

Rayat Shikshan Sanstha's

**D. P. Bhosale College, Koregaon**

**Department of Microbiology (2021-2022)**

**Notice**

Date: 28/12 /2021

All the student of B.Sc. II (C- group) are the here by informed that Department of Microbiology going to organize your Skill based Course on "Aseptic processing- contamination concept & control". It has been scheduled from 1<sup>st</sup> January, 2022 to 31<sup>st</sup> January, 2022 Kindly, remain present at prescribed time in lecture hall.



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



Principal,

**D.P. Bhosale College, Koregaon**

Rayat Shikshan Sanstha's

**D. P. Bhosale College, Koregaon**

**Department of Microbiology (2021-2022)**

**Skill based course (UG)**

**Aseptic Processing- Contamination Concept & Control**

**Registration List**

<b>Sr. No.</b>	<b>Roll No.</b>	<b>Student Name</b>
1.	22541	Barge Sharaddha Dipak
2.	22542	Bhosale Vaishnavi Chandrashekar
3.	22543	Chikate Jyoti Shubhash
4.	22544	Gore Siddhi Suresh
5.	22545	Jagadale Nikita Nandkumar
6.	22546	Jagtap Kedar Ramesh
7.	22547	Kadam Shruti Saudagar
8.	22548	Kadam Vivek Pralhad
9.	22549	Kshirsagar Isha Sudhir
10.	22550	Nikam Prajwal Dattatray
11.	22551	Nikam Rushikesh Vikas

## **Introduction**

This course is designed for the UG students. This course provides a comprehensive understanding of the right knowledge about the basic ideas or principles and skills that are mandatory for conducting Aseptic Dispensation of Sterile Drug Products while maintaining minimum risks. The students obtain the skills essential for controlling the procedure setting & learn the best repetition techniques for decisive media fill sizes also understand the "critical factors" required to maintain compliance.

## **Overview of Aseptic Processing Course**

Aseptic Processing is identified as a process to manufacture Medicinal and Biotechnical products course impartial is to discover the character of aseptic filling to guarantee that industrial production will recall the bareness pledge level prescribed by GMPs

Disinfected products may be largely divided into two major divisions. These divisions depend on the mode of their production. The process includes pasteurization following the satisfying and closing of the ampule and those that are aseptically sterilized. Aseptic Dispensation plays a grave character with large particles that cannot be pasteurized. The confirmation of the procedure to harvest sterile products is gauged through the demo of numerous media fill process imitations. These simulations vary in both numbers and size of the containers and also on the volumes filled over a definite period.

Aseptic Processing contains jeopardy valuation in a continuous manner because of the characteristic risks due to penalties of organization and procedure disappointment and tests within the discovery, separation, control, and organization of creation pollution. Within sterile dispensation, the harshness of the penalties of a failure can be critical to the end user while uncovering barrenness challenges remains rather imperfect because of the trivial number of final products verified. With sheath separation, it is vital to start satisfactory

levels of bacteriological pollution to guarantee both produce security and acquiescence. Additionally, aseptic processes are related to endotoxin control, so it gets managed to satisfactory levels.

A diversity of variable quantities can influence the barrenness pledge and the supplementary endotoxin level. These things always contain personnel, procedure, apparatus, mechanisms, cleansing, dehydrogenation along with facilitates that leave some impact on the organization and dispensation of the ultimate products. Issues that need to be careful include the monitoring of ecological areas and workers, water sources, media, media fills, growing, and cleansing.

## **Syllabus of Course**

### Aseptic Processing – Introduction

- Conservation and control of serious surroundings
- Expansion of procedures for process, standardization, Preventive Maintenance, etc
- Adulteration Sources in Sterile Manufacturing
- Subdivision Content Controls, Cross Pollution Hazards
- Cleaning Process and Agents for Sterile Production

### Why Aseptic Processing?

- Current Good Manufacturing Practices (CGMP)
- Good Documentation Practices (GDP)
- Cleanroom Design and Control
- Microbiology Basics
- Endotoxins
- Micropipetting
- Environmental Monitoring
- Facility Cleaning and Disinfection
- Aseptic Gowning and Cleanroom Behaviors
- Component Preparation
- Solution Preparation and Filtration
- Sterilization Methods
- Equipment set up
- Sterilization process

**Reference Books:-**

- Advanced Aseptic Processing Technology
- Sterile Drug Products: Formulation, Packaging, Manufacturing ...
- Microbial Contamination Control in Parenteral Manufacturing
- Contamination Control and Cleanrooms

**Board of studies-**

Mr. C. B. Jawale.

Miss. S. R. Inje

Miss. S.A. Kshirsagar

Miss. R. M. Nadaf

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**D. P. Bhosale College, Koregaon**

**Department of Microbiology (2021-2022)**

**Skill Based Course (UG)**

**“Aseptic Processing- Contamination Concept & Control”.**

**Timetable of the course**

Class	Time	Saturday 01/01/2022
B.Sc II	11:20 am -12.08 pm	SRI
	12.08 pm -12.56 pm	SAK
	3.00 pm - 4.00 pm	RMN

Class	Time	Friday 07/01/2022	Saturday 08/01/2022
B.Sc II	11:20 am -12.08 pm	SAK	RMN
	12.08 pm -12.56 pm	RMN	SAK
	3.00 pm - 4.00 pm	SRI	SRI

Class	Time	Friday 14/01/2022	Saturday 15/01/2022
B.Sc II	11:20 am -12.08 pm	SRI	SAK
	12.08 pm -12.56 pm	SAK	SRI
	3.00 pm - 4.00 pm	RMN	RMN

Class	Time	Friday 21/01/2022	Saturday 22/01/2022
B.Sc II	11:20 am -12.08 pm	RMN	SAK
	12.08 pm -12.56 pm	SAK	RMN
	3.00 pm - 4.00 pm	SRI	SRI

Class	Time	Friday 28/01/2022	Saturday 29/01/2022
B.Sc II	11:20 am -12.08 pm	RMN	Exam
	12.08 pm -12.56 pm	SAK	
	3.00 pm - 4.00 pm	SRI	

Name of faculty:

Miss. S. R. Inje (SRI)

Miss. S.A. Kshirsagar (SAK)

Miss. R. M. Nadaf (RMN)



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D.P. BHOSALE COLLEGE, KOREGAON

**Skill based course (UG)**

**Question Paper (Aseptic Processing- Contamination Concept & Control)**

**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 suitable for use on tissues for microbial control to prevent infection?

- A. disinfectant
- B. antiseptic
- C. sterilant
- D. water

2. Which of the following best describes a microbial control protocol that inhibits the growth of molds and yeast?

- A. bacteriostatic
- B. fungicidal
- C. bactericidal
- D. fungistatic

3. Which of the following terms is used to describe the time required to kill all of the microbes within a sample at a given temperature?

- A. D-value
- B. thermal death point
- C. thermal death time
- D. decimal reduction time



4. Which of the following peroxygens is widely used as a household disinfectant, is inexpensive, and breaks down into water and oxygen gas?

- A. hydrogen peroxide
- B. peracetic acid
- C. benzoyl peroxide
- D. ozone

5. Why is it important for you to perform hand hygiene prior to leaving an isolated area? Select all that apply.

- A. To reduce the risk of contaminating the surrounding environment the
- B. To reduce the risk of contaminating visitors and other clients
- C. To reduce the risk of contaminating fellow health care professionals.
- D. To reduce the risk of contaminating yourself.

Que. 2 Answer in brief (any 2)

1. Explain Adulteration Sources in Sterile Manufacturing.
2. Write the difference between current good manufacturing practices (CGMP) good documentation practices (GDP).
3. Describe sterilization methods

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**Department of Microbiology (2021-2022)**

**Skill Based Course (UG)**

**Aseptic Processing- Contamination Concept & Control**

## Result

Sr.No	Name of Student	Result	Grade
1	Barge Sharaddha Dipak	PASS	A
2	Bhosale Vaishnavi Chandrashekar	PASS	A
3	Chikate Jyoti Shubhash	PASS	B
4	Gore Siddhi Suresh	PASS	A
5	Jagadale Nikita Nandkumar	PASS	A
6	Jagtap Kedar Ramesh	PASS	B
7	Kadam Shruti Saudagar	PASS	A
8	Kadam Vivek Pralhad	PASS	A
9	Kshirsagar Isha Sudhir	PASS	A
10	Nikam Prajwal Dattatray	PASS	A
11	Nikam Rushikesh Vikas	PASS	B



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**Aseptic Processing- Contamination Concept & Control**

## **Report**

The students obtain the skills essential for controlling the procedure setting & learn the best repetition techniques for decisive media fill sizes also understand the "critical factors" required to maintain compliance. Aseptic Processing is identified as a process to manufacture Medicinal and Biotechnical products course impartial is to discover the character of aseptic filling to guarantee that industrial production will recall the bareness pledge level prescribed by GMPs. The process includes pasteurization following the satisfying and closing of the ampule and those that are aseptically sterilized. Aseptic Dispensation plays a grave character with large particles that cannot be pasteurized. The confirmation of the procedure to harvest sterile products is gauged through the demo of numerous media fill process imitations. These simulations vary in both numbers and size of the containers and also on the volumes filled over a definite period.

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



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# D. P. Bhosale College, Koregaon

NAAC Re Accredited 'A' (with CGPA 3.12) ISO 9001:2015 Certified

DIST- SATARA, MAHARASHTRA, INDIA -415501

## DEPARTMENT OF MICROBIOLOGY



SKILL BASED COURSE

### Certificate

This is to certify that, MR./Miss.....class..... Subject:  
Microbiology Successfully completed One month Skill Based Course on **Aseptic processing - contamination concept & control** Organized by Department of Microbiology, D. P. Bhosale College, Koregaon. District- Satara (M.S.) held in 1<sup>st</sup> January, 2022 to 31<sup>st</sup> January, 2022.

Dr. Mrs. S. P. Nalawade

Convener

Mr. C. B. Jawale

Coordinator

Prin. Dr. V. S. Sawant

Organizing chairman

Rayat Shikshan Sanstha's

D. P. Bhosale College, Koregaon

Department of Microbiology (2021-2022)

Skill based course (UG)

Aseptic Processing- Contamination Concept & Control

Attendance sheet

(From 01/01/2022 to 31/1/2022)

Sr. No.	Roll No.	Name of the Student	1/1/22	2/1/22	3/1/22	4/1/22	5/1/22	6/1/22	7/1/22	8/1/22	9/1/22	10/1/22	11/1/22	12/1/22	13/1/22	14/1/22	15/1/22	16/1/22	17/1/22	18/1/22	19/1/22	20/1/22	21/1/22	22/1/22	23/1/22	24/1/22	25/1/22	26/1/22	27/1/22	28/1/22	29/1/22	30/1/22	31/1/22		
1.	22541	Barge Sharaddha Dipak	P					P	P							P	P						P	P						P	P				
2.	22542	Bhosale Vaishnavi Chandrashekar	P					A	P							P	P						P	P						P	P				
3.	22543	Chikate Jyoti Shubhash	P					P	P							P	A						A	P						P	P				
4.	22544	Gore Siddhi Suresh	P					P	P							P	P						P	P						P	P				
5.	22545	Jagadale Nikita Nandkumar	P					P	P							P	A						P	P						P	P				
6.	22546	Jagtap Kedar Ramesh	P					P	A							P	P						P	P						A	P				
7.	22547	Kadam Shruti Saudagar	P					P	P							P	P						P	A						P	P				
8.	22548	Kadam Vivek Pralhad	P					P	P							A	P						P	P						P	P				
9.	22549	Kshirsagar Isha Sudhir	A					P	P							P	P						A	P						P	P				
10.	22550	Nikam Prajwal Dattatray	P					P	P							P	P						P	P						P	P				
11.	22551	Nikam Rushikesh Vikas	P					P	A							A	P						P	P						P	P				

*Sawale*

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