"Education for Knowledge, Science and Culture"
-Shikshanmaharshi Dr. Bapuji Salunkhe

Shri Swami Vivekanand Shikshan Sanstha's

VIVEKANAND COLLEGE, KOLHAPUR (AUTONOMOUS)

Department Of Microbiology

Value Added Course

"Microbial Quality Control in Pharmaceutical Industries"

Academic Year: 2022-2023

"Education for Knowledge, Science and Culture"

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Shri Swami Vivekanand Shikahan Sanstha's

VIVEKANAND COLLEGE (AUTONOMOUS), KOLHAPUR

Department of Microbiology

Value Added Course (2022-23)

Name of the course – "Microbial Quality Control In Pharmaceutical Industries"

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"Education for Knowledge, Science and Culture"

Dr.Bapuji Salunkhe

Shree Swami Vivekanand Shikshan Sanstha's

Vivekanand College, Kolhapur(Autonomous)

DEPARTMENT OF MICROBIOLOGY

VALUE ADDED COURSE

MICROBIAL QUALITY CONTROL IN PHARMACEUTICAL INDUSTRIES

FEES : RS.500

ADMISSION OPEN

*LIMITED SEATS

CONTACT

MS.V.V.MISAL - 9822376171
MR.S.D.GABALE - 9970191188
MS.S.A.PISE - 7507611308
MS.T.K.ULHALKAR- 7719020896

Dissemination of Education for Knowledge, Science and Culture"

- Shikshanmaharshi Dr. Bapuji Salunkhe

Shri Swami Vivekanand Shikshan Sanstha's

VIVEKANAND COLLEGE, KOLHAPUR (AUTONOMOUS)

Department of Microbiology

Academic Year 2022-23

Date- 02/02/2022

NOTICE

All the students of B. Sc. part I, II, and III are hereby informed that, the admissions for the value added course **"Microbial Quality Control in Pharmaceutical industries",** Department of Microbiology, has been started. All the interested students should contact the department of Microbiology.

Registration Fees- Rs. 500

Dr. G. K. Sontakke
Head/Co-ordinator
Department of Microbiology
Vivekanand College, Kolhapur

VIVEKANAND COLLEGE ESTD. JUNE 1964 KOLHAPUR-416 003

Sr. No.	Department	Signature
1	Botany	
2	Zoology	
3	Chemistry	
4	Biotechnology	
5	Physics	
6	Mathematics	
7	Statistics	
8	Computer Science	
9	Electronics	

NOTE:- Please circulate this notice on your whats app groups.

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VIVEKANAND COLLEGE, KOLHAPUR (AUTONOMOUS)

Department of Microbiology

Academic Year 2022-23

Date- 06/03/2023

NOTICE

All the students who have admitted to value added course **"Microbial Quality Control in Pharmaceutical Industries "** of Department of Microbiology are hereby informed that the lectures will be conducted from **8th March 2023** on every **wednesday – saturday at 10.00 a.m -11.30 a.m.**

Dr.G.K.Sonatakke
Incharge Head
Department Of Microbiology
Vivekanand College, Kolhapur
(Autonomous)

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VIVEKANAND COLLEGE, KOLHAPUR (AUTONOMOUS)

Department of Microbiology

Career Oriented Course

Microbial Quality Control in Pharmaceutical Industries

Course outcome -

After completing this course, students will be able to-

- Understand clean room concept and its applications in pharmaceutical industries
- Apply good laboratory practices during work in pharmaceutical industries.
- Understand various drug acts related to pharmaceutical industries.
- Use biochemical and immunological methods for testing of pharmaceutical products.

TOTAL HOURS: 30

Course	Unit	Topic	lec/Hours
Add-on (Semester)	I	**Microbiological Laboratory and Safe Practices** A. Good laboratory practices - Good laboratory practices, Good microbiological practices B. Biosafety cabinets – Working of biosafety cabinets, using protective clothing, specification for BSL-1, BSL-2, BSL-3. C. Clean Room Concept- Classification, Sampling and control of Microorganisms D. Discarding biohazardous waste – Methodology of Disinfection, Autoclaving & Incineration E. Drug act schedule 1- IP, BP, USBP, GMP	15
	II	**Determining Microbes in Food / Pharmaceutical Sample** A. Biochemical and immunological methods: Limulus lysate test for endotoxin, gel diffusion, sterility testing for pharmaceutical products B. Injectables C. Biosensors. D. Calibration of instruments	15

SUGGESTED READING

1. Jay JM, Loessner MJ, Golden DA (2005) Modern Food Microbiology, 7th edition. Springer
2. Baird RM, Hodges NA and Denyer SP (2005) Handbook of Microbiological Quality control in Pharmaceutical and Medical Devices, Taylor and Francis Inc.

VIVEKANAND COLLEGE BOARD JUNE 1964

Incharge Head
Department of Microbiology
Vivekanand College, Kolhapur
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VIVEKANAND COLLEGE, KOLHAPUR (AUTONOMOUS)

Department of Microbiology

Value Added Course 2022-23

"Microbial Quality Control In Pharmaceutical Industries"

Batch B1

Sr.No	Name
1	Mali Prachi Sanjay
2	Mane Rohan baban
3	Mujawar Abida Altaf
4	Murti Vanshita Sanjay
5	Patil Suhani Sadashiv
6	Sonule Sushant Krushnat
7	Todakar Nirjara Shivaji
8	Wadkar Samrudhi Dhanaji
9	Gaikwad Nikita Nandkumar
10	Gurav Shivani Vinayak
11	Haval Arpita Sachi
12	Kalamkar Asavari Anil
13	Kandalkar Namarta Anil
14	Kashid Snehal Babaso
15	Kesarkar Prachi Chandrakant
16	Madhale Ashlesha Shivaling
17	Padaval Damini Mohan
18	Pardeshi Shrutika Manik
19	Parkar Siddhi Anil
20	Patil Arpita Shivaji
21	Patil Pooja Amar
22	Patil Sanika Sanjay
23	Thorbole Sanika Prakash
24	Vharamble Pranali Shivaji
25	Bangodi Harsh Kishor
32	Bardeskar Stuti Kaitan
26	Basare Gayatri Pramod
33	Koli Priyanka Sunil

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27	Kumthekar Krushnakant Surendra
28	Naik Shalom Vishwas
34	Nalawde Sakshi Sunil
35	Patil Madhura Buddhiraj
29	Patil Shivani Rangrao
30	Tadwale Arohi Anil
31	Tamboli Sayma Rashid
36	Ubale Pratibha Sardar
37	Adav Prachi Jotiba
38	Alave Aarya Rajendra
39	Athanikar Sabira Nijam
40	Awalkar Anchal Nandkumar

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VIVEKANAND COLLEGE, KOLHAPUR (AUTONOMOUS)

Department of Microbiology

Value Added Course 2022-23

"Microbial Quality Control In Pharmaceutical Industries"

Batch B2

Sr.No	NAME
1	Bhatmare Sourabha Sambhaji
2	Chavan Pratiksha Ananda
3	Chougale Nikita Bharat
4	Desai Tasnim Yunus
5	Hadgal Ratuja Tanaji
6	Kadam Neha Krushnat
7	Khanapure Ammar Abdulgafar
8	Lavhate Prachi Suresh
9	Mane Utkarsha Gajendra
10	Notani Disha Santosh
11	Parkar Siddhi Sunil
12	Patil Pornima Yuvraj
13	Patil Rutuja Anandrao
14	Patil Shweta Tanaji
15	Patil Vaishanavi Manohar
16	Patil Vaishanvi Vilas
17	Thombare Ankita Rajendra
18	Vichare Ashwini Raghunath
19	Zirange Pankaj Sunil
20	Mirajkar Sakshi Sandeep
21	Patil Janhavi Jagdish
22	Sardesai Akanksha Anil
23	Makandar Fardin M

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VIVEKANAND COLLEGE (AUTONOMOUS), KOLHAPUR

Department of Microbiology

Add On Course 2022-2023

Name of the course – "Microbial Quality Control In Pharmaceutical Industries"

TIME-TABLE

Time	Monday	Tuesday
9.00am to 10.00am	VVM/SAP/PPD	TKU/SDG/PPD
10.00am to 11.00am	VVM/SAP/PPD	TKU/SDG/PPD

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Department of Microbiology

Value Added Course 2022-23

"Microbial Quality Control In Pharmaceutical Industries"

Presenty Batch B1

Sr. No	Name	04/05	06/05	10/05	11/05	12/05	13/05	17/05	18/05	19/05	20/05
1	Mali Prachi Sanjay										
2	Mane Rohan baban										
3	Mujawar Abida Altaf										
4	Murti Vanshita Sanjay										
5	Patil Suhani Sadashiv										
6	Sonule Sushant Krushna										
7	Todakar Nirjara Shivaji										
8	Wadkar Samrudhi Dhanaji										
9	Gaikwad Nikita Nandkumar										
10	Gurav Shivani Vinayak										
11	Haval Arpita Sachin										
12	Kalamkar Asavari Anil										
13	Kandalkar Namarta Anil										
14	Kashid Snehal Babaso										
15	Kesarkar Prachi Chandrakant										
16	Madhale Ashlesha Shivaling										
17	Padaval Damini Mohan										
18	Pardeshi Shrutika Manik										
19	Parkar Siddhi Anil										
20	Patil Arpita Shivaji										
21	Patil Pooja Amar										
22	Patil Sanika Sanjay										
23	Thorbole Sanika Prakash										
24	Vharamble Pranali Shivaji										
25	Bangodi Harsh Kishor										
26	Basare Gayatri Pramod										
27	Kumthekar Krushnakant Surendra										
28	Naik Shalom Vishwas										
29	Patil Shivani Rangrao										
30	Tadwale Arohi Anil										
31	Tamboli Sayma Rashid										

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VIVEKANAND COLLEGE, KOLHAPUR (AUTONOMOUS)

Department of Microbiology

Value Added Course 2022-23

"Microbial Quality Control In Pharmaceutical Industries"

Presenty Batch B2

Sr.No	NAME	04/05	06/05	10/05	11/05	12/05	13/05	17/05	18/05	19/05	20/05
1	Bardeskar Stuti Kaitan										
2	Koli Priyanka Sunil										
[redacted]	Nalawde Sakshi Sunil										
4	Patil Madhura Buddhiraj										
5	Ubale Pratibha Sardar										
6	Adav Prachi Jotiba										
7	Alave Aarya Rajendra										
8	Athanikar Sabira Nijam										
9	Awalkar Anchal Nandkumar										
10	Bhatmare Sourabha Sambhaji										
11	Chavan Pratiksha Ananda										
12	Chougale Nikita Bharat										
13	Desai Tasnim Yunus										
14	Hadgal Ratuja Tanaji										
15	Kadam Neha Krushnat										
16	Khanapure Ammar Abdulgafar										
17	Lavhate Prachi Suresh										
18	Mane Utkarsha Gajendra										
19	Notani Disha Santosh										
20	Parkar Siddhi Sunil										
21	Patil Pornima Yuvraj										
22	Patil Rutuja Anandrao										
23	Patil Shweta Tanaji										
24	Patil Vaishanavi Manohar										
25	Patil Vaishanvi Vilas										
26	Thombare Ankita Rajendra										
27	Vichare Ashwini Raghunath										
28	Zirange Pankaj Sunil										
29	Mirajkar Sakshi Sandeep										
30	Patil Janhavi Jagdish										
31	Sardesai Akanksha Anil										
32	Makandar Fardin M										

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VIVEKANAND COLLEGE, KOLHAPUR (AUTONOMOUS)

Department of Microbiology

Value Added Course 2022-23

"Microbial Quality Control In Pharmaceutical Industries"

Presenty Batch B1

Sr. No	Name	06/04	13/04	17/4	18/4	19/04	20/04	21/04	24/04	25/04	03/05
1	Mali Prachi Sanjay										
2	Mane Rohan baban	Ab		Ab							
3	Mujawar Abida Altaf			Ab	Ab		Ab		Ab		Ab
4	Murti Vanshita Sanjay					Ab	Ab		Ab		Ab
5	Patil Suhani Sadashiv										
6	Sonule Sushant Krishnat Krishnat	Ab	Ab								
7	Todakar Nirjara Shivaji	Ab									
8	Wadkar Samrudhi Dhanaji	Ab									
9	Gaikwad Nikita Nandkumar										
10	Gurav Shivani Vinayak		Ab				Ab				
11	Haval Arpita Sachin			shaul	Ab	shaul	Ab	shaul	shaul	shaul	shaul
12	Kalamkar Asavari Anil		Ab								
13	Kandalkar Namarta Anil		Ab								
14	Kashid Snehal Babaso	Ab					AB		AB		
15	Kesarkar Prachi Chandrakant		Ab							AB	
16	Madhale Ashlesha Shivaling	Ab									
17	Padaval Damini Mohan										
18	Pardeshi Shrutika Manik		Ab			Ab		Ab		Ab	
19	Parkar Siddhi Anil										
20	Patil Arpita Shivaji	Ab	A								
21	Patil Pooja Amar										
22	Patil Sanika Sanjay										
23	Thorbole Sanika Prakash										
24	Vharamble Pranali Shivaji				Ab		Ab		Ab		
25	Bangodi Harsh Kishor	Ab	A								
26	Basare Gayatri Pramod						Ab			Ab	Ab
27	Kumthekar Krushnakant Surendra						Ab			Ab	Ab
28	Naik Shalom Vishwas	Ab									
29	Patil Shivani Rangrao										
30	Tadwale Arohi Anil	Ab					Ab		Ab	Ab	Ab
31	Tamboli Sayma Rashid	Ab	A				A				

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VIVEKANAND COLLEGE, KOLHAPUR (AUTONOMOUS)

Department of Microbiology

Value Added Course 2022-23

"Microbial Quality Control In Pharmaceutical Industries"

Presenty Batch B2

Sr.No	NAME	06/04	13/04	8/4	18/4	19/04	20/04	21/04	24/04	25/04	03/05
1	Bardeskar Stuti Kaitan	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab
2	Koli Priyanka Sunil	Ab	Ab	Ab	Ab						
3	Nalawde Sakshi Sunil	Ab		Sakshi	Sakshi	Sakshi	Ab	Sakshi	Sakshi	Sakshi	Sakshi
4	Patil Madhura Buddhiraj	Ab		Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab
5	Ubale Pratibha Sardar	Ab					Ab				
6	Adav Prachi Jotiba				Ab		Ab			Ab	
7	Alave Aarya Rajendra	Ab	Ab								
8	Athanikar Sabira Nijam										
9	Awalkar Anchal Nandkumar										
10	Bhatmare Sourabha Sambhaji		Ab							Ab	
11	Chavan Pratiksha Ananda	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	
12	Chougale Nikita Bharat		Ab		Ab		Ab		Ab		
13	Desai Tasnim Yunus			Ab		Ab		Ab	Ab		Ab
14	Hadgal Ratuja Tanaji		Ab		Ab		Ab	Ab		Ab	Ab
15	Kadam Neha Krushnat										
16	Khanapure Ammar Abdulgafar										
17	Lavhate Prachi Suresh		Ab				Ab				
18	Mane Utkarsha Gajendra						Ab				
19	Notani Disha Santosh										
20	Parkar Siddhi Sunil		Ab								
21	Patil Pornima Yuvraj	Ab			Ab						Ab
22	Patil Rutuja Anandrao		Ab				Ab				
23	Patil Shweta Tanaji					Ab		Ab	Ab		Ab
24	Patil Vaishanavi Manohar		Ab						Ab		Ab
25	Patil Vaishanvi Vilas	Ab	Ab		Ab		Ab		Ab		
26	Thombare Ankita Rajendra	Ab									
27	Vichare Ashwini Raghunath		Ab								
28	Zirange Pankaj Sunil	Ab	Ab	Ab			Ab		Ab		Ab
29	Mirajkar Sakshi Sandeep	Ab	Ab				Ab				
30	Patil Janhavi Jagdish	Ab	Ab				Ab				
31	Sardesai Akanksha Anil	Ab	Ab								
32	Makandar Fardin M	Ab		Ab			Ab				Ab

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VIVEKANAND COLLEGE, KOLHAPUR (AUTONOMOUS)

Department of Microbiology

Value Added Course 2022-23

"Microbial Quality Control In Pharmaceutical Industries"

Presenty Batch B2

Sr.No	NAME	8|3	10|3	11|3	15|3	16|3	17|3	18|3	25/3	4/4	05|4
1	Bardeskar Stuti Kaitan					Ab		Ab	Ab	Ab	Ab
2	Koli Priyanka Sunil	Ab	Ab		Ab	Ab	Ab	Ab	Ab		
3	Nalawde Sakshi Sunil		Ab		Ab	Ab	Ab	Ab	Ab		
4	Patil Madhura Buddhiraj	Ab	Ab	Ab			Ab	Ab	Ab		
5	Ubale Pratibha Sardar	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab
6	Adav Prachi Jotiba								Ab		
7	Alave Aarya Rajendra	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab
8	Athanikar Sabira Nijam				Ab		Ab	Ab			
9	Awalkar Anchal Nandkumar						Ab				
10	Bhatmare Sourabha Sambhaji								Ab		
11	Chavan Pratiksha Ananda	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab
12	Chougale Nikita Bharat		Ab		Ab	Ab		Ab			
13	Desai Tasnim Yunus		Ab				Ab	Ab	Ab		
14	Hadgal Ratuja Tanaji	Ab	Ab						Ab		
15	Kadam Neha Krushnat										
16	Khanapure Ammar Abdulgafar								Ab		
17	Lavhate Prachi Suresh	Ab							Ab		
18	Mane Utkarsha Gajendra										
19	Notani Disha Santosh	Ab	Ab				Ab	Ab	Ab		
20	Parkar Siddhi Sunil	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab
21	Patil Pornima Yuvraj	Ab	Ab							Ab	Ab
22	Patil Rutuja Anandrao		Ab								
23	Patil Shweta Tanaji				Ab	Ab	Ab				
24	Patil Vaishanavi Manohar								Ab		
25	Patil Vaishanvi Vilas	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab		
26	Thombare Ankita Rajendra		Ab				Ab	Ab	Ab		
27	Vichare Ashwini Raghunath								Ab		
28	Zirange Pankaj Sunil		Ab						Ab		
29	Mirajkar Sakshi Sandeep	Ab	Ab							Ab	Ab
30	Patil Janhavi Jagdish	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab	Ab
31	Sardesai Akanksha Anil	Ab	Ab							Ab	Ab
32	Makandar Fardin M						Ab	Ab	Ab		

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VIVEKANAND COLLEGE (AUTONOMOUS), KOLHAPUR

Department of Microbiology

Value Added Course

"Microbial Quality Control In Pharmaceutical Industries"

Theory Examination

2022-2023

Date – 18 July 2023 **Total marks- 100**

Time- 3Hrs

Instructions: 1) All questions are compulsory
2) Draw neat labeled diagram wherever necessary.
3) Figures to the right indicates full marks

Q.1 Rewrite the sentence by choosing most correct alternative from the given alternatives. **20**

1.The molecule which are to be measured by using biosensors are known as _____

a) Biological molecules b) Analyzers c) Transductor d) Carrier

2. In biosensor _____ generate electric impulse.

a) Analyzer b) Biological molecules c) Transductor d) Carrier

3. _____ proves that the equipment works correctly & actually leads to correct & reliable results.

a)Calibration b) Qualification c) Quantification d) Analysis

4._____Filter is used for strongly alcoholic solutions.

a) cellulose nitrat b) cellulose acetate c) cellulose oxalate d) cellulose silicate

5. Pharmacopia word is derived from pharmakon & poiea means _____

a) Drug; to make b) Drug;to sale c) Drug;to purchase d) drug;to store

6._____Filter is used in membrane filtration apparatus for weakly alcoholic solutions.

a) cellulose nitrate b) cellulose acetate c) cellulose oxalate d)cellulose silicate

7.What is DTAB ?

a) Drug Technical Advisory Board b) Drug Technology Advisory Board

c) Drug Technical Advice Board d) Drug Technique Advisory Board

8. Efficiency of HEPA filter is _____%

a) 99.97 b) 88.87 c) 90.97 d) 90.00

9. Grade B air born particle is based on classification of _____

a) ISO 9 b) ISO 3 c) ISO 5 d) ISO 8

10.In laminar air flow which type of filter is located _____

a) Membrane filter b) Seitz filter c) HEPA filter d) Vaccum filter

11. _____ area has the lowest chance of producing a biomedical waste.

a) Hospital b) Clinics c) Laboratories d) Agricultural lands

12. LAL test used to determine _____in pharmaceutical products.

a) endotoxin b) endoeneyme c) exotoxin d) exoenzymes

VIVEKANAND COLLEGE ESTD. JUNE 1964 KOLHAPUR

13. _____ of the following is categorized as an incineration waste.

a) Incineration ash b) Animal waste c) Solid waste d) Cytotoxic drugs

14._____ linked chromogen is used in chromogenic reagent.

a) p-aminobenzoic b) p- nitroaniline c) P-aminoaniline d) p- nitropheniline

15. Biosafety levels are ranked as _____

a) 1-4 b) 0.1 – 10 c) 1-8 d) 1-10

16. _____ of the following is Risk Group - 4 agent.

a) Ebola Hemmorrhagic fever virus b) Rabies virus c) *E.coli* d) T4 bacteriaphage

17. _____are known as "total containment cabinates".

a) BSC Class-1 b)BSC 2 Class A c) BSC Class -3 d)BSC 2 Class B1

18._____ types of biosensor measure electric conductivity during a reaction.

a) Conductometric biosensor b) Calorimetric biosensor

c) Potentiometric biosensor d) Optical biosensor

19.A set of rules ,operating procedures to ensure quality & accurate result in laboratory is known as _____

a) Good laboratory practice b) Good manufactured practices

c) Standard operating procedure d) None of these.

20. Sterility test is used to determine presence of _____in pharmaceutical product.

a) Endotoxin b) Virus c) Inactive bacterial product d) Viable bacterial cell

Q.2 Attempt any one - **20**

1. Define biosensor. Discuss in detail components, types & application of biosensor.
2. Define BSC. Explain in detail Class I Biosafety cabinates (BSC) & Class III Biosafety cabinates cabinates.

Q.3Attempt any four- **40**

1. Explain in detail LAL test and its application in pharmaceutical industry
2. Explain in detail Microbial control of cleanrooms.
3. Explain a brief account on Good laboratory practices.
4. Explain in detail BSL -3 & BSL-4.
5. Explain the schedules under the drug Act 1940.
6. Illustrate the qualification needed during calibration of instruments

Q.4 Attempt any four. **20**

1. Good microbiological practices
2. Advisory Administration of Drug Act ,1940
3. Ultraviolet lamp
4. Autoclaving
5. Membrane filtration method of sterility testing
6. Clean room classification

॥ ज्ञान, विज्ञान आणि सुसंस्कार यांसाठी शिक्षण प्रसार ॥
– शिक्षणमहर्षी डॉ. बापूजी साळुंखे

64517

Shri Swami Vivekanand Shikshan Sanstha Kolhapur's

VIVEKANAND COLLEGE, KOLHAPUR (AUTONOMOUS)

SUPPLIMENT

Signature of Supervisor	59/100

Suppliment No. : –

Roll No. : 103

Class :

Subject : Microbial Quality control in pharmaceutical industries.

Test / Tutorial No. : Final Exam

Div. :

Q1]

1]

→ b) Analyzers.

2]

→ b) Biological molecules.

3]

→ a) calibration.

4]

→ b) cellulose acetate.

5]

→ a) oxy :- to make

6]

→ d) cellulose silicate.

7]
→ a) Drugs technical Advisory Board.

8]
→ a) 99.97 %.

9]
→ b) Iso 3

10]
→ c) HEPA Filter.

11]
→ d) Agricultural lands.

12]
→ a) endotoxin.

13] c) So.
→ c) solid waste.

14]
→ b) p-nitroaniline.

15]
→ a) 1-4

16]
a) Ebola Hemorrhagic fever virus.

7]
→ c) B

8]
→ a)

9]
→ a

20]
→ d

16

7]

→ c) B.Sc. class - 3

8]

→ a) conductometric biosensor.

9]

→ a) Good laboratory practices.

20]

→ d) viable bacterial cell.

16

Q2]

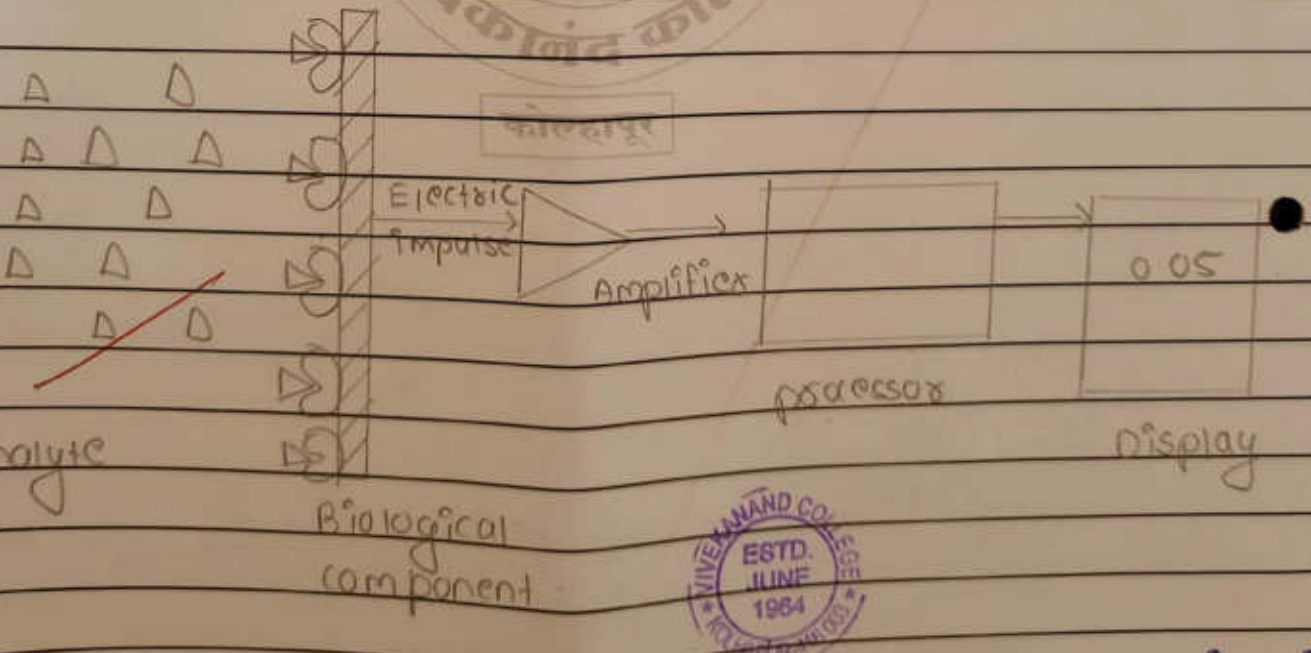
1] Biosensor → The analytical device which measures the concentration of analyte.

i] In biosensor, the analyte reacts with the biological component and produces physical change.

ii] The physical change is detected by the transducer. The signal is amplified and displayed as analyte concentration.

* Leyand. Clark - He was called as father of biosensor. He developed an electrode to detect oxygen called as "Clark electrode"

* components of Biosensor.



1] Analyte :- The component whose concentration is to be measured.
ex :- Blood, urine, serum etc.

2] Biological component - It interacts with the analyte and produce physical change.
ex :- polymer, antibody, enzymes etc.

3] Amplifier :- It detects the electrical impulse and amplifies it.

4] processor :- It process the signal recieved from amplifier.

5] display :- Final concentration of analyte is displayed.

* Working :-
i] When biological component reacts with the biosensor analyte, it produces physical change,
A] Release or absorption of heat
B] production of light.
C] Flow of electrons due to redox reaction.
D] production of electrical signal.

ii] The physical change is detected by the amplifier. It amplifies the signal and signal is processed. Final concentration of analyte is displayed on the screen.

* Types of biosensor

1] optical biosensor.
→ It measures the light emitted by enzyme luciferase.

2] Amperometric biosensor.
→ It measures the flow of electrons.
ex:- Glucose biosensor.

3] Acoustic wave biosensor.
→ It measures the piezoelectric effect.
ex:- Cocaine biosensor.

4] calorometric biosensor.
→ It measures amount of heat absorbed or released.

5] potentiometric biosensor.
→ It measures electric impulse generated.

6] conductometric biosensor.
→ It measure electric conductivity during a reaction.

* Advantages.

i] Easy to use
ii] Fast results.
iii] continous and regular use.
iv] Low amount of sample required.
v] Less amount of reagents required for calibration.

* Applications.

1] In Food industry
→ Biosensor are used to detect the presence of E.coli in food. presence of E.coli is sign of faecal pollution.
ii] Enzymatic biosensor is used in diary industry.

2] Environmental control
→ Biosensors are used to detect sound, air and noise pollution.

3] Health :-
→ Biosensors [Glucose biosensor] to measure amount of glucose in blood.
ii] Thermometer is used to detect fever.
iii] pregnancy kit.

4] Drug discovery :-
→ Biosensors are used in pharmaceutical industry to detect chemical change in drug etc.

16

Q3]

i] LAL test :- Lumulus Amebocyte lysate test is an invitro assay which is carried out to detect presence of endotoxin in pharmaceutical industry.

i] Endotoxin :- It is a potential component present in outercell wall of ~~gne~~ Gram negative bacteria. It acts as an pyrogen. It triggers the immune cells of our body like interlukin - 1 which binds to the hypothalamus ~~to set th~~ and instructs to set the body temperature.

ii] Endotoxin is stable at high pH, temp etc. so detection of it is a crucial step.

* ~~Requirements~~ of LAL Test :-

i] LAL test solution :- Lumulus Amebocyte lysate is aqeous blood Solution obtained from ~~at~~ lantic Horshoe crab.

ii] Blood from horshoe crab is removed from the pericardium.

iii] Then to separate blood from serum, it is centrifuged and then cells are placed in ~~wate~~ o/w.

iv] The ~~s~~ cells swell and it ~~bu~~ bursts. The content of the cell comes out and amebocyte are released which is used to detect endotoxin.

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principle of test :- Amebocytes are mobile cells present in the blood of crab. They contain clotting factor 'coagulogen' which binds to the endotoxin and forms a clot.

* It is carried out by 3 methods.

A] Gel clot assay :- It is most commonly carried out test for qualitative analysis of endotoxin.

Method :- In this, LAL reagent is mixed with equal amount of sample and it is agitated. Then the tubes are incubated at room temperature for 1 hour. After that, tubes are checked for eye detection. If a clot is formed and it remains even if the tube is inverted then the test is positive. If the clot disappears the test is negative.

B] Turbidometric Assay

→ This test is carried out for quantitative analysis of endotoxin. Here, turbidity of solution is checked.

Method :- LAL reagent is mixed with sample and the tubes are incubated. After that the tubes are checked for turbidity. If the solution is turbid, there is presence of endotoxin. Concentration of endotoxin is measured using colorimeter.

c] Chromogenic method :-

→ This test is also called as photometric method. Concentration of endotoxin can be measured by presence of change in yellow colour of solution. The more amount of endotoxin is present, the more darker yellow colour will be observed.

method :- First, LAL reagent is mixed with chromogenic substrate. Then it is added to test sample and tubes are incubated. Tubes are checked for presence of yellow colour or not. The concentration can be measured spectrophotometrically.

* Applications :-

i] LAL test is done to detect the presence of endotoxin in parental products.
ex :- vaccines, antibodies etc.

ii] LAL test is done to detect the pyrogen in drugs

GLP - Good laboratory practices.

i] GLP was first time used in New zealand.

ii] It was implemented in 1970.

Definition :- Set of rules, operating procedures used to ensure quality and accurate result in laboratory.

i] It was implemented after submission of fake reports to FDA by toxicology lab in USA.

ii] After wards, OECD gave few standards, which are followed internationally.

* Components :-

a] personnel

a] i] Qualified personnel is required.

ii] Enough personnel should be there.

b] Facility management.

→ The work of facility management is to implement study director and provide QA place.

c] Sponsor.

→ The work of the sponsor is to help the non-clinical laboratory and submit it to the FDA.

d] Study director.

→ The overall responsibilities of equipments, assessment, QA is under the control of Study director.

E] Quality Assurance unit.
→ It's role is assessment, assurance and final reports should be according to the GLP standards.

2] Lab certification
→ mostly done by external agency.

3] SOP - standard operating procedure.
→ It is protocols and procedure how things should be carried out.

] Analyst certification.
→ i] The analyst should be qualified or must have experience prior.

] Documentation.
i] proper documentation should be carried out.
ii] Record should be kept of every 5 years.

If the laboratory doesn't meet the GLP standards, then the commissioner can send an letter for disqualification of the lab.

08

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3] i] BSL-3
ii] Biosafety

Q4]

i] GMP.

ii] A person working in laboratory might be working with pathogenic organisms or might be handling hazardous reagent. It is important for that person to be protected.

iii] so, person working in microbiological laboratory should follow certain rules which will protect himself and the environment.

* Rules and standards while working in the laboratory :-

1] Wear mask, gloves, labcoat in the laboratory.
2] Use loose shirts with buttons. It should be easy to remove.
3] Bunsen burner should be turned off when not in use.
4] Nichrome wireloop and needles should be flame sterilized before and after use.
5] Drinking, eating and smoking should not be allowded in the laboratory.
6] Wash your hands before and after leaving the laboratory.
7] Disinfect the working space with 10% ethanol each time before working.
8] Replace the caps of the reagent. Label them properly.
9] Discard the broken glass material in broken glass bin.
10] Do not pour anything into the sink.
11] Solid waste should be discarded in biohazardous bag.
12] Materials like needles, blades, scalpels need to be discarded in 'sharp waste' container.
13] Only required items should be kept in the laboratory.
14] If girls have long hair, they need to be tied prior working.
15] Date of manufacture and expiry should be written on the reagents.

04

ultraviolet lamp.

i] u.v. light acts as an disinfectant.

ii] It is normally fixed inside the laminar air flow which provides sterile environment.

iii] DNA absorbs u.v. light between ~~the~~ ~~ear~~ ~~the~~ exactly at 256 nm.

iv] The range of u.v. light is from 10nm to 400 nm.

v] u.v. light acts as microbisidal.

vi] When organism is exposed to u.v. light, his DNA undergoes mutation, thymine-thymine dimer formation takes place due to which eventually it does.

vii] Before working in the biosafety cabinets, u.v. lamp is turned on for 15-20 minutes.

viii] After that the u.v. light is turned off. and blower is turned on.

4] Auto clave

i] Autoclave should be used for disinfecting and sterilizing biomedical waste.

A] while using gravity flow autoclave :-

i] The ~~time~~ & temp. should be 121°C, pressure 15 psi and autoclave residue limit not less than 60 min or

ii] Temp. should be 135°C, pressure 31 psi and autoclave residue limit not less than 45 min or

iii] Temp. not less than 149°C, pressure less than 52 psi and autoclave residue time limit not less than 30 minutes.

B] While using vaccum based autoclave, the equipments should be exposed to vaccum per year.

i] Temperature should not be less than 121°C, pressure 31 psi and autoclave residue time not less than 45 minutes or

ii] Temperature should not be less than 135°C, pressure less than 31 psi and time not less than 30 minutes.

2] If by any chance, the procedure doesn't meet the temperature, pressure and time than the equipments cannot be stated as they are sterilized.

4] In this, case the equipments are autoclaved once more.

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Roll No. : 104
Class :

Subject : Microbial quality control in pharmaceutical Industries.
Test / Tutorial No. : Final Exam
Div. : Tuesday 18 July 2023.

Q1)

1) The molecule which are to be measured by using biosensors are known as Analyzers

2) In biosensor Transductor generate electric impulse.

3) Calibration proves that the equipement works correctly & actually leads to correct & reliable result.

4) Cellulose nitrate filter is used for strongly alcoholic solutions.

5) pharmacopia word is derived from pharmakon & poiea means Drug ; to make.

6) Cellulose acetate filter is used in membrane filtration apparatus for weakly alcoholic solution.

7) DTAB = Drug Technology Advisory Board.

8) Efficiency of HEPA filter is 88.87 %

9) Grade B air born particle is based on classification of ISO 3

10) In laminar air flow which type of filter is located HEPA filter.

11) Agricultural lands area has the lowest chance of producing a biomedical waste.

12) LAL test used to determine Endotoxin in pharmaceutical products.

13) Incineration ash of the following is categorized as an incineration waste

14) p-nitroaniline linked chromogen is used in chromogenic reagent

15) Biosafety levels are ranked as = 1-4

16) Ebola Hemmorhagic fever virus of the following is Risk group-4 agent

17) BSC class-3 are known as "total containment cabinates".

18) conductometric biosensor types of biosensor measure electric conductivity during a reaction.

19) A set of rules, operating procedures to ensure quality & accurate result in laboratory is known as Good laboratory practice

20) Sterility test is used to determine presence of viable bacterial cell in pharmaceutical product

16

2)

1) Biosensor =

It is a device which used to detect or measure the concentration of analyte.

Components =

A) Analyte =

Any substance whose concentration can be measured or determined.

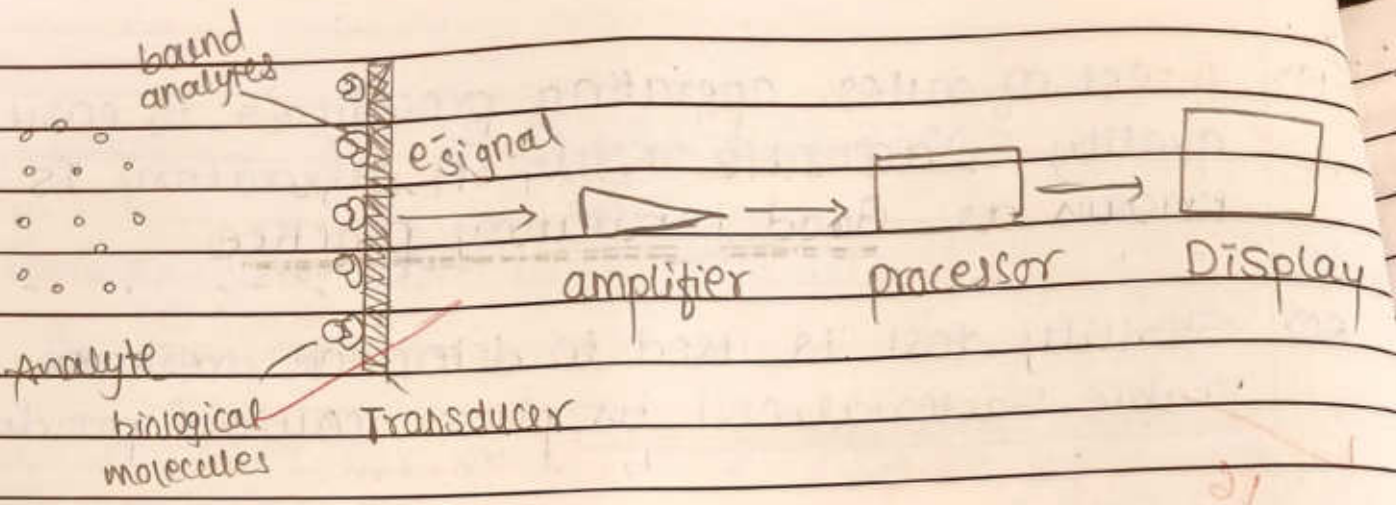
Transducer =

It generate the electric impulse.

Biological molecules =

Any kind of substance like sugar concentration, protein contration, urine concentration, vitamins, peptides binds to analyte or transducer.

In the biosensor the analyte binds the molecule the transducer generate the electric impulse & after amplifying by amplifier it process & display the concentration of sample.



Types of Biosensors

1) Calorimeteric Biosensor –
It is used to detect released (exothermic) & adsorbed (endothermic) during the heat time of reaction.
e.g – Thermometer

2) potentiometeric Biosensor –
It is used to measure potential difference during redox reaction

3) Amperometeric Biosensor –
It is used to measure electric current during reaction.

4) Conductometric Biosensor –
It is used to measure electric conductivity during reaction.

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5) ~~Aguti~~ ~~Ascoustic~~ Acoustic Wave Biosensor =
It is used to measure picrometric effect
e.g- coccain ~~x~~ concentration.

6) Optical Biosensor –
It is used to measure amount of light.
– # luciferase enzyme is responsible for emitts light.

* Leland C. clark is the father of Biosensor

* The 1st time he discovered oxygen concentration in blood by biosensor in 1980.

* The oxygen concentration biosensor named after clark electrode.

Application of Biosensor –

*) There are wide range of application of Biosensor in following fields / sectors.

*) In medical sector –

1) It is used in blood pressure.
2) oxymeter
3) pregnancy kit
4) ~~Glucose~~ To check the glucose concentration
5) Urine concentration.

* In food Industries –

1) It is used to check the pathogen in food.
2) To check the temperature of product / sample

* In Environment sector –

1) It is used to check the pathogen / particles present in air, water, soil
2) It is used for pollutants.

Advantages – 1) cheap 2) Easily available
3) Easy to use 4) Highly efficient
5) Required Small Space 6) Easy stored.

16

(B)

1) LAL Test =

LAL (Limulus Amebocyte Lysate Assay)

It is invitro assay used for detection of endotoxin present in sample.

Biological Endotoxin =

It is a substance like Lipopolysaccharide (LPS) found in the Gram Negative bacterial cell wall, It is very powerful & immunostimulates.

Endotoxin can be measured by two tests -
1) Rabbit pyrogen Test (RPT)
2) Limulus Amebolyte Lysate (LAL)

LAL Test =

- It is common & simple test.
- LAL is a aqueous ~~extract~~ solution extracted from Atlantic horse shoe crab (Limus polyphemus) blood.
- It is easy method which adapted by many countries.
- For the detection of endotoxin LAL test is performed
- The endotoxin released pyrogen

pyrogen = A substance which produce the fever when in contact with blood.

There are Three ways to perform LAL Test
1) Gel clotting Assay
2) Turbidometric Assay
3) Chromogenic Assay.

- LAL Test required horse shoe ~~Crab~~ Crab blood which extracts from there pericardium.
- The blue blood because of Haemocyanin with copper.
- The ~~blood~~ collection & centrifugation & place them in distilled water after the they are swell & burst.
- After burst the sample was collect, purify & then freeze-drying.
- The amoebocyte or amoebocytes are mobile cells in the invertebrates, they moved by pseudopodia, like same in WBCs in the vertebrates.
- The amoebocyte contains granules of coagulase which in contact with proclotting factor activates the clotting factor 'coagulin'.

① Gel Clotting Assay

In this LAL solution is mixed with sample & place the test tube for ~~incubation~~ centrifugation after that place for incubation ~~for~~ for 1 hr. 37°C.

After that the results are observed when the endotoxin is present then the clot is form & the test was positive. & the endotoxin is absent then the sample texture is runny.

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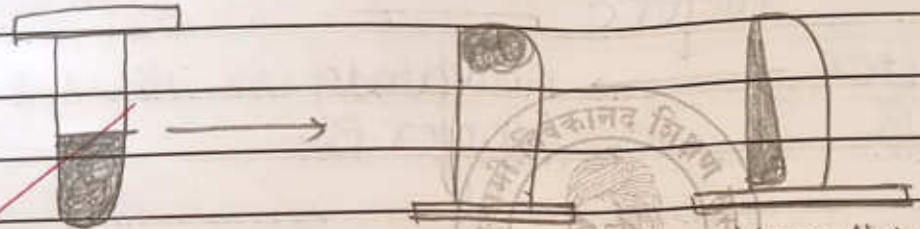

When endotoxin is come in contact with blood in presense of LAL sol^n then it form clot.

② Turbidometric Assay

The LAL solution is mixed with sample test tube the test tube is placed in incubator for 1 hr in 37°C.

The observing result is to increase in turbidity when test positive.

③ Chromogenic Assay –

– It is the photometric assay used to measure colour released by chromophore & developed by chromogenic lysate substrate.

– It is measured by Spectophotometer method

Endotoxin

↓

factor C ⟶ Activating factor C

↓

Factor B ⟶ Activating factor B

↓

proclotting enzyme ⟶ clotting enzyme

↓

Synthetic chromogenic factors ⟶ Boc – Leu – Gly – Arg – pNA

↓

Boc – Leu – Gly – Arg – pNA

+

yellow colour pNA compound.

Application –

1) It is used to detect the endotoxin.

2) It is also used to detect the pyrogen.

⑨

Good laboratory practices

① personnel –
- The enough no. of persons.
- The person should be well qualified.

② Sponsor –
- They make available quality assurance.
- Arrange the stud. facilities.

③ faculty members –
- The arrange study director.
- Maintain the records.

④ Study director –
Arrange the all equipements, reagents, & also maintained, intreption, documentation of records.

⑤ Quality Assurance Unit –
- To provide good / clean labs, equipements reagents.
- Maintain the Standard operating procedures (Sop)

⑥ Maintaince & callibration of equipments –
- All materials, reagents, glassware are properly maintained
- To check all the equipments are properly calibrated or not.

⑦ Labelling (well) :-
- All the composition is need to be mention
- The opening date.
- Manufacturing date
- Expiry date
- The amount to be used.
- All should properly labelled

⑧ Laboratory certificates –
- The lab should be certified.
- The lab should be external certified by authorities
- The lab should follow the SOP & GLP rules.

⑨ Individual certification –
- Individual person certification by analysis authorities like FDA, WHO, BIS, ISO etc.
- The person should be well qualified & well trained.

⑩ Action –
- When the lab is not follow the rule of GLP & SOP
- The lab & lab work follow the rules (not follow) & not & maintain the hygiene, proper ventillation.

⑪ Documentation –
- For the future reference
- The results & records are maintained 5 yrs.

08

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(12) ~~privally~~ primily violence

- primily informance of not registerged lab.
- primily informance of not follow rules
- failure to submit the records

(13) Consequences -

- Commissioner take the written action & pro proposal of disqualification.
- But after you fulfil the the requirements then the disqualification is cancelled

4) BSL - 3 & BSL - 4

* BSL - 3

*) Biosafety level - 3

1) Here they work on highly pathogenic bacteria & viruses.
2) The proper laboratory equipements, eye goggles, slippers, lab coat, ppe kit, mask & are compulsory required.
3) They are work on highly infecteous organ on inside the box in which the gloves are already attached.
4) BSL - 3 are also called Total containments cabinets.
5) Here only well trained & with proper safety studied persons is allowed.
6) The persom with immunity is low is not all
7) The BSL is maintained high positive pressure in ppE kit & negative presure in lab.
8) The lab is fully equiped.

* BSL - 4

Biosafety level - 4

1) Here they work on highly very dangerous pathogenic organism.
2) This lab must be follow all rules, GLP, SOP etc.

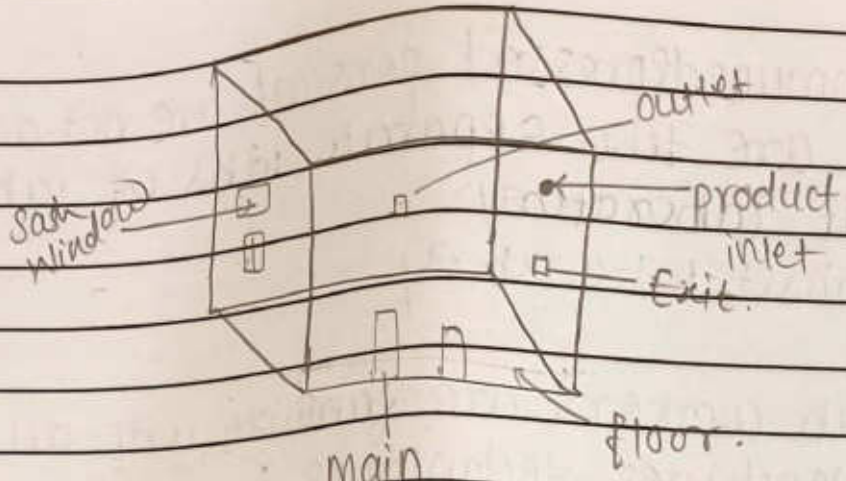
3) The immunodepressed persons are not allow.
4) There are two separate labs of lab worker.
   1) Suit laboratory
   2) Cabinet laboratory

5) All lab workers are familize with all instruction rules, machines, techniques.
6) Must were lab coat, footwear, ppe kit, eye protection, gloves, hair cap etc.
7) In this lab the workers work with organisms whose treatment is not available yet.
8) Its very dangerous & risky labinets.

2)

Cleanroom =

- The proper clean, closed environment known as cleanroom.
- This is designed to generate low particles.
- The designed to remove generated particles
- The designed is to predefined limits.
- The headspace is necessary to avoid contaminants.



- The cleanroom is necessarily maintained
- Cleanroom is classified under 4 types.
  Grade A (about 100)
  Grade B (about 100)
  Grade C (about 10,000)
  Grade D (about 1,00,000)

Grade		Activity
A, B	}	proper sampling & filing
C	–	Filing the sampling should be feed
D	–	Handling contaminants. after disinfectants.

for passive air sampling
for Active air sampling

B

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4)

Good Microbiological pratices

- The person who work in microbiology lab should follow are the instruction, rules & SOP.
- Microbiology lab is closed environment lab where highly pathogenic work is carried out.
- The person who work in microbiology lab are having a chances to expose that organisms, so there are some Good microbiological pratices are as follows -

1) Clean the hands with soap, sanitizer, handwash etc. before you entering & leaving the lab.
2) Wear lab coat where there sleeve are cover you corner, & not touch your head when you off.
3) Avoid loasely fitting garments.
4) Wear proper lab footwears.
5) Tie your hairs or wear hair caps.
6) Wear gloves.

7) Wear eye goggles / eye protection wears.
8) Avoid wearing metals.
9) ~~Extra~~ Extreamely avoid drinking, chewing gum, or eat something in lab.
10) Always wear masks.
11) Don't touch your hands on your face.
12) Use disposible glooves, mask etc.
13) Wear PPE (personal protection kit)
14) Handle every organisms very carefully.

03

8) Ultraviolet lamp -

1) Ultraviolet lamp ~~inte~~ is present in laminar air flow.
2) It is present in every lab to avoid ~~or to~~ micro-~~orgi~~ organisms.
3) Wavelength is 25 nm.
4) Ultraviolet lamp is a mutagenic agent.
5) To expose of U.V. lamp is dangerous, it can cause burning skin.
6) According to CDSCO & GLP the ultraviolet lamp is not neccessary.

2

4) Autoclaving –

1) Autoclaving is used for sterilization purpose.
2) In labs, hospitals or industries autoclave is there or any different sterilization method is present.
3) There are two ~~ster~~ways of sterilization
   1) Steam sterilization &
   2) Dry sterilization.

4) In the hospitals, all scissors, needles, blades, forceps are need to sterilized in autoclave.
5) Usually 121°C for 1hr / 60-90 min are required for autoclave.
6) To Avoid any contamination the autoclave is must.
7) It is necessary to callibrated the autoclave.

3

8) Clean room classification -

Clean room classification is under 4 Types.

Grade A (about 100)
Grade B (about 100)
Grade C (about 10,000)
Grade D (about 1,00,000)

Grade		Activity.
A B	}	for proper sampling & filing.
C	-	Sampling solution to be feed.
D	-	Handeling the contaminants after disinfectants.

Vivekanand College (Autonomous), Kolhapur

Department of Microbiology

Value added course 2022-2023

"Microbial Quality Control In Pharmaceutical Industries"

Result summary

Sr.No	Name of Student	Seat No.	Marks
1	Adav Prachi Jotiba	101	Ab
2	Alave Aarya Rajendra	102	Ab
3	Athanikar Sabira Nijam	103	59
4	Awalkar Anchal Nandkumar	104	67
5	Bangodi Harsh Kishor	105	46
6	Bardeskar Stuti Kaitan	106	Ab
7	Basare Gayatri Pramod	107	45
8	Bhatmare Saurabha Sambhaji	108	36
9	Chavan Pratiksha Ananda	109	Ab
10	Chougale Nikita Bharat	110	57
11	Desai Tasnim Yunus	111	47
12	Gaikwad Nikita Nandkumar	112	58
13	Gurav Shivani Vinayak	113	52
14	Hadgal Ratuja Tanaji	114	38
15	Haval Arpita Sachi	115	71
16	Kadam Neha Krushnat	116	65
17	Kalamkar Asavari Anil	117	63
18	Kandalkar Namarta Anil	118	65
19	Kashid Snehal Babaso	119	57
20	Kesarkar Prachi Chandrakant	120	56
21	Khanapure Ammar Abdulgafar	121	39
22	Koli Priyanka Sunil	122	66
23	Kumthekar Krushnakant Surendra	123	Ab
24	Lavhate Prachi Suresh	124	35
25	Madhale Ashlesha Shivaling	125	44
26	Makandar Fardin M	126	Ab
27	Mali Prachi Sanjay	127	38
28	Mane Rohan baban	128	57
29	Mane Utkarsha Gajendra	129	45
30	Mujawar Abida Altaf	130	44
31	Murti Vanshita Sanjay	131	54
32	Naik Shalom Vishwas	132	35
33	Nalawde Sakshi Sunil	133	40
34	Notani Disha Santosh	134	Ab
35	Padaval Damini Mohan	135	53
36	Pardeshi Shrutika Manik	136	60
37	Parkar Siddhi Anil	137	40

VIVEKANAND COLLEGE ESTD. JUNE 1964 KOLHAPUR 416 003

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Shri Swami Vivekanand Shikshan Sanstha's

VIVEKANAND COLLEGE , KOLHAPUR (AUTONOMOUS)

Department of Microbiology

Value Added Course (2022-2023)

Name of the course – "Microbial Quality Control In Pharmaceutical Industries"

Name of Student: Ms. Haval Arpita Sachin

Exam Seat No. – 115

	Theory	Grand Total	Percentage (%)	Remark
Max. Marks	100	100	71	Pass with first class
Min. Marks for passing	35	-		
Marks Obtained	71	71		

Course Co-ordinator

Principal

PRINCIPAL
Vivekanand College
Kolhapur

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VIVEKANAND COLLEGE,

KOLHAPUR (EMPOWERED AUTONOMOUS)

NAAC Accredited 'A' Grade With CGPA 3.24, College With Potential For Excellence by UGC
Star College By DBT, Govt. Of India

DEPARTMENT OF MICROBIOLOGY

CERTIFICATE

This is to certify that Ms. Haval Arpita Sachin of B.Sc. ~~I/II/III~~ has successfully completed the value-added course on "Microbial Quality Control In Pharmaceutical Industries" carried out in the Department of Microbiology, Vivekanand College, Kolhapur (Empowered Autonomous) during academic year 2022-2023 from 8th March to 18th July 2023. This certificate is awarded to him/her after passing theory examination.

Ms. S. A. Pise
Course Co-ordinator

Dr. R. R. Kumbhar
Principal

PRINCIPAL
Vivekanand College
Kolhapur