# D. P. Bhosale College, Koregaon

## **Department of Microbiology (2020-2021)**

#### **Notice**

Date: 22/03/2021

All the student of B.Sc. III (Microbiology) are the here by informed that Department of Microbiology going to organize your Certificate Course on "Overview of Biopharmaceutical manufacturing". It has been scheduled from 25<sup>th</sup> March 2021 to 24<sup>th</sup> April 2021 Kindly, remain present at prescribed time in lecture hall.

HEAD
DEPARTMENT OF MICROBIOLOGY
D.P. BHOSALE COLLEGE, KOREGAON

TOREGAD!

Principal,
D.P. Bhosale College, Koregaon

# D. P. Bhosale College, Koregaon

# **Department of Microbiology (2020-2021)**

# Certificate course (UG)

## Overview of Biopharmaceutical manufacturing

# **Registration List**

Sr. No.	Roll No.	Student Name
1.	4641	Bansode Pranali Pradip
2.	4642	Ghadge Mayuri Mahendra
3.	4643	Jadhav Akanksha Anandrao
4.	4644	Jadhav Dipti Dipak
5.	4645	Kadam Sampada Vijay
6.	4646	Lokane Sejal Pandurang
7.	4647	Pathan Heena Riyaj
8.	4648	Pathan Sana Firoz
9.	4649	Phadtare Pratiksha Ganpat
10.	4650	Phadtare Ujjwala Nandkumar
11.	4651	Tingare Gayatri Sudhir

#### D. P. Bhosale College, Koregaon

#### **Department of Microbiology (2020-2021)**

#### **Certificate course (UG)**

#### Overview of Biopharmaceutical manufacturing

#### **Introduction:**

This course is designed for the UG students. This course provides a comprehensive understanding of biotech manufacturing processes - what makes biopharmaceutical processes different from small molecules. Course content explores the underlying principles of proteins and cells to provide the foundation for how and why processes manufacture therapeutic proteins. The course studies commonly used manufacturing process operations including cell culture and fermentation; harvest and recovery; viral removal and inactivation; purification processes such as tangential flow filtration, centrifugation, size exclusion, and adsorptive chromatography. The programme aims to develop technical skills and knowledge in some of the core areas which have been identified as skills gaps in the (Bio) pharma sector.

#### **Course Overview**

Having the foundational knowledge of the underlying biopharmaceutical science is critical for developing viable biopharmaceutical processes for the clinical and commercial manufacturing of biotechnology products. Explore commonly used manufacturing process operations including cell culture and fermentation; harvest and recovery; viral removal and inactivation; purification processes such as tangential flow filtration, centrifugation, size exclusion, and adsorptive chromatography.

#### **Syllabus of Course**

- Cell Biology / Biotechnology
   Structure, function, manipulation of cells / cell components (DNA / RNA / protein)
- Supply Chain

From raw materials to final product, value chain mapping, end-to-end manufacturing

Data integrity

Data integrity, data security, data analytics, LIMS / trackwise, statistics

• Regulatory Affairs

Current Good Manufacturing Practice (cGMP), quality mindset, root cause analysis

Health and Safety

Risk assessment, safety data sheets, handling chemicals, microbiology, environmental

Manufacturing for (Bio)Pharma

CIP/SIP, heat transfer, P&ID, automation, single-use bioreactors

Instrumentation

Relevant (bio)pharma equipment / instrumentation, incl. validation

Bioprocessing

Upstream processing / downstream processing, separation science, process monitoring, process control

#### **Reference Books:-**

- Biopharmaceutical Manufacturing, Volume 1
- Biopharmaceutical Technology" by Yu Qiong.
- "Biotechnology and Biopharmaceutical Manufacturing, Processing, and Preservation (Drug Manufacturing Technology Series)" by Kenneth E Avis and Vincent L
- Pharmaceutical Microbiology
- Essentials for Quality Assurance and Quality Control

#### **Board of studies-**

Mr. C. B. Jawale.

Miss. P. R. Barge.

Miss. K. P. Ladh.

Miss. S. R. Phalke.

## D. P. Bhosale College, Koregaon

## **Department of Microbiology (2020-2021)**

# **Certificate course (UG)**

# **Overview of Biopharmaceutical manufacturing**

# **Timetable of the course**

Class	Time	Friday	Saturday					
Class	Time	26/03/2021	27/03/2021					
	11:20 am -12.08 pm	PRB	KPL					
B.Sc. III	12.08 pm -12.56 pm	KPL	SRP					
	3.00 pm - 4.00 pm	SRP	PRB					

Class	Time	Friday 02/04/2021	Saturday 03/04/2021
	11:20 am -12.08 pm	PRB	KPL
B.Sc. III	12.08 pm -12.56 pm	KPL	SRP
	3.00 pm - 4.00 pm	SRP	PRB

Class	Time	Friday 09/04/2021	Saturday 10/04/2021
	11:20 am -12.08 pm	PRB	KPL
B.Sc. III	12.08 pm -12.56 pm	KPL	SRP
	3.00 pm - 4.00 pm	SRP	PRB

Class	Time	Friday 16/04/2021	Saturday 17/04/2021
	11:20 am -12.08 pm	PRB	KPL
B.Sc. III	12.08 pm -12.56 pm	KPL	SRP
	3.00 pm - 4.00 pm	SRP	PRB

Class	Time	Friday	Saturday
Class	Time	23/04/2021	24/04/2021
	11:20 am -12.08 pm	PRB	
B.Sc. III	12.08 pm -12.56 pm	KPL	Exam
	3.00 pm - 4.00 pm	SRP	

Name of faculty:

Miss. P. R. Barge. : PRB

Miss. K. P. Ladh.: KPL

Miss. S. R. Phalke. : SRP

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#### D. P. Bhosale College, Koregaon

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#### **Question Paper (Overview of Biopharmaceutical manufacturing)**

Day & Date: 24/04/2022 Marks – 20

Time - 11:00 am to 12:00 pm

#### Q. 1 Multiple Choice Questions

- 1. Which of the following is a functional unit of a body?
- a) Mitochondria
- b) Cytoplasm
- c) Spleen
- d) Cell
- 2. DNA is stored in which of the following cell organelle?
- a) Cell wall
- b) Cell Membrane
- c) Nucleus
- d) Cytoplasm
- 3. Which of the following is known as the powerhouse of a cell?
- a) Mitochondria
- b) Cytoplasm
- c) Lysosome
- d) Nuclei
- 4. Which of the following is known as the suicide bag of a cell?
- a) Mitochondria
- b) Golgi complex
- c) Lysosome
- d) Nuclei

- 5. The "c" in "cGMP" stands for
- A) Up to date
- B) Commitment
- C) Current
- D) Content

Que. 2 Answer in brief (any 2)

- 1. Define Biopharmaceutical & describe the Biopharmaceuticals manufacturing process
- 2. Define Bioprocessing. Explain upstream processing & downstream processing
- 3. Describe Current Good Manufacturing Practice (cGMP)

## D. P. Bhosale College, Koregaon

## **Department of Microbiology (2020-2021)**

**Certificate course (UG)** 

## **Overview of Biopharmaceutical Manufacturing**

# Result

Sr.No	Name of Student	Result	Grade
1	Bansode Pranali Pradip	PASS	В
2	Ghadge Mayuri Mahendra	PASS	A
3	Jadhav Akanksha Anandrao	PASS	A
4	Jadhav Dipti Dipak	PASS	A
5	Kadam Sampada Vijay	PASS	A
6	Lokane Sejal Pandurang	PASS	A
7	Pathan Heena Riyaj	PASS	A
8	Pathan Sana Firoz	PASS	A
9	Phadtare Pratiksha Ganpat	PASS	В
10	Phadtare Ujjwala Nandkumar	PASS	A
11	Tingare Gayatri Sudhir	PASS	A

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#### D. P. Bhosale College, Koregaon

**Department of Microbiology (2020-2021)** 

**Certificate course (UG)** 

#### Overview of Biopharmaceutical manufacturing

# Report

Having the foundational knowledge of the underlying biopharmaceutical science is critical for developing viable biopharmaceutical processes for the clinical and commercial manufacturing of biotechnology products. Explore commonly used manufacturing process operations including cell culture and fermentation; harvest and recovery; viral removal and inactivation; purification processes such as tangential flow filtration, centrifugation, size exclusion, and adsorptive chromatography.

The 11 students have been participated in the said course with proper knowledge about Biopharmaceutical Manufacturing. After completion of the course certificates are offered individually.



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# D. P. BHOSALE COLLEGE, KOREGAON

Dist-satara, Ms, India - 415501

DEPARTMENT OF MICROBIOLOGY

**CERTIFICATE COURSE** 

# **CERTIFICATE**

This is to certify t	hat Mr./N	liss
Class: <b>B.Sc. III</b>	Subject	Microbiology has successfully completed One month
"Certificate (	Course" i	n "Overview of Biopharmaceutical manufacturing"
From	to	and obtained Grade.

Mr. C. B. Jawale Head,

**Department of Microbiology** 

Principal Prin. Dr. V. S. Sawant

## D. P. Bhosale College, Koregaon

## Department of Microbiology (2020-2021)

## Certificate course (UG)

# Overview of Biopharmaceutical manufacturing

#### Attendance sheet

(From 25/03/2021 to 24/04/2021)

Sr. No.	Roll No.	Name of the Student	2513/21	26/3/21	27/3/21	28/3/21	29(3/21	30/3/21	313121	11412	2/4/21	3)4121	414129	51414	614/21	714121	\$ 14121	314/21	10/412)	11/4/21	12/7/21	13/4/21	18/4/2/	15/4/21	16/4/21	17/4/21	18/4/2	13/4/21	2014/21	211414	22/4/21	23/4/2/
1.	4641	Bansode Pranali Pradip		P	P						P	P	į.					P	A				•	4.	P	P		1				PP
2.	4642	Ghadge Mayuri Mahendra		P	9						P	P						P	A						P	P						P8
· 3.	4643	Jadhav Akanksha Anandrao		P	P						P	P						P	2						P	P						PP
4.	4644	Jadhav Dipti Dipak		P	P						A	P						P	P						P	P						PP
5.	4645	Kadam Sampada Vijay		P	P						P	P						P	P						P	P						PP
6.	4646	Lokane Sejal Pandurang		P	P						P	A						P	P						P	P						PP
7.	4647	Pathan Heena Riyaj		P	P						P	P						P	P						P	P						PP
8.	4648	Pathan Sana Firoz		P	P						P	P						P	A					4	P	P						PP
9.	4649	Phadtare Pratiksha Ganpat		?	P						P	P						P	P						P	A						PP
10.	4650	Phadtare Ujjwala Nandkumar		P	P						12	P						P	P						P	8						PP
11.	4651	Tingare Gayatri Sudhir		P	P						P	P						9	P						P	P						AP
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