ultrasound machine, ventilator, dialyser, heart lung machine, surgical lights, incubator, baby warmer, infusion pumps, annual maintenance, contract requirements, vendor services, quality and safety standards.	10
5	Maintenance of PC Based Medical Instruments: Introduction to PC based medical instruments, system configuration and BIOS, identification and troubleshooting of PC components: motherboard, HDD, FDD, CD-ROM, monitor, printers, modems, ports etc.	6

COURSE OUTCOMES

At the end of the course, students should be able to:

1. Perform needs finding and generate design requirements for medical instruments.
2. Utilize fundamental design principles, machine elements, manufacturing and assembly techniques.
3. Perform risk assessment for prototyping and countermeasure development.
4. Appreciate the need for grounding aspects, maintenance and troubleshooting.

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5. Identify the reasons for equipment failure and formulate solution.
6. Conduct investigation and analyze the data sheets for performance measurement of biomedical instruments.

Text/Reference Books:

1. Paul H. King, Richard C. Fries, Arthur T. Johnson, "Design of Biomedical Devices and Systems", Third Edition, ISBN 9781466569133.
2. John G. Webster (ed), "Medical Instrumentation: Application and Design", 2007.
3. Peter J. Ogradnik, "Medical Device Design: Innovation from Concept to Market", Academic Press Inc; 1 edition (2012), ISBN-10: 0123919428.
4. Stefanos Zenios, Josh Makower, Paul Yock, Todd J. Brinton, Uday N. Kumar, Lyn Denend, Thomas M. Krummel, "Biodesign: The Process of Innovating Medical Technologies", Cambridge University Press; 1 edition (2009), ISBN-10: 0521517427.
5. Medical Equipment Maintenance Manual, Ministry of Health and Family Welfare, New Delhi, 2010.
6. Shakti Chatterjee, Aubert Miller, "Biomedical Equipment Repair", Cengage Learning Technology & Engineering, 2010.
7. David Herres, "Troubleshooting and Repairing Commercial Electrical Equipment", McGrawHill, Professional edition, 2013.
8. L. Nokes, B. Turton, D. Jennings, T. Flint, "Introduction to Medical Electronics Applications", A Butterworth Heinemann Title. 1995.
9. Joseph F. Dyro, "Clinical engineering handbook, Elsevier Academic Press, 2004.

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Name of the Course	VIRTUAL INSTRUMENTATION DESIGN FOR MEDICAL SYSTEM
Course Code: OE-BME803	Semester: Eighth
L-T-P-C: 3-0-0-3	Contact: 3 hrs/week
Objectives:	
1	To impart knowledge on the concepts of virtual instrumentation (VI).
2	To understand the programming concepts of VI and insight to various Common Instrument Interface.
3	To familiarize with the data acquisition system and analyzing tools for medical applications.
Pre-Requisite: Engineering Physiology& Anatomy (PC-BME302), Mathematics-III (BS-M301), Biomedical Instrumentation (PC-BME402)	

M #	Content	Hrs
1	Introduction to Virtual Instrumentation (VI): Historical perspective of VI, architecture and block diagram, comparison of VI with traditional instruments, need of VI, advantages, data flow techniques, graphical programming in data flow, comparison between graphical programming and conventional programming.	6
2	Programming Techniques: VIS and sub-VIS, loops and charts, arrays, clusters and graphs, case and sequence structures, formula nodes, local and global variables, strings, tables, file I/O functions, 2D and 3D plots, instrument drivers, publishing measurement data in the web.	9
3	Data Acquisition Basics: Introduction to data acquisition on PC, sampling fundamentals, I/O techniques and buses. ADC, DAC, digital I/O, counters and timers, DMA, software and hardware installation, calibration, resolution, data acquisition interface requirements.	9
4	Common Instrument Interface: Common instrument interfaces: Current loop, RS 232C/ RS485, GPIB. Bus Interfaces: USB, PCMCIA, VXI, SCSI, PCI, PXI, Firewire, PXI system controllers, Ethernet control of PXI. Networking basics for office & Industrial applications, VISA and IVI.	9
5	Analysis Tools and Designing for Medical Applications: Fourier transform, power spectrum, correlation, windowing, filtering, oscilloscope, waveform generator, Multi-channel data acquisition using LABVIEW, Medical applications: ECG, EMG, Air Flow and Lung Volume, HR variability analysis, noninvasive BP measurement.	7

COURSE OUTCOMES

At the end of the course, students should be able to:

1. Explain applications of mathematical modelling for designing virtual instrument.
2. Relate fundamental physiological properties with virtual biomedical instruments.
3. Demonstrate advanced analysis capabilities that explore potential research topics.
4. Demonstrate clinical utilization of virtual biomedical instrumentation.
5. Categorise functions related to medical device development and tests.
6. Design and implement data acquisition system with PC interfacing.

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Text/Reference Books:

1. Stephan Bennett, Emagic Logic Virtual Instruments, PC Publishing 2003.
2. Anand M M S, Electronic Instruments and Instrumentation Technology, PHI Publishers, 2007.
3. Gary Jonson, "Labview Graphical Programming", McGraw Hill, New York, Fourth edition 2006.
4. Lisa K. Wells, Jeffrey Travis, "Labview for everyone", Prentice Hall Inc., New Jersey; First edition 1997.
5. Gupta S, Gupta J P, "PC interfacing for Data Acquisition & Process Control", Instrument Society of America, Second Edition, 1994
6. K. James, PC Interfacing and Data Acquisition: Techniques for Measurement Instrumentation and Control, Newness, 2000.
7. Sokoloff, Basic Concepts of Labview, Prentice Hall, New Jersey.
8. Technical Manuals for DAS Modules of Advantech and National Instruments

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Name of the Course	DESIGN LAB / INDUSTRIAL PROBLEM RELATED PRACTICAL TRAINING
Course Code: PROJ-BME891	Semester: Eighth
L-T-P-C: 0-0-4-2	Contact: 4 hrs/week
Objectives:	
1	To understand requirement of engineering for new product development and convert them in to design specification.
2	To understand system modeling for system, sub-system and their interfaces and arrive at the optimum system specification and characteristics.
3	To conceptualize, prototype and develop product management plan for a new product and development methodology integrating the hardware, software, controls, electronics and mechanical systems.
4	To understand the global trends and development methodologies of various types of products and services.

GUIDELINES:

- Carry out a comprehensive work on the chosen topic which will stand them in good stead as they face real life situation.
- Convert innovative ideas into working models /systems using all the concepts learnt and use suitable modern tools.
- Take up any challenging practical problems and find solution by formulating proper methodology.
- Expected to exert on design, development and testing of the proposed work.
- Industry related problems are highly encouraged and assess its impact.

COURSE OUTCOMES

At the end of the course, students should be able to:

1. Develop a model or simulation or prototype using industry best practices and tools.
2. Design a medical electronic circuits starting with a given specifications.
3. Solve a specific problem right from its identification till the successful solution of the same.
4. Formulate a real world problem, identify the requirement and develop the design solutions.

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Name of the Course	PROJECT-II
Course Code: PROJ-BME881	Semester: Eighth
L-T-P-C: 0-0-12-6	Contact: 12 hrs/week
Objectives:	
1	To estimate the ability of the student in transforming the theoretical knowledge studied so far into a working model
2	To teach use of new tools, algorithms and techniques required to carry out the projects.
3	To give guidance on the various procedures for validation of the product and analyze the cost effectiveness.
4	To train the students in preparing project reports and to face reviews and viva voce examination.

GUIDELINES:

- The project topics are decided in Phase-1 and the project work is to be carried out in group of 3 or 4.
- Industry projects are encouraged and promoted.
- Submit a report showing the design and implementation along with the literature survey.
- project work is evaluated based on oral presentation and the project report jointly by external and internal examiners

COURSE OUTCOMES

At the end of the course, students should be able to:

1. Prepare a comprehensive technical project report and communicate with engineers and the community at large.
2. Utilize the new tools, algorithms, techniques that contribute to obtain the solution of the project.
3. Test and validate through conformance of the developed prototype and analyze the cost effectiveness.
4. Work independently as well as in teams and manage a project from start to finish.

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Name of the Course	GRAND VIVA-VOCE
Course Code: BME882	Semester: Eighth
L-T-P-C: 0-0-0-1	Contact: NIL
Objectives:	
1	To assess comprehensive knowledge on all courses in under graduate program in Biomedical Engineering.
2	To judge the basic concepts of core courses and techniques applicable to their own area of professional practice.
3	To evaluate knowledge and ideas gained in real world problems and issues relevant to the field.
4	To prepare the students to face interview both at the academic and the industrial sector.

GUIDELINES:

- Viva voce will be conducted at the end of the programme.
- Involvement of external experts is highly appreciated.
- Assessment should be in cognitive, affective and psychomotor domain of learning.

COURSE OUTCOMES

At the end of the course, students should be able to:

1. Explore their field of knowledge, which includes a critical awareness of current problems and/or new insights at the forefront of that field.
2. Demonstrate confidence and versatility in answering the varieties of questions posed by a group of faculty members in a moderately short duration.
3. Demonstrate self-direction and originality in tackling and solving problems, and act autonomously in planning and implementing tasks at a professional or equivalent level.
4. Demonstrate originality in the application of knowledge, together with a practical understanding of how established techniques professional enquiries are used to create and interpret knowledge in their discipline.

Special Remarks:

The above mentioned outcomes are not limited. Institute may redefine course outcomes based on their Program Educational Objectives (PEOs).