BHARATHIAR UNIVERSITY –COIMBATORE–641046
M.PHIL./PH.D.– Medical Textiles

Eligibility for Medical Textile Research Program

Post graduate degree in the areas of

1. Textile sciences/Engineering/Technology (such as Textile Technology, Textile Engineering and Bio Textiles)
2. Life sciences/Engineering/Technology (such as Biotechnology, Biochemistry, Molecular Biology, Microbiology and Nanotechnology)
3. Physical sciences/Engineering/Technology (such as Physics, Medical physics)
4. Chemical sciences/Engineering/Technology (such as Chemistry, Chemical engineering, Polymer chemistry and Polymer science and technology)
5. Medical science (such as Medicine and Pharmaceutical).

PART -1 SYLLABUS (Effective from the academic year 2014-2015 onwards)

Paper I - Research Methodology

Paper II- Research trends in Medical Textiles

Paper III – 1. Textiles for Healthcare

2. Biocompatible materials for Medical Textiles
3. Advanced Textiles for Wound Care
4. Tissue Engineering
5. Implantable Medical Devices

PAPER I - RESEARCH METHODOLOGY

Unit I: Introduction to Research Methodology

What is research? Basic and applied research, Essential steps in research, Defining the research problem, Research/Experimental design, Literature collection, Literature citation, Research report: components, Format of thesis and dissertation, Manuscript/research article, Review monographs, Bibliography and Reference, Significance of research. Design of Experiments – basic designs - CRD, RBD & LSD & examples. Factorial Experiments.

Biostatistics: in medical product regulations, applications and uses of bio statistics as a Science, as figures; Scope and common statistical terms. Clinical trials: types, bias in clinical studies; study design – phases of clinical trials, approaches to data analysis of randomized trials. Regulatory process – clinical trial protocol implementation, source documents, data entry, standard operating procedure development. Statistical methods in clinical study design – basics.

Unit II: General Instrumentation

Bio molecule analysis:

Spectroscopy: UV-Visible, FT-IR, NMR, ESR, FES, AAS, Fluorescence and Mass spectroscopy

Chromatography: Column, paper, TLC, HPTLC, ion exchange, size exclusion, gas chromatography, GC-MS, HPLC, LC-MS, LC/MS/MS and affinity chromatography, Thermal methods: TGA, DSC

Others: X-ray diffraction, Dynamic light scattering, surface plasma resonance methods, optical and electron microscopes

Unit III: Anatomy, Physiology and pharmacology of human system - Basics

Biomechanics of human system - Human Anatomy - Definitions, planes of the body, organ system, optometry. Tissues of the body - epithelium, connective tissue, bone and cartilage. Cell types and their arrangements. Physiology – Cell structure, body fluid compartments, Homeostasis, transport across cell membrane, neuromuscular junction and muscle contraction. Blood – composition and function of blood, erythropoiesis, anaemia, polycythemia, blood coagulation, plasma proteins, blood groups including Rh. Physiology of organ system – basics.

Pharmacology- Definition of terms -Sources of drugs with examples - plants, animals, minerals, synthetic, micro-organisms and genetic engineering. Different routes of drug administration – basics. Adverse drug reactions - Classification, side effects, secondary effects, intolerance, idiosyncrasy, drug allergy, photosensitivity, drug toxicity. Drug interactions - pharmacological basis, clinical significance. Bioassay - Definition, principles of bioassay and types of bioassay. Drugs acting on different systems – basics.

Unit IV: General Microbiology and Immunology

Microbiology – classification of medically important microorganisms. Normal flora of human body. Properties of pathogenic microorganisms. Factors influencing pathogenicity. Implant infections - types, source and different modes of infections. Clinical manisfestations and implications of infected implant and its diagnosis. Different methods of sterilization.

Immunology: Infection, immunity, types of immunity – innate and adaptive. Humoral and cell-mediated immune response; phagocytosis. Cells and organs of immune system – primary and secondary. Immune reactive cells – T and B lymphocytes, macrophages, granulocyte and NK cells. Organ rejection, tissue compatibility, allergic reactions to foreign materials.

Unit V: Medical device regulation, bioethics and intellectual property rights (IPR).

Critical elements for medical device regulation, Post-market surveillance/vigilance, Quality system requirements. BIS, ISI, FDA, CE, EU certificates, Drugs and cosmetics act, Medical Devices regulation act.

Bioethics and intellectual property (IP): Animal and clinical trials for the biological evaluation of medical devices. Ethical issues in animal experimentation and clinical trials for medical devices, composition of (animal/human) institutional ethical committee (IEC) – general ethical issues. Social and ethical implications of biological weapons. IP – types, patents, trademarks, copyright and related rights, Industrial Design, Traditional Knowledge, Geographical Indications. International framework for the protection of IP.

References

1. Kothari, C.R. (2004) Research methodology, Methods and techniques, New Age Internation (P) Ltd, 2nd edition, New Delhi.
2. Sharma, B.K, (2005) Instrumental methods of chemical analysis. 4th revised & enlarged edition, GOEL publishing house, Meerut.
3. Khandpu, R.S, (2003) Handbook of biomedical instrumentation, 2nd edition, Tata McGraw Hill, Punjab.
4. Guyton and Hall (2011) Textbook of Medical Physiology, 12th edition, Saunders Elsevier, Philadelphia, PA, USA.
5. Satoskar, R.S., Bhandarkar, S.D. and Ainapure, S.S. (2005) Pharmacology and Pharmacothrapeutics, Popular Prakashan, 18th edition, Mumbai.
6. Tripathi, K.D. (2008) Essentials of Medical Pharmacology, 6th edition, Jaypee publications, New Delhi.
7. CPCSEA guidelines for laboratory animal facility (CPCSEA) - No.13 Seaward road, Valmiki Nagar, Chennai.
8. Ethical guidelines for biomedical research on human subjects, 2006. ICMR, New Delhi.

PAPER II - RESEARCH TRENDS IN MEDICAL TEXTILES

Unit I: Medical Textile Science

Medical textiles – An overview, classification: Implants, Non implants, Extra corporeal, Health care and hygiene, Medical textile products and processes. Testing methods and international standards.

Unit II: Materials for Medical Textiles: Introduction to materials. Classification of biomaterials – metallic, ceramic. Polymers in biomedical use – natural and synthetic, biodegradable synthetic polymers. Biodegradable nanospheres. Polymer sterilization. Electro conductive polymeric fibers. Bio textile product development. Production of bio textile under GMP conditions.

Unit III: Smart Medical Textiles

Biomedical sensing. Films, coatings, adhesives, polymers and stimuli responsive materials. Smart polymers for Biotechnology and Protective clothing. Intelligent chemical indicators. Implantable sensors for long-term monitoring; Application of phase change and shape memory materials in medical textiles. Micro electro mechanical system (MEMS) based medical textiles.

Unit IV: Medical textiles applications

Textiles in drug delivery. Antimicrobial textiles. Chitosan based gels and hydro gels in biomedical and pharmaceutical sciences. Intelligent garments for pre-hospital emergency care, smart medical textiles in rehabilitation, monitoring pregnancy, heart patients, and children in hospital. Wearable assistants for mobile health monitoring.

Unit V: Tissue Engineering

Tissue engineering - basics, textiles in tissue engineering, textiles for tissue scaffolds, culture types, general aspects of cells in culture, Biology and characterization of cultured cells; transport limits in 3D culture.

References

1. Van Langenhove, L. (2007), Smart textiles for medicine and healthcare, Wood head publishing Ltd, UK.
2. Cass A.E.G and Cooper, J.M. (2004), Biosensors: a practical approach, 2nd edition, Oxford University Press, New York.
3. Eggins, B.R (2002), Chemical Sensors and Biosensors, John Willey & Sons, Wiley publications, England.
4. Mel Schwartz, (2009), Smart materials, CRC press, USA.
5. Lakes RS, (2000), Composite Biomaterials in The Biomedical Engineering Handbook , ed. J. D. Bronzino, CRC Press, Second Edition, Boca Raton, FL.
6. Enderle, J, Blanchard, S and Bronzino, J. (2005) Introduction to Biomedical Engineering, 2nd Edition, Academic Press series in Biomedical Engineering, USA.

PAPER III
1. TEXTILES FOR HEALTH CARE

Unit I: Medical Textiles – An overview.

Medical Textiles – basics, fibres used, classification. Biomaterials in medical textiles. Textile fibres and yarn – introduction, classification, chemical and physical properties. Manufacturing process – fibre and yarn. International standards. Fabric structures: Woven, Knitted, non-woven fabrics. Finishing, coating and coloration of Technical textiles – basics.

Unit II: Implants and Non-implants

Implants and Non-implants: lists, textile material involved, evaluation techniques and standards. Preclinical testing of implants for safety and efficacy - including risk/benefit ratio assessment, evaluation of clinical performance and design of clinical trials. Tissue and organ regeneration. Bandaging, pressure garments and wound care materials – basic manufacturing process and evaluation methods. Specially designed adhesive and non-adhesive patches for post operative surgical application. Infection preventive products.

Unit III: Extracorporeal devices, health care and hygiene products.

Extracorporeal devices – Artificial kidney, liver, lungs, pacemakers, pancreas, skin, the ear, the nose, the eye – materials, function, evaluation techniques. Hollow fibre application in extracorporeal devices. Biological behavior - Biocompatibility, cytotoxicity, immune response. Health care and hygiene products: An overview, application of nonwovens in healthcare and hygiene sector. Manufacturing process, testing and validation methods. Standards. Medical textiles in infection control.

Unit IV: Intelligent textiles for medical applications

Intelligent textiles for emergency care, rehabilitation, monitoring hospital environment, stress level, heart patients, children. Materials involved. Slow and sustained release of drugs.

Unit V: Advanced technologies and instrumentations for Medical Textiles

Electro spinning, Plasma technology, Micro/nano encapsulation, Thin film technology, Ultrasonic sealing, Laser technology, Molecular Imprinting technology. Modeling methods of physiological system for medical textiles – basics. 3D printing of tissues and organs.

Instruments/equipments for the evaluation of medical textile products - implantable devices, wound and surgical dressings, health care and hygiene products. Rapid prototyping. 3D textile structures. Medical textile standards. Data analysis and interpretation.

References

1. Horrocks, A.R and Anand S.C, (2000), Handbook of Technical Textiles, Woodhead publishing Ltd, UK.
2. Anand, S.C, Kennedy, J.F, Miraftab, M and Rajendran S. (2010), Medical and healthcare textiles, 2.6th edition. Woodhead publishing Ltd, UK.
3. Anand, S.C, Traftab, M.M, and Rajendran, S, (2005), Medical Textiles & Biomaterial for Healthcare, Woodhead publishing Ltd, UK.
4. Deborah Chung D.L. (2004), Composite Materials: Science and Applications, Springer International, USA.
5. Goswami, A. (2006), Thin Film Fundamentals, New Age International (P) Ltd, New Delhi.
6. Chen, F.F. (2006), Introduction to Plasma Physics and Controlled Fusion, Springer Publications, USA.

2. BIOCOMPATIBLE MATERIALS FOR MEDICAL TEXTILES

Unit I: Introduction to biomaterials

Biomaterials utilized in medical textiles – an overview. Definition and classification of biomaterials, Structure of biomaterials, Mechanical properties - Elastic behavior, Stress and Strain, Tension and Compression, Shear, Isotropy -Fatigue- Toughness - Effect of Fabrication on Strength.

Unit II: Metallic and ceramic biomaterials

Metallic Biomaterials: Types, medical applications, Characteristics and Properties, Metallic corrosion. Biological tolerance. Ceramic Biomaterials: Relatively bioinert bioceramics. Biodegradable ceramics. Surface reactive or bioactive ceramics. Ceramic surface analysis. Deterioration of ceramics. Characteristics and Properties. Manufacturing technique. Limitations of biomaterials.

Unit III: Biopolymers and nanocomposites

Biopolymers: Polymers in biomedical use – overview, Natural (Chitosan, Alginate, Collagen, etc), Synthetic (PEEK, PMMA, PLA, PLGA, PSU, PU, PVDF, PECA, PAC, etc), Biodegradable Synthetic polymers. Silicone rubber. Plasma polymerization. Polymer sterilization. Biodegradable nanospheres, Cellulose capsules – an alternative to gelatine, Hydrogels in controlled release of drugs and proteins. Liposomes, Poly (lactic acid)-grafted polysaccharides as biodegradable amphiphilic materials, Haemocompatible nanocoatings - preparation and surface analysis, Phospholipid based polymers, heparin/heparan derivatives and coating methods on medical devices. Limitations of biomaterials.

Nanocomposites - Structure – Properties- composite materials, Particulate composite materials, Fiber reinforced composite materials, Porous composites, Biocompatibility, Toxicity.

Unit IV: Tissue derived biomaterials

Tissue derived biomaterials- types - Structure and properties, Isolation, Purification and matrix fabrication technology - Design of biomaterials based medical implants. Cell-Biomaterials interactions at micro and nanoscale. Cell adhesion and migration on biomaterials - Adhesion receptors in tissue structures. Effect of biomaterial on physiological behavior-mammalian cell migration-characteristics - regulation of cell movement-cell migration assays. Host reactions to biomaterials and their evaluation- inflammation, foreign body response- hypersensitivity – toxicity - blood material interactions - tumorigenesis - biomaterials-infections-other immunological reactions.

Unit V: Biomaterial characterization and biological evaluation

Characterization of biomaterials – physical and chemical properties: elasticity, yield stress, toughness, strength, hardness, microstructure, deformation, thermal and optical properties. Surface analysis techniques: overview of principles and methods. Test in simulated and natural body fluids- Elements in contact with the surface of a biomaterial: short and long term reactions to the body- Testing of biomaterials: *in vitro, in vivo* and clinical tests.

References

1. Anand, S.C., Traftab, M.M., and Rajendran, S. (2010), Medical Textiles & Biomaterial for Healthcare, Woodhead publishing Ltd, UK.
2. Shoseyov, O. and Levy, I. (2008), Nanobiotechnology-Bio Inspired Devices and Materials of the Future, Humana Press Inc, Totowa, NJ.
3. Nicolini, C., (2009), Nanobiotechnology & Nanobiosciences, Pan Stanford Publishing Pvt. Ltd, Singapore.
4. Ian Freshney, R. (2011), Culture of Animal Cells: A manual of basic Techniques, 6th edition. Wiley publications.
5. Emo Chiellini, (2001), Biomedical polymers and polymer therapeutics, 2001 edition, Springer publication.
6. Sujata V.B, (2002), Biomaterials, Narosa Publishing House, New Delhi.
7. Chu, P.K, Chen, JY, Wanga, L.P. and Huang, N. (2002), Plasma-surface modification of biomaterials. Materials Science and Engineering, USA.

3. ADVANCED TEXTILES FOR WOUND CARE

Unit I: W**ound management and dressings**

Wound – an overview, classification, pathophysiology, principles of macro and micro vascular circulation. Overview of involved growth factors in wound healing, factors affecting wound healing – local and systemic factors; complications of wound healing, Scar modification, Diagnostic images in wound care.

Unit II: Wound assessment, textile materials and structures for wound care products.

Wound assessment – different models; wound bed, wound measurement, exudates, infection, pain and wound cleansing. Treatment strategies – surgical options for wound care, hyperbaric oxygen therapy – principle and management. Dressings and bandages used in different types of wounds - materials and textile processes involved; Interactive wound dressings and their role in moist wound management; applications and limitations in wound healing. Future trends.

Unit III: Bioactive dressings to promote wound healing

Introduction - principles and roles of bioactive dressings; types and structures of bioactive dressings - examples of bioactive dressings: di-O-butyrylchitin (DBC). Bioactive dressings for drug delivery, applications and limitations of current drug delivery systems. Future trends.

Unit IV: Advanced textiles for wound compression

Compression stockings, biomechanical factors for designing compression devices, dynamic characteristics of compression devices. Elastic compression bandages, venous leg ulcers and their treatment, compression therapy with gradient pressure, bandaging system, bandage characteristics and its applications, 3D spacer compression bandages, evaluation of bandages. Contraindications/risks associated with compression therapy. Antimicrobial textile dressings in managing wound infection – microbial infection and wound bed pH, systemic and topical antimicrobials with examples and mode of action. Novel textiles for the management of burn

wounds, chronic leg ulcers of normal and diseased eg: pressure and diabetes. Role of low adherent and odour adsorbing dressings in the management of infected wounds.

Unit V: Smart textiles for wound care

Basic principles, types and characteristics of smart textiles - textiles to control exudates. Response of dressings to bacteria. Composite dressings for wound care - structure of composite dressings; materials and textile structures. Types and trends in composite dressings: embroidery technology. Textile based scaffolds for tissue engineering.

References

1. Surgical Royal Colleges of Great Britain, (2008), Intercollegiate MRCS examination indicative syllabus.
2. Hardman, Joel G., and Lee E. Limbird, eds, Alfred Goodman Gilman, consulting editor. Goodman and Gilman's, (2001), The Pharmacological Basis of Therapeutics, 10th edition, McGraw-Hill, New York.
3. Hernandez, M.A and Rathinavelu A. (2006), Basic pharmacology: Understanding drug action and reactions, CRC press, NW.
4. Ohio University College of Osteopathic Medicine, Centers for Osteopathic Research and Education, 2008. Wound care syllabus.
5. Rajendran, S, (2009), Advanced textiles for wound care, 1st edition, Woodhead pubilishing Ltd, UK.
6. Rajendran, S and Anand, C.S., (2002), Developments in Medical Textiles, Textile progress, woodhead pubilishing Ltd, UK.

4. TISSUE ENGINEERING

Unit I: Basics of tissue engineering

Introduction to tissue culture: culture media; Serum and protein free defined media and their applications. Balanced salt solutions and simple growth medium: Physical, Chemical and Metabolic functions of different constituents of culture medium; Role of carbon dioxide, serum, growth factors, glutamine in cell culture; Structure and organization of tissues – epithelial, connective; vascularity, lymph. Basic developmental biology – transport properties of tissues.

Unit II: Cell and Tissue Engineering

Techniques of cell and tissue culture. Isolation, selection and maintenance of primary and early passage cultures; organ culture and 3D culture, feeder layers, cell synchronization, transport limits in 3D cultures, Biology and characterization of cultured cells: Cell-Matrix & Cell-Cell Interactions – cell growth and death measurement parameters, cryopreservation. Differential cell adhesion and tissue organization – hormone and growth factor signaling – growth factor delivery in tissue engineering.

Unit III: Biomaterials for tissue engineering

Tissue Engineering: Principles; biomaterials in tissue engineering; Biomaterials-Tissue Interactions: The principles of materials science and cell biology. Natural and Synthetic polymers. Hydrogels based on N—isopropylacrylamide and biodegradable bioceramics. Biomaterials surface characterization methods and protein adsorption analysis. Molecular and cellular interactions with biomaterials in terms of unit cell processes, such as matrix by synthesis, degradation, and contraction. Applications: artificial organs - Tissue and Organ regeneration. Mechanisms underlying wound healing and tissue remodeling following implantation in various organs.

Unit IV: Stem cells

Stem cells: characteristics and classification; stem cell niche; Embryonic and adult stem cells; HSC, MSC, NSC, UCBS cells, iPS cells. Ectodermal cells - skin and nervous system. Mesodermal cells - muscles, bones, heart and blood vessels. Stem cell culture. Stem cell markers. Cell adhesion theory. Effect of biomaterial on physiological behavior. Introduction to cell characteristics, regulation, assays, mathematical models for cell migration and tissue growth. Stem cell banking. Therapeutic applications. Ethical issues in stem cell research and tissue engineering.

Unit V: Scaffold design and fabrication for tissue engineering

Materials used, Scaffold processing methods: Solvent casting, membrane lamination, freeze-drying, polymer-ceramic composite forms, phase separation, gas foam processing. Microencapsulation methods: Agarose - PSS a (polystyrene sulfonic acid), alginate (Ca^{2+} - Induced gelation). Textiles used for tissue scaffolds and scaffold fabrication. Relationship between textile architecture and cell behavior. Tissue repair. Skin grafts. Connective tissue grafts. Bulk space fillers, maxillofacial implants, fluid transfer implants. Transplantation immunology - basics. Recent development in scaffold fabrication.

References

1. Freshney, R.I, (1992), Animal cell culture; A practical approach, 2nd Edition, IRL Press, Oxford, England.
2. Robert Lanza, John Gearhart, Brigid Hogan, (2009), Essentials of stem biology, Academic Press, USA.
3. Saltzmann, W. M, (2002), Tissue Engineering: Engineering principles for the design of replacement organs and tissues, In preparation for Oxford University Press, UK.
4. Anand, S.C., Traftab, M.M., Rajendran, S. (2010), Medical Textiles & Biomaterial for Healthcare, Woodhead Publicating Ltd, UK.

5. IMPLANTABLE MEDICAL DEVICES

Unit I: Introduction to implantable medical devices

Implantable medical devices (IMD) - Introduction to the design and materials for implantable medical devices, classification. Types – soft tissue and hard tissue implants, methods of introduction and implementation; features, advantages and limitations.

Unit II: Sutures – design, development and evaluation

Suture – Types – Biodegradable - material involved - Collagen, polylactide, polyglycolide etc, Non biodegradable suture – material involved - Polyamide, Polyester, Polypropylene, PTFE etc. Barbed Sutures, suture-tissue interaction; suture free systems, recent developments, advancements and limitations.

Unit III: Class III devices – design, development and evaluation

Vascular implants – types, materials involved, limitations

Artificial heart: raw materials and technology adopted, characteristics. Heart patch - textile material, manufacturing process and characterization. Limitations.

Nerve implants: Function of nervous system, nerve generation, nerve grafting, material used in nerve generation, resorbable artificial nerve graft, Hernia mesh – classification, non absorbable and synthetic material, Selection of mesh material.

Unit IV: Class III devices – design, development and evaluation

Orthopeadic implants – column, hip, knee – materials involved – implant kinematics, stability and fixing. Artificial ligaments and tendons: Introduction, raw materials and technology used. characteristics. Artificial joints: Introduction, manufacturing technology. Artificial skin manufacturing technology. Advantages and limitations

Unit V: Class III devices and IMD characterization

Joint replacement and Oral implants: textile material involved and manufacturing technologies. Biological effect – *in vitro, in vivo* preclinical, *in vivo* clinical studies. Procedures for marketing a device – regulatory authorities involved, export and import permission/license. Legal requirements, risks involved with non compatibility of implantation.

Reference

1. Anand, S.C., Traftab, M.M. and Rajendran, S. (2010), Medical Textiles & Biomaterial for Healthcare, Woodhead Publication, UK.
2. Sujata V Bhat, (2002), Biomaterials, Narosa Publishing House, New Delhi.
3. Hench, L, Jones, J. (2005), Biomaterials, artificial organs and tissue engineering Woodhead Publishing, UK.