

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.**

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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 body 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 as 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 Programme for ASU drugs.

14. Introduction to bioinformatics, scope of bioinformatics, role of computers in biology. Introduction to Data base- 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).

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PART-B

40 marks

MEDICAL STATISTICS

Teaching hours: 80

- 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 and 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's correlation co-efficient, 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

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PRACTICAL

100 marks

I. RESEARCH METHODOLOGY

Teaching hours 120

PRACTICAL NAME

- 1 **Pharmaceutical Chemistry**
Familiarization and demonstration of common lab instruments for carrying out analysis as per API
- 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, ELISA- techniques, nephelometry.

Demonstration of blood sugar estimation, lipid profiles, kidney function test, liver function test. HbA1, 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 used in a 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**

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II. MEDICAL STATISTICS

Practical hours:20

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 |

REFERENCE BOOKS:-

Pharmacognosy:

1. Aushotosh Kar "Pharmacognosy & Pharmacobiotechnology" New Age International Publisher. Latest Edition. New Delhi
2. Drug Survey by Mayaram Uniyal
3. Fahh A (1981). Plant Anatomy 3rd Edition Pergamon Press, Oxford
4. Kokate, CK., Purohit, AP, Gokhale, SB (2010). Pharmacognosy. Nirali Prakashan. Pune.
5. Kokate, CK., Khandelwal and Gokhale, SB (1996). Practical Pharmacognosy. Nirali Prakashan. Pune.
6. Trease G E and Evans W C, Pharinacognosy, Bailliere Tindall, Eastbourne, U K.
7. Tyler V C., Brady, L R., and Robers J E., Pharmacognosy, Lea and Febiger, Philadelphia.
8. Tyler VE Jr and Schwarting AE., Experimental Pharmacognosy, Burgess Pub. Co, Minneaplis, Minnesota.
9. Wallis- TE (2011)- reprint. Practical Pharmacogonosy (Fourth Edition) Pharma Med Press, Hyderabad.
10. Wallis T E, Analytical Microscopy, J & A Churchill limited, London.
11. Wallis T E., Text Book of Pharmacognosy, J & A Churchill Limited, London.
12. WHO guidelines on good agricultural and collection practices- (GACP) for medicinal plants (2003).World Health Organ Geneva.
13. WHO monographs on selected medicinal plants (1999)—Vol. 1. 1.Plants, Medicinal 2.Herbs 3.Traditional medicine. ISE 154517 8. WHO Geneva.

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Pharmaceutical chemistry, quality control and drug standardization:

1. Ayurvedic Pharmacopoeia of India. Part I- volume 1 to 8 and Part II- volume 1to 3. Ministry of Health and Family V Controller of Publication. Govt of India. New Delhi.
2. Brain, KR and Turner, TD. (1975). The Practical Evaluation Phytopharmaceuticals. Wright Scienctehnica, Bristol.
3. Galen Wood Ewing (1985). Instrumental Methods of Chemical Analysis. McGraw-Hill College ; Fifth edition
4. Harborne, JB (1973). Phytochemistry Methods. Chapman and Hall, International Edition, London.
5. HPTLC- Fingerprint atlas of Ayurvedic Single Plant Drugs mentioned in Ayurvedic Pharmacopoeia Vol- III and IV. CE COUNCIL FOR RESEARCH IN AYURVEDA AND SIDDHA. New Delhi.
6. Kapoor, RC (2010). Some observations on the metal based preparations in Indian System of Medicine. Indian Jo Traditional Knoledge. 9(3): 562-575
7. Khopkar, S. M. Analytical Chemistry, New Age International Publishers , 3 rd edition
8. Laboratory Guide for- The Analysis of Ayurved and Siddha Formulations – CCRAS, New Delhi.
9. Mahadik KR, Bothara K G. Principles of Chromatography by, 1st edition, Nirali Prakashan.

10. Qadry JS and Qadry S Z., Text book of Inorganic Pharmaceutical and Medicinal Chemistry, B. S. Shah Pral Ahmedabad.
11. Quality Control Methods for Medicinal Plant Material. Reprint (2002). WHO- Geneva.
12. Rangari V.D., Pharmacognosy & Phytochemistry, Vol I, II, Career Publication,
13. Sharma BK. Instrumental Methods of Chemical Analysis by, Goel Publishing House.
14. Srivastav VK and Shrivastav KK. Introduction to Chromatography (Theory and Practice)
15. Stahl E., Thin Layer Chromatography - A Laboratory Handbook, Springer Verlag, Berlin.
16. Sukhdev Swami Handa, Suman Preet Singh Khanuja, Gennaro Longo and Dev Dutt Rakesh (2008). Extraction Techn for Medicinal and Aromatic Plants -INTERNATIONAL CENTRE FOR SCIENCE AND HIGH TECHNOLOGY- Trieste, **Biochemistry and Laboratory techniques:**
 1. Asokan P. (2003) Analytical Biochemistry, China publications,
 2. Campbell, P.N and A.D .Smith, Biochemistry Illustrated, 4th ed, Churchill Livingstone.
 3. David Frifelder. W. H. Freeman. (1982). Physical Biochemistry by; 2 edition
 4. David Sultan (2003).Text book of Radiology and Imaging, Vol-1, 7th Edition.
 5. Deb, A.C., Fundamentals of Biochemistry, Books and Allied (P) Ltd, 2002.
 6. Harold Varley. Practical Clinical Bio-chemistry
 7. Kanai L.Mukherjee. Clinical Pathology:,Medical Laboratory Technology Vol. I.Tata McGrawHill 1996, New Delhi.
 8. Gradwohl, Clinical Laboratory-methods and diagnosis, Vol-I
 9. Clinical Biochemistry -Sabitri Sanyal, Clinical Pathology, B.I.Churchill Livingstone (P) Ltd, New Delhi.2000.
 10. Satyanarayanan,U. Essentials of Biochemistry, Books and allied(P) Ltd.2002
 11. Zubay, G.L. Biochemistry, W.M.C. Brown Publishers, New York 1998.
 12. Text book of Radiology and Imaging, Vol-1, David Sultan, 7th Edition. 2003.

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Research methodology:

1. Alley, Michael. The craft of scientific writing. Englewood Cliffs. N.N. Prentice 1987.
2. Ayurvediya Anusandhan Paddhati – P.V. Sharma
3. Altick and Fenstermaker. (2007). *The Art of Literary Research*, 4th ed, W. W. Norton, Castle, Gregory, *Blackwell G Literary Theory*. Blackwells,
4. Bowling, A. (2002). *Research Methods in Health* (2nd ed). Buckingham: Open University Press.
5. Day R.A. How to write a scientific paper. Cambridge University Press.
6. Cooray P.G. Guide to scientific and technical writing.
7. Deepika Chawla and Neena Sondhi. (2011). *Research Methods- Concepts and cases*. New Delhi: Vikas Publishing Ho
8. Greenhalgh, T. (2006) *How to Read a Paper: The Basics of Evidence-Based Medicine*. (3rd ed) Blackwell
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10. Kumar, R. 2005. *Research Methodology: a Step-by-Step Guide for Beginners*, 2nd ed. Thousand Oaks, CA, Londer Publications.
11. Petter Laake, Haakon Breien Benestad and Bjørn Reino Olsen. (2007). *Research Methodology in the Medical and Bi sciences*. Academic Press is an imprint of Elsevier, 84 Theobald's Road, London WC1X 8RR, UK. ISBN: 978-0-12-3738
12. Relevant portions of Ayurvedic Samhitas and other texts

Drug research and development:

1. RICK NG, (2009). DRUGS- from discovery to approval. John Wiley & Sons, Inc., Hoboken, New Jersey
2. Research guidelines for evaluating the safety and efficacy of herbal medicines. (1993). . WHO- (Regional Office Western Pacific – Manila) ISBN 92 9061 110 3 (NLM Classification: WB 925).
3. Jagdeesh, Sreekant Murthy, Gupta, YK and Amitabh Prakash Eds. *Biomedical Research (From Ideation to Publication)* Wolters Kluwer/ Lippincott Williams and Wilkins.
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5. Natural products isolation. (2006) 2nd ed. / edited by Satyajit D. Sarker, Zahid Latif, Alexander I. Gray. (Metl biotechnology; 20). Includes bibliographical references and index. Humana Press Inc. ISBN 1-58829-447-1 (acid-free p ISBN 1-59259-955-9 (eISBN)
6. Gazette Extraordinary Part- II-Section 3 - Sub section (i) December 2008. Govt of India. AYUSH Guidelines on safety & Rule 170 of Drugs and Cosmetics Act.
7. OECD (2000) Guidance Document on Acute Oral Toxicity. Environmental Health and Safety Monograph Series on Test Assessment No 24.
8. OECD Guideline for the Testing of Chemicals – Repeated Dose 90-day Oral Toxicity Study in Rodents, 408, 1998. <http://browse.oecdbookshop.org/oecd/pdfs/free/9740801e.pdf> (latest version)
9. OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring, 1998. http://www.oecd.org/document/63/0,2340,en_2649_34381_2346175_1_1_1_1,00.php
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11. Ghosh M.N.: Fundamentals of Experimental Pharmacology, *Scientific Book Agency, Bombay.*
12. *Bombay.*
 - 12- Jaju B.P.: Pharmacological Practical Exercise Book, *Jaypee Brothers, New Delhi.*
 - 13- Kulkarni S.K.: Hand Book of Experimental Pharmacology, *Vallabh Prakashan, New Delhi*
 - 14- Ravindran R.: X-Pharm (Software), *Indian Journal of Pharmacology, JIPMER, Pondicherry.*

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Biotechnology and Bio-informatics:

1. Angela M. Meireles A (2009). Extracting Bioactive compounds for food products. Theory and applications. CRC- Press and Francis Group.
2. Bergeron BP 2002 Bioinformatics Computing 1st Edition, Prentice Hall
3. Chikhale, N.J. and Virendra Gomase, Bioinformatics- Theory and Practice, Publisher: Himalaya Publication House, 1st edition (July, 2007) ISBN-13: 978-81-8318-831-9
4. Lesk, A.M. Introduction to Bioinformatics Oxford 2002.
5. Satyanarayana, U.: Biotechnology, Books and Allied (P) Ltd, Kolkata, 2005
6. Setubal J. C and J. Meidanis, Introduction to Computational Molecular Biology, PWS Publishing Company, 1997.
7. <http://www.iitb.ac.in/~crnts>
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8. <http://www.zygogen.com>.
9. <http://www.dsir.nic.in/reports/tifp/database/metallo.pdf>
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10. www.consort-statement.org
11. www.strobe-statement.org
12. www.icmr.nic.in

Clinical Evaluation:

1. CDSCO, Good Clinical Practices For Clinical Research in India, Schedule Y (Amended Version – 2005), <http://cdsco.nic.in/html/GCP1.php>
2. Ethical Guidelines for Biomedical Research on Human subjects. (2000). Indian Council of Medical Research- New Delhi
3. Gallo P., Chuang-Stein C., Dragalin V., Gaydos B., Krams M., Pinheiro J. Adaptive Designs in Clinical Drug Development. Executive Summary of the PhRMA Working Group. *Journal of Biopharmaceutical Statistics*. 16: 275–283; 2006
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6. ICH Harmonised Tripartite Guidelines for Good Clinical Practices.(1997)- Quintiles- Published by Brookwood Publications. Richmond, Surrey. United Kingdom.
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9. William C. Scheffer Introduction to Clinical Research

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Medical Statistics:

1. Armitage, P. and Berry, G. (1994) Statistical Methods in Medical Research (3rd ed). Blackwell Science.
2. Armitage P, Berry G, Matthews JNS: *Statistical Methods in Medical Research*. Fourth edition. Oxford, Blackwell Science 2002
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14. Sundar Rao, Jesudian Richard - An Introduction to Biostatistics.
15. Suhas Kumar Shetty- Medical statistics made easy

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THEORY- 100 marks

PAPER-II

THEORY- 100 marks

PART-A

**Practical- Viva-Voce-100
50 marks**

1. Learning and Teaching methodology available in Samhita- Tantrayukti, Tantraguna, Tantradasha, Tachchilya, Vada Kalpana, Arthashraya, Trividha Gyanopadesha, meaning of Pada, Paada, Shloka, Vakya, Vakyartha, meaning and so different Sthana and Chatushka of Brihat Samhita.
2. Manuscriptology - Collection, conservation, cataloguing, Critical editing through collation, reception (A critical revision or incorporating the most plausible elements found in varying sources), emendation (changes for improvement) and criticism (critical analysis) of manuscripts. Publication of edited manuscripts.
3. Concept of Bija chatustaya (Kush, Vyadhi, Kriyakaal, Aushadha according to Sushrut Samhita).
4. Introduction and Application of Nyaya (Maxims) - Like Shukra Nyaya, Kapinjaladhikaran Nyaya, Ghunakshara Gopalivardana Nyaya, Naprishtah Guravo Vadanti Nyaya, Shukra Nyaya, Chhatrino Gacchhanti Shatan, Vedana Nyaya, Suchikatah Nyaya.
5. Importance and utility of Samhita in present era.
6. Importance of ethics and principles of ideal living as mentioned in Samhita in the present time in relation to life style disorder.
7. Interpretation and co-relation of basic principles with contemporary sciences.

PART-B

50 marks

1. Definition of Siddhanta, types and applied examples in Ayurveda.
2. Karma and its components as described in Samhita.
3. Principles of Karana-Karyavada, its utility in advancement of research in Ayurveda.
4. Theory of evolution of Universe (Srishti Utpatti), its process according to Ayurveda and Darshan.
5. Importance and utility of Triskandha (Hetu, Linga, Aushadh) and their need in teaching, research and clinical practice.
6. Applied aspects of various fundamental principles: Tridosha, Triguna, Purusha and Prakmanirupana, Shatpadartha, Vihara. Scope and importance of Pariksha (Pramana).
7. Importance of knowledge of Vir Prakriti and Manas Prakriti.
8. Comparative study of Principles of Ayurveda and Shad Darshanas.

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1. REFERENCE BOOKS:-

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|----|-----------------------|----------------------------------|
| 1 | Charak Samhita | Chakrapani commentary |
| 2 | Sushrut Samhita | Dalhana Comment |
| 3 | Ashtanga Samgraha | Indu commentary |
| 4 | Ashtanga Hridaya | Arundutta and Hemadri commentary |
| 5 | Vaisheshika Darshan | Prashastapada Bhasya |
| 6 | Nyaya Darshan | Vatsyayan Bhasya Patanjala |
| 7 | Shad Darshan | Vyas Bhasya |
| | Vedantsara | |
| 9 | Sarvadarshan Samgraha | |
| 10 | Bhartiya Darshan | Baldev Upadhayaya |