



**PRAVARA INSTITUTE OF MEDICAL SCIENCES
(DEEMED TO BE UNIVERSITY)
Loni, Tal. Rahata, Dist. Ahmednagar 413736
NAAC Re-accredited with 'A' Grade**

**SYLLABUS
Post Graduate Diploma in Herbal Medicine
(Centre for Biotechnology)
(Academic Council Meeting Dated 25th August, 2022)**

Title: Post Graduate Diploma in Herbal Medicine (PGD-HM)

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PREAMBLE

Herbal medicine has also been termed as “complementary” or “alternative” medicine for primary health care since time immemorial. Herbal medicines are naturally occurring, plant-derived substances that have been used worldwide to treat illness as part of healing practices. Due to their therapeutic actions, these plants are known as medicinal plants. Herbal medicine has become a popular form of healthcare. The therapeutic practices using herbal medicines continue to expand rapidly across the world. The last decade witnessed tremendous upwelling in the use of herbal medicines in both developing and developed countries. Around 4 billion (80% world’s population) peoples worldwide use herbal medicine as the primary source of healthcare. Medicinal plants are an effective and affordable source to combat serious diseases. Herbal medicines are considered a balanced and moderate approach to healing and individuals who use them as home remedies and over-the-counter drugs. According to the World Health Organization (WHO), 21,000 medicinal plants are well-known for their therapeutic values. Around 2500 medicinal plants are characterized in India for their therapeutic values out of which 150 are commercially used in biopharmaceutical industries as mainstream drugs. India is the major producer of medicinal plants but only a small percentage of plants are fully characterized for their molecular contents of bioactive compounds that could be more effective and less toxic natural phytomedicines or drugs in the future.

The beneficial or therapeutic potential of medicinal herbs is attributed to metabolites and phytochemicals that are synthesized within these plants. According to literature black box of herbal-based treatments lies here. Inadequate understanding of constituents or lack of information about the composition of the remedy restricts utility. Moreover, the chemical composition of medicinal plants varies depending on several factors, such as botanical species, used chemotypes, the anatomical part of the plant used (seed, flower, root, leaf, and so on), and also storage, sun, humidity, type of ground, time of harvest, geographic area and so on. Adverse side effects are another open problem of herbal medicines.

INTRODUCTION OF THE PROGRAMME:

Herbal medicines comprise herbs, herbal parts, preparations, and finished products that contain bioactive ingredients parts of plants or plant materials or combinations, and are used exclusively for the prevention and management of diseases. Herbal medicine is primary healthcare around the world, especially in rural areas. These herbal medicines have long traditional history& claim health benefits.

This Post Graduate Diploma in Herbal Medicine (PGDHM) is ideal for anyone interested in herbal medicine and human healthcare. Herbal medicine is the use of medicinal plants for the prevention and treatment of diseases. Knowledge of the predictors of herbs used as therapeutics may help health care providers treat human

diseases. The use of herbal medicines is common nowadays. Medicinal plants are a major resource base for the herbal medicine & herbal industry. Building a valid scientific basis for knowledge in herbal medicine is required to utilize these natural resources. In this perspective, using Ayurveda and other Indian literature, the government of India launched National Medicinal Plants Board (NMPB) under the Ministry of Ayush, which coordinates all matters relating to Medicinal Plants.

This PDGHEM programme provides a holistic perspective on background, history, geographical occurrence, pharmacological qualities, bioactive ingredients, and safety issues related to herbal medicine. This PDGHEM programme familiarises the field of ethnopharmacology of herbs for developing drugs from these plants to treat various ailments. PDGHEM programme provides theoretical and hands-on experiments in drug preparations, characterizations, and bioactive compound identifications, biological assays *in vitro* and *in vivo* studies.

1. SCOPE AND HIGHLIGHTS

Indeed, herbal medicines as therapeutics are gaining attention worldwide. Almost 80% of people in Asian countries and a large proportion of populations in European countries rely on traditional plant-based medicines for healing health complications. The harmful side effects of synthetic chemical drugs, and the effective, affordable, safe, and stable nature of herbal medicines incline researchers towards the discovery of natural plant-based therapeutics worldwide. In this perspective, herbal medicines need a powerful and deep valuation of their background, history, geographical occurrence, pharmacological qualities, bioactive ingredients, and safety issues. This PGDHM programme provides the necessary background of herbal medicines, particularly in regards to the history of herbal medicine, therapeutic properties, efficacy, and safety concerns, including quality control and potential adverse effects. This programme also provides necessary knowledge about the purification and characterization of bioactive compounds from these herbs.

Keeping in view of the strong demand for alternatives to pharmaceuticals for human healthcare, this programme will train the individual who will demonstrate the role of herbal medicines in healthcare, therapeutic actions, and methods for creating bio-formulations of these herbs. He/she will also get insight on herb-drug interactions, quality control and safety issues of herbal medicines. It is anticipated that the experts trained under this programme will find job opportunities and also self-employment prospects in the following areas:

1. Medicinal plant research.
2. *In-situ* & *ex-situ* conservation of medicinal plants.
3. Research and Development sector in:
 - a). Universities and Institutions.
 - b). Health care and pharmaceutical industries
 - c). National Medicinal Plants Board, India
 - d). Food industry

2. OBJECTIVES:

- To provide historical and general perspectives of medicinal plants
- To provide theoretical knowledge on herbal drugs preparations, characterizations, and bioactive compounds identifications
- To provide hands-on isolation, purification, and characterization of bioactive compounds
- To provide insight on herb-drug interactions and quality control & safety issues
- To provide awareness on intellectual properties right (IPR) & Patent filing

3. LEARNING OUTCOMES OF P.G. DIPLOMA PROGRAMME IN PLANT TISSUE CULTURE:

S. No.	Learning Outcomes
1.	After undergoing this programme, students will be able to: Conduct research work and surveys in herbal medicine
2.	Government jobs in the healthcare sectors
3.	Expertise in phytochemical isolation, extraction, and characterization of medicinal plants
4.	To set up small-scale industries for herbal drug formulations
5.	Awareness of drug quality control and safety issues
6.	Awareness about IPR & patent filling

4. ELIGIBILITY

A candidate for being eligible for admission to the Post Graduate Diploma in Plant Tissue Culture must have taken either:

- Bachelor of Science in Life Sciences/Agricultural Sciences/Pharmacy

5. FEE STRUCTURE: As per the PIMS-DU rule**Fee Structure for PG Diploma Programmes at Centre for Biotechnology**

No	PG Diploma Programme	Intake	Tuition Fee	Eligibility & Registration Fee	Other Fee	Security Deposit	Total Fee
1	PG Diploma in Herbal Medicine	5	25,000	2250	6,500	5,000	38,750

6. DURATION OF THE COURSE AND COURSE COMPLETION

The duration of the Diploma programme shall be one year and there shall be a University Examination at the end of each semester. The PG Diploma in Herbal Medicine shall not be conferred upon a candidate unless he/she has passed in all subjects, practicals, and successful completion of the project.

7. EXAMINATION FOR COURSE.

The performance of the student for a semester for each course shall be evaluated as under.

- a). For the theory & practical courses, there shall be two components of the examination.
 - 1) Continuous Internal Assessment (CIA) for a maximum of 30 % of total marks of a course comprising of two tests (written test/home assignments/seminars etc.)
 - 2) Semester End Examinations (SEE) for each course for a maximum of 70% of total marks. The duration of the theory examination shall be 3 hours.
- b). For the practical courses, there shall be Semester End Examinations for the entire 70%marks allotted to the course as per course structure and matrix. The Practical Examinations shall be for 6 hours.
- c). The marks sheet/list for Internal Assessment shall be submitted to the office of the Controller of Examination at least one week before the commencement of SEE.

8. CONDUCTION OF EXAMINATION AND EVALUATION.

- a). The Office of the Controller of Examination shall arrange to conduct the Semester End Examination for subjects.
- b). The Controller of Examination shall announce the calendar of examination specifying the aspects regarding the registration of candidates, eligibility certification for the list of candidates, payment of fees prescribed and tentative schedule of examination.
- c). The Controller of Examination shall arrange to assign the registration numbers and issue 'Hall Tickets' through the college to the certified eligible students.
- d). The Controller of Examination shall announce the detailed 'Time-Table' and arrange to conduct the examination as per the prescribed rules and procedures specified in Examination Manual.
- e). The University Board of Appointment of Examiners (BoAE), would constitute the Board of Examiners (BoE) for each subject.
- f). The Board of Studies of each subject shall submit the approved list of examiners to the office well in time based on seniority, specialization and other details.
- g). The Board of Examiners shall arrange to set 3 sets of question papers for each of the assigned courses based on the syllabi. It shall set separate sets of question papers for repeaters/improvement candidates, in case of change in the syllabi. It shall follow the model question paper approved by the Board of Studies.

- h). There shall be a Central Evaluation of the theory answer scripts for subjects. The Semester End Practical or Field Work Examination for each course shall be conducted by two examiners: preferably one internal and one external examiner.
- i). The Office of the Registrar (Evaluation) shall arrange for the tabulation of marks awarded and determine the results.

9. STANDARD OF PASSING

- a). A candidate securing minimum marks of 50% and above in aggregate of Internal Assessment Marks and of Semester End Examination for each of the courses in a semester shall be declared to have passed in the said course.
- b). There will be 50% marks for passing in continuous internal assessment.
- c). The minimum for passing in the Semester End Examination of any course is 50% of the maximum marks, wherever there is an Internal Assessment component.
- d). Candidates failing in any of the courses of a semester are eligible to reappear for the supplementary examination of said courses of the semester within 6 months.

10. DECLARATION OF RESULTS AND AWARD OF CLASS AND RANKS

- a) The degree shall be awarded to the candidates who have passed all the courses of the programme for the two semesters.
- b) After the completion of tabulation of marks for each course, grade points, and credit points for each course are calculated, only in the case of successful candidates.
- c) Then the SGPA of the semester and CGPA of the semesters are calculated. The specimen of the marks card is given in **Annexures 1-2**.
- d) The class will be awarded to the successful candidates considering the total marks secured in the courses during the I to VI semesters.
- e) The classification of successful candidates for the award of classes and CGPA, letter grade for the Programme is as follows:

Cumulative Grade Point Average (CGPA)	Total Percentage of Marks	Class to be Awarded	Letter Grade
7.5 to 10.0	> 75%	First class with Distinction	A +
6.0 and above but below 7.5	60 – 74.9%	First Class	A
5.5 and above but below 6.0	55 – 59.9 %	High Second Class	B +
5.0 and above but below 5.5	50 – 54.9 %	Second Class	B
Below 5.0	-	Fail	F

The CoE / Registrar Evaluation shall arrange to issue the marks cards for all the semesters & overall passes of all semesters indicating both marks system with the class system as well CGPA with a letter grade. Only the grades and class shall be used for only the declaration of final /overall results. On other semester examinations, it is pass or fail remarks.

11. COURSE STRUCTURE

S. No.	Course Code	Course Name	No. of Hours per Week			Credit	Distribution of Marks		
			Lecture/Tutorials	Practical	Total		Int. Exam	Univ. Exam	Total
FIRST SEMESTER									
1.	PGD-HM 101	Traditional knowledge of herbal medicines	4	-	4	4	30	70	100
2.	PGD-HM 102	Phyto-pharmacological medicines	4	-	4	4	30	70	100
3.	PGD-HM 103	Analytical techniques in herbal drugs	4	-	4	4	30	70	100
4.	PGD-HM 104	Biological assays for herbal drugs	4		4	4	30	70	100
5.	PGD-HM 105	Practical - 1 based on Paper PGD-HM 101	-	4	4	2	30	70	100
6.	PGD-HM 106	Practical - 2 based on Paper PGD-HM 103	-	4	4	2	30	70	100
7.	PGD-HM 107	Practical - 2 based on Paper PGD-HM 104		4	4	2	30	70	100
		Total	16	12		22			700
SECOND SEMESTER									
1.	PGD-HM 201	Research Methodology	4	-	4	4	30	70	100
		IPR & Laboratory Practices							
2.	PGD-HM 202	Quality control & Good Manufacturing Practices for Herbal Drugs	4	-	4	4	30	70	100
3.	PGD-HM 203	Project Dissertation & Viva Voce	-	-		16	-	-	250
4.	PGD-HM 204	Seminar, Presentation/ Group Discussion	2	-		2	-	-	50
		Total	10		08	26			500

FIRST SEMESTER

Traditional Knowledge of Herbal Medicines (PGD-HM 101)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-HM 101	Core	Traditional Knowledge of Herbal Medicines	4		2	120	6

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Introduction & History	<ul style="list-style-type: none"> The history of herbal medicine Introduction to herbal medicine, nutritive, curative, or preventive properties of herbal medicines. Introduction to medicinally important plant parts: Fruits, Leaves, Stems, Roots and their modifications. 	12
Unit II	Plant Identification	<ul style="list-style-type: none"> Classifications of plants used in Western medicine. Elementary knowledge of Binomial nomenclature – Outline of Bentham and Hooker classification – Herbarium techniques. 	14
Unit III	Ethnobotany	<ul style="list-style-type: none"> Definition importance, scope, categories, and significance. Ethno-botanical and cultural aspects of medicinal plants Cultivation and conservation of Ayurvedic and Indigenous medicinal plants Propagation methods of medicinal plants 	14
Unit IV	Conservation of medicinal plants	<ul style="list-style-type: none"> Need for conservation - Worldwide trade of medicinal plants - TRIPS agreement, Indian patent law- Case studies of Turmeric and Neem 	10
Unit V	Institutes	<ul style="list-style-type: none"> National and state agencies for promoting the cultivation of medicinal plants <ol style="list-style-type: none"> Ayush CIMAP NMPB SMPBs AICRPE and TDU 	10

Reference books

1. Ethnobiology - R.K.Sinha & Shweta Sinha - 2001. Surabhe Publications - Jaipur.
2. Tribal medicine - D.C. Pal & S.K. Jain 1998, Naya Prakash, 206, Bidhan Sarani, Calcutta - 700 006.
3. Contribution to Indian Ethnobotany - S.K. Jain 1995, 3rd edition, scientific publishers P.B.No. 91, Jodhpur, India.
4. Herbs that Heal, Acharya Vipul Rao - Diamond Pocket Books, New Delhi.
5. Encyclopedia Of Herbal Medicine, by Chevallier A. Publisher : DK (1 March 2016)

Phyto-pharmacological Medicines (PGD-HM 102)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-HM 102	Core	Phyto-pharmacological Medicines	4		2	120	6

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Natural products	<ul style="list-style-type: none"> • Introduction of natural products & secondary metabolites, classifications & physiochemical properties • Detailed study of the following natural products with special reference to the source, chemical nature, and medicinal properties. <ol style="list-style-type: none"> 1. Caffeine 2. Curcumin 3. Aspirin 4. Morphine 5. Taxol 6. Lysergic Acid Diethylamide (LSD) 	12
Unit II	Ethnopharmacology	<ul style="list-style-type: none"> • Introduction, scope, and relevance. A brief account of Phytochemistry, pharmacodynamics, and pharmacokinetics. • Difference between herbal/botanicals and pharmaceutical medicine. • Classification and sources of crude drugs. • Quality, safety, and efficacy of herbal medicines/ nutraceuticals. • Role of ethnopharmacology in drug development. 	14
Unit III	Ethnomedicine	<ul style="list-style-type: none"> • Definition, history, and its scope: Inter-disciplinary approaches in Ethnobotany. • Collection of ethnic information. • Role of ethnomedicine and its scope in modern times. 	10
Unit IV	Analytical Pharmacognosy	<ul style="list-style-type: none"> • History, Definition, and scope of pharmacognosy • Classification of Crude drugs, Preparation of crude and commercial drugs • Drug adulteration and detection. Biological 	12

Sr. No.	Topic	Details of Syllabus	Hrs.
		testing of herbal drugs. <ul style="list-style-type: none"> Phytochemical investigations with reference to secondary metabolites of locally available medicinal plants. 	
Unit V	Medicinal Plant Biotechnology	<ul style="list-style-type: none"> Plant tissue culture, Historical development of plant tissue culture, types of cultures, Infrastructure for Plant tissue culture facility, Culture media components, growth and their maintenance, Hardening of tissue cultured plants. Applications of plant tissue culture in pharmacognosy. 	12

Reference books

- Herbal Remedies Handbook, by Chevallier A. Publisher : DK (1 March 2018)
- Phytopharmaceutical Analysis, by Raj Kumari Kataria, Lambert publications,
- A Manual of Ethnobotany – S.K.Jain, 1995, 2nd edition.
- Pharmacognosy, S.B.Gokhale, Dr.C.K. Kokate, A.P. PurohitPublisher: Nirali Prakasham, Pune.
- Practical Pharmacognosy. Dr.C.K. Kokate et al.
- An Introduction to Medicinal Botany and Pharmacognosy – N.C. Kumar, EmkayPublications, Delhi.
- A Textbook of Pharmacology, by Uma Bhandari, Biotech Pharma Publications.

Analytical Techniques in Herbal Drugs (PGD-HM 103)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-HM 103	Core	Analytical Techniques in Herbal Drugs	4		2	120	6

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Introduction	<ul style="list-style-type: none"> Need and significance for standardization of herbal drugs. Apparatus used for testing, and assays – Nessler Cylinders, Sieves, Thermometers, Volumetric Glass wares, Weights and Balances. Basic calculations in pharmaceutical analysis: Percentage volume / volume (%v/v), percentage weight in volume (%w/v), Dilutions, Preparation of standard stock solutions, percentage weight / weight (%w/w), parts per million calculation (ppm), Molar & Normal Solutions. 	12
Unit II	Instrumentations	Applications of the following analytical techniques in herbal medicine <ul style="list-style-type: none"> UV/Visible spectrophotometry FT-IR spectrophotometry Chromatography Mass Spectrometry X-ray Diffraction Nuclear Magnetic Resonance spectroscopy 	14
Unit III	Tests and Determination	Determination of different Physico-chemical parameters <ul style="list-style-type: none"> Foreign matter, Moisture content, Total ash content, Acid insoluble ash, Water soluble ash, Alcohol soluble extractives, Water soluble extractives Fixed oil content, Determination of saponification value, Unsaponifiable matter, Foaming index, Acid value, Iodine value, Alcohol content, Swelling 	12

Sr. No.	Topic	Details of Syllabus	Hrs.
		index, Mineral oil, Rancidity test. <ul style="list-style-type: none"> Extraction and estimation of volatile oil content. 	
Unit IV	Extraction and separation techniques	<ul style="list-style-type: none"> Maceration, Infusion, Percolation, Decoction, Soxhlet extraction, Microwave assisted extraction (MAE) Supercritical fluid extraction (SFE), Ultrasound-assisted extraction Enzyme-assisted extraction 	12
Unit V	Phytochemical screening	<ul style="list-style-type: none"> Qualitative analysis - Steroids, Sugars (Total sugar, Reducing and Non-reducing), Terpenoids, Alkaloids, Phenolics, flavonoids, saponins, tannins, cardiac glycosides and anthraquinones. Quantitative analysis-Determination of total alkaloids, Flavonoids, Phenolics, Saponins, Tannins, and Glycosides. 	10

Reference books

1. Practical Handbook On Analytical Techniques For Quality Control Of Herbal Drugs by Dr B.Ramya Kuber, Publisher: Notion Press
2. Herbal Drug Technology (2nd Edition), by Agrawal & Paridhavi, Publisher: Orient Blackswan Private Limited - New Delhi.
3. Pharmaceutical Biotechnology - Concepts and Applications, Gary Walsh, Publisher: John Wiley & Sons Inc
4. Chromatographic Fingerprint Analysis of Herbal Medicines, by Hildebert Wagner, Publisher : Springer; 2nd ed. 2011 edition
5. Lab Manual Of Herbal Drug Technology, by Sneha, Kaushik, Sanjesh, Publisher : Pv Books
6. Herbal Drug Technology (PB 2019), Malviya N, Publication: CBS
7. Principles and Techniques of Biochemistry and Molecular Biology, Wilson and Walkers, Cambridge University Press.

Biological Assays for Herbal Drugs (PGD-HM 104)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-HM 104	Core	Biological Assays for Herbal Drugs	4		2	120	6

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Herbal Remedies	<ul style="list-style-type: none"> Toxicity and Regulations: Herbal drugs vs Conventional drugs Efficacy of Herbal medicine products Validation of herbal therapies Pharmacodynamic and Pharmacokinetic issues 	10
Unit II	Adulteration and Deterioration	<ul style="list-style-type: none"> Introduction, Types of Adulteration/ Substitution of Herbal drugs Causes and Measures of Adulteration Sampling Procedures, Determination of Foreign Matter DNA Fingerprinting techniques in the identification of drugs of natural origin Detection of heavy metals. Pesticide residues, phytotoxin, microbial contamination in herbs and their formulations. 	12
Unit III	Analytical Profiles & Biological activities of Herbal Drugs	<ul style="list-style-type: none"> <i>Andrographis paniculata</i> <i>Boswellia serata</i> <i>Coleus forskholii</i> <i>Curcuma longa</i> <i>Embelica officinalis</i> <i>Psoralea corylifolia</i> 	12
Unit IV	Biological Screening of Herbal Drugs	<ul style="list-style-type: none"> Introduction and Need for Phyto-Pharmacological Screening New Strategies for evaluating Natural Products Biological Screening: <i>in vitro</i> antioxidant activity, antimicrobial activity, <i>in vitro</i> anti 	16

Sr. No.	Topic	Details of Syllabus	Hrs.
		diabetic activity and <i>in vitro</i> anticancer drugs, Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardioprotective, Diuretics, and Antifertility evaluation <ul style="list-style-type: none"> • Toxicity studies as per OECD guidelines 	
Unit V	Drugs of plant origins	<ul style="list-style-type: none"> • Cardiac drugs of plant origins, anticoagulants – basic mechanism of action. Pulmonary/respiratory disorders – asthma bronchitis – the common cold – allergy – Remedy from plants. • Drugs for urinogenital disorders, Drugs for dissolving kidney stones, Antiinflammatory drugs, and anti-cancer drugs 	10

Reference books

1. Herbal Drug Technology (2nd Edition), by Agrawal & Paridhavi, Publisher: Orient Blackswan Private Limited - New Delhi.
2. Pharmaceutical Biotechnology - Concepts and Applications, Gary Walsh, Publisher: John Wiley & Sons Inc
3. Chromatographic Fingerprint Analysis of Herbal Medicines, by Hildebert Wagner, Publisher : Springer; 2nd ed. 2011 edition
4. Lab Manual Of Herbal Drug Technology, by Sneha, Kaushik, Sanjesh, Publisher : Pv Books
5. Herbal Drug Technology (PB 2019), Malviya N, Publication: CBS

Paper – PGD HM 105: Practical 1 Based on paper PGD HM 101

1. Visit a tribal area and collect information on their traditional method of treatment using crude drugs
2. Observe the plants of ethnobotanical importance in your area & submit a note on any 10 plants
3. Identification and Medicinal value of locally available medicinal plants
4. Familiarize with at least 5 folk medicines
5. Students have to make submissions of 05 crude drugs with critical notes
6. Identify the drug with its binomial and morphology of the source plant

Paper – PGD HM 106: Practical 2 Based on paper PGD HM 103

1. Qualitative analysis of Steroids, Total sugar, Reducing and Nonreducing sugar, Terpenoids, Alkaloids, Phenolic compounds, Flavonoids, Saponins, Tannins, Cardiac glycosides, and Anthraquinones.
2. Soxhlet extraction of phytoconstituents from plants
3. Identification of bioactive constituents from plant extracts: Estimation of total Alkaloids, Flavonoids, Phenolics, Saponins, Tannins, and Glycosides.
4. Analysis of recorded spectra of simple phytoconstituents
5. UV Vis spectrophotometer analysis of crude herbal extracts
6. Separation of phytoconstituents from extracts using TLC.
7. Column chromatography of herbal extracts
8. Development of fingerprint of selected medicinal plant extracts

Paper – PGD HM 107 Practical 3 Based on paper PGD HM 104

1. *In vitro* evaluation of selected herbal extracts for antimicrobial activity
2. *In vitro* evaluation of herbal extracts for anti-diabetic activity
3. *In vitro* evaluation of herbal extracts for Antioxidants and Anticancer potential
4. Demonstration of *In vivo* evaluation of herbal drugs for Antidiabetic, Hepatoprotective, & Cardioprotective action
5. HPLC analysis of selected herbal extracts

SECOND SEMESTER

Research Methodology (PGD-LAM 201 ELV)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-HM 201 ELV	Elective	Research Methodology	4			60	4

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Introduction of Research	<ul style="list-style-type: none"> • Characteristics of Research • Steps involved in Research • Research in Pure and Applied Sciences - Inter-Disciplinary Research. • Factors that hinder Research • Significance of Research • Research and scientific methods • Research Process- Criteria of Good Research • Problems encountered by Researchers • Literature review. 	12
Unit II	Identification of Research Problem	<ul style="list-style-type: none"> • Selecting the Research problem • The necessity of defining the problem • Goals and Criteria for identifying problems for research. 	08
Unit III	Research Design	<ul style="list-style-type: none"> • Need for Research design • Formulation of Research design • Features of a research design • Important concepts related to Research design. • Different research designs • Computer and internet in research designs. 	10
Unit IV	Interpretation and Report Writing	<ul style="list-style-type: none"> • Meaning and Technique of Interpretation • Precautions in interpretation • Significance of report writing • Different steps in writing a report • The layout of a Research report. • Types of reports • Mechanics of writing a research report • Precautions for writing a research report 	10
Unit V	Statistical Techniques and Tools	<ul style="list-style-type: none"> • Introduction to statistics, Functions & Limitations • Sample size estimation • Measures of central tendency • Calculation of percentage and frequency • Arithmetic mean - Median - Mode • Standard deviation & Standard Error 	20

Sr. No.	Topic	Details of Syllabus	Hrs.
		<ul style="list-style-type: none"> • Co-efficient of variation (Discrete serious and continuous serious) • Correlation & Regression • Sampling distribution • Concept of point and interval estimation • Level of significance • Degree of freedom • Analysis of variance (ANOVA & ANOVA followed by different tests) • One-way and two-way classified data • 'F'-test, 'Z' test & Chi-square Test • Basic knowledge of SPSS, GraphPad Prism, R and EPI-Info 	

Recommended Books/References

1. A Hand Book of Methodology of Research, Rajammall, P. Devadoss and K. Kulandaivel, RMM Vidyalaya press, 1976.
2. Research Methodology Methods & Techniques, C.R. Kothari - New Age international Publishers, Reprint 2008.
3. Research Methodology, R. Panneerselvam, PHI Learning Pvt. Limited, Delhi.
4. Thesis and Assignment Writing, J. Anderson, Wiley Eastern Ltd., 1997.
5. Research Methodology, Mukul Gupta, Deepa Gupta - PHI Learning Private Ltd., New Delhi, 2011.
6. Fundamentals of Mathematical statistics, S.C. Gupta and V.K. Kapoor, Sultan Chand& Sons, New Delhi, 1999.
7. Statistical Methods, G.W. Snedecor and W.G. Cochrans, Iowa State University Press, 1967.
8. Methods in Biostatistics by B. K. Mahajan
9. Fundamentals of Biostatistics by Khan & Khanum
10. Fundamentals of Biostatistics by U.B. Rastog
11. Basic & Clinical Biostatistics, Beth Dawson and Robert G. Trapp. Lange Medical Books/McGraw-Hill Medical Publishing Division

IPR & Laboratory Practices (PGD-LAM 201 ELV)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-HM 201 ELV	Elective	IPR & Laboratory Practices	4			60	4

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Overview of Intellectual Property	<ul style="list-style-type: none"> Introduction and the need for intellectual property right (IPR) - Kinds of Intellectual Property Rights: Patent, Copyright, Trade Mark, Design, Geographical Indication, Plant Varieties and Layout Design Genetic Resources and Traditional Knowledge Trade Secret IPR in India: Genesis and development IPR in abroad - Major International Instruments concerning Intellectual Property Rights: Paris Convention, 1883, the Berne Convention, 1886, the Universal Copyright Convention, 1952, the WIPO Convention, 1967, the Patent Co-operation Treaty, 1970, the TRIPS Agreement, 1994 	09
Unit II	Patent	<ul style="list-style-type: none"> Patents - Elements of Patentability: Novelty, Non-Obviousness (Inventive Steps), Industrial Application - Non - Patentable Subject Matter - Registration Procedure, Rights and Duties of Patentee, Assignment and license, Restoration of lapsed Patents, Surrender and Revocation of Patents, Infringement, Remedies & Penalties - Patent office and Appellate Board 	08
Unit III	Trademarks	<ul style="list-style-type: none"> Concept of Trademarks Different kinds of marks (brand names, logos, signatures, symbols, well-known marks, certification marks and service marks) Non Registrable Trademarks Registration of Trademarks Rights of holder and assignment and licensing of marks Infringement, Remedies & Penalties Trademarks registry and appellate board 	08
Unit IV	Other forms of IP	<ul style="list-style-type: none"> Design: meaning and concept of the novel and original - Procedure for registration, the effect of registration and term of protection Geographical Indication (GI) Geographical indication: meaning, and the difference between 	05

Sr. No.	Topic	Details of Syllabus	Hrs.
		GI and trademarks -	
Unit V	Introduction Good Documentati on Practices - GLP and Quality Assurance	<ul style="list-style-type: none"> History of Good Laboratory Practices Good Laboratory Practices- Introduction, OECD, FDA and WHO Guidelines on GLP & GMP Quality assurance in Good Laboratory Practices Good record keeping: Forms update: Form-C, Form-D, Part-A, Part -B, Firm -E, etc., 	08
Unit VI	Quality standards and Quality Assurances	<ul style="list-style-type: none"> Quality Standards- Advantages and Disadvantages Quality Assurance- Their functions and advantages Quality assurance and quality management in the industry Customer requirement of quality Government and trade standards of quality Federal Food and Drug Law FDA Action BSTI Laws, BSTI action and activities Other food laws (Legalization) Trade and Company Standards Control by National, International, Social Organizations (example: FAO, GAFTA, WHO, UNICEF, CAB), Society (example: NSB, Professional societies) 	12
Unit VII	Biosafety	<ul style="list-style-type: none"> General lab equipment Introduction & development of Biosafety Practices & Principles Definitions & Biosafety levels, 1, 2, 3, 4,; Biological safety cabinets Shipment of biological specimens Decontaminations Biosafety manuals; Medical surveillance, Emergency response. Biological waste management 	10

Recommended Books/References/Website:

1. T. M. Murray & M. J. Mehlman, Encyclopedia of ethical, legal and policy issues in biotechnology, John Wiley & sons 2000.
2. Ethical Issues in Biotechnology by Richard Sherlock & John D. Morrey, Rowman& Littlefield Publishers.
3. Nithyananda, K V. (2019). Intellectual Property Rights: Protection and Management. India, IN: Cengage Learning India Private Limited.
4. Neeraj, P., &Khusdeep, D. (2014). Intellectual Property Rights. India, IN: PHI learning Private Limited.
5. Ahuja, V K. (2017). Law relating to Intellectual Property Rights. India, IN: Lexis Nexis.

6. Subramanian, N., &Sundararaman, M. (2018). Intellectual Property Rights – An Overview. Retrieved from <http://www.bdu.ac.in/cells/ipr/docs/ipr-eng-ebook.pdf>
7. World Intellectual Property Organisation. (2004). WIPO Intellectual property Handbook. Retrieved from https://www.wipo.int/edocs/pubdocs/en/intproperty/489/wipo_pub_489.pdf
8. Cell for IPR Promotion and Management (<http://cipam.gov.in/>)
9. World Intellectual Property Organisation (<https://www.wipo.int/about-ip/en/>)
10. Office of the Controller General of Patents, Designs & Trademarks (<http://www.ipindia.nic.in/>)
11. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, Volume I & II, Mumbai.
12. Good Laboratory Practice Regulations, Sandy Weinberg Vol. 69, Marcel Dekker Series.
13. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, WHO Publications.
14. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series.

Quality Control & Good Manufacturing Practices for Herbal Drugs (PGD-HM 202)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-HM 202	Core	Quality Control & Good Manufacturing Practices for Herbal Drugs	4			60	4

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Basic tests for drugs	<ul style="list-style-type: none"> WHO guidelines for quality control of herbal drugs. Medicinal plants materials and dosage forms Evaluation of commercially available crude drugs intended for use 	08
Unit II	Quality assurance	<ul style="list-style-type: none"> Infrastructural requirements, working space, storage area, machinery and equipment, standard operating procedures, health and hygiene, documentation and records A brief study of quality assurance in herbal drug industry of cGMP, GMP, and GLP in traditional system of medicine Components of GMP (Schedule - T) and its objectives 	15
Unit III	WHO Guidelines	<ul style="list-style-type: none"> WHO Guidelines on current good manufacturing Practices (cGMP) for Herbals. EU and ICH guidelines for quality control of herbal drugs. WHO, FDA and AYUSH guidelines for safety monitoring of natural medicine 	10
Unit IV	Research Guidelines	<ul style="list-style-type: none"> Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines. Stability testing of herbal medicines. 	10
Unit V	Documentations / Challenges	<ul style="list-style-type: none"> Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Documentations for new drug applications and export registration 	17

PGD- HM 203: Project

The purpose of introducing project work is to enable the students to apply the knowledge, skills, and attributes, acquired during the entire course, to the solution of specific problems related to practical work. The students will have to go through all the steps of problem-solving such as defining the problem, analysis of the problem, collecting required information and resources, formulating alternatives, selecting the best solution, and practicing it.

The project work aims at, besides developing problem-solving abilities in the students, the development of confidence and expertise in a particular field. The student may get the required skills to analyze the problem, use instruments, and use techniques and orientation of learning experiences towards their applications in the world of work. Students shall identify the problem with the help of their project guide.

PRAVARA INSTITUTE OF MEDICAL SCIENCES
(DEEMED TO BE UNIVERSITY)

Centre for Biotechnology

Loni 413736, Ahmednagar District, Maharashtra State, India

Post Graduate Diploma Program in Herbal Medicine
The Pattern of Marks Statement

Semester: I

Month & Year: _____ **Name of the**

Student: _____ **Reg. No:** _____

Course number & code	Title of course	Credits	Internal Assessment marks		Semester End Exam.			Total Marks			GP	CP
			Max.	Secured	Max.	Min. for pass	Marks secured	Max.	Min. for pass	Secured		
PGD-HM 101	Traditional knowledge of herbal medicines	4	30		70	35		100	50			
PGD-HM 102	Phyto-pharmacological medicines	4	30		70	35		100	50			
PGD-HM 103	Analytical techniques in herbal drugs	4	30		70	35		100	50			
PGD-HM 104	Biological assays for herbal drugs	4	30		70	35		100	50			
PGD-HM 105	Practical - 1 based on Paper PGD-HM 101	2	30		70	35		100	50			
PGD-HM 106	Practical - 2 based on Paper PGD-HM 103	2	30		70	35		100	50			
PGD-HM 107	Practical - 2 based on Paper PGD-HM 104	2	30		70	35		100	50			
Grand Total		22						700				

Annexure - 2

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Centre for Biotechnology

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Post Graduate Diploma Program in Herbal Medicine
The Pattern of Marks Statement


Semester: II

Month & Year: _____ Name of the

Student: _____ Reg. No: _____

Course number & code	Title of course	Credits	Internal Assessment marks		Semester End Exam.			Total Marks			G P	C P
			Max.	Secured	Max.	Min. for pass	Marks secured	Max.	Min. for pass	Secured		
PGD-HM 201-ELE	Research Methodology	4	30		70	35		100	50			
PGD-HM 201-ELE	IPR & Laboratory Practices (Choose anyone)				70	35						
PGD-HM 202	Quality control & Good Manufacturing Practices for Herbal Drugs	4	30		70	35		100	50			
PGD-HM 203	Project Dissertation & Viva Voce	16	30					250	50			
PGD-HM 204	Seminar, Presentation/ Group Discussion	2	30					50	50			
Grand Total		26						500				




Registrar
 Pravara Institute of Medical Sciences
 (Deemed to be University)
 Loni - 413736, Tal. Rahata
 Dist. Ahmednagar (M.S. India)