M.D.-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 andlimitations
C. Defining research problem and formulation of hypothesis
D. Defining general and specific objectives
E. Research design: observational and interventional, descriptive and analytical, preclinical andclinical, 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 fillingup 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**.**Tadvidya sambhasha, vadmarga and tantrayukti** 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**
   a. Fundamental research on concepts of Ayurveda
   b. Panchamahabhuta and tridosha.
   c. Concepts of rasa, guna, virya, vipak, prabhav and karma
   d. Concept of prakriti-saradi bhava, ojas, srotas, agni, aam and koshtha.

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 parametersas 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 withAYUSH 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 approachtechniques; 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 andFocus Group Discussion.

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

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

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

PART–B **40 marks**

MEDICAL STATISTICS **Teaching hours: 80**

1 **Definition of Statistics :** Concepts, relevance and general applications of Biostatistics in Ayurveda
Collection, classification, presentation, analysis and interpretation of data (Definition, utility andmethods)

2 **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

3 **Measures of Central tendency** – Mean, Median and Mode.

4 **Variability:** Types and measures of variability – Range, Quartile deviation, Percentile, Mean deviationand Standard deviation

5 **Probability**: Definitions, types and laws of probability,

6 **Normal distribution**: Concept and Properties, Sampling distribution, Standard Error, Confidence Intervaland its application in interpretation of results and normal probability curve.

7 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

8 Univariate analysis of categorical data:

Confidence interval of incidence and prevalence, Odds ratio, relative risk and Risk difference, and theirconfidence intervals

9 **Parametric tests:**
'Z' test, Student's 't' test: paired and unpaired, 'F' test, Analysis of variance(ANOVA) test, repeated measures analysis of variance

10 **Non parametric methods:**
Chi-square test, Fisher's exact test, McNemar's test, Wilcoxon test, Mann-Whitney U test, Kruskall – Wallis with relevant post hoc tests (Dunn)

11 Correlation and regression analysis:
Concept, properties, computation and applications of correlation, Simple linear correlation, KarlPearson's correlation co-efficient, Spearman's rank correlation.
Regression- simple and multiple.

12 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 sizecomputation, computation of sample size for comparing two means, two proportions, estimating meanand proportions.

13 **Vital statistics and Demography**:
computation and applications - Rate, Ratio, Proportion, Mortality andfertility rates, Attack rate and hospital-related statistics

14 **Familiarization with the use of Statistical software** like SPSS/Graph Pad

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 researchDrug 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 abasic 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

II. MEDICAL STATISTICS

Practical houís: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:Research methodology -10 Mark
4. Medical statistics -10 marks
5. 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. Fahn A (1981). Plant Anatomy 3rd Edition Pergamon Press, Oxford
4. Kokate, CK., Purohit, AP, Gokhale, SB (2010). Pharmacognosy. Nirali Prakashan. Pune.
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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 Pharmacgonosy (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 medicinalplants (2003).World Health Organization- Geneva.
13. WHO monographs on selected medicinal plants (1999)—Vol. 1. 1.Plants, Medicinal 2.Herbs 3.Traditional medicine. ISBN 92 4 154517 8. WHO Geneva.

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 ofHealth and Family Welfare. Controller of Publication. Govt of India. New Delhi.
2. Brain, KR and Turner, TD. (1975). The Practical Evaluation Phytopharmaceuticals. Wright Scienctechnica, 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. CENTRAL COUNCIL FOR RESEARCH IN AYURVEDA AND SIDDHA. New Delhi.
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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 Prakashan, 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 Technologies 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

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6. Harold Varley. Practical Clinical Bio-chemistry
7. Kanai L.Mukherjee. Clinical Pathology:,Medical Laboratory Technology Vol. I.Tata McGrawHill1996, New Delhi.
8. GradWohl, Clinical Laboratory-methods and diagnosis, Vol-I
9. Clinical Biochemistry -Sabitri Sanyal, Clinical Pathology, B.I.Churchill Livingstone (P) Ltd, NewDelhi.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.

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 Fensternmaker. (2007).*The Art of Literary Research*. 4th ed. W. W. Norton. Castle,Gregory. *Blackwell Guide to 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 House.
8. Greenhalgh, T. (2006) How to Read a Paper: The Basics of Evidence-Based Medicine. (3rd ed)Blackwell
9. Kothari- CR (2004). Research Methodology- Methods and Techniques (Second Revised Edition).New Age International Publishers- New Delhi.
10. Kumar, R. 2005. *Research Methodology: a Step-by-Step Guide for Beginners, 2nd ed.* ThousandOaks, CA, London: Sage Publications.
11. Petter Laake, Haakon Breien Benestad and Bjørn Reino Olsen. (2007). Research Methodology in the Medical and Biological sciences. Academic Press is an imprint of Elsevier, 84 Theobald's Road,London WC1X 8RR, UK. ISBN: 978-0-12-373874-5
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, NewJersey
2. Research guidelines for evaluating the safety and efficacy of herbal medicines. (1993). . WHO- (Regional Office for the Western Pacific – Manila) ISBN 92 9061 110 3 (NLM Classification: WB925).
3. Jagdeesh, Sreekant Murthy, Gupta, YK and Amitabh Prakash Eds. Biomedical Research (FromIdeation to Publication) (2010). Wolters Kluwer/ Lippincott Williams and Wilkins.
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6. Gazette Extraordinary Part- II-Section 3 - Sub section (i) December 2008. Govt of India. AYUSHGuidelines on safety studies- Rule 170 of Drugs and Cosmetics Act.
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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
10. ICH Harmonised Tripartite Guideline (2000). Maintenance of the ICH Guideline on Non-clinicalSafety Studies for t he conduct of Human Clinical Trials for Pharmaceuticals M3 (R1).
11. Ghosh M.N.: Fundamentals of Experimental Pharmacology, *Scientific Book Agency.*
12. *Bombay.*\
13. Jaju B.P.: Pharmacological Practical Exercise Book, *Jaypee Brothers, New Delhi.*
14. Kulkarni S.K.: Hand Book of Experimental Pharmacology, *Vallabh Prakashan, New Delhi*
15. Ravindran R.: X-Pharm (Software), Indian Journal of Pharmacology, *JIPMER, Pondicherry.*

Biotechnology and Bio-informatics:

1. Angela M. Meireles A (2009). Extracting Bioactive compounds for food products. Theory andapplications. CRC- Press Taylor 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: HimalayaPublication House, India; 1 edition (July, 2007) ISBN-13: 978-81-8318-831-9
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5. Satyanarayana, U.: Biotechnology, Books and Allied (P) Ltd, Kolkata, 2005
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8. http://www.zygogen.com.
9. http://www.dsir.nic.in/reports/tifp/database/metallo.pdf.
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 MedicalResearch- New Delhi.
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4. Good Clinical Practices- (2001). Guidelines for Clinical Trial on Pharmaceutical Products in India. Central Drugs Standard Control Organization. Directorate General of Health Services. New Delhi.(http//WWW.cdsco.nic.in.ich.org)
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9. William C. Scheffer Introduction to Clinical Researchs

Medical Statistics:

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2. Armitage P, Berry G, Matthews JNS: *Statistical Methods in Medical Research*. Fourth edition.Oxford, Blackwell Science Ltd; 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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M.D.-AYURVEDA PRELIMINARY
RASA SHASTRA AND BHAISHAJYA KALPANA
(Iatrocemistry & Pharmaceuticals Science)
PAPER-II

Theory 100 marks

PART-A 50 marks

1. Fundamental principles of Rasa Shastra and Bhaishajya Kalpana, introduction to Rasachikitsa, Ashuddha and Apakwa Bhasma- sevan Dosha and its management, introduction to Aushadha Sevan Kaal and Prayoga Marga (routes of administration).
2. Introduction to basic principles of Aushadha Yoga (formulations).
3. Classification of Rasa Dravya - concept and relevance.
4. Introduction to principles of Aushadha Nirmana, concept of Shodhan, Marana, Jarana, Murcchhana, Sattvapatan and Amritikarana.
5. Concept of Kashaya, Panchavidha Kashaya and other Kalpana.
6. Concept of Rasashala, Rasa Mandapa with introduction to pharmacy in accordance with the Good Manufacturing Practices (GMP).
7. Critical study of Rasa Ratnasamuchchaya, Rasendra Chintamani, Rasa Tarangini, Sharngadhara Samhita, Chakradutta and Bharat Bhaishajya Ratnakara with special reference to Aushadha-Nirmana.

PART-B 50 marks

1. Introduction to methods of analytical, toxicity, experimental and clinical validation of classical and proprietary Ayurvedic formulations.
2. Introduction to new dosage forms.
3. Introduction to advance instruments of analysis like XRD, XRF, SEM-E-Dax, ICP analysis, Chromatography: TLC, gas chromatography, HPTLC, concept of Nanotechnology and its relevance to Aushadha-Nirman.
4. Concept of Pharmacopoeia and Formulary with introduction of 'The Ayurvedic Pharmacopoeia of India' (API) and 'The Ayurvedic Formulary of India' (AFI).
5. Introduction to databases of medicinal plants published by CCRAS, ICMR and others.

PRACTICAL 100 marks

Contents:

1. Shodhan, Marana, Amritikarana of Rasa Dravya (10 practicals)
2. Preparation of different dosage forms (10 forms)
3. Pharmacop oeial standards of raw and prepared drugs (20 practicals)

Raw Materials

1. **Minerals and Metals**

Mineralogical Identification Mineralogical Identification

1. Physical form - Crystal and Amorphous
2. Hardness on Moh's scale
3. Brittleness test

4. Fracture and Cleavage
5. Streak test
6. Luster

2. Plant Material

Macroscopic and Microscopic examination

a. Orgnaoleptic testing
b. Estimation of Foreign materials
c. Microbial load
d. Moisture content
e. Determination of ash value - total, water soluble and acid Insoluble ash
f. Specific gravity
g. Solubility- water and alcohol
h. Extract values- water and alcohol
i. TLC
j. Determination of optical density
k. Refractive index
l. Aflatoxins
m. Limit tests for heavy metals
n. pH estimation

Prepared dosage forms:

1. **Solid dosage forms Rasaushadhi**

a) Bhasma and Pishti Pariksha
b) Determination of Particle size
c) Limit tests for heavy metals
d) Determination of moisture content, specific gravity, pH and acid value.

Kasthaushadhi

a. **Powders (Churna)**

1. Particle size
2. Bulk density
3. Solubility
4. Estimation of Foreign material
5. Microbial load
6. Moisture content
7. Determination of ash value - total, water soluble and acid insoluble ash
8. Solubility - water and alcohol
9. Extract values - water and alcohol
10. TLC
11. Determination of Optical density
12. Refractive Index
13. Aflatoxins
14. Limit tests for Heavy metals

15. pH Value estimation

b. Tablets

1. Uniformity in weight and size
2. Tablet hardness
3. Tablet friability
4. Tablet disintegration
5. Tablet dissolution

c. Semisolid dosage forms

a. Moisture content
b. Sugar content
c. Microbial load

d. Liquids

- pH value
- Specific gravity
- Determination of refractive index
- Acid value
- Viscosity
- Saponification value
- Iodine value

Note:

- All practicals should be performed in accordance with Authoritative Text Books of Schedule-I of D.C.Act-1940.
- All practicals related to Pharmacopoeial Standards should be performed in accordance with Methods Published in Protocol for testing of ASU Medicines and Laboratory Guidelines for the Analysis of Ayurveda & Siddha Formulations published by Deptt. of AYUSH, Government of India.

Distribution of marks (Practical)

- Practical Record Book - 10 Marks
- Practicals related to Preparation of Drugs
  - Major practical- one - 20 Marks
  - Minor practical- one - 10 Marks
- Drug analysis
  - Major practical- one - 20 Marks
  - Minor practical- one - 10 Marks
- Spotting - 10 Marks
- Viva-voce - 20 Marks

REFERENCE BOOKS:

1. Rasahridaya Tantra
2. Rasarnava

3. Rasaratna Samuccahaya
4. Ayurved Prakasha
5. Rasendrachudamani
6. Rasendra Chintamani
7. Rasatarangini
8. Rasapraksha Sudhakar
9. Rasamrita
10. Rasa Chandanshu : CCRAS Publication
11. Sharangadhara Samhita
12. Sharangadhara Darpan (BP Pandey)
13. Bhavaprakasha
14. Yoga Ratnakara
15. Bhaishajya Ratnavali
16. Siddha Bhaishajya Manimala
17. Bharat Bhaishajya Ratnakara
18. Rasayoga Sagara
19. Siddha Bhaishajya Manimala
20. Sahasrayoga
21. Siddha Yoga Sangraha – Yadavaji Trikamji Acharya
22. Vaidyaka Paribhasha Pradeepa
23. Ayurvediya Aushadhikarana – Puranik and Dhamanakar
24. Dravyaguna Vijnan Part - 1 and 2 - Yadavji Trikamji
25. Chakradatta - Ratnaprabha, Relevant Parts from Charaka Samhita, Sushruta Samhita, Kashyapa Samhita, Ashtanga Sangraha, Ashtanga Hridaya,
26. Remington: Science and Practice of Pharmacy
27. Theory and Practice of Industrial Pharmacy – Leon Lachman et al
28. Clinical Pharmacology, KD Tripathi
29. Clinical Pharmacology, Lawrence Benette
30. Drug Discovery and Evaluation (Pharmacological assays) HG Vogel
31. Pharmacological Basis of therapeutics – Goodman and Gilman
32. Data Base of Medicinal Plants of CCRAS
33. Quality and Standards of Medicinal Plants – ICMR publication
34. Quality Control of Ayurvedic Drugs – PLIM, Gaziabad
35. Ayurvedic Pharmacopeia of India
36. Ayurvedic Formulary of India
37. Indian Pharmacopeia
38. British Pharmacopeia
39. United States Pharmacopeia
40. Pharmacopeia Codex
41. Current Good Manufacturing Practices
42. Drugs and Cosmetic Act 1940 and Rules 1945 with latest amendments
43. Drugs and Magic remedies (Objectionable advertisement) Act-1954
44. Prevention of Food Adulteration (PFA) act
45. Laws pertaining to Narcotics

46. Factory and Pharmacy Acts
47. Consumer Protection Act -1986
48. Brief information on the peer reviewed journals, official websites and other official search engines along with their links (related with the subject)
49. Rutleys Elements of Mineralogy
50. Bhasma Vigyaniyam
51. Kupipakva Vigyaniyam
52. Anupana Manjari

M.D.-AYURVEDA FINAL

RASA SHASTRA AND BHAISHAJYA KALPANA

(Iatrocemistry & Pharmaceuticals Science

RASA SHASTRA AND BHAISHAJYA KALPANA

Paper I Rasa Shastra

Part A

1. History and Chronological evolution of Rasashastra, concept of Raseshwara darshan. Fundamental Principles of Rasashastra Technical terminologies (Paribhasha) used in Rasa shastra.
2. Detailed knowledge of ancient and contemporary Yantropakarana and their accessories used in aushadhikaran and their contemporary modification such as yantras, mushas, putas, Koshthis, bhrashtris, muffle furnaces and other heating appliances, ovens, driers etc. used in manufacturing of Rasaushadhis in small scale and large scale along with their applications.
3. Study of Samskara, Role of agni (Heat), jala and other dravas (water and other processing liquids), kala (Time span), paatra (container) etc. and their significance in aushadhikarana.
4. Concept of Bhavana, study of Mardana and its significance and knowledge of ancient and contemporary grinding techniques.
5. Detailed Knowledge of different procedures of Shodhana, Jarana Murchana and Marana, concept of Puta, definition, types and specifications of different Putas. Significance of different Putas in relation to Bhasmikarana and therapeutic efficacy of dravya under process. Bhasma pariksha vidhi and its significance in relation to contemporary testing procedures**.** Amritikaran and Lohitikarana.
6. Detailed knowledge of Satva and Druti, Satva shodhan, mrudukaran and Maran of Satva, its significance, in relation to therapeutic efficacy of dravya under process.
7. Concept of Pratinidhi dravya and discussion on controversial drugs.

PART – B

1. Detailed ancient and contemporary knowledge of Parada and its compounds with reference to source, occurrence, physico-chemical characterization, graahya agraahyatva, Parada dosha, Parada gati, Parada shodhan, Study of Ashta sanskara, ashtadasha sanskara etc., Hingulottha Parada. Concept of Parada jaran, moorcchana, bandhan, pakshaccheda and marana etc. Therapeutic properties and uses of Parada.
2. Detailed ancient & contemporary knowledge with Geochemical / mineralogical / biological identification, source, occurrence, physico-chemical characterization, graahya-agraahyatva, Shodhan Maranadi vidhi and therapeutic properties and uses of dravyas etc. included in Maharasa, Uparasa, Sadharana rasa, Dhatu, Upadhatu,

Ratna, Uparatna, Visha, Upavisha, Sudha varga, Lavana varga, Kshara varga, Sikata varga and other miscellaneous drugs used in Rasashastra.

3. Detailed knowledge of manufacturing, pharmacopeial standards, storage, shelf life, therapeutic efficacy, dose, anupana, vikarashanti upaya and development of technology with Standard Operating Procedures of processing, standardization, quality control of Bhasmas and Pishtis

   Bhasma - Abhraka Bhasma, Svarnamakshika Bhasma, Kasis Bhasma, Svarna Bhasma, Rajata Bhasma, Tamra Bhasma, Loha Bhasma, Mandur Bhasma, Naga Bhasma, Vanga Bhasma, Yashad Bhasma, Trivanga Bhasma, Pittala, Kamsya and Varthaloha Bhasma, Shankha Bhasma, Shukti Bhasma, Kapardika Bhasma, Godanti Bhasma, Praval Bhasma, Mrigashringa Bhasma, Mayurpiccha Bhasma, Kukkutand twak Bhasma, Hiraka Bhasma, Manikya Bhasma.

   Dravaka - Shankha Dravaka

   Pishti - Praval pishti, Manikya Pishti, Mukta pishti, Jahara mohara pishti, Trinakanta mani pishti etc.

4. Detailed knowledge of manufacturing, storage, shelf life, pharmacopeial standards, therapeutic efficacy, dose, anupana and development of technology with Standard Operating Procedures of processing, standardization and quality control of Kharaliya rasa, Parpati, Kupipakva rasa and Pottali rasa.
5. Study of classical texts with respective commentaries and special emphasis on Rasarnava, Rasahridaya tantra, Rasa Ratna Samucchaya, Rasendra Chintamani, Rasendra Chudamani, Rasa Ratnakara, Rasadhyaya, Rasa Kamdhenu, Anandkanda, Siddha Bheshaja Manimala, Ayurveda Prakash, Rasatarangini, Bhaishajya Ratnavali, Rasamritam etc. and the books mentioned in the Schedule I of D & C Act – 1940. Relevant portions of Brihatrayi.

Paper II Bhaishajya Kalpana

Part A

1. History and Chronological evolution of Bhaishajya Kalpana, Concept of Bheshaja and Aushadh, fundamental principles of Bhaishajya Kalpana. Technical terminologies (Paribhasha) used in Bhaishajya Kalpana.
2. Classical and Contemporary concepts of Collection, storage, Saviryata Avadhi and preservation methods of different fresh and dry Aushadhi dravyas and their graahya agraahyatva
3. Detailed knowledge of routes of drug administration, Aushadha matra, Anupana, Sahapana, Aushadha Sevana Kala, Kala Avadhi, Pathya, Apathya (Posology).
4. Detailed knowledge of manufacturing, standardization, quality control, pharmacopeial standards, storage, shelf life and development of innovative technology with Standard manufacturing Operating Procedures of following dosage forms

i) Panchavidha Kashaya, Churna, Rasakriya, Ghana, Avaleha, Pramathya, Mantha, Panaka, Sarkara, Kshirapaka, Ushnodaka, Aushadha Siddha Udaka, Sadangodaka, Tandulodaka, Laksharasa, Arka, Satva, Kshara, Lavana, Masi, Gutika, Vatika, Modaka, Guggulu and Varti etc.

ii) Sneha Kalpana: Concept of accha sneha and sneha pravicharana and Murchhana. Sneha paka, types of sneha paka and sneha siddhi lakshana, Avartana. Sneha kalpa karmukata (Pharmacokinetics and dynamics of sneha kalpa). Role of Sneha in relation to absorption of drug.

iii) Kritanna and Bheshaja Siddha Anna Kalpana, Aharopayogi varga, concept of medicinal and functional food, dietary supplements and neutraceuticals etc. iv) Sandhana kalpana: Madya varga and Shukta varga. Asava yoni. Alcoholic and acidic fermentation. Sandhana kalpa karmukata (Pharmacokinetics and dynamics). Advancements in fermentation technology. Knowledge of regulations in relation to alcoholic drug preparations.

v) Bahya Prayogartha Kalpana : Lepa, Upanaha, Udvartan, Avachurnana / Avadhulana, Abhyanga, Dhupana, Malahara.

vi) Mukha, Karna, Nasa, Netropacharartha Kalpana:

vii) Basti Kalpana: Basti Yantra Nirmana, Types of basti. Anuvasana and Asthapana basti. Karma, kala and yoga basti etc. Basti Kalpa (Madhutailika, Piccha basti etc.), Comparison of Asthapana and Anuvasana basti with evacuation and retention enema.

Part B

All the following procedures are to be studied in relevance to Ayurvedic Bhaishajya Kalpas.

1. Methods of Expression and Extraction: Maceration, percolation, distillation, infusion and decoction.
2. **Liquids:** Clarified liquid, syrup, elixir, filtration techniques
3. **Solid dosage Forms: Powders:** Size reduction, separation techniques, particle size determination, principles of mixing**. Tablets:** Methods of tableting, suppositories, pessaries and capsules, sustained release dosage forms.
4. **Semisolid dosage forms**, emulsions, suspensions, creams and ointments, sterilization of ophthalmic preparations.
5. An introduction to various cosmetic preparations.
6. Drying, open and closed air drying, freeze drying, vacuum drying and other drying methods pharmaceutical excipients.
7. Study of classical texts with special emphasis on Chakradatta, Sharangadhara Samhita, Bhaishajya Ratnavali, Bhava Prakasha, Yogaratnakara, relevant portions of Brihatrayi**,** Ayurvedic Pharmacopeia of India, Ayurvedic Formulary of India.

Paper III Rasa Chikitsa & Aushadha Yoga Vigyana

PART- A

1. Rasachikitsa, Kshetrikaran, Rasajirna, Lohajirna, Aushadhi Sevana Vikarashanti Upaya. Ashuddha, Apakva, Avidhi Rasadravya Sevanajanya Vikara evam Vikara shanti upaya.
2. Detailed knowledge of Aushadhi patha Nischiti and sanyojan (formulation composition), dose, anupana and method of administration, therapeutic efficacy and uses (indications and contra-indications), probable mode of action etc. of the following Aushadhi yogas

i. Kharaliya Rasa : Shwasa kuthara Rasa, Tribhuvana kirti Rasa, Higuleshwara Rasa, Ananda bhairava Rasa, Maha Lakshmivilasa Rasa, Vasnata kusumakara Rasa, Vasanta malti Rasa, Brihat vata chintamani Rasa, Laghu suta shekhar Rasa, Suta shekhara Rasa, Ram ban Rasa, Chandra kala Rasa, Yogendra Rasa, Hridyarnava rasa, Grahani kapata Rasa, Garbha pala Rasa, Jalodarari Rasa, Mrityunjaya Rasa, Madhumalini vasanta Rasa, Arsha kuthara Rasa, Krimi mudgara Rasa, Suchika bharana Rasa, Tri netra Rasa, Smruti sagara Rasa, Vata gajankusha Rasa, Agni kumar Rasa, Ekangavir Rasa, Kama dugha Rasa, Purna chandrodaya Rasa, Pratap lankeshwara Rasa, Maha vata vidhwansaka Rasa, Kasturi bhairava Rasa, Ashwa kanchuki Rasa, Gulma kuthara Rasa, Maha jwarankusha Rasa, Chandra mrita Rasa, Kapha ketu Rasa, Prabhakara Vati, Pravala Panchamrita, Gandhaka Rasayana, Chaturbhuj rasa, Navajivan rasa, Shonitargal rasa, Raktapitta kulakandan rasa, Amavatari Rasa, Kravyada Rasa, Garbha chintamani Rasa, Chintamani Rasa, Trilokya chintamani Rasa, Pradarantaka Rasa, Vangeshwara Rasa, Brihat vangeshwara Rasa, Shwasakasa Chintamani Rasa, Arogya vardhini Vati, Chandra prabha Vati, Agni tundi vati, Shankha Vati.

ii. Kupipakva Rasa: Rasa Sindura, Makaradhwaja, Sidha makaradhwaja, Samira pannaga Swarnavanga, Malla sindura, Rasa karpura, Rasa pushpa, Manikya Rasa.

iii. Parpati Rasa : Rasa Parpati, Loha Parpati, Tamra Parpati, Suwarna Parpati, Gagana Parpati, Vijay Parpati, Panchamrit Parpati, Shwet Parpati, Bola Parpati

iv. Pottali Rasa: Rasagarbha pottali, Hemagarbha pottali, Mallagarbha pottali, Hiranyagarbha pottali, Shankagarbha pottali, Lokanatha rasa, Mriganka Pottali

v. Loha evam Mandura Kalpa: Ayaskriti, Loha Rasayana, Amla pittantaka loha, Chandanadi loha, Dhatri loha, Navayasa loha, Putapakva vishama jwarantaka loha, Shilajatwadi loha, Tapyadi loha, Saptamrita loha, Dhatri loha Amritasara Loha, Shankaramat loha, Pradarantaka loha, Rohitaka loha. Punarnava Mandura, Shatavari Mandura, Tara Mandura, Triphala Mandura, Mandura Vataka etc.

Part B

Detailed knowledge of Aushadhi patha Nischiti and sanyojan (formulation composition), dose, anupana and method of administration, therapeutic efficacy and uses (indications and contra-indications), probable mode of action etc. of the following Aushadhi yogas

i. Panchavidha Kashayas and their Upakalpa: Ardraka swarasa, Tulasi swarasa, Vasa putapaka swarasa, Nimba kalka, Rasona kalka, Kulattha Kwath, Punarnavasthaka kwatha, Rasna saptaka kwatha, Dhanyak hima, Sarivadi hima, Panchakola phanta, Tandulodaka,

Mustadi pramathya, Kharjuradi mantha, Shadanga paniya, Laksha rasa, Arjuna kshirapaka, Rasona kshirapaka, Chincha panaka, Candana panaka, Banapsha sharkara, Nimbu sharkara, Amrita satva, Ardraka satva, Ajamoda arka, Yavanyadi arka **ii. Kritanna and Bheshaja Siddha Ahara Kalpana:** Yavagu, (Krita and Akrita), Ashtaguna manda, Laja manda, Peya, Vilepi, Krishara, Yusha, Mudga yusha, Kulattha yusha, Saptamushtika yusha, Khada, Kambalika, Raga, Shadava, Mamsarasa, Veshavara, Dadhi, Katvar Dadhi, Dadhi Mastu, Takra, Ghola, Udasvita, Mathita, Chhacchika etc.

iii. **Churna:** Sitopaladi Churna, Talisadi Churna, Triphala Churna, Hingvashtaka Churna, Avipattikara Churna, Swadishta Virechana Churna, Bhaskar Lavana Churna, Sudarshana Churna, Maha Sudarshana Churna, Gandharva Haritaki Churna, Pushyanuga Churna, Ajamodadi Churna, Hingvadi Churna, Eladi Churna, Dadimashtaka Churna, Trikatu Churna, Vaishwanara Churna, Gangadhara Churna, Jati phaladi Churna, Narayana Churna etc.

iv. **Gutika:** Arogya vardhani vati, Chandra prabha vati, Chitrakadi Gutika, Sanjivani Vati, Lasunadi vati, Lavangadi Vati, Vyoshadi vati, Khadiradi Vati, Kankayana Vati, Abhayadi modaka, Marichyadi gutika, Amalakyadi gutika, Samshamini Vati, Kutaja Ghana vati, Amarasundari Vati, Shiva Gutika, Eladi Vati, Kasturyadi Gutika, Arshoghni Vati.

v. **Guggulu:** Yogaraja Guggulu, Maha yogaraja Guggulu, Trayodashanga Guggulu, Kanchanara Guggulu, Rasnadi Guggulu, Triphala Guggulu, Simhanada Guggulu, Gokshuradi Guggulu, Kaishora Guggulu, Panchatikta Guggulu, Amritadi Guggulu, Vatari Guggulu, Lakshadi Guggulu, Abha Guggulu, Navaka Guggulu, Nava Karshika Guggulu.

vi. **Sneha Kalpa**

Sneha Moorchhana - Ghrita Murchana, Taila Murchhana

Siddha Ghrita - Shatavari Ghrita, Jatyadi Ghrita, Phala Ghrita, Dadimadi Ghrita, Kshirashatpala Ghrita, Mahatriphala Ghrita, Dhanvantari Ghrita, Amritaprasha Ghrita, Kalyanaka Ghrita, Brahmi Ghrita, Changeri Ghrita, Panchatikta Ghrita, Sukumara Ghrita, Panchagavya Ghrita

Siddha Taila - Maha Narayana Taila, Maha Masha Taila, Bala Taila, Nirgundi Taila, Shadbindu Taila, Vishagarbha Taila, Sahacharadi Taila, Jatyadi Taila, Apamarga Kshara Taila, Tuvaraka Taila, Kshirabala Taila (Avartita), Lakshadi Taila, Anu Taila, Kumkumadi Taila, Hingutriguna Taila, Kottumchukadi Taila, Prasarinyadi Taila, Dhanwantari Taila, Balashwagandhadi Taila, Balaguduchyadi Taila, Nilibhringyadi Taila, Brihadavadi Taila, Irimedadi Taila, Chandanadi Taila, Panchaguna taila, Arka taila, Pinda Taila, Kasisadya Taila

vii. **Rasakriya, Avaleha, Khanda etc.:** Darvi Rasakriya, Vasa Avaleha, Brahma rasayana, Chyavanprasha Avaleha, Kushmanda Avaleha, Dadima Avaleha, Bilvadi Avaleha, Kantakaryavaleha, Haridra Khanda, Narikela khanda, Saubhagya shunthi paka, Amrita Bhallataka, Kamsa Haritaki, Chitraka Haritaki, Vyaghri Haritaki, Bahushala Guda, Kalyana Guda **viii. Sandhana Kalpa:** Lodhrasava, Kumaryasava, Ushirasava, Chandanasava, Kanakasava, Sarivadyasava, Pippalyasava, Lohasava, Vasakasava, Kutajarishta, Draksharishta, Raktamitrarka, Dashamularishta, Abhayarishta, Amritarishta, Ashokarishta, Sarasvatarishta,

Arjunarishta, Khadirarishta, Ashwagandha Arishta, Vidangarishta, Takrarishta, Mahadrakshasava, Mritasanjivani sura, Maireya, Varuni, Sidhu, Kanji, Dhanyamla, Madhu Shukta, Pindasava.

ix. Anya Kalpa : Phala varti, Chandrodaya varti, Arka lavana, Narikela lavana, Triphala masi, Apamarga kshara, Snuhi kshara, Ksharasutra, Atasi upanaha, Sarjarasa malahara, Gandhaka malahara, Sindhuradi Malahara, Shatadhouta Ghrita, Sahasra Dhouta Ghrita, Siktha taila, Dashanga lepa, Doshaghna lepa, Bhallataka taila patana, Jyotishmati Taila, Bakuchi Taila, Dashanga dhupa, Arshoghna dhupa, Nishadi Netra bindu, Madhutailika Basti, Piccha Basti, Yapana Basti.

PAPER – IV Pharmacology and Pharmacy Management

PART - A

1. General Pharmacology:
   - **a)** Principles of Pharmacology, Pharmcodynamics & Pharmacokinetics: Absorption, distribution, Metabolism & excretion, mechanism of action, dose determination and dose response, structure activity relationship.
   - **b)** Routes of drug administration
   - **c)** Factors modifying drug effect, Bioavailability and Bioequivalence, drug interactions, adverse drug reaction and drug toxicity
   - **d)** Preclinical evaluation: experimental pharmacology [bioassay, in vitro, in vivo, cell line studies] animal ethics.
2. Clinical pharmacology: Evaluation of New Chemical Entity – phases and methods of clinical research. Ethics involved in human research.
3. Elemental constituents of human body and its physiological importance. Deficiencies and excess of various elements (micro-nutrients).
4. Toxicity of heavy metals and chelation therapy.
5. Knowledge of toxicity and pharmacological activities of herbo-mineral compounds.
6. Detailed Knowledge of Pharmacovigilance – National and International Scenario. Pharmacovigilance of Ayurvedic Drugs

Part B

1. Scope and evolution of pharmacy. Information resources in pharmacy and pharmaceutical Science.
2. Pharmaceutical dosage form design (Pre-formulation)
3. Packaging materials and Labeling
4. Management of pharmacy, store and inventory management, personnel management, Good Manufacturing Practices related to Ayurvedic drug industry.
5. Pharmaceutical Marketing, product release and withdrawals.
6. Hospital, Dispensing and Community pharmacy.
7. Patenting and Intellectual Property Rights.
8. Laws Governing Ayurvedic drugs

i. Relevant regulatory provisions of Ayurvedic drugs in Drug and Cosmetics Act - 1940 and Rules - 1945 ii. Laws pertaining to Drugs and Magic remedies (Objectionable Advertisement) Act - 1954.

iii. Prevention of Food Adulteration (PFA) act.
iv. Food Standards and Safety Act - 2006
v. Laws pertaining to Narcotics
vi. Factory and Pharmacy Acts
vii. Consumer Protection Act -1986

9. Regulatory Affairs related to International Trade and Practices of Ayurvedic Drugs

10. Introduction to Ayurvedic Pharmacoepia of India, Ayurvedic Formulary of India.

11. Introduction to Indian Pharmacoepia, British and United States Pharmacoepia, Pharamcoepial Codex

12. Introduction to Traditional Knowledge Digital Library

Practicals:-

Minimum 150 Practicals are to be performed covering all the dosage forms.

Educational Visits to minimum Five (5) GMP approved Ayurvedic Pharmacies.

Ten days posting in R & D / Production unit in GMP certified Ayurvedic Pharmacy.

Minimum attendance in three National Conferences within three academic years. Minmum 10 clinical cases using different dosage forms are to be studied and recorded for efficacy and ADRs (if any).

Minimum one research paper on the core contributory work of dissertation published or accepted in peer reviewed, indexed journal.

Examinee has to submit supporting documents in relation to above mentioned academic activities at the time of Practical examination.

Pattern of Practical Examination **Total Marks : 100**

Duration of the practical: 2 days

1. **Identification of the specimen:** 10 Marks
2. **Drug Processing** 30 Marks (10+10+5+5)

i) Major Practicals: 2 (1 Rasashastra and 1 Bhaishajya Kalpana)

ii) Minor Practicals: 2 (1 Rasashastra and 1 Bhaishajya Kalpana)

3. Drug testing and Analysis 10 Marks (5+5)

i) Rasaushadhi – 1
ii) Kashthaushadhi – 1

4. Power Point Presentation on dissertation work: 15 Minutes 10 Marks

6. **A Demo Lecture** on any subject topic: 10 Minutes. 10 Marks
7. **Documentation** 15 Marks
   i. Journals (Practical Records) of minimum 75 practicals (25 each from Rasa Shastra, Bhaishajya Kalpana and Analytical part).
   ii. Reports of the Visits iii. Case Records
8. **Viva Voce examination** **15 Marks**

Reference Books:-

Rasahridaya Tantra
Rasarnava
Rasaratna Samuccahaya

Ayurved Prakasha

Rasendrachudamani

Rasendra Chintamani

Rasatarangini

Rasapraksha Sudhakar

Rasamrita

Rasa Chandanshu : CCRAS Publication

Sharangadhara Samhita

Sharangadhara Darpan (BP Pandey)

Bhavaprakasha

Yoga Ratnakara

Bhaishajya Ratnavali

Siddha Bhaishajya Manimala

Ayurvediya Aushadhikarana – Puranik and Dhamanakar Bharat Bhaishajya Ratnakara

Rasayoga Sagara

Siddha Bhaishajya Manimala

Siddha Yoga Sangraha – Yadavaji Trikamji Acharya

Sahasrayoga

Vaidyaka Paribhasha Pradeepa

Dravyaguna Vijnan Part - 1 and 2 - Yadavji Trikamji Chakradatta - Ratnaprabha,

Relevant Parts from Charaka Samhita, Sushruta Samhita, Kashyapa

Samhita, Ashtanga Sangraha, Ashtanga Hridaya,

Remington: Science and Practice of Pharmacy

Theory and Practice of Industrial Pharmacy – Leon Lachman *et al* Clinical Pharmacology, KD Tripathi

Clinical Pharmacology, Lawrence Benette

Drug Discovery and Evaluation (Pharmacological assays) HG Vogel Pharmacological Basis of therapeutics – Goodman and Gilman Data Base of Medicinal Plants of CCRAS

Quality and Standards of Medicinal Plants – ICMR publication

Quality Control of Ayurvedic Drugs – PLIM, Gaziabad

Ayurvedic Pharmacopeia of India

Ayurvedic Formulary of India

Indian Pharmacopeia

British Pharmacopeia

United States Pharmacopeia

Pharmacopeia Codex

Current Good Manufacturing Practices

Drugs and Cosmetic Act 1940 and Rules 1945 with latest amendments

Drugs and Magic remedies (Objectionable advertisement) Act-1954

Prevention of Food Adulteration (PFA) act

Laws pertaining to Narcotics

Factory and Pharmacy Acts

Consumer Protection Act -1986

Brief information on the peer reviewed journals, official websites and other official search engines along with their links (related with the subject) Rutleys Elements of Mineralogy

Bhasma Vigyaniyam

Kupipakva Vigyaniyam

Anupana Manjari

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