



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the information given in the attached documents are verified by me and is true to the best of my knowledge.

Dr. Sujith Varma.K **PRINCIPAL**
Principal National College of Pharmacy
Manassery, Kozhikode
National College of Pharmacy
Manassery, Mukkam, Kozhikode





NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

ACADEMIC YEAR 2021-2022

SINO	NAME OF ADD ON CERTIFICATES PROGRAME	COURSE CODE	NO OF STUDENTS ENROLLED	TYPE ON ADD ON COURSE PROGRAME
1	Basics In Research	BIR 21	85	Self Framed Course
2	Biopharmaceutical Production And Challenges	BPC 21	80	Self Framed Course
3	Herbal Drug Delivery Systems: Innovations And Challenges	HDD 21	82	Self Framed Course
4	Drug Regulatory Affairs	DRA 22	83	Self Framed Course
5	Introduction To OTC Drug Regulation And Safety	OTC 22	81	Self Framed Course



[Signature]
PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences

COURSE 1



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

From,
Dr.S.Kathirvel
Professor
Department of Pharmaceutical Analysis
National College of Pharmacy Manassery, Kozhikode

To,
The IQAC,
National College of Pharmacy
Manassery, Kozhikode

Dear Sir,

Subject: Request for Permission to Conduct a Add on course

I am writing on behalf of the Curriculum Committee, to formally request youesteemed permission to conduct a Add on course for our students of B.Pharm M.pharm and PharmD .This initiative is in line with our commitment to enhancing the educational experience and fostering academic growth among our students.

The Add on course details are outlined as follows:

- **Title: Basics In Research**
- **Date: 04-03-2021-05-04-2021**
- **Venue: SEMINAR HALL**

Thank you for considering our request.

Yours sincerely,

S.Kathirvel
Dr.S.Kathirvel
Coordinator,
Department of Pharmaceutical Analysis
National College of Pharmacy
Manassery, Kozhikode
Date -12-02-2021

PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode

Srijithra





NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

From,
The IQAC,
National College of Pharmacy

To,
The Principal,
National College of Pharmacy
Manassery, Kozhikode

Dear Principal,

I hope this letter finds you well. The Curriculum Committee in collaboration with the Internal Quality Assurance Cell (IQAC), seeks permission to organize a Add on course for students of B.Pharm M.pharm and Pharm.D on the topic **Basics In Research** from **04-03- 2021-05-04-2021**. We kindly request your authorization to proceed with this educational endeavor, which we believe will contribute significantly to the academic growth and development of our students.

Thank you for your consideration.

Sincerely,

IQAC Coordinator

National College of Pharmacy

Manassery

Date : 13-02-2021

PRINCIPAL
National College of Pharmacy





NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

CIRCULAR

EVENT ANNOUNCEMENT

Dear Students,

We are delighted to inform you that the Curriculum Committee ,in collaboration with the Internal Quality Assurance Cell (IQAC), has organized a Add on course on the topic of **Basics In Research** for Students of B.Pharm M.pharm and PharmD

The details of the Add on course are as follows:

- **Date: 04-03-2021-05-04-2021**
- **Venue: SEMINAR HALL**

We look forward to your enthusiastic participation and making this Add on course a success.

Principal

Date: 01-03-2021

PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode





NATIONAL COLLEGE OF PHARMACY

KMCT Medical College campus, Manassery, Mukkam

Basics in Research

Date: 04-03-2021 to 05-04-2021 **Modules:**

- Module 1: Contemporary approaches in preclinical research
- Module 2: Clinical Trials
- Module 3: Understanding the approach to scientific publications

Resource person: Dr. Biju George

Dr. S Kathirvel

Mr. Ranjith

PRINCIPAL

For more enquiries please contact coordinator: Dr. S Kathirvel, Principal, National College of Pharmacy, Manassery, Mukkam, Kozhikode, Kerala. Phone: 83301973509

Module 4: EBSCO Training





NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

Course Curriculum

Year 2021-2022

Course 1:

Course Name:	Basics In Research (BIR 21)
Course duration:	30 hours (04-03-2021 to 05-04-2021)
Name of the resource person	Dr Biju George Dr S Kathirvel Mr Ranjith

Course Objective: The objective of the "Basics in Research" course is to provide participants with a foundational understanding of key concepts and practices in the field of research. By the end of this course, participants will have the knowledge and skills required to embark on research endeavours with a solid foundation in preclinical and clinical research methodologies, scientific publishing, and effective utilization of research databases like EBSCO.

Course content:

Module 1: Contemporary approaches in preclinical research (7 hours)	Describe the principles and methodologies involved in preclinical research. Explore current trends and innovations in preclinical research techniques. Analyze the ethical considerations and regulations governing preclinical studies.
---	--



[Signature]
PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

Module 2: Clinical Trials (10 hours)	<p>Define the phases and design of clinical trials.</p> <p>Examine the ethical and regulatory frameworks governing clinical research.</p> <p>Evaluate the role of randomized controlled trials and their significance in clinical practice.</p>
Module 3: Understanding the approach to scientific publications (10 hours)	<p>Comprehend the importance of scientific publications in knowledge dissemination.</p> <p>Learn how to write and structure scientific papers effectively.</p> <p>Gain insights into the peer review process and strategies for successful publication</p>
Module 4: EBSCO Training (3 hours)	<p>Familiarize oneself with the EBSCO host platform and its research resources.</p> <p>Learn advanced search techniques for efficient literature retrieval.</p> <p>Understand how to access and evaluate scholarly articles using EBSCO databases.</p>



Sujitha
PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

ADD ON COURSE: SUMMARY REPORT

Course code and Name: BIR21/ Basics in Research

Date of add on program: 04-03-2021 to 05-04-2021

Course Duration: 30 Hrs

Year Offered: B. Pharm, Pharm D, M. Pharm

Course instructors: Dr. Biju George

Dr. S Kathirvel

Mr. Ranjith

Course Outcome:

Upon completion of this course students shall be able to

1. Contemporary approaches in preclinical research
2. Clinical Trials
3. The peer review process and strategies for successful publication
4. Evaluate scholarly articles using EBSCO databases.

Course type: Add on course

Assessment Mode

Attendance: 80%

Number of Participants: 85

Scheme of Exam: MCQ Type, offline mode

Date of Exam: 07-04-2021

COURSE COORDINATOR

Dr. S. Kathirvel
J. Kall



PRINCIPAL
PRINCIPAL

National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences

COURSE 2



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

From,
Nihal.P
Assistant Professor
Department of Pharmaceutics
National College of Pharmacy Manassery, Kozhikode

To,
The IQAC,
National College of Pharmacy
Manassery, Kozhikode

Dear Sir,

Subject: Request for Permission to Conduct a Add on course


I am writing on behalf of the Curriculum Committee, to formally request your esteemed permission to conduct a Add on course for our students of B.Pharm M.pharm and PharmD along This initiative is in line with our commitment to enhancing the educational experience and fostering academic growth among our students.

The Add on course details are outlined as follows:

- **Title: BIOPHARMACEUTICAL PRODUCTION AND CHALLENGES**
- **Date: 25-06-2021-25-07-2021**
- **Venue: SEMINAR HALL**

Thank you for considering our request.

Yours sincerely,


Nihal.P
Coordinator,
Department of Pharmaceutics
National College of Pharmacy
Manassery, Kozhikode
Date -05-06-2021




PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

From,
The IQAC,
National College of Pharmacy

To,
The Principal,
National College of Pharmacy
Manassery, Kozhikode

Dear Principal,

I hope this letter finds you well. The Curriculum Committee in collaboration with the Internal Quality Assurance Cell (IQAC), seeks permission to organize a Add on course for students of B.Pharm M.pharm and Pharm.D on the topic of **Biopharmaceutical Production And Challenges** from **25-06-2021-25-07-2021**. We kindly request your authorization to proceed with this educational endeavor, which we believe will contribute significantly to the academic growth and development of our students.

Thank you for your consideration.

Sincerely,


IQAC Coordinator

National College of Pharmacy
Manassery

Date : 07-06-2021




PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

CIRCULAR

EVENT ANNOUNCEMENT

Dear Students,

We are delighted to inform you that the Curriculum Committee, in collaboration with the Internal Quality Assurance Cell (IQAC), has organized a Add on course on the topic of **Biopharmaceutical Production And Challenges** for Students of B.Pharm M.pharm and PharmD

The details of the Add on course are as follows:


- **Date: : 25-06-2021-25-07-2021**
- **Venue: SEMINAR HALL**

We look forward to your enthusiastic participation and making this Add on course a resounding success.

Principal

Date: 22-06-2021




PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

KMCT Medical College campus, Manassery, Mukkam

BIOPHARMACEUTICAL PRODUCTION AND CHALLENGES

Date: 25/06/2021-25/07/2021

Modules:

- Module 1: Traditional Medicine
- Modernization
- Module 2: Biopharmaceutical
- Production and Challenges

Resource person: Mrs. Dhanya K P

Mr. Akhil Hari



For more enquiries please contact coordinator: Mr. Nihal P. Raj


PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode
8089962406



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA.

Course Curriculum

Year 2021-2022

Course 2:

Course Name:	Biopharmaceutical Production And Challenges (BPC 21)
Course duration:	30 hours (25-06-2021 to 25-07-2021)
Name of the resource person	Ms Dhanya K P Mr Akhil Hari

Course Objective: The course "Biopharmaceutical Production and Challenges" aims to provide participants with a comprehensive understanding of the production processes and the unique challenges associated with biopharmaceuticals.

By the end of this course, participants will have a comprehensive knowledge of the modernization of traditional medicine, the intricacies of biopharmaceutical production, and the specific challenges and regulatory considerations that are essential for successful biopharmaceutical development and manufacturing.

Course content:

Module 1: Traditional Medicine Modernization (15 hours)	Examine the evolution of traditional medicine and its integration into modern healthcare. Evaluate the cultural, economic, and regulatory aspects of traditional medicine adoption. Explore case studies showcasing successful traditional medicine modernization efforts.
--	--



[Signature]
Principal
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
.....Affiliated to Kerala University of Health Sciences, Accredited by NBA

Module 2:

Biopharmaceutical Production And
Challenges(15 hours)

Describe the fundamental principles of biopharmaceuticals and analyze the various production methods for biopharmaceuticals, including cell culture and microbial fermentation.

Identify the critical stages of biopharmaceutical production, from upstream processing to downstream purification.

Recognize the unique challenges associated with biopharmaceutical manufacturing, such as cell line development, process optimization, and scalability.

Discuss quality control and assurance measures in biopharmaceutical production.



Sujithaamma
National College of Pharmacy,
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

ADD ON COURSE: SUMMARY REPORT

Course code and Name: BPC21/ Biopharmaceutical Production and Challenges

Date of add on program: 25/06/2021-25/07/2021

Course Duration: 30Hrs

Year Offered: B. Pharm, Pharm D, M. Pharm

Course instructors: Mrs. Dhanya K P

Mr. Akhil Hari

Course Outcome:

Upon completion of this course students shall be able to

1. Evaluate the cultural, economic, and regulatory aspects of traditional medicine adoption.
2. Recognize the unique challenges associated with biopharmaceutical manufacturing, such as cell line development, process optimization, and scalability.

Course type: Add on course

Assessment Mode

Attendance: 80%

Number of Participants: 80

Scheme of Exam: MCQ Type, offline mode

Date of Exam: 25/07/2021

COURSE COORDINATOR

NIHAL- P



PRINCIPAL

PRINCIPAL

National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences

COURSE 3



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

From,
Jyothi.M.Jo
Professor
Department of Pharmacognosy
National College of Pharmacy Manassery, Kozhikode

To,
The IQAC,
National College of Pharmacy
Manassery, Kozhikode

Dear Sir,

Subject: Request for Permission to Conduct a Add on course

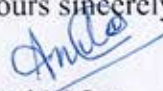
I am writing on behalf of the Curriculum Committee, to formally request your esteemed permission to conduct a Add on course for our students of B.Pharm M.pharm and PharmD along This initiative is in line with our commitment to enhancing the educational experience and fostering academic growth among our students.

The Add on course details are outlined as follows:


- **Title: HERBAL DRUG DELIVERY SYSTEMS:INNOVATIONS AND CHALLENGES**
- **Date: 04-08-2021-05-09-2021**
- **Venue: SEMINAR HALL**

Thank you for considering our request.

Yours sincerely,


Jyoti.M.Joy
Coordinator,
Department of Pharmacognosy
National College of Pharmacy
Manassery, Kozhikode .
Date -20-07-2021




PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

From,
The IQAC,
National College of Pharmacy

To,
The Principal,
National College of Pharmacy
Manassery, Kozhikode

Dear Principal,

I hope this letter finds you well. The Curriculum Committee in collaboration with the Internal Quality Assurance Cell (IQAC), seeks permission to organize a Add on course for students of B.Pharm M.pharm and Pharm.D on the topic of **Herbal Drug Delivery Systems:Innovations And Challenges** from **04-08-2021-05-09-2021**. We kindly request your authorization to proceed with this educational endeavor, which we believe will contribute significantly to the academic growth and development of our students.

Thank you for your consideration.

Sincerely,

IQAC Coordinator

National College of Pharmacy

Manassery

Date : 22-07-2021



Sujithra
PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

CIRCULAR

EVENT ANNOUNCEMENT

Dear Students,

We are delighted to inform you that the Curriculum Committee, in collaboration with the Internal Quality Assurance Cell (IQAC), has organized a Add on course on the topic of **Herbal Drug Delivery Systems: Innovations And Challenges** for Students of B.Pharm M.pharm and PharmD

The details of the Add on course are as follows:

- **Date: 04-08-2021-05-09-2021**
- **Venue: SEMINAR HALL**

We look forward to your enthusiastic participation and making this Add on course a resounding success.

Principal

Date: 31-07-2021

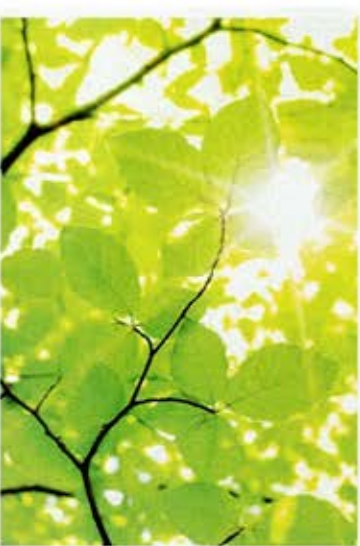


Sujitha
PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode
www.nationalcollegeofpharmacy.org



NATIONAL COLLEGE OF PHARMACY

KMCT Medical College campus, Manassery, Mukkam



Herbal Drug Delivery Systems: Innovations and Challenges

Date: 04-08-2021-05-09-2021

Modules:

- Module 1: Potential Therapeutic Applications of Plant secondary metabolites
- Module 2: Advances in herbal drug standardization and quality control
- Module 3: Plant derived Antioxidants and their health benefits :An integrative approach

Resource person:

Prof. Jyothi M Joy

Mrs. Athira A

For more enquiries please contact **PRINCIPAL** Prof. Jyothi M Joy, PH: 9048016613
National College of Pharmacy
Manassery, Kozhikode





NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

Course Curriculum

Year 2021-2022

Course 3:

Course Name:	Herbal Drug Delivery Systems: Innovations And Challenges (HDD 21)
Course duration:	30 hours (04-08-2021 to 05-09-2021)
Name of the resource person	Ms Jyothi M Joy Ms Athira A

Course Objective:

The course "Herbal Drug Delivery Systems: Innovations and Challenges" is designed to provide participants with a comprehensive understanding of herbal medicine delivery, potential therapeutic applications of plant secondary metabolites, advancements in herbal drug standardization and quality control, and the health benefits of plant-derived antioxidants.

By the end of this course, participants will have a comprehensive understanding of herbal medicine delivery systems, the therapeutic potential of plant secondary metabolites, quality control in herbal drug production, and the health benefits associated with plant-derived antioxidants, enabling them to make informed decisions in the field of herbal medicine and drug development.

Course content:

Module 1: Potential Therapeutic Applications of Plant secondary metabolites (10 hours)	Understand the diversity and significance of plant secondary metabolites in traditional and modern medicine. Identify specific secondary metabolites with therapeutic potential for various health conditions.
---	---



Sujitha
National College of Pharmacy,
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

	Analyze case studies and research findings showcasing the efficacy of plant secondary metabolites in disease management.
Module 2: Advances in herbal drug standardization and quality control (10 hours)	Examine the importance of quality control in herbal drug production. Learn about modern analytical techniques for herbal drug standardization. Explore international regulations and guidelines governing herbal product quality and safety.
Module 3: Plant derived Antioxidants and their health benefits :An integrative approach (10 hours)	Understand the role of antioxidants in maintaining health and preventing diseases. Explore various plant-derived antioxidants and their natural sources. Assess the potential health benefits of consuming antioxidants from plant-based foods and supplements.




National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

ADD ON COURSE: SUMMARY REPORT

Course code and Name: HDD21/ Herbal Drug Delivery Systems: Innovations and Challenges

Date of add on program: 04-08-2021-05-09-2021

Course Duration: 30 hours

Year Offered: B. Pharm, Pharm D, M. Pharm

Course instructors: Prof. Jyothi M Joy

Mrs. Athira A

Course Outcome:

The course "Herbal Drug Delivery Systems: Innovations and Challenges" was designed to provided participants with a comprehensive understanding of herbal medicine delivery, potential therapeutic applications of plant secondary metabolites, advancements in herbal drug standardization and quality controlled, and the health benefits of plant-derived antioxidants

Upon completion of this course, participants would had a comprehensive understanding of herbal medicine delivery systems, the therapeutic potential of plant secondary metabolites, quality controlled in herbal drug production, and the health benefits associated with plant-derived antioxidants, enabling them to make informed decisions in the field of herbal medicine and drug development.

Course type: Add on course

Assessment Mode

Attendance: 80%

Number of Participants: 82

Scheme of Exam: MCQ Type, offline mode

Date of Exam: 05-09-2021

COURSE COORDINATOR

Jyothi M. Joy

**PRINCIPAL
PRINCIPAL**

National College of Pharmacy
Manassery, Kozhikode





NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences

COURSE 4



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

From,
Jereena .E
Associate Professor
Department of Pharmacy Practice
National College of Pharmacy Manassery, Kozhikode

To,
The IQAC,
National College of Pharmacy
Manassery, Kozhikode

Dear Sir,

Subject: Request for Permission to Conduct a Add on course


I am writing on behalf of the Curriculum Committee, to formally request your esteemed permission to conduct a Add on course for our students of B.Pharm M.pharm and PharmD along This initiative is in line with our commitment to enhancing the educational experience and fostering academic growth among our students.

The Add on course details are outlined as follows:


- **Title: DRUG REGULATORY AFFAIRS**
- **Date: 01-04-2022-02-05-2022**
- **Venue: SEMINAR HALL**

Thank you for considering our request.

Yours sincerely,


Jereena.E
Coordinator,
Department of Pharmacy Practice
National College of Pharmacy
Manassery, Kozhikode
Date -11-03-2022




PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

From,
The IQAC,
National College of Pharmacy


To,
The Principal,
National College of Pharmacy
Manassery, Kozhikode

Dear Principal,

I hope this letter finds you well. The Curriculum Committee in collaboration with the Internal Quality Assurance Cell (IQAC), seeks permission to organize a Add on course for students of B.Pharm M.pharm and Pharm.D on the topic of **DRUG REGULATORY AFFAIRS** from. **01-04-2022-02-05-2022**. We kindly request your authorization to proceed with this educational endeavor, which we believe will contribute significantly to the academic growth and development of our students.

Thank you for your consideration.

Sincerely,


IQAC Coordinator

National College of Pharmacy

Manassery

Date : 12-03-2022




PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

CIRCULAR

EVENT ANNOUNCEMENT

Dear Students,

We are delighted to inform you that the Curriculum Committee, in collaboration with the Internal Quality Assurance Cell (IQAC), has organized an Add on course on the topic of **DRUG REGULATORY AFFAIRS** for Students of B.Pharm M.pharm and PharmD

The details of the Add on course are as follows:

- **Date: 01-04-2022-02-05-2022**
- **Venue: SEMINAR HALL**

We look forward to your enthusiastic participation and making this Add on course a resounding success.

Principal

Date: 29-03-2022




PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

KMCT Medical College campus, Manassery, Mukkam



Drug Regulatory Affairs

Date: 01-04-2022 to 02-05-2022

Resource person: Mr. Abdu Rahman T
Mrs. Romila Antony
Mrs. Jinsha P

Modules:

- Module 1: Introduction to drug regulatory affairs
- Module 2: Regulatory submissions
- Module 3: Drug approval process
- Module 4: Intellectual property rights

- For more enquiries please contact **coordinator: Mrs. Jereena . E, Ph: 9746953003**

National College of Pharmacy
Manassery, Kozhikode





NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

Course Curriculum

Year 2021-2022

Course 4:

Course Name:	Drug Regulatory Affairs (DRA 22)
Course duration:	30 hours (01-04-2022 to 02-05-2022)
Name of the resource person	Mr Abdurahman Ms Romila Antony Ms Jinsha P

Course Objective: The course "Regulatory Affairs in Drug Development" is designed to provide participants with an in-depth understanding of the field of drug regulatory affairs, including the drug approval process, regulatory submissions, and intellectual property rights.

By the end of this course, participants will have a comprehensive understanding of drug regulatory affairs, the intricacies of regulatory submissions, the drug approval process, and the importance of intellectual property rights in the pharmaceutical and biotechnology sectors. This knowledge will prepare them for roles in regulatory affairs and related fields within the drug development industry.

Course Content:

Module 1: Introduction to drug regulatory affairs (8 hours)	Understand the role and importance of regulatory affairs in the pharmaceutical and biotechnology industries. Explore the historical development and evolution of drug regulatory agencies. Identify key stakeholders and their roles in
--	---



[Signature]
PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode.



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

	drug regulation.
Module 2: Regulatory submissions (7 hours)	<p>Learn the fundamentals of preparing and submitting regulatory documents to health authorities.</p> <p>Understand the various types of regulatory submissions, including Investigational New Drug (IND) applications and New Drug Applications (NDAs).</p> <p>Familiarize yourself with regulatory requirements for data, labeling, and packaging.</p>
Module 3: Drug approval process(7 hours)	<p>Explore the stages and milestones of drug development, from preclinical studies to post-marketing surveillance.</p> <p>Analyze the regulatory pathways for drug approval, including accelerated approval and orphan drug designation.</p> <p>Evaluate the roles of regulatory agencies such as the FDA, EMA, and others in the approval process.</p>
Module 4: Intellectual property rights (8 hours)	<p>Understand the importance of intellectual property (IP) protection in the pharmaceutical industry.</p> <p>Learn about patents, trademarks, copyrights, and trade secrets as they relate to drug development.</p> <p>Analyze international IP agreements and their impact on global drug markets.</p>



Sujitha
PRINCIPAL
National College of Pharmacy,
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

ADD ON COURSE: SUMMARY REPORT

Course code and Name: DRA22/ Drug Regulatory Affairs

Date of add on program: 01-04-2022 to 02-05-2022

Course Duration: 30 Hours

Year Offered: B. Pharm, Pharm D, M. Pharm

Course instructors: Mr. Abdu Rahman T

Mrs. Romila Antony

Mrs. Jinsha P

Course Outcome:

The course "Regulatory Affairs in Drug Development" was designed to provide participants with an in-depth understanding of the field of drug regulatory affairs, including the drug approval process, regulatory submissions, and intellectual property rights.

Upon completion of this course, participants would have a comprehensive understanding of drug regulatory affairs, the intricacies of regulatory submissions, the drug approval process, and the importance of intellectual property rights in the pharmaceutical and biotechnology sectors. This knowledge would prepare them for roles in regulatory affairs and related fields within the drug development industry.

Course type: Add on course

Assessment Mode

Attendance: 80%

Number of Participants: 83

Scheme of Exam: MCQ Type, offline mode

Date of Exam: 02-05-2022

COURSE COORDINATOR

Jeejeha E

PRINCIPAL

National College of Pharmacy
Manassery, Kozhikode





NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences

COURSE 5



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

From,
Sareena. A
Assistant Professor
Department of Pharmacy Practice
National College of Pharmacy Manassery, Kozhikode

To,
The IQAC,
National College of Pharmacy
Manassery, Kozhikode

Dear Sir,

Subject: Request for Permission to Conduct a Add on course

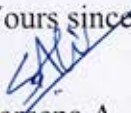
I am writing on behalf of the Curriculum Committee, to formally request your esteemed permission to conduct a Add on course for our students of B.Pharm M.pharm and PharmD along This initiative is in line with our commitment to enhancing the educational experience and fostering academic growth among our students.

The Add on course details are outlined as follows:

- **Title: INTRODUCTION TO OTC DRUG REGULATION AND SAFETY**
- **Date: 20-05-2022-30-05-2022**
- **Venue: SEMINAR HALL**

Thank you for considering our request.

Yours sincerely,


Sareena.A
Coordinator,
Department of Pharmacy Practice
National College of Pharmacy
Manassery, Kozhikode
Date -30-04-2022




PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

From,
The IQAC,
National College of Pharmacy


To,
The Principal,
National College of Pharmacy
Manassery, Kozhikode

Dear Principal,

I hope this letter finds you well. The Curriculum Committee in collaboration with the Internal Quality Assurance Cell (IQAC), seeks permission to organize a Add on course for students of B.Pharm M.pharm and Pharm.D on the topic of **Introduction To OTC Drug Regulation And Safety** from **20-05-2022-30-05-2022** .We kindly request your authorization to proceed with this educational endeavor, which we believe will contribute significantly to the academic growth and development of our students.

Thank you for your consideration.

Sincerely,


IQAC Coordinator

National College of Pharmacy

Manassery

Date : **02-05-2022**




PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

CIRCULAR

EVENT ANNOUNCEMENT

Dear Students,

We are delighted to inform you that the Curriculum Committee, in collaboration with the Internal Quality Assurance Cell (IQAC), has organized an Add on course on the topic of **Introduction To Otc Drug Regulation And Safety** for Students of B.Pharm M.pharm and PharmD

The details of the Add on course are as follows:

- **Date: 20-05-2022-30-05-2022**
- **Venue: SEMINAR HALL**

We look forward to your enthusiastic participation and making this Add on course a resounding success.

Principal

Date: 17-05-2022





NATIONAL COLLEGE OF PHARMACY

KMCT Medical College campus, Manassery, Makkam

Introduction to OTC Drug Regulation and Safety

Date: 20-05-2022 to 30-05-2022

Resource person: Mrs. Zuhara Maryam
Mrs. Shamila Thasneem

PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode

For more enquiries please contact coordinator: Mrs. Sareena. A, Ph: 8157034627



Modules

Module 1: Labelling and packaging

Module 2: OTC Drug marketing

Module 3: OTC Drug categories

Module 4: Post marketing

surveillance and pharmacovigilance



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

Course Curriculum

Year 2021-2022

Course 5:

Course Name:	Introduction To OTC Drug Regulation And Safety (OTC 22)
Course duration:	30 hours (20--05-2022 to 30-05-2022)
Name of the resource person	Ms Zuhara Maryam Ms Shamila Thasneem

Course Objective: The course "Introduction to OTC Drug Regulation and Safety" is designed to provide participants with a comprehensive understanding of over-the-counter (OTC) drug regulation, safety considerations related to labelling and packaging, marketing of OTC drugs, different OTC drug categories, and the importance of post-marketing surveillance and pharmacovigilance.

By the end of this course, participants will have a comprehensive understanding of OTC drug regulation, safety considerations in labeling and packaging, marketing strategies, OTC drug categories, and the critical role of post-marketing surveillance and pharmacovigilance in ensuring the safety and effectiveness of OTC medications. This knowledge will be valuable for professionals working in regulatory affairs, healthcare, and the pharmaceutical industry.

Course content:

Module 1: Labelling and packaging (7 hours)	Identify the crucial elements of OTC drug labelling and packaging to ensure consumer safety. Explore best practices for clear and informative labelling, including drug facts, dosing instructions, and warnings.
---	--



Sujithamma
PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

	Analyse case studies of labelling and packaging errors and their impact on consumer safety.
Module 2: OTC Drug marketing (8 hours)	Examine the marketing strategies and advertising regulations specific to OTC drugs. Learn how OTC drugs are promoted to consumers, including direct-to-consumer advertising. Understand the ethical considerations and limitations in OTC drug marketing.
Module 3: OTC Drug categories (7 hours)	Categorize OTC drugs based on their therapeutic indications and active ingredients. Discuss the differences between various OTC drug categories, such as analgesics, antacids, and cough and cold remedies.
Module 4: Post marketing surveillance and pharmacovigilance (8 hours)	Examine the importance of ongoing safety monitoring for OTC drugs after they enter the market. Learn about pharmacovigilance programs and their role in detecting and mitigating adverse effects. Understand the reporting requirements and processes for adverse events associated with OTC drugs.



Sujitha
National College of Pharmacy
Manassery, Kozhikode



NATIONAL COLLEGE OF PHARMACY

Approved by Pharmacy Council of India, AICTE, DME & Govt of Kerala
Affiliated to Kerala University of Health Sciences, Accredited by NBA

ADD ON COURSE: SUMMARY REPORT

Course code and Name: OTC22/ Introduction to OTC Drug Regulation and Safety

Date of add on program: 20-05-2022 to 30-05-2022

Course Duration: 30 Hrs

Year Offered: B. Pharm, Pharm D, M. Pharm

Course instructors: Mrs. Zuhara Maryam

Mrs. Shamila Thasneem

Course Outcome: The course "Introduction to OTC Drug Regulation and Safety" was designed to provide participants with a comprehensive understanding of over-the-counter (OTC) drug regulation, safety considerations related to labelling and packaging, marketing of OTC drugs, different OTC drug categories, and the importance of post-marketing surveillance and pharmacovigilance.

Upon completion of this course, participants would have had a comprehensive understanding of OTC drug regulation, safety considerations in labeling and packaging, marketing strategies, OTC drug categories, and the critical role of post-marketing surveillance and pharmacovigilance in ensuring the safety and effectiveness of OTC medications. This knowledge has been valuable for professionals working in regulatory affairs, healthcare, and the pharmaceutical industry.

Course type: Add on course

Assessment Mode

Attendance: 80%

Number of Participants: 81

Scheme of Exam: MCQ Type, offline model

Date of Exam: 30-05-2022

COURSE COORDINATOR

Saxena A



PRINCIPAL
National College of Pharmacy
Manassery, Kozhikode