



**Dayananda Sagar University**  
School of Health Sciences  
**College of Pharmaceutical Sciences**

**Syllabus for Ph.D. Entrance Test in Pharmaceutical Sciences**

**DISCIPLINE: PHARMACEUTICS**

**Unit I**

**Preformulation studies**

Preformation concepts, polymers and excipients in formulation development, Drug excipient interactions, different methods used to study drug excipient interactions, kinetics of stability, Stability testing. Consideration of physicochemical properties of new drug molecules for different dosage forms. Solubility: aqueous solubility, organic solubility, intrinsic solubility, methods of enhancement of solubility-surfactants, pH, co-solvency, solid dispersion and complexation.

**Unit II**

**Optimization**

Optimization techniques in pharmaceutical formulation and processing: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation. QbD, elements and tools of QbD.

**Unit III**

**ADME of drugs**

Gastro-intestinal absorption of drugs, mechanisms of drug absorption, Factors affecting drug absorption: Biological, Physiological, Physicochemical, Pharmaceutical. Methods of determining absorption: *In vitro*, *in situ* and *in vivo* methods. Concepts of distribution, metabolism and elimination of drugs.

**Bioavailability and Bioequivalence**

Objectives and consideration in bio-availability studies, purpose of bioavailability studies, relative and absolute availability. Measurements of bio-availability, determination of the rate of absorption. Concept of bioequivalents, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.

**Unit IV**

**Sustained and controlled release drug delivery systems**

Introduction, concept, advantages and disadvantages, rationale of sustained and controlled release drug delivery systems. Physico-chemical and biological factors to be considered for the design and development of sustained and controlled release drug delivery systems.

**Targeted drug delivery systems**

Concept of drug targeting. Development, evaluation and application of polymeric nanoparticles, lipid based nanocarriers, monoclonal antibodies and m-RNA based drug delivery.

## Unit V

### Computers in pharmaceutical research and development

Computational Modeling of Drug Disposition: Modeling Techniques- Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution and Drug Excretion. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Computers in Clinical Data Collection and Management

### References

1. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
2. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
4. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002
5. Lachmann and Libermann's Theory and Practice of Industrial Pharmacy, Fourth edition, CBS Publishers & Distributors, New Delhi.
6. Modern Pharmaceutics; By Gillbert S. Banker, Juergen Siepmann, Christopher Rhodes, CRC Press.
7. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991.
8. Shargel and Yu's Applied Biopharmaceutics & Pharmacokinetics, 8th Edition. McGrawHill
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.

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**DISCIPLINE: PHARMACOLOGY**

**Unit I**

Molecular Mechanisms in Cell regulation, Signaling molecules and their receptors  
Molecules: Nitric oxide, carbon monoxide, neurotransmitters, cytokines, peptide hormones, growth factors and eicosanoids.

Receptors: Cell surface Receptors: Ion channels, G-protein coupled receptors, tyrosine kinase receptors, cytokine receptors, nuclear receptors.

Recent developments in drug discovery and development process for new drugs including biopharmaceuticals and medical devices.

**Unit II**

Pharmacotherapy of Ischemic heart disease, CCF, Cardiac arrhythmias and Dyslipidemia, Atherosclerosis, Parkinson's disease, Alzheimer's disease, Schizophrenia, Stroke, Arteriosclerosis, Asthma and COPD, Epilepsy, Rheumatoid & Osteoarthritis, Myasthenia gravis, Inflammatory bowel diseases, Constipation and Diarrhea.

**Unit III**

Principle and applications of Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y. Alternative methods to animal toxicity testing.

Preclinical models employed in the screening of new drugs belonging to the following categories: Antipsychotic agents, Antianxiety agents, Nootropic drugs, Antidepressant drugs, Antiparkinsonian agents, Analgesics, Antiepileptics, Anti-inflammatory agents, Antiulcer agents, Antianginals and myocardial infarction, Antiarrhythmics, Antiatherosclerosis drugs, Hepatoprotectives, Antidiabetics, Antihypertensives and Anticancer agents

**Unit IV**

Modern techniques to elucidate the mechanism of drug actions- Cell culture and maintenance: Concepts of in-vitro screening, Different cell lines (animal & human) used in screening techniques. Primary and secondary cultures, Principles of techniques involved in cell culture and its maintenance. Alternatives to animal screening procedures- cell-line, patch-clamp technique and invitro models.

**Unit V**

Recombinant DNA Technology: Principles, process and applications. Gene cloning: Isolation, cloning vectors, enzymes used in molecular cloning, PCR (Polymerase chain reaction), LCR (Ligation chain reaction), micro array technique, SDS page, ELISA and western blotting and their applications. Importance of siRNA and micro-RNA, gene mapping and gene sequencing.

Types of Immunotherapeutics, humanization antibody therapy, immunotherapeutics in clinical practice.

Principles and applications of Biosimilars.

## References

1. Pollard TD, Earnshaw WC, Lippincott-Schwartz J, Johnson G. Cell Biology E-Book: Cell Biology E-Book. Elsevier Health Sciences; 2022.
2. Dennis EA, Bradshaw RA, editors. Intercellular Signaling in Development and Disease: Cell Signaling Collection. Academic Press; 2011.
3. Reyon D, Khayter C, Regan MR, Joung JK, Sander JD. Current protocols in molecular biology engineering designer transcription activator-like effector nucleases (TALENs). Current protocols in molecular biology/edited by Frederick M. Ausubel...[et al.]. 2012.
4. Vogel HG, editor. Drug discovery and evaluation: pharmacological assays. Springer Science & Business Media; 2002.
5. Goodman LS, Gilman A, Gilman AG, Koelle GB. The pharmacological basis of therapeutics. In BAILLIERE TINDALL 1975.
6. Ritter JM, Flower RJ, Henderson G, Loke YK, MacEwan D, Robinson E, Fullerton J. Rang & Dale's Pharmacology: Rang & Dale's Pharmacology E-Book. Elsevier Health Sciences; 2023.
7. Golan DE, Tashjian AH, Armstrong EJ, editors. Principles of pharmacology: the pathophysiologic basis of drug therapy. Lippincott Williams & Wilkins; 2011.
8. Parmar NS, Prakash S. Screening methods in Pharmacology. Alpha Science International, Limited; 2006.
9. Tripathi KD. Essentials of medical pharmacology. JP Medical Ltd; 2013 Sep 30.
10. Eder J, Sedrani R, Wiesmann C. The discovery of first-in-class drugs: origins and evolution. Nature Reviews Drug Discovery. 2014; 13(8):577-87.
11. Knablein J, editor. Modern Biopharmaceuticals, 4 Volume Set: Design, Development and Optimization. John Wiley & Sons; 2005.



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**DISCIPLINE: PHARMACEUTICAL CHEMISTRY**

**Unit I: Computer aided drug design**

1. Structure based drug design:
  - a. Molecular and Quantum Mechanics in drug design
  - b. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation
  - c. Molecular docking and drug receptor interactions
  - d. Molecular dynamics
2. Ligand based drug design:
  - a. Quantitative structure activity relationship (QSAR): History and development
  - b. Hammett and Taft equation, Hansch analysis, Free Wilson analysis, applications and relationship between them.
  - c. Statistical methods like Regression analysis, PLS and other multivariate statistical methods, 3D QSAR approaches.

**Unit II: Advanced Organic Chemistry**

1. Basic Aspects of Organic Chemistry
  - a. Chemical bonding: emphasizing localized, delocalized and bonding weaker than covalent bonds.
  - b. Organic reaction intermediates: carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
  - c. Various types of reaction mechanism, reaction and methods of determining them.
2. Detailed study of the following topics:
  - a. Substitution reactions (aliphatic nucleophilic, aromatic electrophilic, aliphatic electrophilic, aromatic nucleophilic and free radical substitutions).
  - b. Addition reactions (both carbon-carbon and carbon-heteroatom multiple bonds).
  - c. Elimination reactions (E1, E2 and Hoffman Saytzeff's) and Rearrangement reactions.
  - d. Oxidation – reduction reactions and the reagents used for such reactions.
  - e. Protection and deprotection of various groups.

**Unit III: Medicinal Chemistry**

1. Drug Discovery, lead optimization and SAR of the synthetic drugs
  - a. Antineoplastic drugs
  - b. Antiviral drugs
  - c. Antihypertensive drugs
  - d. Diuretics
  - e. COX-2 inhibitors
2. Combinatorial Chemistry: Introduction and concept
3. Prodrugs: Designing and applications

**Unit IV:** Study of Natural products as leads for new pharmaceuticals for the following class of drugs

1. Antibiotics
  - a. Beta-lactam antibiotics: Penicillins and Cephalosporins
  - b. Beta-lactamase inhibitors
  - c. Amino glycosides
  - d. Macrolides
  - e. Tetracyclines
2. Herbal products
  - a. Anticancer Drugs: Vinca alkaloids, Paclitaxel and Docetaxel, Etoposide, and Teniposide
  - b. Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
  - c. Neuromuscular Blocking Drugs: Curare alkaloids
  - d. Anti-malarial drugs and analogues

**Unit V:** Instrumentation of the following instruments and their applications in the interpretation of organic and natural products

1. UV-Visible spectroscopy
2. IR spectroscopy
3. Nuclear Magnetic Resonance
4. Mass Spectroscopy

## REFERENCES

1. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
2. Introduction to Quantitative Drug Design by Y.C. Martin.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975.
4. Principles of Drug Design by Smith and Williams.
5. Advanced Organic chemistry, Reaction, Mechanisms and Structure”, J March, John Wiley and Sons, New York.
6. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley (India) Pvt. Ltd.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Wilson and Gisvold’s Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lippincott Williams & Wilkins, Wolters Kluwer (India) Pvt.Ltd, New Delhi.
9. Burger’s Medicinal Chemistry
10. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004
11. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
12. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991
13. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.



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**DISCIPLINE: PHARMACOGNOSY**

**Unit I**

1. General methods of isolation, purification, identification and estimation of Phytoconstituents (with special emphasis on HPLC & HPTLC).
2. WHO guidelines for assessment of crude drugs
  - Evaluation of identity, purity and quality of crude drugs.
  - Determination of pesticide residue.
  - Determination of arsenic and heavy metals.
  - Determination of microorganisms

**Unit II**

3. Detailed phytochemical study of following class of phytoconstituents.
  - Phospholipids
  - Terpenes and Terpenoids
  - Resins and related compounds
  - Plant phenols
  - Alkaloids
  - Glycosides
  - Steroids
  - Marine antibiotics

**Unit III**

4. a) Enzymes:
  - Types and properties of enzymes
  - Isolation and purification of enzymes
  - Immobilization of enzymes and its applications
  - Enzyme reactors
  - Detailed study of plant enzymes – Papain and Bromelain
- b) Bioprocessing of industrially important microbial metabolites:
  - Antibiotics - Penicillin, Streptomycin, Griseofulvin
  - Vitamins - B12, Riboflavin and Vitamin C

## Unit IV

### 5. Tissue Culture:

Type, techniques and application of callus, suspension, haploid, embryo, Organ and immobilized culture.

- Organogenesis, embryogenesis, synthetic seed and somaclonal variation.
- Micropropagation
- Production of secondary metabolites – Strategies involving use of Precursor, growth regulators and Elicitors: Production of Shikonin.
- Hairy root culture and Multiple shoot culture and their application.
- Protoplast culture and protoplast fusion.
- Biotransformation.

## Unit V

### 6. Patents:

Indian and International patent laws, proposed amendments as applicable to Herbal/natural products and processes; important points to be kept in mind while drafting and filing a patent.

### 7. Herbal Cosmetics:

- Raw materials of herbal origin used in cosmetics: Oil, waxes, gums, Hydrophilic colloids, colours, perfumes, protective agents, bleaching agents, Preservatives, anti-oxidants and other ancillary agents.
- Formulation aspects incorporating herbal extracts in various preparation like Skin care creams, deodorants, anti-perspirants, hair care preparations.
- Detailed methods of preparation of few representative preparations and standardization of above categories.

## References:

1. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
2. Biren Shah, A.K.Seth. Text book of Pharmacognosy & Phytochemistry. 2nd Edition. Elsevier, A division of Reed Elsevier India Private Limited, 2014.
3. Trease and Evans'. Pharmacognosy, 16th Edition. Harcourt Brace & Company Asia PTE Ltd. W.B. Saunders Company, A Division of Harcourt Brace & Company, 2009.
4. W.C.Evans, Trease and Evans Pharmacognosy, 16<sup>th</sup> Edition, W.B. Saunders & Co., London, 2009.
5. Vyas and Dixit, Pharmaceutical Biotechnology, CBS Publishers & Distributors, New Delhi.
6. Stanbury F.P., Whitakar A., and Hall J.S., Principles of fermentation technology, 2<sup>nd</sup> edition, Aditya books Ltd., New Delhi.

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**DISCIPLINE: PHARMACEUTICAL ANALYSIS**

**UNIT-1** a. UV-Visible spectroscopy: Introduction of Electromagnetic spectrum, Theory, Laws, Instrumentation and terminology associated with UV-Visible spectroscopy, Choice of solvents and Applications of UV-Visible spectroscopy.

b. IR Spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation and Applications of IR Spectroscopy.

c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of Fluorescence Spectrophotometer.

d. Flame Emission and Atomic Absorption Spectroscopy: Principle, Instrumentation, Interferences and Applications.

**UNIT-2** Chromatography: Principle, Apparatus, Instrumentation, Chromatographic parameters and Applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Column chromatography d) Gas chromatography e) High Performance Liquid chromatography f) High Performance Thin Layer chromatography.

**UNIT- 3** Proton nuclear magnetic resonance spectrometry: Principle, Quantum numbers and their role in NMR, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift and factors influencing chemical shift, Applications.

**UNIT- 4** Mass spectrometry: Principle, Instrumentation of Mass Spectroscopy, different types of ionization techniques, Mass Analysers, Types of ions and Applications.

**UNIT-5** a. Calibration, validation and cleaning validation for the following instruments used in pharmaceutical industry: g) HPLC b) HPTLC c) GC d) IR e) UV

b. Analytical method and bio analytical method development and its validation according to ICH and USP guidelines.

c. Statistical Analysis - Introduction, Significance of statistical methods, normal distribution, probability, degree of freedom, standard deviation, variance, accuracy, precision, errors, Correlation and Regression.

**References:**

1. Indian Pharmacopoeia all editions and volumes
2. Instrumental Methods of Chemical Analysis (Analytical Chemistry) By. Dr. B.K. Sharma, Goel Publishing House, Meerut. 18th Edition (1999) (Part - Spectroscopy)

3. Spectrophotometric Identification of Organic compounds – Robert M Silverstein, 6<sup>th</sup> edition, John Wiley & Sons, 2004.
4. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern Press, Bangalore, 1998.
5. Instrumental Methods of Analysis - Willards, 7<sup>th</sup> edition, CBS Publishers.
6. Practical Pharmaceutical Chemistry- Beckett and Stenlake, Vol II, 4<sup>th</sup> edition, CBS Publishers, New Delhi, 1997.
7. Organic Spectroscopy – William Kemp, 3<sup>rd</sup> edition, ELBS, 1991.
8. Quantitative Analysis of Drugs in Pharmaceutical formulation – PD Sethi, 3<sup>rd</sup> Edition, CBS Publishers, New Delhi, 1997.
9. Pharmaceutical Analysis- Modern Methods-Part B-JW Munson, Vol 11, Marcel Dekker series.
10. ICH Q2(R1 & R2) Validation of Analytical procedures.



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**DISCIPLINE: PHARMACY PRACTICE**

**Unit I**

**Introduction to Clinical Pharmacy and Its Services**

Definition, evolution and scope of clinical pharmacy  
National (India) and International scenario of clinical pharmacy practice  
Pharmaceutical care  
Ward round participation  
Drug Utilization review  
Medication history interview (MHI)  
Patient medication counselling in a systematic approach  
Documentation of clinical pharmacy services and its significance  
Quality assurance of clinical pharmacy services  
Medication errors

**Unit II**

**Drug and Poison Information Services**

Definition, scope and need for drug information service  
Definition, scope and need for poison information service  
Systematic approach in answering information queries

**Unit III**

**Pharmacotherapeutics**

Cardiovascular system  
Respiratory system  
Endocrine system  
Infectious diseases  
Gastrointestinal system  
Haematology  
Bone and joint disorders  
Oncology disorders  
Dermatology disorders  
Renal disorders

**Unit IV**

**Significance of Patient Laboratory Data Interpretation**

Lung Function test  
Thyroid function test  
Renal function test  
Liver function test

Fluid and Electrolyte balance  
Cardiac Biomarker  
Microbial culture sensitivity test  
Haematological function test

## **Unit V**

### **Clinical Research**

Scope of clinical research  
Drug development process  
Phases of clinical trials  
Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines  
Composition, responsibilities, procedures of IRB / IEC  
Designing of clinical study documents (protocol, CRF, ICF, PIC)  
Designing of clinical study documents (protocol, CRF, ICF, PIC)  
Basic concept of Pharmacovigilance, Hemovigilance, Materiovigilance  
Adverse event reporting systems- India, USA, Europe, Australia, Malaysia

### **Reference:**

1. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.
2. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication 4<sup>th</sup> edition
3. Pharmacotherapy: A Pathophysiologic Approach - Joseph T. Dipiro et al. 11<sup>th</sup> edition Appleton & Lange.
4. Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
5. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins 2<sup>nd</sup> edition
6. Applied Therapeutics: The Clinical Use of Drugs. Lloyd Young and Koda-Kimble, MA
7. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited. Relevant review articles from recent medical and pharmaceutical literature.
8. Hospital Pharmacy by William E. Hassan
9. A textbook of Hospital Pharmacy S.H. Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh
10. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
11. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills, Dr. G.Parthasarathi et al, Orient Orient Langram Pvt. Ltd.
12. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
13. V V Pillay. Handbook of Forensic Medicine And Toxicology. Thirteenth edition 2003 Paras Publication, Hyderabad
14. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
15. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian
16. Council of Medical Research, New Delhi. Textbook of Clinical Trials edited by David Machin, Simon Day, and Sylvan Green, March 2005, John Wiley and Sons.



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**DISCIPLINE: PHARMACEUTICAL REGULATORY AFFAIRS**

**Unit I**

**Documentation in Pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, BE and drug product assessment, in –vivo scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

**Unit II**

**Regulatory requirement for product approval:** API, biologics, novel therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. Overview of drug approval process by CDCSO

**Audits:** Types of audits, Auditing strategies, preparation and conducting audit, auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies.

**Unit III**

**CMC and post approval regulatory affairs:** Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

**Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB)

**Unit IV**

**Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA-new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

**Unit V**

**Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments):**

**Food Safety and Standards Act:** Organization and functions, regulations for import, manufacture and sale of nutraceutical products in India, USA and EU. Recommended Dietary Allowances (RDA) in India, USA and EU.

**Herbal Products:** Quality, safety and legislation for herbal products in India, USA and European Union.

**References**

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel

and Isader Kaufer, Marcel Dekker series, Vol.143.

2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited by Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams.
7. [www.ich.org/](http://www.ich.org/)
8. [www.fda.gov/](http://www.fda.gov/)
9. [europa.eu/index\\_en.htm](http://europa.eu/index_en.htm)
10. <https://www.tga.gov.au/tga-basics>



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**DISCIPLINE: PHARMACEUTICAL QUALITY ASSURANCE**

**Unit 1: Introduction to Quality:** Evolution of Quality, Definition of Quality, Dimensions of Quality. Strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality.

**Unit II: Pharmaceutical quality Management:** Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements, Out of Specifications (OOS), Out of Trend (OOT), Deviations and Complaints, Corrective & Preventive Actions, (CAPA), Concept of IPQC.

**Unit III: Drug Stability and Good Laboratory Practice:** ICH guidelines for stability testing of drug substances and drug products. Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

**Unit IV: Technical Documents and Quality test:** Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Quality control for tablets, capsules and parenteral as per IP and USP. Quality control test for Containers, closures and secondary packing materials. Expiry date calculation, calculation of yields, production record review, change control.

**Unit V: Qualification of analytical instruments:** Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS. Difference between calibration and validation. Installation qualification, Operational qualification, Performance qualification. Concept, Process and documentation of Process Validation.

**Reference:**

1. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
2. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
3. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
4. Quality Assurance Guide by organization of Pharmaceutical Procedures of
5. India, 3rd revised edition, Volume I & II, Mumbai, 1996.

6. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
7. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
8. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991
9. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
10. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
11. ICH guidelines
12. ISO 9000 and total quality management
13. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
14. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia. Pharmaceutical product development. Vandana V. Patrevala. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.



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## **PART B**

### **Syllabus for Ph.D. Entrance Test in Physiotherapy**

Unit I: Gross anatomy and functional anatomy: Cardiovascular system, respiratory system, central and peripheral nervous system, musculoskeletal system.

Unit II: Physiology and applied physiology of: Cardiorespiratory system, central and peripheral nervous system, special senses, muscles and blood.

Unit III: Physical agents: Low frequency currents – types of low frequency currents used for therapeutic purposes including electrodiagnostic, Medium frequency currents, High frequency Modalities - ultrasound, wax bath, infrared radiations, ultraviolet radiations, shortwave diathermy, microwave diathermy, LASER, cryotherapy.

Unit IV: Therapeutic exercises and massage: Basics of mechanics of human body, types of movements, muscle grading, types of strengthening exercises, exercises for joint mobility, suspension therapy, hydrotherapy, crutch walking, types of massage manipulations including physiological effects and limitations. Unit V: Biomechanics and pathomechanics of: Spine, TM joint, upper extremity, lower extremity, posture, gait, respiration.

Unit VI: Physiotherapy in neurological conditions: Neuro Anatomy & Neuro Physiology Principles of assessment and treatment for motor system, sensory system, higher mental functions, perception in central nervous system pathologies, peripheral nervous system pathologies and myopathies. Concepts: motor relearning program, bobath approach, brunstrom approach, proprioceptive neuromuscular facilitation, roods approach and neurodevelopmental therapy. Principles of Assessment & Motor control theories . Neural control of locomotion. Neurophysiological approaches. Spinal cord injuries- complications, consequences, SCI in children & adult rehabilitation. Various treatment approaches for medical and surgical management. 16. Stroke, Parkinson's disease & its PT management. Movement Disorder. Sensory evaluation and treatment. Motor control evaluation and treatment Traumatic head injury Peripheral nerve lesion Lesions of central nervous system.

Unit VII: Physiotherapy in orthopaedic conditions: Principles of assessment and treatment in fractures, soft tissue injuries, post operative conditions including joint replacements, joint and spinal pathologies. Concepts: Cyriax, Mackenzie and Maitland. Soft tissue approach - myofascial technique, neutral tissue mobilisation, muscle energy methods.. Classification of hand injuries. Principles & methods of hand rehabilitation. Spinal cord injuries- complications, consequences, SCI in children & adult rehabilitation including sports rehab. Physiotherapy Management of cervical & thoracic spine disorders. Physiotherapy Management of conditions affecting shoulder, elbow, hip, knee, ankle & foot. Physiotherapy Management of spinal fractures, pelvic fractures & spinal cord injury. Upper & Lower limb injuries & PT management.

Unit VIII: Physiotherapy in cardiopulmonary conditions: Cardio-thoracic applied anatomy. Respiratory and cardio vascular physiology .Principles of assessment and treatment in cardiac rehabilitation and pulmonary rehabilitation, stress testing and exercise prescription, Principles of assessment and treatment in intensive care unit setting and post operative conditions. Burn and Physiotherapy management. Mechanics of ventilation. ECG, exercise ECG testing, Echo, PFT and ABG

analysis etc. Chest Physiotherapy techniques.. Exercise physiology compared with abnormal exercise physiology. Common pulmonary diseases, including assessment and management. Detail study of various conditions (obstructive, restrictive, surgical conditions) patient intervention. Respiratory muscle training. Fitness, definition, aspects and parameters for testing. Scientific basis for exercise programs. Stress modifications by exercise.

Unit IX: Physiotherapy in Gynecological & Obstetrical conditions: Anatomy & Physiology of female reproductive system. Physiology of urinary and faecal continence. Principles of assessment and treatment in antenatal and post natal period. Fitness in women's health. Gynecological infections. Pelvic inflammatory diseases. Infertility. Contraception and family planning. Gynecological surgeries. Types of Prolapse.. Menopause and osteoporosis. Laparoscopy and laser surgeries in Gynaecological condition. Incontinence scales. Gynaecologic problems in Female athletes. Musculoskeletal changes during Pregnancy. Common complication and discomforts during Pregnancy. Stages and mechanism of labour. Complication in labour. Physiotherapy management of edema in Pregnancy. Physiotherapy management of GDM, High risk Pregnancy. Management of common problem in Antenatal period.

Unit X: Rehabilitation medicine and community based physiotherapy: Concept of rehabilitation and team approach, disability evaluation, architectural barrier, orthotics and prosthetic services. Principles of Geriatric Rehabilitation.

#### REFERENCES :

- 1) Biomechanical basis of human movement, Joe Hamill Publishers – Williams & Wilkins, 3 rd edition.
- 2) Samson Wright Applied Physiology – Cyril A. Keele, Eric Neil & Normal Joels, oxford, 13 th edition.
- 3) Sports Physiology – Mcardie, Katch & Katch , Publisher – Lea & Febiger, 4 th edition.
- 4) Sports Physiology - Edward L.Fox – College publishing, 2 nd edition.
- 5) Clayton's Electrotherapy – Therapy & Practice – Angela Forster, All India Traveler, book seller, 9 th edition.
- 6) Electrotherapy Explained – John Low & Ann Reed, Butterwith Heinmann, 3 rd edition.
- 7) Massage for therapists – Margaret Hollis, Blackwell Science Ltd, 2 nd edition.
- 8) The Principles of Exercise therapy – M.Deena Gardiner, CBS Publications & Distributors, 4 th edition.
- 9) Therapeutic Exercise : Foundations & Techniques – Carolyn Kisner, F.A.Davis, 5 th edition.
- 10) Brunnstroms Clinical Kinesiology, Laura K.Myth et al, Publishers – F.A.Davis
- 11) Joint Structure & Function, Cynthia C.Norkin et al, Publishers – F.A.Davis, 4 th edition., 5 th edition.
- 12) DeJongs The Neurologic Examination, William W. Campbell, Wolters Kluwer, 7 th edition.
- 13) Physical Rehabilitation , O'Sullivan, F.A.Davis company, 6 th edition.
- 14) Electrodiagnosis in Diseases of nerve & muscle: Principles & practice, Jun Kimura, OUP USA, 4 th edition.
- 15) Neurological Rehabilitation – Darcy Ann Umphred, Elsevier, 6 th edition.
- 16) Paediatric Neurological Physiotherapy – Suzan Campbell, Elsevier, 4 th edition.
- 17) Essentials of Orthopaedic Physical Assessment, David J.Maggie, Elsevier, 3 rd edition.
- 18) Mechanical diagnosis & therapy – Robin McKenzie, 2 nd edition.
- 19) Aspects of Manipulative therapy – Glasgow, Twomey, Churchill Livingstone, 2 nd edition.
- 20) T.B. of Orthopaedic Medicine – James Cyriax, Bailliere Tindall, 11 th edition.
- 21) Cardio Pulmonary Rehabilitation – Frown Felter & Dean , Mosby, 5 th edition.
- 22) Cardio Pulmonary Rehabilitation – Irwin & Tecklin, 3 rd edition.
- 23) Physiotherapy in Obstetrics & Gynaecology – Polden & Mantle, Jaypee Brothers, 2 nd edition.
- 24) Women's Health – Ruth Sapsford, Lippincott, 1 st edition .
- 25) Rehab of movement – Theoretical basis of clinical practice, Judith Pitt- Brooke, W.B.Saunders

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## **PART A**

### **Research Methodology and Applied Statistics**

Unit –I Introduction: Methods of acquiring knowledge problem solving and scientific method.

Research – definition types characteristics Terminology used in research, purpose, scope and of research. Research and Nursing: Purpose scope and need for Nursing Research, development of research in Nursing, areas of Nursing research

Unit – II Research process overview: Statement of the problem and research objectives, concepts and constructs, variables assumptions, definitions hypotheses formulation and types Delimitation

Unit – III Review of related literature Need purpose and sources: Library, -On-line search, retrieval of database from different CD-ROMs and use of A.V. Aids.

Unit-IV Research approaches and Designs: -

- Historical approaches
- Survey and experimental approaches,
- Qualitative research approaches, ethnography and phenomenology.
- Longitudinal, cross sectional and cohort studies-advantages and disadvantages.
- Experimental designs-Purposes, characteristics, types of design, pre-experimental and quasi and true implemented design, steps of experimental research
- Sampling Methods-size, criteria of Population, Techniques of sampling criteria, determination of sample size
- Data collection-Tools and techniques, types, purposes, characteristics and uses.
- Scale/Construction of tools-Selection/Construction of tools, Testing validity and reliability.
- Techniques of data collection: Technique, tools used for qualitative research, observation, Focus group discussion, measurement and record analysis and field trips.

Unit-V Data collection procedures, analysis & interpretation and data management.

Unit – VI Ethical considerations in Nursing Research

- General considerations
- Ethical considerations specific to approaches, design and data collection procedures.
- Ethics Committee – composition, role and importance
- Guidelines for ethical clearness
- Ethical issues the relation to scientific and professional community (Plagiarism)

Unit – VII Qualitative and quantitative analysis

- Descriptive, inferential and advance statistics
- Parametric and Non parametric methods
- Multivariate analysis

Unit – VIII Communicating research findings

- Research critic
- Project proposal for funding
- Research utilization



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## **PART B**

### **Syllabus for Ph.D. Entrance Test in Nursing Sciences**

**Note: Candidates will choose a discipline depending on their specialization in PG study and answer.**

#### **DISCIPLINE: MEDICAL SURGICAL NURSING**

**(Cardiology, Neurology, Nephrology, GIT, Orthopedics, Oncology, Nephrology, Urology)**

**Cardiac disorders and nursing management:** Hypertension, Coronary Artery Disease, Angina of various types, Cardiomegaly, Myocardial Infarction, Congestive cardiac failure, Heart Failure, Pulmonary Edema, Shock. Rheumatic heart disease and other Valvular Diseases, Inflammatory Heart Diseases, Infective Endocarditis, Myocarditis, Pericarditis. Cardiomyopathy, dilated, restrictive, hypertrophic. Arrhythmias, heart block and associated illnesses.

**Altered pulmonary conditions:** Bronchitis, Bronchial asthma, Bronchiectasis, Pneumonias, Lung abscess, lung tumour, pulmonary tuberculosis, fibrosis, pneumoconiosis etc. Pleuritis, effusion, Pneumo, haemo and pyothorax, Interstitial Lung Disease, Cystic fibrosis, Acute and Chronic obstructive pulmonary disease (conditions leading to) Cor pulmonale, Acute respiratory failure, Adult respiratory distress syndrome, Pulmonary embolism and Pulmonary Hypertension.

**Vascular disorders** Disorders of arteries, Disorders of the aorta, Aortic Aneurysms, Aortic dissection, Raynaud's phenomenon, Peripheral arterial disease of the lower extremities, Venous thrombosis, Varicose veins, Chronic venous insufficiency and venous leg ulcers, Pulmonary embolism.

**Congenital Heart Diseases :** Etiology, clinical manifestations, diagnosis, prognosis, related pathophysiology, treatment modalities and nursing management of: Embryological development of heart, Classification – cyanotic and acyanotic heart disease, Tetralogy of Fallots, Atrial Septal Defect, Ventricular Septal Defect, Eisenmenger's complex, Patent ductus arteriosus, AP window, Truncus Arteriosus, Transposition of great arteries, Total Anomaly of Pulmonary Venous Connection, Pulmonary stenosis, atresia. Coarctation of aorta, Ebstein's anomaly, Double outlet right ventricle, Single ventricle and Hypoplastic left heart syndrome.

**cardio thoracic surgery :** Indications, selection of patient, Preoperative assessment and preparation; counselling. Intraoperative care: Principles of open heart surgery, equipment, anaesthesia, cardiopulmonary bypass. Surgical procedures for Coronary Artery Bypass Grafting, recent advances and types of grafts, Valve replacement or reconstruction, cardiac transplant, Palliative surgery and different Stents, vascular surgery, other recent advances.

**Thoracic surgery:** lobectomy, pneumonectomy, tumour excision etc. Immediate postoperative care: assessment, post operative problems and interventions : Bleeding, Cardiac tamponade, Low cardiac output, Infarction, Pericardial effusion, Pleural effusion, Pneumothorax, Haemothorax, Coagulopathy, Thermal imbalance, Inadequate ventilation/perfusion, Neurological problems, renal problems, Psychological problems, Chest physiotherapy. Nursing interventions- life style modification, complementary therapy

/alternative systems of medicine. Intermediate and late post operative care after CABG, valve surgery, others and Follow up care.

**Cardiac rehabilitation:** Process, Physical evaluation, Life style modification, Physical conditioning for cardiovascular efficiency through exercise, Counseling and Follow up care.

**Pain Management :** Pain & Sedation in Critically ill patients, Theories of pain, Types of pain, Pain assessment, Systemic responses to pain, pain management-pharmacological and non-pharmacological measures and Placebo effect.

**Burns :** Clinical types, classification, pathophysiology, clinical features, assessment, diagnosis, prognosis, Management: Medical, Surgical & Nursing management of burns, Fluid and electrolyte therapy – calculation of fluids and its administration, Pain management, Wound care, infection control, Prevention and management of burn complications, Grafts and flaps, Reconstructive surgery and Rehabilitation.

### **Cancer Treatment Modalities and Nurse's Role: Surgery**

Principles and classification of chemotherapeutics, Pharmacology of antineoplastic drugs- Mechanism of action, Absorption, protein binding, Bio-transformation, excretion, common side effects.

Radiation Therapy: Physics of radiotherapy, Types of ionizing rays, Radiation, equipments: Linear accelerator, cobalt, Implants, Isotopes, Types of therapies: Oral, Brachy therapy, tele therapy, selectron therapy, Effects of radiation on the body tissue, Radiation biology – cell damage, hypoxic cells, alteration of tumor kinetics.

Bone Marrow Transplantation / stem cell Transplantation: **Palliative care:** Home care, Hospice care and Role of nurse in palliative care.

**Pediatric malignancies:** Leukemia, Lymphoma, Neuro- blastoma, Wilm's tumor, Soft tissue sarcoma, Retinoblastoma and Nursing Management of children with Paediatric Malignancies.

### **Physiological Conditions and Symptoms of Cancer Patient**

Nutrition: effects of cancer on nutritional Status and its consequences:-Anemia, Cachexia, Xerostomia, mucositis, Dysphagia , nausea and vomiting, constipation, diarrhoea, electrolyte imbalances, taste alterations. Impaired mobility: Decubitus ulcer, pathologic fractures, thrombophlebitis, pulmonary embolism, contractures, footdrop. Other symptoms: Dyspepsia & hiccup, dyspnoea, intestinal obstruction, Fungating wounds, Anxiety & depression, insomnia and Lymph edema. Impact of cancer on sexuality; Effects of radiotherapy/ chemotherapy/surgery on sexuality of the cancer patient nursing management of cancer patients experiencing sexual dysfunction and Sexual counseling.

**Cancer Emergencies:** Disseminated intravascular coagulation (DIC), malignant pleural effusion, neoplastic cardiac tamponade and septic shock, spinal cord compression, Superior venacava syndrome. Metabolic emergency: hyper and hypocalcemia, Surgical emergency, Urological emergency, Hemorrhage, Organ obstruction, Brain metastasis and Nurses role in managing oncologic emergencies. **Cerebro**

**vascular disorders :** Causes, pathophysiology, clinical types, clinical features, diagnosis and prognosis.

Management: medical, surgical and nursing management of Stroke & arterio venous thrombosis, Haemorrhagic embolus, Cerebro vascular accidents, Intracranial aneurysm, Subarchnoid Haemorrhage, Arterio venous fistula, Brain tumours, Diseases of cranial nerves; Trigeminal neuralgia, Facial palsy and Bulbar palsy.

**Degenerating and demyelinating disorders :** Causes, pathophysiology, Clinical types, clinical features, diagnostic, Prognosis, Management: medical, surgical and Nursing management of Motor neuron diseases, Movement disorders- Tics, dystonia, chorea, Wilson's disease, essential tremors, Dementia, Parkinson's disease, Multiple sclerosis and Alzheimer's disease.

**Neuro infections: Causes, pathophysiology, clinical types, clinical features, diagnostic and prognosis.**

Meningitis-types, Encephalitis, Poliomyelitis, Parasitic infections, Bacterial infections, Neurosyphilis, HIV & AIDS and Brain abscess.

### **Paroxysmal disorders:**

Causes, pathophysiology, Clinical types, Clinical features, diagnosis, Prognosis, Management: medical, surgical and nursing management of Epilepsy and seizures, Status epilepticus, Syncope, Menier's syndrome and Cephalgia.

### **Developmental disorders :**

Causes, pathophysiology, clinical types, clinical features, diagnostic, prognosis, management: medical, surgical and nursing management of Hydrocephalus, Craniosynostosis, spina bifida- Meningocele, Meningomyelocele, encephalocele, syringomyelia, Cerebro vascular system anomalies, Cerebral palsies and Down's syndrome.

**Neuro muscular disorders :** Causes, pathophysiology, Clinical types, Clinical features, diagnostic, Prognosis , Management: medical, surgical and Nursing management of Polyneuritis – G B Syndrome, Muscular dystrophy, Myasthenia gravis, Trigeminal neuralgia, Bell's palsy, Menier's disease, Carpal tunnel syndrome and Peripheral neuropathies.

Neoplasms – surgical conditions: Causes, pathophysiology, Clinical types, Clinical features, diagnostic, Prognosis, Management: medical, surgical and nursing management of Space occupying lesions –types and common tumors of CNS.

### **Renal immunopathy/Immunopathology**

Urinary tract infections- pyelonephritis, lower urinary tract infections, Disorders for ureters, bladder and urethra, Urinary dysfunctions- urinary retention, urinary incontinence, urinary reflux, Bladder disorders- neoplasms, calculi, neurogenic bladder, trauma, congenital abnormalities, benign prostrate hypertrophy (BPH) Ureteral disorders: ureteritis, ureteral trauma, congenital anomalies of ureter, Urethral disorders- tumours, trauma and congenital anomalies of ureters.

**Glomerular disorders and nursing management:** Glomerular nephritis- chronic, acute, nephritic syndrome, Acute Renal failure and chronic renal failure. Renal calculi, renal tumours- benign and malignant, renal trauma, Renal abscess, Diabetic nephropathy, Vascular disorders, Renal tuberculosis, Polycystic, Congenital disorders and Hereditary renal disorders.

**Management of Renal emergencies:** Anuria, acute renal failure, poisoning, trauma, urine retention, acute graft rejection, hematuria and nurse's role.

**Kidney transplantation, nursing management of a patient with kidney transplantation, kidney transplantations- immunology of graft rejections, the recipient of a renal transplant, renal preservations, Human leucocytic antigen (HLA) typing matching and cross matching in renal transplantation. Surgical techniques of renal transplantations, chronic renal transplant rejection, complication after KTP**

Rehabilitation of patient with nephrological problems, risk factors and prevention, rehabilitation of patients on dialysis and after kidney transplant, rehabilitation of patients after urinary diversions, family and patient teaching.

#### **Neuro – Muscular Disorders**

**Disorders of the spine** Intervertebral disc prolapse, Fracture of the spine, Low back disorder – Low back pain, PND, spinal stenosis and spondylosis.

**Infections of bones and Joints:** Causes, pathophysiology, clinical types, clinical features, diagnosis, prognosis, management, medical surgical and nursing management of: Tuberculosis, Osteomyelitis, Arthritis and Leprosy.

**Nutritional/Metabolic and Endocrine Disorders :** Rickets, Scurvy, Hyper vitaminosis A and D, Osteomalacia, Osteoporosis, Paget's disease, gout, Gigantism, Dwarfism, Acromegaly, and Therapeutic diets for various orthopedic disorders.

**Chronic/Degenerative Diseases of Joints and Autoimmune Disorders:** Causes, pathophysiology, clinical types, clinical features, diagnosis, prognosis – medical, surgical and nursing management of Osteo Arthritis, Rheumatoid Arthritis, Ankylosing spondylitis, Spinal disorders and Systemic Lupus Erythematosus.

#### **Text book reference:**

1. Alford Alonso, David D Mc Manus. Text book of peripheral vascular disease. Canada: Jones and Barlett publishers; 2006.
2. Emile R Mahler. Alan T Hirsch. Peripheral arterial disease. Canada: Jones and Barlett publishers; 2006.
3. Joyce M Black, Jane Hawks. Text book of Medical surgical nursing. 7th Edition. New Delhi: Elsevier publication; 2005.

#### **Reference Books:**

1. Phipps Wilma J. Shafer's Medical Surgical Nursing. 7th ed. Bangalore: B.T.Publication; 1995.
2. B.T.Basavanthappa. Medical Surgical Nursing. 3rd ed. New Delhi: Jaypee publishers; 2015.
3. Lewis Heitkemper, Dirksen O'Brien. Medical Surgical Nursing. 7th Edition. Missouri: Elsevier; 2008

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**SUB DISCIPLINE: OBSTETRIC AND GYNECOLOGICAL NURSING**

**Management of problems of women during pregnancy:** Placenta Previa, Abruptio placenta. Hypertensive disorders in pregnancy, pre-eclampsia, eclampsia, Rh and ABO incompatibility. Hematological problems in pregnancy, Hydramnios-oligohydramnios, prolonged pregnancy, post maturity, multiple pregnancies, Intra uterine infection, Intra Uterine Growth Retardation (IUGR), Premature Rupture of Membrane (PROM) and intra uterine death.

**Pregnancies at risk-due to pre-existing health problems:** Anemia, Hepatitis, essential hypertension and chronic renal failure. Psychiatric disorders, Infections: Toxoplasmosis Rubella cytomegalo virus Herpes (TORCH), Reproductive Tract Infection (RTI), STD; HIV/AIDS, Vaginal infections.

**Abnormal labour, pre-term labour & obstetrical emergencies:** Atony of uterus, precipitate labour, prolonged labour, abnormal lie, presentation, position, compound presentation. Contracted pelvis-CPD, dystocia, Obstetrical shock, vasa Previa, inversion of uterus, amniotic fluid embolism, rupture uterus, presentation and prolapse cord, Augmentation of labour, Medical and surgical induction, Version, Manual removal of placenta, Obstetrical operation: Forceps delivery, Ventouse, Caesarian section, Destructive operations, Genital tract injuries-Third degree perineal tear, VVF, RVF. Complications of third stage of labour: Postpartum Hemorrhage and Retained placenta.

**Post-partum complications:** Puerperal sepsis, urinary complications, puerperal venous thrombosis and pulmonary embolism. Sub involution of uterus and thrombophlebitis. Psychological complications, post-partum blues, depression, psychosis

**High Risk Newborn :** Small for gestational age, post-mature infant and baby of diabetic and substance use mothers. Asphyxia neonatorum, meconium aspiration syndrome, pneumo thorax, Icterus neonatorum, Hypoxic ischemic encephalopathy, Neonatal seizures, Neonatal hypocalcaemia, hypoglycemia, hypomagnesaemia. Neonatal heart diseases, Neonatal hemolytic diseases, Neonatal infections, neonatal sepsis, ophthalmia neonatorum, congenital syphilis, HIV/AIDS.

**HIV/AIDS:** Screening and Parent to child transmission (PTCT), Prophylaxis for mother and baby, Standard safety measures, Counseling, Breast feeding issues.

**Gynecological problems and nursing management:** Menstrual irregularities, Genital tract infections, Uterine displacement, Genital prolapsed, Genital injuries, Uterine malformation, Uterine fibroid, ovarian tumors, Breast carcinoma, Pelvic inflammatory diseases, reproductive tract malignancies, hysterectomy – vaginal and abdominal.

**Administration and management of obstetrical and gynecological unit:** Infection control; Standard safety measures, Quality Assurance:-Obstetric auditing –records /reports. Norms, policies and protocols.

**Education and training in obstetrical and gynecological care:** Staff orientation, training and development, In-service education program and clinical teaching programs.

**Text book references:**

5. I. M. Bobak, D. L. Lowdermilk & S.E. Perry. Maternity Nursing. 4<sup>th</sup> edition. St. Louis: Mosby; 1995.
6. D.C. Dutta. Textbook of obstetrics. 6<sup>th</sup> edition. Calcutta: New central book agency; 2004.
7. Diane M. Fraser. Myles textbook for midwives. 14<sup>th</sup> edition. Edinburgh: Churchill Livingstone; 2004.
8. Annamma Jacob. A comprehensive textbook of midwifery. New Delhi; Jaypee medical publishers 2005.

**Reference Books:**

5. James David K. High risk Pregnancy managements options. 2<sup>nd</sup> ed. London; W B Saunders; 1999.
6. Lee Richard V. Ed. Medical care of the pregnant patient. 1<sup>st</sup> ed. Philadelphia; American college; 2000.
7. Alexander J.O. Midwifery Practices care topics. 1<sup>st</sup> ed. London; Macmillan: 1996.
8. Kargar Ishbel Ed. Challenges in the Midwifery Care. 1<sup>st</sup> ed. London; Macmillan: 1997



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**SUB DISCIPLINE: CHILD HEALTH NURSING: SYLLABUS**

**Child with respiratory disorders:**

Child with upper respiratory tract & Lower respiratory tract:

Child with gastro-intestinal disorders Child with Hepatic disorders

Child with renal/ urinary tract disorders

Child with cardio-vascular disorders: Acquired: Rheumatic fever, Rheumatic heart disease, Congenital: Cynotic and acynotic.

Child with endocrine/metabolic disorders: Diabetes insipidus, Diabetes Mellitus – IDDM, NIDDM, hyper and hypo thyroidism, phenylketonuria, galactosemia.

Child with Neurological disorders: Convulsions, Meningitis, encephalitis, guillian- Barre syndrome. Child

with oncological disorders: Leukemias, Lymphomas, Wilms' tumor, nephroblastomas, neuroblastomas, Rhabdomyosarcoma, retinoblastoma, hepatoblastoma, bone tumors,

Child with blood disorders Child with skin disorders

Common Eye and ENT disorders and common Communicable diseases.

**Gastrointestinal system:** Cleft lip, cleft palate and conditions requiring plastic surgery, Tracheo esophageal fistula/atresia, Hirschsprungs' disease/megacolon, malrotation, intestinal obstruction, duodenal atresia, gastrochisis, exomphalus, anorectal malformation, omphalocele, diaphragmatic hernia.

Anomalies of the nervous system: Spina bifida, Meningocele, Myelomeningocele, hydrocephalus.

Anomalies of the genito-urinary system: Hypospadias, Epispadias, Undescended testes, Exstrophy bladder.

Anomalies of the skeletal system Eye and ENT disorders

Head injury, abdominal injury, poisoning, foreign body obstruction, burns & Bites.

Management of stomas, catheters and tubes, management of wounds and drainages.

**Intensive care for pediatric client:** Resuscitation, stabilization & monitoring of pediatric patients

Anatomical & physiological basis of critical illness in infancy and childhood, Care of child requiring long-term ventilation

Nutritional needs of critically ill child

**High Risk Newborn:**

Post-mature infant and baby of diabetic and substance use mothers.

Respiratory conditions: Asphyxia neonatorum, neonatal apnoea, meconium aspiration syndrome, pneumo thorax, pneumo mediastinum. Icterus neonatorum,

Birth injuries, Hypoxic ischaemic encephalopathy, Congenital anomalies.

Neonatal seizures, Neonatal hypocalcaemia, hypoglycemia, hypomagnesaemia. Neonatal heart diseases

Neonatal hemolytic diseases

Neonatal infections, neonatal sepsis, ophthalmia neonatorum, congenital syphilis, HIV/AIDS, Advanced neonatal procedures, Calculation of fluid requirements.

Hematological conditions – erythroblastosis fetalis, hemorrhagic disorder in the newborn,

**Developmental disturbances and implications for nursing:** Adjustment reaction to school, learning disabilities, Habit disorders, speech disorders, Conduct disorders, early infantile autism, Attention deficit hyperactive disorders (ADHD), depression and childhood schizophrenia.

**Challenged child and implications for nursing:** Physically challenged, causes, features, early detection & management. Cerebral palsied child, mentally challenged child, Training & rehabilitation of challenged children.

**Crisis and nursing intervention:** The hospitalized child, Terminal illness & death during childhood and Nursing intervention-counselling.

**Drugs used in Paediatrics:** Criteria for dose calculation: Administration of drugs, oxygen and blood, Drug interactions, Adverse effects and their management.

**Text book references:**

4. Wong. Whaley & Wong's Nursing care of Infants & Children. 5<sup>th</sup> ed. St. Louis; Mosby: 1995.
5. Meharban Singh. Care of the Newborn. 6<sup>th</sup>ed. New Delhi; Sagar: 2004.
6. Marlow Dorothy. Textbook of Paediatric Nursing. 6<sup>th</sup> ed. Philadelphia; W.B.Saunders: 2001.

**Reference books:**

4. Gupte. Short Textbook of Paediatrics. 10<sup>th</sup> edition. New Delhi: Jaypee; 2004.
5. Datta. Paediatric Nursing. 3<sup>rd</sup> edition. New Delhi: Jaypee publishers; 2014.
6. Guha. Practical Newborn Critical care Nursing. 1<sup>st</sup> edition. New Delhi: Jaypee publishers; 2015.

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**SUB DISCIPLINE: MENTAL HEALTH NURSING: SYLLABUS**

**Schizophrenia and Other Psychotic Disorders (Check ICD10):** Schizophrenia –Types: Disorganized Schizophrenia, Catatonic Schizophrenia, Paranoid Schizophrenia, Undifferentiated Schizophrenia and Residual Schizophrenia. Other Psychotic disorders: Schizoaffective Disorder, Brief Psychotic Disorder, Schizophrenic form Disorder, Psychotic Disorder Due to a General Medical Condition and Substance-Induced Psychotic Disorder, Treatment and Nursing Management.

**Mood Disorders:** The Grief Response, Maladaptive Responses To Loss, Types Of Mood Disorders, Depressive disorders, Bipolar disorders, Treatment and Nursing Management.

**Neurotic, stress related and somatisation disorders:**

☐ **Anxiety Disorders:** Types: Panic Disorder, Generalized Anxiety Disorder, Phobias, Obsessive-Compulsive Disorder, Posttraumatic Stress Disorder, Anxiety disorder due to a general Medical condition, substance-induced anxiety disorder, treatment modalities. Psychopharmacology & Nursing Management.

☐ **Adjustment and Impulse Control Disorders:** Adjustment Disorders, Impulse Control Disorders, treatment and nursing management.

**Substance Use Disorders:** Substance-Use Disorders, Substance-Induced Disorders, Classes of Psychoactive Substances and predisposing Factors the dynamics of Substance-related disorders, The Impaired Nurse, Codependency, Treatment Modalities for Substance-Related Disorders and Nursing Management.

**Personality and Sexual Disorders:**

☐ Types of Personality Disorders: Paranoid Personality Disorder, Schizoid Personality Disorder, Antisocial Personality Disorder, Borderline Personality Disorder, Histrionic Personality Disorder, Narcissitic Personality Disorder, Avoidance Personality Disorder, Dependent Personality Disorder, Obsessive-Compulsive Personality Disorder and Passive-Aggressive Personality Disorders. Identification, diagnostic, symptoms, psychopharmacology, treatment & nursing management.

☐ Eating Disorders: Predisposing Factors; Anorexia Nervosa And Bulimia Nervosa obesity, Psychopharmacology, Treatment & Nursing Management.

☐ Development of Human Sexuality, Sexual Disorders, Variation In Sexual Orientation and Nursing Management.

**Behavioural & Emotional Disorders occurring during Childhood and Adolescence:** Mentally Challenged, Autistic Disorders, Attention-Deficit Hyperactivity Disorder, Conduct Disorders, behavioural disorders, Oppositional Defiant Disorder, Tourette's Disorders, Separation Anxiety Disorder, Psychopharmacological Intervention and Nursing Management.

**Organic Brain Disorders & Somatoform Disorders:**

☐ Delirium, Dementia, Amnesia, Psychopharmacological Intervention and Nursing Management.

☐ Somatoform Disorders, Historical Aspects, Epidemiological Statistics, Pain Disorder, Hypochondriasis, Conversion Disorder, Body Dysmorphic Disorder, Sleep Disorder, Treatment Modalities and Nursing Management.

☐ **Dissociative Disorders and Management :** Historical Aspects, Epidemiological Statistics, Application of the Nursing Management Treatment Modalities and Nursing Management.

**Psychiatric Emergencies and Crisis Intervention:**

☒ **Suicide:** Risk Factors. Predisposing factors, Theories of Suicide-Psychological, Sociological, Biological and Nursing Management.

☒ **Anger/ Aggression Management:** Anger and Aggression, Types, Predisposing Factors, Management and Role of the Nurse.

☒ **Crisis Intervention :** Crisis, Definition, Phases In The Development of A Crisis, Types of Crisis; Dispositional Anticipated Life Transitions, Traumatic Stress, Maturation/ Development, Reflecting Psychopathology, Psychiatric Emergencies and their management, Grief and grief reaction, Crisis Intervention; Phases. Post traumatic stress disorder (PTSD) and role of the Nurse.

**Community Mental Health Nursing:** National Mental Health Program- Community mental health program, The Changing Focus of care, The Public Health Model, The Role of the Nurse, Case Management. The community as Client: Primary Prevention, populations at Risk, Secondary prevention, Tertiary Prevention and Community based rehabilitation.

**Special Considerations in Mental Health Nursing:**

☒ **Medical Conditions due to Psychological Factors**

☒ **The Aging Individual.**

☒ **The person living with HIV Disease.**

☒ **Problems Related to Abuse or Neglect**

☒ **Psychosocial rehabilitation.**

☒ **Counseling**

**Text book references:**

6. Townsend Mary. Psychiatric Health Nursing. 3<sup>rd</sup> edition. Philadelphia: F.A.Davis;2005.

7. StaurtSundeen. Principles & practices of psychiatric Nursing. 7<sup>th</sup> edition. New Delhi: Harcourt Mosby Inc; 2001.

8. Sreevani.R. A Guide to Mental health psychiatric nursing. 1<sup>st</sup> edition. New Delhi: Jaypee; 2004.

9. Kapoor Bimla. Textbook of Psychiatric Nursing. 1<sup>st</sup> edition. Delhi: Kumar publishers; 1998.

10. Ahuja Niraj. A Short Text Book of Psychiatry. 4<sup>th</sup> edition. Jaypee: New Delhi; 1999.

**Reference Books:**

5. Prisch Noreen. Psychiatric Mental Health Nursing. 2<sup>nd</sup> edition. Australia: Thomson Delmer; 2002.

6. Fontaine. K.L. Mental Health Nursing. 1<sup>st</sup> edition. New York: Addison Wisley; 1999.

7. Vyas.J.N. Text book of Post Graduate Psychiatry. 2<sup>nd</sup> edition. New Delhi: Jaypee; 1999.

8. Boyd.Mary Ann. Psychiatric Nursing. 2<sup>nd</sup> edition. Philidelphia: Lippincott; 2002

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## Dayananda Sagar University

School of Health Sciences  
COLLEGE OF NURSING SCIENCES

### **SUB DISCIPLINE - COMMUNITY HEALTH NURSING: SYLLABUS**

**Epidemiology :** Concept, scope, definition, trends, Contribution of epidemiology, Implications, Epidemiological methods, Measurement of health and disease: Health policies, Epidemiological approaches, Study of disease causatives, Health promotion, Levels of prevention, Epidemiology of Communicable diseases, Non-communicable diseases, Emerging and re-emerging diseases Epidemics, National Integrated disease Surveillance Programme, Health information system, Epidemiology study and reports, Role of Community health nurse

**National Health and Family Welfare Programmes :** Objectives, Organization/manpower/ resources, Activities, Goals, inter-sectoral approach, implementation, item/purpose, role and responsibilities of community health nurse: National Vector Borne Disease Control Programme (NVBDCP), National Filaria Control Programme, National Leprosy Eradication Programme, Revised national TB Control Programme, National Programme for Control of Blindness, National Iodine Deficiency disorders Control Programme, National Mental Health Programme, National AIDS Control Programme, National Cancer Control Programme, RCH I and II, Non-communicable disease programmes and NRHM, Health Schemes: ESI, CGHS and Health insurance.

**School Health:** concepts, objectives, Health assessment, Screening, identification, referral and follow up, Safe environment, Services, programmes and plans- first aid, treatment of minor ailments, Inter-sectoral coordination, Adolescent health, Disaster, disaster preparedness, and management, Guidance and counseling, School health records - maintenance and its importance, Roles and responsibilities of community health nurse.

**International health :**Global burden of disease, Global health rules to halt disease spread, Global health priorities and programs, International quarantine, Health tourism, International cooperation & assistance, international travel and trade, health & food legislation, laws and adulteration of food, Disaster management, Migration, International health agencies –World Health organizations, World health assembly, UNICEF, UNFPA, UNESCO, ILO, CARE, SIDA, US AID, DANIDA, DFID. Aus AID etc. International health issues and problems, International nursing practice standards, International health vis-a vis national health, International health days and their significance

**Education and administration :** Quality assurance, Standards, Protocols, Policies and Procedures, Infection control; Standard safety measures, Nursing audit and Design of Sub- Centre/Primary Health Centre/Community health center, Staffing; Supervision and monitoring- Performance appraisal, Budgeting and Material management, Role and responsibilities of different categories of personnel in community health, Referral chain- community outreach services, Transportation, Public relations, Planning in-service educational programme and teaching, Training of various categories of health workers preparation of manuals.

**Geriatric:** Concept, trends, problems and issues. Aging process, and changes, Theories of ageing, Health problems and needs, Psycho-physiological stressors and disorders, Myths and facts of aging, Health assessment, Home for aged-various agencies, Rehabilitation of elderly, Care of elderly, Elderly abuse, Training and supervision of care givers, Government welfare measures, Programmes for elderly- Role of NGOs, Roles and responsibilities of Geriatric nurse in the community.

**Rehabilitation:** Introduction: Concepts, principles, trends, issues, Rehabilitation team, Models, Methods. Community based rehabilitation, Ethical issues, Rehabilitation Council of India, Disability and rehabilitation- Use of various prosthetic devices, Psychosocial rehabilitation, Rehabilitation of chronic diseases, Restorative rehabilitation and Vocational rehabilitation. Role of voluntary organizations, Guidance and counseling, Welfare measures, Role and responsibilities of community health nurse.

**Community mental health:** Magnitude, trends and issues, National Mental Health Program- Community mental health program, The Changing Focus of care and The Public Health Model. case management- Collaborative care, crisis intervention, Welfare agencies and Population at Risk. The community as Client: Primary Prevention, Secondary prevention and Tertiary Prevention. Community based rehabilitation, Human rights of mentally ill, Substance use, mentally challenged groups and role of community health nurse.

**Occupational health:** Introduction: Trends, issues, Definition, Aims, Objectives and Workplace safety, Ergonomics and Ergonomic solutions. Occupational environment- Physical, social, Decision making and Critical thinking. Occupational hazards for different categories of people physical, chemical, biological, mechanical and Accidents. Occupational diseases and disorders. Measures for Health promotion of workers; Prevention and control of occupational diseases, disability limitations and rehabilitation. Women and occupational health. Occupational education and counseling. Violence at workplace: Child labour. Disaster preparedness and management. Legal issues: Legislation, Labour unions, ILO and WHO recommendations, Factories act, ESI act. Role of Community health nurse, Occupational health team.

**Textbook references:**

6. Park.J.E. Textbook of Preventive & Social Medicine. 18<sup>th</sup> edition. Jabalpur: BanarasidasBhanot; 2005.
7. Rao KasturiSundar. Introduction to Community Health Nursing. 3<sup>rd</sup> edition. Chennai: B.I.Publication; 2000.
8. Stanhope. Community Health Nursing. 1<sup>st</sup> edition. Philidelphia: Mosby; 2008.
9. Clement Stone, Susane. Comprehensive Community Health Nursing. 8<sup>th</sup> edition. New Delhi: B.I.Waverly; 1998.
10. Hatroberta. Introduction to Community based. 2<sup>nd</sup> edition. Philidelphia: Lippincott; 2001.

**Reference Books:**

4. Roa. Sridhar. Principles of Community Medicine. 3<sup>rd</sup> edition. New Delhi: A.I.T.B.S; 2002.
5. Gupta. M.C. and Mahajan. Textbook of Preventive and Social Medicine. 3<sup>rd</sup> edition. New Delhi: Jaypee brothers; 2003.
6. Park. K. Essentials of Community Health Nursing. 3<sup>rd</sup> edition. Jadel: BanarasidasBhanot ; 2000.

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