

**M.D./M.S.-AYURVEDA PRELIMINARY
PAPER-I
RESEARCH METHODOLOGY AND MEDICAL STATISTICS**

**PART-A
RESEARCH METHODOLOGY**

1 Introduction to Research

- A. Definition of the term research
- B. Definition of the term anusandhan
- C. Need of research in the field of Ayurveda

2 General guidelines and steps in the research process

- A. Selection of the research problem
- B. Literature review: different methods (including computer database) with their advantages and limitations
- C. Defining research problem and formulation of hypothesis
- D. Defining general and specific objectives
- E. Research design: observational and interventional, descriptive and analytical, preclinical and clinical qualitative and quantitative
- F. Sample design
- G. Collection of the data
- H. Analysis of data.
- I. Generalization and interpretation, evaluation and assessment of hypothesis.
- J. Ethical aspects related to human and animal experimentation.
- K. Information about Institutional Ethics Committee (IEC) and Animal Ethics Committee (AEC) and their functions. Procedure to obtain clearance from respective committees, including filling up of the consent forms and information sheets and publication ethics.

3 Preparation of research proposals in different disciplines for submission to funding agencies taking EMR-AYUSH scheme as a model.

4. Scientific writing and publication skills.

- a. Familiarization with publication guidelines- Journal specific and CONSORT guidelines.
- b. Different types of referencing and bibliography.
- c. Thesis/Dissertation: contents and structure
- d. Research articles structuring: Introduction, Methods, Results and Discussions (IMRAD)

5 Classical Methods of Research.

Concept of Pratyakshadi Pramana Pariksha, their types and application for Research in Ayurveda.
Dravya-, Guna-, Karma-Parikshana Paddhati
Aushadhi-yog Parikshana Paddhati
Swastha, Atura Pariksha Paddhati
Dashvidha Parikshya Bhava
Tadvidya sambhasha, vadmarga and tantrayukti

6 Comparison between methods of research in Ayurveda (Pratigya, Hetu, Udaharana, Upanaya, Nigaman) and contemporary methods in health sciences.

7. Different fields of Research in Ayurveda

Fundamental research on concepts of Ayurveda

- a. Panchamahabhuta and tridosha.
- b. Concepts of rasa, guna, virya, vipak, prabhav and karma
- c. Concept of prakriti-saradi bhava, ojas, srotas, agni, aam and koshta.

8. Literary Research-

Introduction to manuscriptology: Definition and scope. Collection, conservation, cataloguing. Data mining techniques, searching methods for new literature; search of new concepts in the available literature. Methods for searching internal and external evidences about authors, concepts and development of particular branches of knowledge.

9. Drug Research (Laboratory-based)- Basic knowledge of the following:

Drug sources: plant, animal and mineral. Methods of drug identification.

Quality control and standardization aspects: Basic knowledge of Pharmacopoeial standards and parameters set by Ayurvedic Pharmacopoeia of India.

Information on WHO guidelines for standardization of herbal preparations. Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP).

10. Safety aspects: Protocols for assessing acute, sub-acute and chronic toxicity studies. Familiarization with AYUSH guidelines (Rule 170), CDCSO and OECD guidelines.

11. Introduction to latest Trends in Drug Discovery and Drug Development

- Brief information on the traditional drug discovery process
- Brief information on the latest trends in the Drug Discovery process through employment of rational approach techniques; anti-sense approach, use of micro and macro-arrays, cell culture based assays, use of concepts of systems biology and network physiology
- Brief introduction to the process of Drug development

12. Clinical research:

Introduction to Clinical Research Methodology identifying the priority areas of Ayurveda

Basic knowledge of the following:-

Observational and Interventional studies

Descriptive & Analytical studies

Longitudinal & Cross sectional studies

Prospective & Retrospectives studies

Cohort studies

Randomized Controlled Trials (RCT) & their types

Single-case design, case control studies, ethnographic studies, black box design, cross-over design, factorial design.

Errors and bias in research.

New concepts in clinical trial- Adaptive clinical trials/ Good clinical practices (GCP)

Phases of Clinical studies: 0,1,2,3, and 4.

Survey studies -

Methodology, types, utility and analysis of Qualitative Research methods. Concepts of in-depth interview and Focus Group Discussion.

13. Pharmacovigilance for ASU drugs. Need, scope and aims & objectives. National Pharmacovigilance Program for ASU drugs.

14. Introduction to bioinformatics, scope of bioinformatics, role of computers in biology. Introduction to Data bases - Pub med, Medlar and Scopus. Accession of databases.

15. Intellectual Property Rights- Different aspect and steps in patenting. Information on Traditional Knowledge Digital Library (TKDL).

PART-B
MEDICAL STATISTICS

- 1 **Definition of Statistics** : Concepts, relevance and general applications of Biostatistics in Ayurveda
- 2 **Collection, classification, presentation, analysis and interpretation of data** (Definition, utility and methods)
- 3 **Scales of Measurements** - nominal, ordinal, interval and ratio scales.
Types of variables - Continuous, discrete, dependent and independent variables.
Type of series - Simple, Continuous and Discrete
- 4 **Measures of Central tendency** - Mean, Median and Mode.
- 5 **Variability**: Types and measures of variability - Range, Quartile deviation, Percentile, Mean deviation Standard deviation
- 6 **Probability**: Definitions, types and laws of probability,
- 7 **Normal distribution**: Concept and Properties, Sampling distribution, Standard Error, Confidence Interval and its application in interpretation of results and normal probability curve.
- 8 **Fundamentals of testing of hypotheses**:
Null and alternate hypotheses, type I and type 2 errors.
Tests of significance: Parametric and Non-Parametric tests, level of significance and power of the test, P value and its interpretation, statistical significance and clinical significance
- 9 **Univariate analysis of categorical data**:
Confidence interval of incidence and prevalence, Odds ratio, relative risk and Risk difference, and their confidence intervals
- 10 **Parametric tests**: 'Z' test, Student's 't' test: paired and unpaired, 'F' test, Analysis of variance (ANOVA test, repeated measures analysis of variance
- 11 **Non parametric methods**: Chi-square test, Fisher's exact test, McNemar's test, Wilcoxon test, Mann-Whitney U test, Kruskal - Wallis with relevant post hoc tests (Dunn)
- 12 **Correlation and regression analysis**:
Concept, properties, computation and applications of correlation, Simple linear correlation, Karl Pearson correlation coefficient, Spearman's rank correlation.
Regression- simple and multiple.
- 13 **Sampling and Sample size computation for Ayurvedic research**:
Population and sample. Advantages of sampling, Random (Probability) and non random (Non-probability) sampling. Merits of random sampling. Random sampling methods- simple random, stratified, systematic cluster and multiphase sampling. Concept, logic and requirement of sample size computation, computation of sample size for comparing two means, two proportions, estimating mean and proportions.
- 14 **Vital statistics and Demography**: computation and applications - Rate, Ratio, Proportion, Mortality and fertility rates, Attack rate and hospital-related statistics
- 15 **Familiarization with the use of Statistical software** like SPSS/Graph Pad

PRACTICAL

I. RESEARCH METHODOLOGY

PRACTICAL NAME

- 1 **Pharmaceutical Chemistry**
Familiarization and demonstration of common lab instruments for carrying out analysis as
- 2 **Awareness of Chromatographic Techniques**
Demonstration or Video clips of following:
 - Thin-layer chromatography (TLC).
 - Column chromatography (CC).
 - Flash chromatography (FC)
 - High-performance thin-layer chromatography (HPTLC)
 - High Performance (Pressure) Liquid Chromatography (HPLC)
 - Gas Chromatography (GC, GLC)
- 4 **Pharmacognosy**
Familiarization and Demonstration of different techniques related to:-
Drug administration techniques- oral and parenteral.
Blood collection by orbital plexuses puncturing.
Techniques of anesthesia and euthanasia.
Information about different types of laboratory animals used in experimental research
Drug identification as per API including organoleptic evaluation
- 5 **Pharmacology and toxicology**
Familiarization and demonstration of techniques related to pharmacology and toxicology
- 6 **Biochemistry (Clinical)**
Familiarization and demonstration of techniques related to basic instruments used in a clinical
biochemistry laboratory – semi and fully automated clinical analyzers, electrolyte analyzer
techniques, nephelometry.
Demonstration of blood sugar estimation, lipid profiles, kidney function test, liver function
cystatin and microalbumin estimation by nephelometry or other suitable techniques.
Interpretation of the results obtained in the light of the data on normal values.
- 7 **Clinical Pathology**
Familiarization and demonstration of techniques related to basic and advanced instruments
basic clinical
pathology lab. Auto cell counter, urine analyzer, ESR, microscopic examination of urine.
- 8 **Imaging Sciences**
Familiarization and demonstration of techniques related to the imaging techniques.
Video film demonstration of CT-Scan, MRI-scan and PET-scan.
- 9 **Clinical protocol development**

**Statistical exercise of examples from Topic number 4, 5, 8-12, 14, 15.
Records to be prepared.**

Distribution of marks (practical):

- | | |
|--|------------|
| 1. Instrumental spotting test | - 20 marks |
| 2. Clinical protocol writing exercise on a given problem | - 20 marks |
| 3. Records: | |
| 4. Research methodology | -10 Mark |
| 5. Medical statistics | -10 marks |
| 6. Viva- Voce | -40 Marks |

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