PUNJAB TECHNICAL UNIVERSITY, JALANDHAR
M. Pharm. (PHARMACEUTICS)
Scheme and Syllabus

FIRST SEMESTER

S.No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Exam. (hr)	Credit
			L	T		Int	Ext	Total		
01	PHCEU 131	Pharmacokinetics and Biopharmaceutics	4	1	3	20	80	100	3	5
02	PHCEU 133	Dosage form design, Development and Process Validation	4	1	3	20	80	100	3	5
03	PHCEU 135	Novel drug delivery systems	4	1	3	20	80	100	3	5
04	PHCEU 137	Pharmaceutics laboratory-I	-		8	20	80	100	8	5
		Total (31)	12	03	16	80	320	400		20

SECOND SEMESTER

S.No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Exam. (hr)	Credit
			L	T	P	Int	Ext	Total		
01	PHCEU 132	Pharmaceutical technology	4	1	-	20	80	100	3	5
02	PHCEU 134	Drug Regulatory Affairs and IPR	4	1	-	20	80	100	3	5
03	PHCEU 136	Nanotechnology & Biotechnology	4	1	-	20	80	100	3	5
04	PHCEU 138	Pharmaceutics laboratory-II	-		16	20	80	100	8	5
		Total (31)	12	03	16	80	320	400		20

THIRD AND FOURTH SEMESTER [Credit = 12]
Research Work for one year
The thesis shall be presented by the candidate at the end of record academic year. The thesis shall be evaluated as under :
Evaluation of written thesis : MM 200
Presentation of seminar on thesis and viva-voce : MM 100
Total : 300 marks
[Note : Credit System : 1 credit = 20 marks, L- Lecture – Tutorial , P – Practical]

M. PHARM. SEMESTER-I

S.No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
01	PHCEU 131	Pharmacokinetics and	4	1	-	20	80	100	5

		Biopharmaceutics							

Module 01

Compartmental pharmacokinetics :
Review of fundamentals, Terminology, Basics of kinetics of single and multiple dose administration following instantaneous and non-instantaneous routes, one and two compartment body model kinetics, limitations of compartmental analysis.

Module 02

Non-compartmental Pharmacokinetic Modeling Approach :
Merits of model-independent non-compartmental approaches, definition and significance, statistical moments, AUC, AUMC and their determination using trapezoidal and log-trapezoidal techniques, MRT and its significance in pharmacokinetics, computation of statistical moments from plasma and urine data, cut-off error, MDT, MTT, MAT, problem solving.

Module 03

Nonlinear Pharmacokinetics :
Definition, significance and applications with literature examples, recognition of non-linearity, computation of nonlinear pharmacokinetic parameters (V_m, K_m, AUC, etc.) by single Michaelis Menten kinetics.

Module 04
Clinical Pharmacokinetics :
Introduction; pharmacokinetic relationships; duration of response; kinetics of pharmacological response; explanation of clinical response via pharmacokinetics; monitoring plasma concentrations of drugs during clinical use, Therapeutic drug monitoring (TDM), turnover concepts, individualization of dosage and dosage regimen, variability, Effect of genetics, age, weight, pharmacokinetics, disease and interacting drugs, use of creatinine clearance, problem solving.

Module 05
Protein Binding :
Theory of plasma protein binding and implications, elements of Scatchard, Klotz and Rosenthal analysis for computation of binding parameters, experimental techniques to determine protein binding with their merits and limitations, factors influencing protein binding, effect of binding on drug pharmacokinetics.
Biopharmaceutics :
Review of physicochemical, pharmaceutical and physiological variables affecting drug absorption from gastrointestinal tract.

Module 06
Bioavailability and Bioequivalence Concepts :
Assessment of bioavailability from plasma and urine level data, design and analysis of bioequivalence trials, Crossover designs, bioavailability of oral and non-oral dosage forms, statistical analysis of bioavailability and bioequivalence, pharmacodynamic models, Federal perspectives.
***In vitro-In vivo* correlations (IVIVC) :**
Concepts, Biopharmaceutical Classification Scheme (BCS), varied IVIVC approaches with applications and limitations, dissolution as a surrogate to bioavailability for immediate release and extended release formulations, Federal perspectives

READING MATERIAL RECOMMENDED

1. J.G. Wagner, Fundamentals of Clinical Pharmacokinetics, Drug Intelligence Publications, Hamilton, III, 1975.
2. J.G. Wagner, Pharmacokinetics for the Pharmaceutical Scientist, Technomic, Pa, 1993.
3. L. Shargel, and A. Yu, Applied Biopharmaceutics and Pharmacokinetics, Appleton and Large, Norwalk, CT, 1993.
4. M. Gibaldi and D. Perrier, Pharmacokinetics, J. Swarbrick, ed., Marcel Dekker, NY
5. M. Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics, Lea & Febiger, Philadelphia.
6. R.D.Purves, "Optimum Numerical integration methods for the estimation of area under the curve (AUC) and area under the moment curve (AUMC)". J.Pharmac. Biopharma., 20 (3), 211-226,1992.
7. P.G.Welling, F.L.S. Tse and S.V. Dighe (eds*) Pharmaceutical Bioequivalence*, Marcel Dekker Inc. New York, USA 1991.

S.No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
02	PHCEU 133	Dosage form design, Development and Process Validation	4	1	-	20	80	100	5

Module 01

Preformulation :

The Scope of Preformulation Studies: Introduction, Preformulation Testing Criteria, Regulatory Requirements, Testing Systems, Solid-State Characterization, Transport Across Biological Membranes

Dissociation, Partitioning and Solubility: Introduction, The Ionization Principle, Quantitative Structure–Activity Relationships, Partitioning, Measurement Strategies
Release, Dissolution, and Permeation: Introduction, Release, Assay Systems, The Biopharmaceutics Drug Classification Systems

Solid-State Properties: Introduction, Crystal Morphology, Polymorphism, High-Throughput Crystal Screening, Solvates, Hydrates, Amorphous Forms,Hygroscopicity, Solubility, Study Methods
Dosage Form Considerations in Preformulation: Introduction, Solid Dosage Form Considerations, Solution Formulations, Emulsion Formulations, Freeze- Dried Formulations, Suspensions, Topical, Pulmonary Delivery, General Compatibility

Module 02
Chemical Drug Substance Characterization: Introduction, Scheme of Characterization, Impurities, Good Manufacturing Practice
Characterization of Biopharmaceutical Drugs: Introduction, Preformulation Studies, Packaging and Materials, Physio-Chemical Characterization Tests, Design of Preformulation Studies
Methods in material characterization
Particle dimensions: Particle size and powder surface area, Particle shape and surface morphology.
Characterization of solid state structure: Spectroscopy in pharmaceutical analysis, X-ray diffraction, Solid-state nuclear magnetic resonance, Vibrational spectroscopy, Calorimetry in pharmaceutical analysis, Thermal analysis techniques, Isothermal microcalorimetry, Water vapor sorption, Microscopy, Density measurements.

Module 03

Excipients
Excipients: General considerations of excipients used in formulations and factors governing selection.
Compatibility issues regarding excipients: drug-excipients and excipient-excipient,
excipients-package interactions, Safety and regulatory issues of excipients
Study of novel excipients:
Superdisintegrants, directly compressible and spray dried diluents, film coating materials, solubilizing agents like surfactants, Cyclic Glucose Polymers, polymeric excipients for controlled release applications, Improved excipients functionality by co processing, Standardization of excipients

Module 04
Polymers :
Polymer classification, physiochemical properties and polymer solutions. Biodegradable and Nonbiodegradable polymers. Application of polymers in controlled release of drugs, transport of small molecules in polymers, ionic polymers as drug carriers.

Module 05

Advances in Industrial Process:
Granulation: Roller Compaction Technology, High-Shear Granulation, Low-Shear Granulation, Batch Fluid Bed Granulation, Extrusion/Spheronization as a Granulation Technique, Effervescent Granulation, Melt Granulation and Pelletization, Rapid Release Granulation, Continuous Granulation Technologies
Lyophilization: LYOGUARD (New Concept for Bulk Freeze-Drying)
Coating: Film-coating materials and their properties
Sterilization
Air handling: AHUs, Laminar Airflow Equipment, HEPA and VEPA filters, HVAC, Clean room classification

Module 06

Pharmaceutical Process Validation :

Basic concept, definition and regulatory basis of validation. Benefits of validation. Phases of quipment validation such as pre-purchase,post-purchase (IQ,OQ and PQ) and qualification of established /in-use equipment. Types of process validation related to prospective, retrospective and concurrent process validation. Re-validation of validation process and scale-up and post approval changes (SUPAC). Validation of tablets, liquids and sterile products. Validation of steam, dry heat, gaseous, radiation and filtration sterilization processes. Analytical Validation.

READING MATERIAL RECOMMENDED

1. S H Yalkowsky (Ed), Techniques of Solubilization of Drugs, Marcel Decker Inc., Newyork USA
2. A Martin, Physical Pharmacy, 3rd Edition. B. I. Waverly Pvt. Ltd., New Delhi, India 1995.
3. J.I. Wells, Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances, Ellis Horwood, Chiechester (UK), 1998.
4. R. Berry and R. A. Nash, Pharmaceutical Process Validation, Marcel Dekker, N.Y. (1993)
5. N. K. Jain (Editor), Pharmaceutical Product Development, Ist Edition, CBS Publisers and Distributer, New Delhi.
6. N. K. Jain (Editor), Controlled and novel drug delivery systems. Ist Edition, CBS Publisers and Distributer, New Delhi.
7. G.S Banker and C.T. Rhodes, Modern Pharmaceutics, second edition, Marcel Decker Inc., Newyork USA
8. S.P.Vyas and R.K.Khar, controlled drug delivery, concept and advances, first edition 2002, vallabh prakashan , Delhi.

S.No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
03	PHCEU 135	Novel Drug Delivery Systems	4	1	-	20	80	100	5

Module 01

Controlled Drug Delivery :

Fundamentals of Controlled Release (CR) Drug Delivery: Rationale of sustained/controlled drug delivery; Physicochemical and biological factors influencing design and performance of CR products, therapeutic status of CDDS. Theory of mass transfer; Fick's first and second laws and their applications in drug release and permeation. Pharmacokinetic/ pharmacodynamic basis of controlled drug delivery; bioavailibility assessment of CR systems

Design and fabrication of technology based CR systems :

Strategies and design of oral controlled release delivery systems, oral systems based on dissolution, diffusion and dissolution, ion-exchange resins, pH-independent formulations, altered density formulations. Bucco/mucoadhesive systems. Osmotic controlled oral drug delivery

Module 02

Parenteral System :

Parenteral systems, biopharmaceutic considerations, design and development, polymeric microspheres, dispersed drug delivery.

Implantable therapeutic systems, biocompatibility of polymers and carriers; Intrauterine devices and intravaginal devices.

Module 03

Transdermal Drug Delivery System :

Transdermal therapeutic systems (TTS): Drug absorption through skin, permeation enhancers, basic components of TTS, approaches to development and kinetic evaluation, Testing of transdermal patches, pressure sensitive adhesives; iontophoresis, sonophoresis and electroporation.

Module 04

Design and fabrication of technology based CR systems :

Novel ocular drug delivery systems: Ocular therapeutics and constraints to effective delivery, formulation considerations to improve the ocular bioavailibility, ocular inserts including insoluble and soluble inserts, non-corneal routes and their use for systemic drug delivery.

Colloidal and supramolecular delivery systems -I :

- Closed bi-layered system: Historical background, structural aspects, preparation, characterization, evaluation and applications, specialized liposomes and niosomes.

- Nanoparticles, microspheres: Method of preparation, characterization, evaluation and pharmaceutical applications.
- Multiple w/o/w emulsions as drug vehicles. Introduction, composition of the multiple emulsion and stability, influence of the nature of oily phase, methods for stabilizing w/o/w multiple emulsions, mechanisms of transport of solutes, *in vivo* studies.

Module 05

Colloidal and supramolecular delivery systems -II :

Microemulsions: Introduction, structure of microemulsions, solubilization and formulation of microemulsions, Self-emulsifying drug delivery systems (SEDDS), transport properties and pharmaceutical applications of emulsions.

Protein and peptide drug delivery :

Considerations in the physiological delivery of therapeutic proteins; carrier-mediated transport of peptides and peptide analogues, problems associated with the delivery of protein and peptides.

Module 06

Targeted drug delivery :

History, concept, types and key elements; ideal carrier system and approach with special reference to organ targeting (e.g. brain, tumor, lung, liver and lymphatics); Basics of temperature, pH and magnetically induced targeting tactics.

Reading Material Recommended

1. J.R. Robinson & V.H.L. Lee (Eds), Controlled Drug Delivery, Fundamentals and applications, Vol. 29&Vol. 31, 2nd Edition, Marcel Dekker, N.Y. 1987
2. Y.W. Chien (Ed.), Transdermal Controlled Systemic Medications, Marcel Dekker, N.Y. 1987.
3. S.D. Bruck, Controlled Drug Delivery, Vol.1 (Basic Concepts) CRC Press. Florida, 1983
4. S.D. Bruck, Controlled Drug Delivery, Vol. II (Clinical Applications) CRC Press. Florida, 1983.
5. L.F. Prescot and W.S. Nimmo, Novel Drug and its Therapeutic Applications, John Willy and Sons, Chichester (1990).
6. N.K. Jain, Controlled and novel drug delivery, 1997, CBs, New Delhi.
7. N.K. Jain, Advances in Controlled and novel drug delivery, 2001, CBS, New Delhi.

S.No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
04	PHCEU 137	Pharmaceutics laboratory-I	-		16	20	80	100	5
		Total (31)	12	03	16	80	320	400	20

- Experiment based on Biopharmaceutics and Pharmacokinetics
- Experiment based on dosage form Design
- Experiment based on Novel Drug Delivery System

M.PHARMACY PHARMACETICS - SEMESTER II

S.No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
01	PHCEU 132	Pharmaceutical Technology	4	1	-	20	80	100	5

Module 01

Improved tablet production and coating systems :

Benefits, process design considerations; materials handling, processing step combination and elimination, tablet production equipment, layout and design of facilities, materials flow, quality assurance procedures including in-process quality control, construction, equipment and environmental considerations, materials management and inventory control. Advances in coating process, fluid-bed coating, particle coating.

Module 02

Processing of parenteral and related sterile products :]

Material management, humidity and temperature controls, air filtration systems, dust collectors, etc. manufacturing including various aspects of preparing SVP solutions, suspensions, powders/ freeze dried powders for reconstitution, filling, sealing, inspection and labeling, raw materials including water, stability, storage and inventory control, batch mixing, clarification by membrane filters and support systems. Environmental factors in the design of parenteral production facilities.

Module 03-04

Capsules & microencapsulation :

3.1 Hard gelatin capsules : Development of hard gelatin capsules as a dosage form . Manufacturing process and material used in the shell and the steps used in its manufacturing such as sorting, printing, size and shapes, sealing and self locking closures. Different materials used for automatic filling based on auger, vibratory and piston tamp fill (Dosing Disk and Dosator Machines) principles. General considerations in the design of hard gelatin capsule for formulations ,storage, packaging and stability consideration.

3.2 Soft gelatin capsules: General considerations of the development of soft gelatin capsules as a dosage form composition of shell, formulation strategies and carriers of the drug used and their manufacturing devices.

3.3 Materials other than gelatin used for capsule formulation.

3.3 Micro-encapsulation: Microencapsules and microspheres as drug delivery systems. Different techniques and methods employed for micro-encapsulation.

Module 05

Spheronization :

Introduction, Extrusion-spheronization methods, formulation, process variable, equipments, evaluation of pellets.

Packaging developments :

Introduction and importance of packaging

Design and development of packaging units: Recent advances in packaging techniques for various types of sterile and non sterile dosage forms. Regulatory aspects of packaging, Stability aspects of packaging, Specifications and quality.

Module 06

Different packaging materials: Paper- and board-based packaging materials and their use in pack security systems, Glass containers, Plastic, Films, foils and laminations, Metal containers, Closures and closure systems, Sterile products and the role of rubber components, Blister, strip and sachet packaging, The packaging line, Warehousing, handling and distribution, Printing and decoration, Present and future trends.

Reading Material Recommended

1. Pharmaceutical dosage forms Lachman et al.,: Tablets, volume I,II,III
2. Pharmaceutical dosage forms Lachman et al. : Parenterals, volume I,II
3. Remington, Science and practice of Pharmacy, Vol.1, 2000, Lippincot williams and wilkins.
4. J.T. Carstensen, Drug Stability: Principles and Practices, Marcel Dekker, N.Y.
5. N.K. Jain , Pharmaceutical product development. CBS publication and distributors, New Delhi.
6. G.S. Banker and C.T.Rhodes, Modern Pharmaceutics, IInd edition , Marcel Dekker, INC, NewYork.

S.No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
02	PHCEU 134	Drug Regulatory Affairs and IPR	4	1	-	20	80	100	5

Module 01

Drug Regulatory Affairs :

Harmonization of regulatory requirements including ICH activity. Regulatory requirements of different regions applicable to pharmaceutical developments, manufacturing, quality control on finished products, extended release products, biopharmaceutical and bioequivalence assessment and good clinical practices and Comparison with regulation in India. Filing of INDA, NDA and ANDA for approval and registration.

Module 02

Stability Testing :

Role of stability testing, stability test guidelines. Protocol of stability testing including testing under different climatic zones and conditions. Conduct of stability testing. Presentation and recording of stability data, determination of shelf life. Stability test equipment and recent developments in this area.

Module 03

Documentation :

Importance of documentation, statutory requirements and procedure for documentation, critical examination of documents.

GMP of Pharmaceuticals :

Current GMP in manufacturing, processing, packaging of drugs. GMP for finished products. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, container and closures, production and process, packaging and labeling, laboratory and control of records and reports.

Module 04

Intellectual property right (IPR) :

Introduction to IPR & Patents – Development of IP law in India, IPR regime, Introduction to IP laws in India, Role of IP in pharma industry growth.

Patenting in India – Introduction, Patent legislation, Indian Patents Act 1970 and amendments, Procedure for patent application, Grant and opposition proceedings, Patent licensing, Patent infringement proceedings, IPAB – role and functions (IP Appellate Board), Indian IP Case laws

Module 05

International treaties and conventions on IPR - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO, Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003

Module 06

Introduction to Geographical indication / Trademark/ copyright: Filing procedures **Patent search, Patent analysis & Patent drafting**

Allied Patents Related Issues: Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage

Reading Material Recommended

1. Pharmaceutical product development 2006, edited by N.K. Jain, CBS publishers and distributors. New Delhi, and references there in.
2. Good manufacturing practices for pharmaceuticals: A plan for total quality control from manufacturer to customer, 5th edition, revised and expanded by Sidney H. Willig, Marcel and Dekker.
3. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).]
4. Orange Book, ICH guidelines, Indian Patents Act
5. Country specific Regulatory Guidelines (available from internet)
6. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc
7. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
8. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.

S.No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
03	PHCEU 136	Nanotechnology & Biotechnology	4	1	-	20	80	100	5

Module 01 -02

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BIONANOTECHNOLOGY: History, opportunities and challenges of bionanotechnology, growth potential of bionanotechnology, significance of nanosize in biotechnology and medicine.

NANO-DRUG DELIVERY: Conventional delivery of biotechnologicals and its limitations, biological barriers in delivery of therapeutics, importance of nanosize in site-selective delivery. Targeted delivery of biotechnological using nanoconstructures, application of nanocarriers in delivery of biotechnologicals, nano-drug delivery chip.

SAFETY CONCERN OF BIONANOTECHNOLICALS

Inhalation, contact/dermal delivery, environmental impact, explosion hazards.

Module 03

INSTRUMENTATION AND PRINCIPLES: Electrophoresis techniques, laser confocal microscopy, digital image analysis, biosensors in diagnostics, enzyme purification and assay techniques. Techniques in cytogenetics: DNA sequencing, DNA microarray.Spectral analysis techniques: Introduction, estimation of proteins, DNA and RNA.

Module 04

Gene cloning :

Introduction to gene cloning. Main steps of gene cloning, Gene cloning procedures, Restriction endonucleases, Isolation of DNA to be cloned (Creation and screening of gene library), Bacterial plasmids, Plasmid cloning vectors and isolation of plasmid with DNA inserts. Application of genetic engineering with special reference to the production of proteins of pharmaceutical significance such as insulin, human growth hormone & tissue Plasminogen activator (t-PA).

Module 05

Immobilised enzymes :

Definition, advantages over soluble enzymes, different methods of immobilization, effect on the stability of the enzymes, potential applications and uses of immobilized enzymes, Kinetics of immobilized enzyme catalysed reactions and different parameters like temperature, pH, enzyme and substrate concentration which influence the velocity of a reaction.

Module 06

Monoclonal Antibodies :

Production of monoclonal antibodies, diagnostic, therapeutic and analytical applications and their role in drug targeting.

Gene Therapy :

An introduction to genetic disorders, concepts and principles of gene, viral and non- viral gene delivery systems, safety and ethical considerations.

Reading Material Recommended

1. Molecular Biology and Biotechnology by Smith and Wood, 1991,Chapman and Hall, New York and London
2. A textbook of Industrial Microbiology by Wulf Crueger and Anneliese Cruegar, 2nd edition, Sinauer Associates, INC, Sunderland MA01375
3. Martin's Physical Pharmacy and Pharmaceutical Sciences by Patrick J. Sinko, Vth edition, Lippincott Williams and Wilkins by Patrick J. Sinko
4. J. Woodward (Editor), Immobilized cells and Enzymes, A Practical Approach, IRL Press.
5. E.S. Papazoglou and A. Parthasarathy, "Bionanotechnology". 1st Ed. Morgan and Claypool.
6. N.H. Malsch. 2005. "Biomedical nanotechnology" CRC Press.
7. D.S. Goodsell, 2004. "Bionanotechnology: lessons from nature" Wiley-Liss Publication.
8. T. Vo-Dinh, "Nanotechnology in biology and medicine: methods, devices, and applications" CRC Press.
9. V. Labhasetwar, D.L. Leslie-Pelecky, 2007. "Biomedical applications of nanotechnology".Wiley-Interscience: Hoboken.
10. S.P. Vyas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific andcontrolled drug delivery" CBS Publishers and Distributors.

S.No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
04	PHCEU 138	Pharmaceutics laboratory-II	-		16	20	80	100	5

1. Experiment based on tablets
2. Experiment based on capsule and microencapsulation
3. Experiment based on parentral
4. Experiment based on Nanotechnology
5. Experiment based on biotechnology
6. Experiments based on Enzyme-Kinetics

THIRD & FOURTH SEMESTER

Research Work
The thesis shall be presented by the candidate at the end of record academic year. The thesis shall be evaluated as under :

Evaluation of written thesis : MM 200
Presentation of seminar on thesis and viva-voce : MM 100

Total : 300 marks