MAHARSHI DAYANAND UNIVERSITY ROHTAK

(Established under Haryana Act No. XXV of 1975)
'A+' Grade University accredited by NAAC

No. ACS-III/F-26/2021/ 7382-92
Dated: 21/06/21

To

Chairperson

1 Prof. Sanju Nanda, HOD & Dean,
Faculty of Pharmaceutical Sciences,
M.D. University, Rohtak
2 Dr. Arun Nanda, Professor,
Dept. of Pharmaceutical Sciences,
M.D. University, Rohtak
3 Dr. Narasimhan B., Professor,
Dept. of Pharmaceutical Sciences,
M.D. University, Rohtak
4 Dr. Munish Garg, Professor,
Dept. of Pharmaceutical Sciences,
M.D. University, Rohtak
5 Dr. Harish Dureja, Prof.,
Dept. of Pharmaceutical Sciences,
M.D. University, Rohtak
6 Dr. Deepak Kaushik, Associate Professor,
Dept. of Pharmaceutical Sciences,
M.D. University, Rohtak
7 Dr. Saloni Kakkar, Assistant Professor,
Dept. of Pharmaceutical Sciences,
M.D. University, Rohtak
8 Prof. D.P. Pathak,
Delhi Institute of Pharmaceutical Education & Research,
Sector III, Pushp Vihar, New Delhi-17
9 Prof. Sanjula Baboota,
School of Pharmaceutical Education and Research,
Jamia Hamdard, Hamdard Nagar, New Delhi-62
10 Prof. Gulshan Lal Taneja, Registrar-cum-Secretary,
M.D.University, Rohtak.

Sub: Minutes of emergent Meeting of the Faculty of Pharmaceutical Sciences to be held on 15.06.2021 at 11:00 A.M

Sir/Madam,

Please find enclosed the copy of minutes of emergent meeting of the Faculty of Pharmaceutical Sciences held on 15.06.2021 at 11:00 A.M. in the office of Dean, Pharmaceutical Sciences M.D. University, Rohtak duly approved by the Vice-Chancellor in anticipation of approval of Academic Council.

This is for your information.

Yours faithfully

21/6/21
Superintendent (Academic)
For Deputy Registrar
Dated 21/06/21

Encl.: As above.

Endst. No. ACS-III/2021/ 7393-97

Copy of the above is forwarded to the following for information and necessary action:

1. Controller of Examinations, M. D. University, Rohtak.
2. Assistant Registrar (Secrecy, Conduct, R & S), M. D. University, Rohtak.
3. Director, UCC for uploading the minutes on the University website.

21/6/21
Superintendent (Academic)
For Deputy Registrar

MAHARSHI DAYANAND UNIVERSITY ROHTAK

MINUTES OF THE MEETING OF THE FACULTY OF PHARMACEUTICAL SCIENCES IN BLENDED MODE HELD ON 15.06.2021 AT 11:00 AM IN THE OFFICE OF THE DEAN, FACULTY OF PHARMACEUTICAL SCIENCES.

MEMBERS PRESENT:-

1. Dr. Sanju Nanda, Head & Dean — Chairperson
2. Dr. Arun Nanda, Professor
3. Dr. Narasimhan B., Professor
4. Dr. Munish Garg, Professor
5. Dr. Harish Dureja, Professor
6. Dr. Deepak Kaushik, Associate Professor
7. Dr. Saloni Kakkar, Assistant Professor
8. Prof. D.P. Pathak — Outside Expert(online mode)
9. Prof. Sanjula Baboota — Outside Expert(online mode)
10. Mr. M.L. Batra, Deputy Registrar (Academic)

1. Confirmed the minutes of previous meeting of the Faculty of Pharmaceutical Sciences held on 18.07.2020 (already circulated).

2. Considered the recommendations of Board of Studies in Pharmaceutical Sciences made vide Reso. NO. 3 of its meeting held on 22.03.2021 that the Syllabus and Scheme of Examination of Ph.D Course Work in Pharmaceutical Sciences w.e.f the session 2020-21 may be prescribed as per Annexure-I pages 1 to 10.

RESOLVED THAT THE SYLLABUS OF THE ABOVE PROGRAM BE APPROVED WITH AMENDMENTS IN PAPER ENTITLED PHARMACEUTICAL SCIENCES THAT 'FEEDBACK REGULATED ORAL DDS' BE ADDED IN UNIT -1 AND 'ETHICS AND ANIMAL EXPERIMENTATION' BE ADDED IN UNIT- 4 OF THE SAID PAPER.

COURSE CODE I.E '20MPCC1' IN RESPECT OF PAPER ENTITLED 'RESEARCH & PUBLICATION ETHICS' SHALL BE APPLICABLE FOR ALL M.PHIL/PH.D COURSE WORK AS ALREADY NOTIFIED BY THE UNIVERSITY.

FURTHER RESOLVED THAT THE SCHEME OF EXAMINATION OF THE PROGRAM BE RECOMMENDED TO THE ACADEMIC COUNCIL FOR APPROVAL.

15/6/21 (SANJU NANDA) (ARUN NANDA) 15/6/21 (NARASIMHAN B.) 15/6/21 (MUNISH GARG)

15/6/21 (HARISH DUREJA) 15/6/21 (DEEPAK KAUSHIK) 15/6/21 (SALONI KAKKAR) (M.L BATRA)

DEPARTMENT OF PHARMACEUTICAL SCIENCES
MAHARSHI DAYANAND UNIVERSITY, ROHTAK

PH. D. COURSE WORK IN PHARMACEUTICAL SCIENCES

PROGRAM SPECIFIC OUTCOMES

1. The program aims to develop deep methodological skills and an understanding of contemporary research in Pharmaceutical Sciences and implement innovative research practices under the guidance of faculty advisor to the Ph.D. scholars.

2. Apply contemporary research in their respective area of emphasis to industry contexts and be able to engage in innovative practices informed by such research pertinent to pharmaceutical sciences and their area of emphasis in diverse contexts.

3. Provide teaching assistance to master's and fellow Ph.D. students who are less advanced than they are in their respective doctoral programs.

4. Launch an independent research agenda in their respective area of emphasis under the guidance of their faculty advisor.

5. Complete and orally defend an acceptable dissertation based on original investigation and supervised by their dissertation committee showing mastery of an area of emphasis within pharmaceutical sciences, capacity for independent research, and a scholarly result.

PROGRAM OUTCOMES

By completion of program, the student will be able to:

1. Know about the research ethics.

2. Understand the drug discovery and development process.

3. Get in-depth knowledge of their respective field.

4. Air new ideas and discuss them amongst peers/members of scientific community.

5. Utilize his/her attained knowledge in academia or industry.

For Ph.D. course work

(Only for subjects where there is no M.Phil. programs are available)

Duration: One Semester (Six months)
Total Credit requirement: 14 credits
Program Structure:

SEMESTER 1						
Course Code	**Nomenclature of Course**	**Theory marks-end semester examination**	**Internal Assessment marks**	**Maximum marks**	**Hours /Week**	**Credits**
20MPCC1 (Compulsory for all Ph.D. Course work)	Research and Publication Ethics	40	10	50	2	2
20PHARMPH11C1	Research Methodology	80	20	100	4	4
20PHARMPH11C2	Scientific Writing and Communication Skills	80	20	100	4	4
20PHARMPH11C3	Pharmaceutical sciences	80	20	100	4	4
Total marks/Credits				**350**		**14**

Note: i. The compulsory course on 'Research and Publication Ethics' shall be offered by Ch. Ranbir Singh Institute of Social and Economic Change for all UTDs/Centres/Institutes passed vide Resolution No. 27 of the 271st meeting of EC held on 29.7.2020.
ii. Coding for nomenclature of courses shall be in the following sequence:
Academic Year of introduction-Program Code-1st year/2nd year-Semester-Course Number

Template for Ph.D. Course Work syllabus

Name of the Program	Ph.D. Course work	**Program Code**	PH
Name of the Course	Research and Publication ethics	**Course Code**	20CCPH11C1
Hours/Week	2	**Credits**	2
Max. Marks.	40	**Time**	3 Hours

Note: The examiner has to set a total of nine questions (two from each unit and one compulsory question consisting of short answer from all units. The candidate has to attempt one question each from each unit along the compulsory question (5 x 8 = 40 marks)

Course Objectives:

1. To study the philosophy of ethics
2. To study the scientific conduct of research
3. To study the publication ethics
4. To know about various journal citation databases
5. To know the importance of quality publication.

Course Outcomes:

By completion of course the student is able to

1. Ethics in conduct of scientific research
2. Know the scientific misconducts
3. How to avoid plagiarism and what are the penalties of plagiarism
4. Know the quality of research publications
5. Write research and review articles.

Unit – I

PHILOSOPHY AND ETHICS

1. Introduction to philosophy: definition, nature and scope, concept, branches
2. Ethics: definition, moral philosophy, nature of moral judgments and reactions

SCIENTIFIC CONDUCT

1. Ethics with respect to science and research
2. Intellectual honesty and research integrity
3. Scientific misconducts: Falsification, Fabrication, and Plagiarism (FFP)
4. Redundant publications: duplicate and overlapping publications, salami slicing
5. Selective reporting and misrepresentation of data

Unit – II

PUBLICATION ETHICS

1. Publication ethics: definition, introduction and importance
2. Best practices / standards setting initiatives and guidelines: COPE, WAME, etc.
3. Conflicts of interest
4. Publication misconduct: definition, concept, problems that lead to unethical behavior and vice versa, types
5. Violation of publication ethics, authorship and contributorship
6. Identification of publication misconduct, complaints and appeals
7. Predatory publishers and journals

Unit – III

DATABASES AND RESEARCH METRICS

(A) Databases

1. Indexing databases
2. Citation databases: Web of Science, Scopus, etc.

(B) Research Metrics

Impact Factor of journal as per Journal Citation Report, SNIP, SIR, IPP, Cite Score Metrics: h-index, g index, i10 index, altmetrics

Unit – IV

Practice

OPEN ACCESS PUBLISHING

1. Open access publications and initiatives
2. SHERPA/RoMEO online resource to check publisher copyright & self-archiving policies
3. Software tool to identify predatory publications developed by SPPU
4. Journal finder/journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer Journal Suggested, etc.

PUBLICATION MISCONDUCT

(A) Group Discussions

1. Subject specific ethical issues, FFP, authorship
2. Conflicts of interest
3. Complaints and appeals: examples and fraud from India and abroad

(B) Software tools (2 hrs.): Use of plagiarism software like Tumitin, Urkund and other open source software tools

References:

1. Bird, A. (2006). Philosophy of Science, Routledge
2. Chaddah, P. (2018). Ethics in Competitive Research: Do not get scooped; do not get plagiarised.
3. Indian National Science Academy (INSA). (2019). Ethics in Science Education, Research and Governance.
4. Beall, J. (2012). Predatory publishers are corrupting open access. Nature, 489(7415), 179.
5. National Academy of Sciences, National Academy of Engineering and Institute of Medicine (2009). On being a Scientist: A guide to Responsible Conduct in Research, Third Edition, national Academic press.

Name of the Program	Ph.D. Course work	**Program Code**	PHARM
Name of the Course	Research Methodology	**Course Code**	20PHARMPH11C1
Hours/Week	4	**Credits**	4
Max. Marks.	80	**Time**	3 Hours

Note:The examiner has to set a total of nine questions (two from each unit and one compulsory question consisting of short answer from all units. The candidate has to attempt one question each from each unit along the compulsory question (5 x 16 = 80 marks)

Course Objectives:

1. To demonstrate knowledge of research processes
2. To identify, explain or compare elements of research components
3. To choose relevant techniques
4. To clear the fundamentals of research
5. To collect data and analyse it

Course Outcomes:

After completion of the course, student is able to

1. Understand the principles of statistics
2. Interpret the raw data by using statistics
3. Understand the applications of the different research design.
4. Understand research methods
5. Generate research design

Unit – I

Plan and conduct of study:

Meaning and importance of Research, Objectives of research, Types of research, Selection and formulation of Research Problem. Research study Design: Principles and concepts of study designs, Need and Features of a good study design, Study types, Preparing the research design, determining sample design. Sources of bias.

Types of data. Confidence intervals. Distributions commonly used in statistics: Frequency distributions and Probability distribution.

Unit – II

Hypothesis:
What is a Hypothesis? Concept and the practice, developing the hypothesis, null hypothesis.

Testing hypothesis: Basic concepts concerning testing of Hypotheses, Flow Diagram for Hypothesis Testing, Measuring the Power of a Hypothesis Test.

Hypothesis testing of Means, Hypothesis testing for comparing two related samples, Hypothesis testing of proportions, Hypothesis testing for comparing a Variance to some hypothesized Population Variance, Testing the Equality of Variances of two Normal

Populations, Hypothesis testing of Correlation Coefficients, Limitations of the Tests of Hypotheses.

Unit – III

Data Handling:

Parametric tests: Purpose and significance; t-test (paired or unpaired); ANOVA (one-way and two-way); Correlation analysis - Correlation - Karl Pearson's coefficient of correlation and Multiple correlation; Regression Analysis - Linear regression- Analysis of standard cures in drug analysis, Curve fitting by least-squares method, weighted regression, Multiple regression, Standard error of regression.

Optimization: Basic concepts of Qbd and Design of experiments, Advantages and limitations of DoE, Response surface methodology, Optimization using factorial design and central composite design.

Unit – IV

Data Analysis

Basics of tests on variability and distributions, Sample Size and Power. Estimation and Meta-Analysis; Important Non-Parametric Tests - Purpose and significance of non-parametric tests. Chi-square test, sample sign test, sample Wilcoxon signed rank test, Friedman test, Mann-Whitney test and Kruskal-Wallis test; Risks, Odds, and ROC Curves: Sensitivity, Specificity, and Accuracy, Predictive Values and Critical Value.

References:

1. Bolton, S., Bon, C. (2004). Pharmaceutical Statistics.Marcel Dekker, INC. USA.
2. Kothari, C. R. (2004). Research methodology: Methods and techniques. New Age International.
3. Salkind, N. J. (2010). Encyclopedia of research design (Vols. 1-0). Thousand Oaks, CA: SAGE Publications, Inc.
4. Martin, W.E., Bridgmon, K. D. (2012). Quantitative and statistical research methods: From hypothesis to results. John Wiley & Sons.
5. Mishra, S. B., Alok, S. (2017). Handbook of research methodology. Educreation Publishing.

Name of the Program	Ph.D. Course work	**Program Code**	PHARM
Name of the Course	Scientific Writing and Communication Skills	**Course Code**	20PHARMPH11C2
Hours/Week	4	**Credits**	4
Max. Marks.	80	**Time**	3 Hours

Note: The examiner has to set a total of nine questions (two from each unit and one compulsory question consisting of short answer from all units. The candidate has to attempt one question each from each unit along the compulsory question (5 x 16 = 80 marks)

Course Objectives:

1. To understand the need and types of research communications
2. To understand the methods of writing and publishing good research paper
3. To under effective presentations of oral and poster
4. To understand the IPR issues and technology transfer
5. To understand the issues of securing financial grants

Course Outcomes:

After completion of the course, student is able to

1.Understand the different types of scientific communications
2. How to make a good publication.
3. How to make an effective poster and oral presentation
4. How to protect Intellectual property rights and to do technology transfer
5. How to secure fellowships and research projects.

Unit – I

1. Basics of Scientific Communication skill.
2. Various types of Scientific Communication.
3. Presentation of text in suitable format and practical knowledge of MS Word, Ms-Excel, Ms-Powerpoint to prepare thesis and research papers in a presentable format.

Unit – II

1. Importance of publishing a paper and various types.

2. Various aspects of preparation and publishing research paper :

Choosing a Journal, Title, Authorship, Abstract and key words, Introduction section, Materials and Methods selection, Result and Discussion section, Figures and Tables, Styles of References Communication with the Editor while Handling Referees' Comments etc.

Unit – III

1. Aspects of preparation and delivery of an effective Poster and Oral Presentation.
2. Importance of Protections of IPRs and process of securing a Patent.

3. Importance and process of Technology Transfer, MoUs, Confidentially Agreements

Unit – IV

1. Need and Importance to secure financial grants for research.
2. Types of financial grants for research like, Fellowships, Research project grants, infrastructure and lab up gradation grants and Grants at department/Institute level.
3. Various Government and private agencies to secure financial grants for research.
4. Methods of applying and preparing a good application to secure financial grants.

References:

1. Johnson, S., Scott, J. (2019). Study and Communication Skills for the Biosciences. Oxford University Press.
2) Day, A. R. (1994). Write and Publish a Scientific Paper. The Oryx Press.
3) Peat, J. (2002). Scientific Writing: Easy when you know how. BMJ Books.
4) Chapin, P. G. (2004). Research Projects and Research Proposals: A Guide for Scientists Seeking Funding. Cambridge University Press.
5) Garg, M., Garg, C. (2017). Communication Skills in Scientific Research. Studium Press. INDIA Pvt Limited.
6) Divan, A. (2009). Communication skills for the biosciences: a graduate guide. Oxford University Press.

Name of the Program	Ph.D. Course work	**Program Code**	PHARM
Name of the Course	Pharmaceutical sciences	**Course Code**	20PHARMPH11C3
Hours/Week	4	**Credits**	4
Max. Marks.	80	**Time**	3 Hours

Note:The examiner has to set a total of nine questions (two from each unit and one compulsory question consisting of short answer from all units. The candidate has to attempt one question each from each unit along the compulsory question (5 x 16 = 80 marks)

Course Objectives:

1. To know about the process of drug discovery and development
2. To know about preclinical studies
3. To know about basic techniques used in drug development
4. To know about regulatory requirements for getting marketing approval of drugs
5. To know about various drug delivery systems and factors affecting them

Course Outcomes:

After completion of the course, student is able to

1. Understand the discovery and development of the new drug
2. Understand the different types of the drug delivery system.
3. Understand the use of the different animal models in the area of drug development.
4.Understand the basics of regulatory requirements
5. Understand basic techniques

Unit – I

Central Drug Standard Control Organisation (CDSCO)

1. Functions and responsibilities Investigational New Drug: Need of an IND, Content and Format of an IND application, Submission of an IND, FDA review of IND. The New Drug Application: Overview, Law regulations and Guidance, new drug development and approval, NDA development preclinical investigation, new drug application (phase I, phase II, phase IV and post marketing surveillance),contents of the NDA (chemistry, manufacturing, testing, packaging, labelling, controls, preclinical, clinical data), Human Pharmaco-kinetic and bioavailability testing requirements, Common technical document (CTD) for NDA, Submission, review and maintenance of NDA.

Oral Controlled drug delivery systems

1. Design and fabrication of diffusion controlled, dissolution controlled, osmotic, gastro-retentive delivery systems, biodegradable polymeric delivery systems. Controlled drug delivery polymers, roles of polymers in drug delivery, pharmacokinetic/ pharmacodynamic basis of oral controlled drug delivery. Feedback regulated Oral DDS

Unit – II

Drug Design

History and development of QSAR. Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages Craig plot, Topliss scheme, CoMFA analysis, Simplex method. Energy Minimization Methods, Molecular docking and drug receptor interactions: Rigid docking, flexible docking, De novo drug design, Concept of Pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modelling, Homology modelling

Unit – III

EXTRACTION

1. Different techniques adopted for the extraction of phytoconstituents like Maceration, percolation, sonication, Soxhlet assisted extraction, ultrasound assisted extraction, super critical carbon dioxide extraction and Microwave assisted extraction.
2. Study of Nutraceuticals and their regulations

Unit – IV

COMMON ANIMAL MODELS

1. Ethics in Animal Experimentation
2. Common animal models for selected categories of drugs: anti-hypertensive, anti-inflammatory, anti-diabetic, anti-ulcer, anti-oxidants.
3. Biological drugs and their testing methods

References:

1. Silverman, R. B., Holladay, M. W. (2015). The Organic Chemistry of the Drug Design and Drug action. Academic Press.
2. Patrick, G. L. (2005). An Introduction to Medicinal Chemistry. Oxford University Press.
3. Trease, G. E., Evans, W. C. (2002). Trease and Evans' Pharmacognosy. W.B. Saunders Edinburgh, New York.
4. Central Drugs Standard Control Organization Guidance for Industry:
http://cdsco.nic.in/CDSCOGuidanceForIndustry. pdf
5. Vogel, H.G. (2002). Drug Discovery and Evaluation: Pharmacological Assays. Springer.