

COURSE FILE OF
INDUSTRIAL PHARMACY

7TH SEM

2024

PREPARED BY

MRS. KUMARI VARSHA

DEPARTMENT OF PHARMACEUTICS



**GAUTAM COLLEGE OF PHARMACY,
HAMIRPUR.**

DEPARTMENT OF PHARMACEUTICS

Academic Year: 2024-2025

Course Name :B. Pharmacy

Student's Batch :2021-2025

Semester :7thsemester

Name of Subject : Industrial Pharmacy-II

Subject Code :BP 702T.

Faculty In-charge : Mrs. Kumari Varsha

HOD

Principal

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1. ACADEMIC CALENDER:

HP TECHNICAL UNIVERSITY, HAMIRPUR 177001, HP

Academic Calendar: 2024-25**1st Semester of 2024-25 (Odd Semester: 2024-25 Session)**

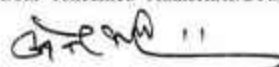
SN	Event(s)	Date(s)
1	*Registration of all students for all courses (UG & PG) except 1 st Year	15.07.24 to 18.07.24
2	Commencement of classes of these courses	16.07.24
3	*Registration of students of 1 st Year (UG/PG)	29.07.24 to 31.07.24
4	Induction programme for 1 st year students	29.07.24 to 11.08.24
5	1 st Periodical Exams (Mid Sem Tests I)	16.09.24 to 19.09.24
6	HPTU Sports Meet	11.10.24 to 13.10.24
7	2 nd Periodical Exams (Mid Sem Tests II)	24.10.24 to 28.10.24
8	Diwali Vacations	29.10.24 to 03.11.24
9	End of Teaching work for all semesters	23.11.24
10	Reporting of shortage of attendance cases & display of internal assessment	26.11.24
11	End Semester Practical Examinations	27.11.24 to 30.11.24
12	End Semester Theory Examinations	03.12.24 to 25.12.24
13	Vacations	30.12.24 to 14.01.25

2nd Semester of 2024-25 (Even Semester: 2024-25 Session)

SN	Event(s)	Date(s)
1	*Registration of all students for all courses (UG & PG)	15.01.25 to 17.01.25
2	Commencement of classes	16.01.25
3	Four months' Industrial training /Project based work (B. Tech. 8 th Sem.)	16.01.25 to 15.05.25
4	1 st Periodical Exams (Mid Sem Tests I)	25.02.25 to 01.03.25
5	HPTU Youth Festival	16.03.25 to 18.03.25
6	2 nd Periodical Exams (Mid Sem Tests II)	16.04.25 to 19.04.25
7	End of Teaching work	03.05.25
8	Reporting of shortage of attendance cases & display of internal assessment	06.05.25
9	End Semester Practical Examinations	07.05.25 to 10.05.25
10	End Semester Theory Examinations	14.05.25 to 31.05.25
11	Conduct of final Viva Voce of students of B. Tech. 8 th Sem. (as per SN 2 above) & submission of final awards to Exam. Branch of HPTU	By 25.05.25
12	Declaration of results of last semester of all courses	1 st Week of July, 25
13	Industrial/Institutional Training of students: 4 to 6 weeks (wherever applicable)	02.06.25 to 14.07.25
14	Vacations	09.06.25 to 14.07.25

*Fine @ Rs. 50/- per day, upto 10 days from the last date of registration, is chargeable on account of late registration as per Notification No. HimTU-(GA) C.3/2011-5384-5387 Dated 03.11.2022

- The Academic Calendar is subjected to change upon receipt of advisory from concerned Authorities/Bodies. Such change, if any, will be communicated accordingly.



Course Code:- BP-702T

Course Title:- Industrial Pharmacy-II

2. SYLLABUS

UNIT-I

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT-III

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies. 147

UNIT-IV

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

3. MASTER TIME TABLE:-

GAUTAM COLLEGE OF PHARMACY, HAMIRPUR (H.P.)
7TH SEMESTER TIME TABLE

SEMESTER TIME TABLE										
DAY	LH	Sem	9:00-10:00 am	10:00-11:00 am	11:00-12:00 noon	12:00-1:00 pm	1:00-2:00 pm	2:00-3:00 pm	3:00-4:00 pm	4:00-5:00 pm
Monday	LH-08	VII-A	Pharmacy Practice (MB)	IP-II (KV)	IMA (AS)	LUNCH	NDDS (Dr.D. G)	Practice School		IMA (AS)
Tuesday	LH-08	VII-A	Pharmacy Practice (MB)	Practice School	NDDS (Dr.D. G)		Comm. Skills. (MB)	NDDS (Dr.D. G) Tut.	Practice School	IP-II (KV)
Wednesday	LH-08	VII-A	IP-II (KV)	Practice School	NDDS (Dr.D. G)		Practice School	Comm. Skills. (MB)	IMA (AS)	Pharmacy Practice (MB)
Thursday	LH-08	VII-A	IMA (AS) Practical batch A L-3, Practice School Batch-B				LUNCH	Practice School	Comm. Skills Practical Lab, Entry/ Practice School	
Friday	LH-08	VII-A	IMA (AS) Practical batch B L-1, Practice School Batch-A				LUNCH	Practice School		IMA (AS) Tut.
Saturday	LH-08	VII-A	IMA (AS)	Practice School	Pharmacy Practice (MB)	LUNCH	Pharmacy Practice (MB) Tut.	IP-II (KV) Tut.	NDDS (Dr.D. G)	Practice School

Lectures / Subject: 4 Hours / Week – IMA: Instrumental Methods of Analysis, NDDS: Novel Drug Delivery System, Comm. Skills: Communication Skills, IP-II: Industrial Pharmacy-II, Practice School

Dr. D.G: Dr. Darsh Gautam, MB: Ms. Madhu Bala, KV: Mrs. Kumari Varsha, AS: Mr. Abhishek Saini.


Academic Incharge
Prof. (Dr.) Darsh Gautam


Director, Quality Assurance
Prof. (Dr.) Darsh Gautam
Director, Quality Assurance
Gautam College of Pharmacy
Hamirpur (H.P.)

4. INDIVIDUAL TIME TABLE:

Mrs. Kumari Varsha

Total Workload: 4 hrs.

Gautam College of Pharmacy, Hamirpur

Individual Time Table for the Academic Session July 2024 to Dec.2024

DAY	SEM/ YEAR	9:30- 10:30 am	10:30- 11:30am	11:30- 12:30p m	12:30- 1:00pm	1:00- 2:00pm	2:00- 3:00pm	3:00- 4:00p m	4:00- 5:00pm
Monday	B7		IP-II(KV)		LUNCH				
Tuesday	B7								IP-II (KV)
Wednesday	B7	IP-II(KV)			LUNCH				
Thursday	B7					LUNCH			
Friday	B7				LUNCH				
Saturday	B7						IP-II (KV)		

5. COURSE OBJECTIVES:-

Upon completion of the course, the student shall be able to:

Know the process of pilot plant and scale up of pharmaceutical dosage forms

Understand the process of technology transfer from lab scale to commercial batch

Know different Laws and Acts that regulate pharmaceutical industry

Understand the approval process and regulatory requirements for drug products

6. TEACHING PLAN:-

Sr. No.	Course content	Total no. of hours	Scheduled Date	Pedagogy	Assignment	Objectives and Learning Outcomes	Remark
1.	UNIT-1 Pilot plant scale up techniques: General considerations - including significance of personnel requirements	2	16/7/24 20/7/24	PPT/ PDF & Notes through on line mode	Assignment on Pilot plant scale up techniques and SUPAC guidelines	After completion of the topic the students learned about the Pilot plant scale up techniques and SUPAC guidelines.	
2.	Space requirements	1	22/7/24				
3.	Raw materials	1	23/7/24				
4.	Tutorial	1	24/7/24				
5.	Pilot plant scale up considerations for solids	2	25/7/24 29/7/24				
6.	Pilot plant scale up considerations for liquid orals	1	30/7/24				
7.	Tutorial	1	31/7/24				
8.	Pilot plant scale up considerations for semi solids and relevant documentation	1	3/8/24				
9.	SUPAC guidelines	1	5/8/24				
10.	Introduction to platform technology	1	6/8/24				
11.	Tutorial	1	7/8/24				
12.	UNIT-II: Technology development and transfer: WHO guidelines for Technology Transfer(TT)	1	12/8/24	PPT/ PDF & Notes through on line mode	Assignment on WHO guidelines for Technology Transfer, Quality risk management, qualification and validation, quality control	After completion of the topic the students learned about the WHO guidelines for Technology Transfer(TT), qualification and validation, quality control.	
13.	Terminology, Technology transfer protocol	1	13/8/24				
14.	Quality risk management,	1	14/8/24				

	Transfer from R & D to production (Process, packaging and cleaning)						
15.	Tutorial	1	17/8/24				
16.	Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments,	1	19/8/24				
17.	qualification and validation, quality control	1	20/8/24				
18.	analytical method transfer	1	21/8/24				
19.	Tutorial	1	24/8/24				
20.	Approved regulatory bodies and agencies	1	28/8/24				
21.	Commercialization - practical aspects and problems (case studies)	1	31/8/24				
22.	TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing	2	2/9/24 3/9/24				
23.	Tutorial	1	4/9/24				
24.	MoUs, legal issues	1	7/9/24				
25.	UNIT-III: Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities	1	9/9/24	PPT/ PDF & Notes through on line mode	Assignment on Regulatory affairs, Regulatory requirements for drug approval, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB)	After completion of the topic the students learned about the Regulatory affairs, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals and Regulatory requirements for drug approval	
26.	Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals	1	10/9/24				
27.	Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology	1	11/9/24				
28.	Tutorial	1	21/9/24				
29.	Drug Metabolism	2	23/9/24				

	and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB)		24/9/24				
30.	New Drug Application (NDA), Clinical research / BE studies.	1	25/9/24				
31.	Tutorial	1	28/9/24				
32.	Clinical Research Protocols	1	30/9/24				
33.	Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies	1	1/10/24				
34.	Data Presentation for FDA Submissions	1	5/10/24				
35.	Tutorial	1	7/10/24				
36.	Management of Clinical Studies	1	8/10/24				
37.	UNIT-IV: Quality management systems: Quality management & Certifications: Concept of Quality	1	9/10/24	PPT/ PDF& Notes through on line mode	Assignment on Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Introduction to ISO 9000 series of quality systems standards	After completion of the topic the students learned about the Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Introduction to ISO 9000 series of quality systems standards And ISO 14000	
38.	Total Quality Management, Quality by Design (QbD)	1	14/10/24				
39.	Six Sigma concept, Out of Specifications (OOS)	1	15/10/24				
40.	Change control	1	16/10/24				
41.	Introduction to ISO 9000 series of quality systems standards	1	19/10/24				
42.	ISO 14000	1	21/10/24				
43.	NABL	1	22/10/24				
44.	GLP	1	23/10/24				
45.	UNIT-V: Indian Regulatory Requirements: Central Drug Standard Control	2	4/11/24 5/11/24	PPT/ PDF& Notes through on line mode	Assignment on Central Drug Standard Control Organization	After completion of the topic the students learned about the Central Drug Standard	

	Organization (CDSCO)				(CDSCO), Approval procedures for New Drugs	Control Organization (CDSCO), State Licensing Authority: Organization, Responsibilities, Approval procedures for New Drugs	
46.	State Licensing Authority: Organization, Responsibilities	2	6/11/24 11/11/24				
47.	Certificate of Pharmaceutical Product (COPP)	1	12/11/24				
48.	Tutorial	1	13/11/24				
49.	Regulatory requirements	1	16/11/24				
50.	Approval procedures for New Drugs	1	18/11/24				

Kumari Varsha Assistant Professor

TEACHER INCHARGE

PRINCIPAL

7. UNIVERSITY QUESTION PAPER

Roll No. _____ Total Pages: 03

Jan-21-R-211

B. Pharmacy (PC) EXAMINATION, Jan. 2021

Semester VII (PC)

INDUSTRIAL PHARMACY-II

BP-701 T

Time: 3 Hours

Maximum Marks: 75

The candidate shall find their answers precisely within the answer-book (40 pages) issued to them and no supplementary/continuation sheet will be issued.

Note: Section A is compulsory. From Section B attempt any two questions. From Section C attempt any seven questions.

Section A

10+2=20

1. Write full form of:

(a) DND

(b) NABE

Q.11111111111111111111

ETEL

- (a) CDSCO
- (b) APCTD
- (c) NRDC
- (d) THAC
- (e) NCEL
- (f) TBSE
- (g) SIDBI
- (h) OOS

Section B

2+10=12

2. Discuss the pilot plant scale up considerations for solids.
3. Discuss the ICH guidelines on quality risk management.
4. Discuss the technology transfer process related to API and excipients.

Section C

2+5=10

5. What are the responsibilities Regulatory Affairs Professionals?
6. Discuss about Clinical Research Protocols.

WJaw-21-R-211

2

7. Show the Data Presentation is done by FDA Submission?

8. Discuss the concept of Six Sigma setup.

9. Write a note on organization and responsibilities of Central Drug Standard Control Organization.

10. Discuss the role of leadership in TQM.

11. Write a note on ISO 9000 series.

12. Briefly discuss GMP.

13. What are the regulatory requirements and approval procedures for New Drugs?

Q.11111111111111111111

14

8. QUESTION BANK (THEORY)

Unit 1

2 Marks Questions

1. Define pilot and scale up?
2. What is the difference between pilot scale and scale-up?
3. Why to conduct pilot plant studies?
4. What are the advantages of pilot studies?
5. What is SUPAC?
6. What is the purpose of SUPAC guidelines?
7. Define platform technology?

5 Marks Questions

1. What are the objectives and significance of pilot plants?
2. Explain SUPAC guidelines?
3. Discuss the uses of platform technology?

10 Marks Questions

1. Discuss the general factors to be considered in pilot plant scale up technology?
2. Discuss pilot plant scale up consideration for solids dosage solids.
3. Discuss pilot plant scale up consideration for liquid orals.
4. Discuss pilot plant scale up consideration for semi-solids.
5. what are difference platform technology and explain

Unit 2

2 Marks Questions

1. Define the technology transfer according to WHO and how it is classified?
2. What are the goal of technology transfer?
3. What are the advantage of technology transfer?
4. What is good manufacturing practices (GMP)?
5. What do you mean by SU &RU
6. Define quality risk management (QRM) and write its principle
7. What do you mean by intercompany and intracompany?
8. What is standard operating procedure (SOP) ?
9. What is validation and process validation?
10. What is validation protocol (VP) and validation report (VR) ?
11. what is the drug master file (DMF) ?
12. What is analytical method transfer?
13. What is design qualification (DQ) and installation qualification (IQ) ?
14. What is operational qualification (OQ) and performance qualification(PQ) ?

5 Marks Questions

1. Explain technology transfer sample protocol in pharmaceuticals
2. Discuss technology transfer from R & D to production as per WHO guidelines?
3. Discuss granularity of TT process (API, excipients, finished products, packaging material) as per WHO guidelines for TT ?
4. Discuss about documentation, premises, and equipments for TT as per WHO guidelines
5. Discuss about qualification and validation for TT as per WHO guidelines?
6. How analytical methods are exchanged in a technology transfer ?

10 Marks Questions

1. Discuss stage involved in TT in pharmaceutical industry?

UNIT 3

2 Marks Questions

1. What is regulatory affairs ? what its goal?
2. what is investigational new drug and application?
3. what is New drug application (NDA) /
4. what is clinical trial?
5. what is clinical trial protocol?
6. what are BE & BA studies? why they are required?
7. Mention the major regulatory bodies in the world?
8. What is the organisational structure of regulatory affairs ?
9. Which is the health care product regulated by RA ?
10. What is CTD ?

5 Marks Questions

1. Discuss the role and responsibilities of RA professional.
2. Write a note on Drug development team and their functions.
3. Discuss regulatory authorities and their responsibilities.
4. Write a note on Non-clinical drug development process.
5. Write a note on Investigator's Brochure (IB).
6. Discuss the different phase of clinical trial.
7. How Bioequivalence are documented.
8. Write a note on clinical Research protocol.
9. Discuss about Management of clinical studies.
10. Discuss the various Modules in CTD.

10 Marks Questions

1. Explain Regulatory Requirement Approval for obtaining NDA.
2. Discuss general consideration of Investigational New drug Application.

UNIT-4

2 Marks Questions

1. Define GLP
2. Define NABL
3. Define MFR
4. Define OOS

5 Marks Questions

1. Explain Quality management system
2. Note on OOS
3. Note on six Sigma concept
4. Differentiate ISO 9000 and ISO 14000
5. Note on Total quality management

10 Marks Questions

1. Discuss about ISO 9000 with series

2. Explain ISO 14000.
3. Explain NABL
4. Discuss about role and importance of GLP in pharmaceutical industry
5. Discuss about quality by design

UNIT 5

2 Marks Questions

1. What is CDSCO
2. What is COPP
3. What is MOU
4. Why COPP is required by pharmaceutical industry

5 Marks Questions

1. Discuss about the responsibility of state council authority
2. Write various function of CDSCO
3. Write a note on MOU

10 Marks Questions

1. Explain COPP in detail.
2. Write about Regulatory requirements and approval procedures for New Drugs

9. QUESTION BANK (ORAL)

1. Technology transfer is
 - A Purpose-oriented
 - B Process- oriented
 - C Technology- oriented
 - D Commercial- oriented
2. Binding to die walls can also be overcome by designing the die to be inch wider the upper than at the centre in order to relieve pressure during ejection.
 - A 0.001 to 0.005
 - B 0.01 to 0.05
 - C 0.001 to 0.05
 - D 0.01 to 0.005
3. Parameter to be considered for scale up of Fluidized bed dryer
 - A Optimum load
 - B Air flow rate
 - C Inlet air temperature and humidity of the incoming air
 - D All of above
4. NDA takes
 - A 12 years
 - B 15 years
 - C 10 years
 - D 5 years
5. Types of TT involves
 - A Vertical
 - B Horizontal
 - C A & b BOTH
 - D None

6. Design space includes
- A Variables and process parameters
 - B Attributes
 - C DMF
 - D Process parameters
7. Identification of critical elements of a process is also known as
- A Design space
 - B Gap analysis
 - C IPQC
 - D Acceptance criteria
8. Which of the following guideline provides principles for QRM ?
- A Q8
 - B Q9
 - C Q10
 - D Q11
9. The art of designing of prototype using the data obtained from the pilot plant model
- A Scaling
 - B Art work
 - C Scale up
 - D Model design
10. Full form of HVAC
- A Heating, ventilation, and air cooling
 - B Heat, ventilation, and air conditioning
 - C Heating, ventilation, and air conditioning
 - D None of above
11. APCTT Was established in
- A Pune
 - B Delhi
 - C Geneva
 - D Bangalore
12. DIB stands for
- A Drug information board
 - B Drug investigational board
 - C Drug information branch
 - D None of above
13. In NDA Classification of drugs is done in
- A 7 class
 - B 5 class
 - C 6 class
 - D 4 class
14. ANDA takes
- A 2-5 years
 - B 5-10 years
 - C 1-2 years
 - D 5-8 years

15. There are Phases of clinical trials

- A 4
- B 3
- C 2
- D 5

16. Food, drug and cosmetic act (FD&C Act) comes in

- A Since 1938
- B since 1945
- C since 1935
- D since 1940

17. Kefauver-Harris Amendments to the FD & C Act comes in

- A 1956
- B 1968
- C 1972
- D 1962

18. CoPP format is recommended by the

- A GMP
- B FDA
- C WHO
- D all of the above

19 pilot CoPP is issued by

- A GMP
- B U S FDA
- C WHO
- D CDSCO

20. NDA Can consist of as many as Sections.

- A 17
- B 16
- C 15
- D 13

21. Which of following is certification system for laboratory accreditation?

- A ISO
- B WHO
- C NABL
- D GMP

22. . ——— Guideline of ICH describes Quality management system

- A ICH Q8
- B ICH Q9
- C ICH Q10
- D ICH Q11

23. The words Quality comes from

- A Latin word
- B English word
- C Greek words
- D Sanskrit words

24. What Is The Meaning Of User Based Quality?

- A fitness for use
- B at right time

- C accurate measurement
- D right quality for use

25. Who gave definition of quality?

- A Joseph M. JURAN
- B Philip Crosby
- C John Ruskin
- D Armand Feigenbaum

26. Who is the father of quality evaluation?

- A Dr. W Edward Deming
- B John Ruskin
- C Armand Feigenbaum
- D Joseph M. Juran

27. TQM is _____ oriented system.

- A personal
- B method
- C system
- D procedure

28. the drug and cosmetic act comes on

- A 1940
- B 1950
- C 1955
- D 1960

29. the headqoter of CDSCO is located at

- A New Delhi
- B Kolkata
- C MUMBAI
- D Chennai

30. Which one is not the zonal office o0f CDSCO.

- A Bangalore
- B Kolkata
- C Mumbai
- D Chennai

31. sub zonal office of CDSCO

- A Goa
- B Indoor
- C Varanasi
- D All Of The Above

32. Central drug laboratory of CDSCO is situated at.

- A kasauli
- B Kolkata
- C both A and B
- D Chennai

33. Price charged for a technology should depend upon following:

- A Technology
- B High profit
- C Research cost
- D Market force

34. Research phase of technology transfer involves:
- A Design of procedure
 - B Selection of excipients
 - C identification of excipients
 - D All of above
35. Colored Ribbon Is Design dated The
- A Certificate of COPP
 - B color of COPP
 - C Type Of COPP
 - D None of the above
36. For easy handling order which system should be followed?
- A LIFO
 - B FIFO
 - C Above both
 - D None of above
37. State the other name of dry granulation?
- A Mixing
 - B Reduction
 - C Slugging
 - D Blending
38. Which of the following is not a part of space requirement in general consideration of pilot plant?
- A Physical testing area
 - B Standard equipment floor space
 - C Storage area
 - D Raw material
39. What the term scale up means:
- A Increasing batch size
 - B Decreasing batch size
 - C Increasing production rate
 - D Increasing quality of batch
40. What the term scale down means:
- A Increasing batch size
 - B Decreasing batch size
 - C Increasing production rate
 - D Increasing quality of batch

10. ATTENDANCE RECORD

Subject: <u>Industrial Pharmacy</u>		Faculty: <u>K. K. K.</u>		Section: <u>2021-22</u>		Semester: <u>7th</u>	
		Date		L/T/P			
Sl.No.	Roll No.	Name	1	2	3	4	5
1.	2013301001	Aarti Thakur	1	2	3	4	5
2.	2	Aayush	1	2	3	4	5
3.	3	Ashish Thakur	1	2	3	4	5
4.	4	Aditya	1	2	3	4	5
5.	5	Aditya Nathania	1	2	3	4	5
6.	6	Akshita	1	2	3	4	5
7.	7	Akshita Sharma	1	2	3	4	5
8.	8	Aman Sharma	1	2	3	4	5
9.	9	Anand Kumar	1	2	3	4	5
10.	10	Anshu Kumar	1	2	3	4	5
11.	11	Anshu Kumar	1	2	3	4	5
12.	12	Anshu Kumar	1	2	3	4	5
13.	13	Anshu Kumar	1	2	3	4	5
14.	14	Anshu Kumar	1	2	3	4	5
15.	15	Anshu Kumar	1	2	3	4	5
16.	16	Anshu Kumar	1	2	3	4	5
17.	17	Anshu Kumar	1	2	3	4	5
18.	18	Anshu Kumar	1	2	3	4	5
19.	19	Anshu Kumar	1	2	3	4	5
20.	20	Anshu Kumar	1	2	3	4	5
21.	21	Anshu Kumar	1	2	3	4	5
22.	22	Anshu Kumar	1	2	3	4	5
23.	23	Anshu Kumar	1	2	3	4	5
24.	24	Anshu Kumar	1	2	3	4	5
25.	25	Anshu Kumar	1	2	3	4	5
26.	26	Anshu Kumar	1	2	3	4	5
27.	27	Anshu Kumar	1	2	3	4	5
28.	28	Anshu Kumar	1	2	3	4	5
29.	29	Anshu Kumar	1	2	3	4	5
30.	30	Anshu Kumar	1	2	3	4	5
31.	31	Anshu Kumar	1	2	3	4	5
32.	32	Anshu Kumar	1	2	3	4	5
33.	33	Anshu Kumar	1	2	3	4	5

Subject: <u>Industrial Pharmacy</u>		Faculty: <u>K. K. K.</u>		Section: <u>2021-22</u>		Semester: <u>7th</u>	
		Date		L/T/P			
Sl.No.	Roll No.	Name	1	2	3	4	5
1.	2013301001	Aarti Thakur	1	2	3	4	5
2.	2	Aayush	1	2	3	4	5
3.	3	Ashish Thakur	1	2	3	4	5
4.	4	Aditya	1	2	3	4	5
5.	5	Aditya Nathania	1	2	3	4	5
6.	6	Akshita	1	2	3	4	5
7.	7	Akshita Sharma	1	2	3	4	5
8.	8	Aman Sharma	1	2	3	4	5
9.	9	Anand Kumar	1	2	3	4	5
10.	10	Anshu Kumar	1	2	3	4	5
11.	11	Anshu Kumar	1	2	3	4	5
12.	12	Anshu Kumar	1	2	3	4	5
13.	13	Anshu Kumar	1	2	3	4	5
14.	14	Anshu Kumar	1	2	3	4	5
15.	15	Anshu Kumar	1	2	3	4	5
16.	16	Anshu Kumar	1	2	3	4	5
17.	17	Anshu Kumar	1	2	3	4	5
18.	18	Anshu Kumar	1	2	3	4	5
19.	19	Anshu Kumar	1	2	3	4	5
20.	20	Anshu Kumar	1	2	3	4	5
21.	21	Anshu Kumar	1	2	3	4	5
22.	22	Anshu Kumar	1	2	3	4	5
23.	23	Anshu Kumar	1	2	3	4	5
24.	24	Anshu Kumar	1	2	3	4	5
25.	25	Anshu Kumar	1	2	3	4	5
26.	26	Anshu Kumar	1	2	3	4	5
27.	27	Anshu Kumar	1	2	3	4	5
28.	28	Anshu Kumar	1	2	3	4	5
29.	29	Anshu Kumar	1	2	3	4	5
30.	30	Anshu Kumar	1	2	3	4	5
31.	31	Anshu Kumar	1	2	3	4	5
32.	32	Anshu Kumar	1	2	3	4	5
33.	33	Anshu Kumar	1	2	3	4	5

Subject Industrial Pharmacy Faculty KV
Class B.I.PH

Sl.No.	Roll No.	Name	1
		Date <u>16/11</u>	
		L/T/P	
1.	21013314001	Aarti Thakur	1
2.	2	Aayon	1
3.	3	Abhishek Thakur	1
4.	4	Aditya	1
5.	5	Aditya Pathania	1
6.	6	Akanksha	1
7.	7	Akhi Sharma	1
8.	8	Aman Sharma	1
9.	9	Anchal Kumari	1
10.	11	Ashika Kumari	1
11.	12	Ashika Thakur	1
12.	13	Arunhati Rana	1
13.	14	Aryan Singh Mahes	1
14.	15	Ayush Thakur	1
15.	17	Ayush Sharma	1
16.	18	Bhakti Dood	1
17.	19	Deeksha Kumari	1
18.	20	Dhruv Kumar	1
19.	21	Diksha Kaundal	1
20.	22	Disha	1
21.	23	Esha	1
22.	24	Isha Thakur	1
23.	27	Kanika Kaushal	1
24.	28	Karan	1
25.	29	Kartik Sharma	1
26.	30	Komal	1
27.	31	Kushika	1
28.	32	Lakshit	1
29.	33	Manisha	1

	49	50	51	52	53	54	55	56	57	58	59
	49	50	51	52	53	54	55	56	57	58	59
01	46	47	48	49	50	51	52	53			
02	47	48	49	50	51	52	53	54			
03	46	47	48	49	50	51	52	53			
04	46	47	48	49	50	51	52	53			
05	48	49	50	51	52	53	54	55			
06	48	49	50	51	52	53	54	55			
07	46	47	48	49	50	51	52				
08	48	49	50	51	52	53	54	55			
09	48	49	50	51	52	53	54	55			
11	48	49	50	51	52	53	54				
12	46	47	48	49	50	51	52	53			
13	49	50	51	52	53	54	55	56			
14	46	47	48	49	50	51	52	53			
15	47	48	49	50	51	52	53	54			
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18	48	49	50	51	52	53	54	55			
19	48	49	50	51	52	53	54	55			
20	47	48	49	50	51	52	53	54			
21	47	48	49	50	51	52	53	54			
22	48	49	50	51	52	53	54	55			
23	46	47	48	49	50	51	52	53			
26	48	49	50	51	52	53	54	55			
27	46	47	48	49	50	51	52	53			
28	47	48	49	50	51	52	53	54			
29	49	50	51	52	53	54	55	56			
30	49	50	51	52	53	54	55	56			
31	48	49	50	51	52	53	54	55			
32	47	48	49	50	51	52	53	54			
33	48	49	50	51	52	53	54	55			

Subject Industrial Pharmacy Faculty Kyran
II Class L. K. Rao

Sl.No.	Roll No.	Name	1
		Date	6/7
		LT/IP	
30	34	Meghna	1
31	35	Mohit Gwalia	1
32	36	Mohit Sharma	1
33	37	Muskan	1
34	38	Namisha Sharma	1
35	39	Nidhi Sharma	1
36	40	Nikhil Kumar	1
37	41	Niraj Kumar	1
38	42	Nishant Sharma	1
39	43	Palvi	1
40	44	Pavai	1
41	45	Priyanka Devi	1
42	46	Priyush Kachhap	1
43	47	Pannam Pahal	1
44	48	Pragya Rana	1
45	49	Prakhar Rana	1
46	50	Prince Verma	1
47	51	Raina Chandel	1
48	52	Rishika Devi	1
49	53	Rohini Kumar	1
50	54	Rohini	1
51	55	Rishika Sharma	1
52	56	Rishi	1
53	57	Sahil Sharma	1
54	58	Sakshi Sharma	1
55	59	Sakshi Thakur	1
56	60	Sakshi Thakur	1
57	61	Shruti Kumari	1
58	62	Shivani Thakur	1

49	50	51	52	53	54	55	56	57	58	59
11	5	6	11	12	13	16	17			
34	48	49	50	51	52	53	54	55		
35	47	48	49	50	51	52	53	54		
36	45	46	47	48	49	50	51	52		
37	48	49	50	51	52	53	54	55		
38	48	49	50	51	52	53	54	55		
39	48	49	50	51	52	53	54	55		
40	47	48	49	50	51	52	53	54		
41	49	50	51	52	53	54	55	56		
42	45	46	47	48	49	50	51	52		
43	48	49	50	51	52	53	54	55		
44	48	49	50	51	52	53	54	55		
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60	48	49	50	51	52	53	54	55		
61	48	49	50	51	52	53	54	55		
62	48	49	50	51	52	53	54	55		

Subject <u>Industrial Pharmacy</u> Faculty <u>KKS</u>			1
Class <u>B.Ph</u>			
Date <u>10/1</u>			
L/T/P			
Sl.No.	Roll No.	Name	
59	63	Soumya	1
60	64	Soumya Patil	1
61	65	Sujal Saini	1
62	66	Sumit Kumar	1
63	67	Sumit Kumar	1
64	68	Tarundeep Kaurhal	1
65	69	Michael Kumar	1
66	2202334401	Ashwini Thakur	1
67	2	Akash	1
68	3	Rohit R. Patil	1
69	4	K.H.B. Kumar	1
70	5	Ritik Saini	1

40	50	51	52	53	54	55	56	57	58
41	5	6	11	12	13	14	15	16	17
63	47	48	49	50	51	52	53	54	
64									
65	44	45	46	47	48	49	50	51	
66	45	46	47	48	49	50	51	52	
67	46	47	48	49	50	51	52	53	
68	46	47	48	49	50	51	52	53	
69	48	49	50	51	52	53	54	55	
001	47	48	49	50	51	52	53	54	
002	48	49	50	51	52	53	54	55	
003	46	47	48	49	50	51	52	53	
004	46	47	48	49	50	51	52	53	
005	47	48	49	50	51	52	53	54	

11. CONTINUOUS ASSESMENT

Component	Components of Evaluation	Nature of exam
Theory	First sessional exam	Multiple choice questions, Short essay and long essay questions
	Second sessional exam	Multiple choice questions, Short essay and long essay questions
Practicals	Daily evaluation	Maintaining observation notebook, viva-voce
	Practical examination	Synopsis and viva-voce, major experiment and minor experiment
	Laboratory manual	Communication, data interpretation
Beyond syllabus	Assignments Tests Seminar Quiz	
Overall evaluation	External exam – semester wise	Multiple choice questions, Short essay and long essay questions

Gautam College of Pharmacy, Hamirpur											
Sessional & Continuous Mode Sheet, Semester: 7th											
Award Sheet (Theory & Practical) Sessional Examination (Session August - December 2024)											
Sr.No	Student Name	Roll.No	Subject Name & Code: Industrial Pharmacy-II, Code: BP-702 T								
			Theory								
			Sessional Exam				Continuous Mode			CM (T2)	TM/25 (T1+T2)
			1st	2nd	3rd	Avg/30	Computat For/25 (T1)	Attendance	Academic activities		
1	Aarti Thakur	21013314001	30	30	30	18	9	4	3	3	10
2	Aaryan	21013314002	5	5	25	16	8	4	2	2	8
3	Abhishek Thakur	21013314003	8	0	23	16	8	3	2	3	8
4	Aditya	21013314004	23	24	24	24	12	4	3	3	10
5	Aditya Pathania	21013314005	15	30	28	24	12	4	3	3	10
6	Akanksha	21013314006	22	28	25	25	13	4	3	3	10
7	Akshat Sharma	21013314007	10	9	25	18	9	4	3	3	10
8	Aman Sharma	21013314008	22	21	22	21	11	4	3	3	10
9	Anchal Kumari	21013314009	22	28	25	25	13	4	3	3	10
10	Anshu Kumar	21013314010	25	25	25	25	13	4	3	3	10
11	Aryan Thakur	21013314011	7	2	20	17	9	3	3	3	9
12	Arundhati Rana	21013314012	29	25	28	29	15	4	3	3	10
13	Aryas Singh Mathias	21013314013	3	5	23	14	7	3	3	3	6
14	Aryan Thakur	21013314014	Absent	Absent	25	13	7	4	3	3	10
15	Anil Sharma	21013314015	21	23	22	22	11	4	3	3	10
16	Bharti Doshi	21013314016	23	23	23	23	12	4	3	3	10
17	Deeksha Kumari	21013314017	21	Absent	22	22	11	4	3	3	10
18	Dheeraj Kumar	21013314018	17	9	26	22	11	4	3	3	10
19	Diksha Koundal	21013314019	22	27	25	25	13	4	3	3	10
20	Disha	21013314020	24	25	25	25	13	4	3	3	10
21	Esha	21013314021	20	23	21	21	11	4	3	3	10
22	Isha Thakur	21013314022	21	25	23	23	12	4	3	3	10
23	Kaushik Kumbhal	21013314023	18	22	20	20	10	4	3	3	10

24	Karan	21013314024	21	0	24	23	12	4	3	3	10
25	Kartik Sharma	21013314025	25	27	25	25	13	4	3	3	10
26	Kunal	21013314026	27	28	28	28	14	4	3	3	10
27	Kritika Rathi	21013314027	14	24	19	19	10	4	3	3	10
28	Lakshmi Sharma	21013314028	3	8	15	15	8	4	3	3	10
29	Manisha Kumari	21013314029	25	27	26	26	13	4	3	3	10
30	Maghan	21013314030	23	27	20	20	10	4	3	3	10
31	Mehar Guleria	21013314031	19	10	15	15	8	4	3	3	10
32	Mohit Sharma	21013314032	11	Absent	24	18	9	3	3	3	9
33	Muskan	21013314033	26	28	27	27	14	4	3	3	10
34	Namisha Sharma	21013314034	20	27	24	24	12	4	3	3	10
35	Nidhi Sharma	21013314035	22	28	25	25	13	4	3	3	10
36	Nidhi Kumar	21013314036	20	25	23	23	12	4	3	3	10
37	Nidhi Kumar	21013314037	19	25	22	22	11	4	3	3	10
38	Nishant Sharma	21013314038	Absent	0	28	14	7	3	3	3	9
39	Pahar	21013314039	23	27	25	25	13	4	3	3	10
40	Payal	21013314040	23	26	26	26	13	4	3	3	10
41	Prachi Devi	21013314041	20	28	24	24	12	4	3	3	10
42	Priyank Kashyap	21013314042	15	16	16	16	8	4	3	3	10
43	Poonam Pahal	21013314043	28	29	29	29	15	4	3	3	10
44	Pragya Rana	21013314044	26	27	27	27	14	4	3	3	10
45	Prashant Rana	21013314045	27	29	28	28	14	4	3	3	10
46	Prince Varma	21013314046	21	19	20	20	10	4	3	3	10
47	Priya Chandel	21013314047	21	27	24	24	12	4	3	3	10
48	Priyanka Devi	21013314048	25	25	25	25	13	4	3	3	10
49	Rahul Kumar	21013314049	1	7	15	15	8	4	3	3	10
50	Ravi	21013314050	0	2	13	7	3	3	3	3	9
51	Richa Sharma	21013314051	26	25	26	26	13	4	3	3	10
52	Rishi Kumar	21013314052	4	26	24	24	12	4	3	3	10
53	Sahil Sharma	21013314053	11	23	17	17	9	4	3	3	10
54	Sakshi Sharma	21013314054	25	25	25	25	13	4	3	3	10
55	Shagun Thakur	21013314055	25	27	26	26	13	4	3	3	10
56	Shakam	21013314056	16	22	19	19	10	4	3	3	10
57	Sheetal Kumari	21013314057	24	26	25	25	13	4	3	3	10

58	Shivani Thakur	21013314058	22	26	24	24	12	4	3	3	10
59	Sourav	21013314059	14	9	26	20	10	4	3	3	10
60	Sojal Saxi	21013314060	15	3	24	20	10	4	2	3	9
61	Sumit Kumar	21013314061	Absent	13	18	18	9	4	2	2	8
62	Sumit Kumar	21013314062	5	0	23	14	7	4	2	2	8
63	Tarun Deep Kaulhal	21013314063	Absent	2	24	13	7	3	2	3	8
64	Vishal Kumar	21013314064	21	22	22	22	11	4	3	3	10
65	Ashay Thakur	22023314065	17	17	17	17	9	4	3	3	10
66	Akash	22023314066	25	20	28	24	12	4	3	3	10
67	Rajat Bhunia	22023314067	17	11	14	14	7	4	2	3	9
68	Rishik Kumar	22023314068	Absent	Absent	13	13	7	3	2	3	8
69	Rishik Saini	22023314069	18	15	17	17	9	4	3	3	10

Subject Incharge

U/C Examination

U/C Academic

Director cum Principal

12. SESSIONAL I: QUESTION PAPER, ATTENDANCE RECORD, RESULT

QUESTUION PAPER

Gautam College of Pharmacy, Hamirpur
B. Pharmacy First Sessional Theory Examination Sep 2024

Subject: Industrial Pharmacy-I **Sub. Code: BP 702T**
Sem: 7th **Time: 1:00 hrs** **MM: 30**

Attempt any one question from section A, two questions from section B, and section C is compulsory.

Section A (1x10=10)

Q.1 What is Pilot plant scaleup? Describe in detail the general considerations for any pilot plant scaleup technology.
Q.2 Discuss in detail about the scale up technique for solid dosage form.

Section B (5x2=10)

Q.3 Explain the technology transfer protocol following WHO guidelines.
Q.4 Discuss about quality risk management in detail.
Q.5 Write a note on technology transfer agencies in India.
Q.6 Write a note on SUPAC guidelines.

Section C (2 Marks each)

Q.7 a) Define platform technology and its application. b) Define In-process control c) Define DMF
d) Define Validation master plan e) Define finished pharmaceutical products

ATTENDANCE RECORD

Gautam College Of Pharmacy, Haringar									
Attendance Sheet									
1st Sessional Examination September 2024									
Date		23-09-2024		24-09-2024		25-09-2024		26-09-2024	
Session		Morning		Evening		Morning		Evening	
Subject Code		BP 701T		BP 702T		BP 703T		BP 704T	
Sl No.	Roll No.	Student Name	BP 701T	BP 702T	BP 703T	BP 704T	BP 705T Labral Entry	BP 706 PS	
1	21013314001	Aarti Thakur	Aarti	Aarti	Aarti				
2	21013314002	Aaryan	Aaryan	Aaryan	Aaryan	Aaryan			
3	21013314003	Akhil's Thakur	Akhil's	Akhil's	Akhil's	Akhil's			
4	21013314004	Aditya	Aditya	Aditya	Aditya	Aditya			
5	21013314005	Aditya Pattnaik	Aditya	Aditya	Aditya	Aditya			
6	21013314006	Akash	Akash	Akash	Akash	Akash			
7	21013314007	Akhil Sharma	Akhil	Akhil	Akhil	Akhil			
8	21013314008	Aman Sharma	Aman	Aman	Aman	Aman			
9	21013314009	Anchal Kumar	Anchal	Anchal	Anchal	Anchal			
10	21013314011	Anshu Kumar	Anshu	Anshu	Anshu	Anshu			
11	21013314012	Arjun Thakur	Arjun	Arjun	Arjun	Arjun			
12	21013314013	Arunachal Rana	Arunachal	Arunachal	Arunachal	Arunachal			
13	21013314014	Arjun Singh Mahajan	Arjun	Arjun	Arjun	Arjun			
14	21013314015	Arjun Thakur	Absent	Absent	Absent	Absent			
15	21013314017	Atul Sharma	Atul	Atul	Atul	Atul			
16	21013314018	Bharti Dand	Bharti	Bharti	Bharti	Bharti			
17	21013314019	Deeksha Kumar	Deeksha	Deeksha	Deeksha	Deeksha			
18	21013314020	Dhruv Kumar	Dhruv	Dhruv	Dhruv	Dhruv			
19	21013314021	Disha Khandel	Disha	Disha	Disha	Disha			
20	21013314022	Disha	Disha	Disha	Disha	Disha			
21	21013314023	Esha	Esha	Esha	Esha	Esha			
22	21013314026	Isha Thakur	Isha	Isha	Isha	Isha			
23	21013314027	Kanika Khandel	Kanika	Kanika	Kanika	Kanika			
24	21013314028	Karan	Karan	Karan	Karan	Karan			
25	21013314029	Karish Sharma	Karish	Karish	Karish	Karish			
26	21013314030	Komal	Komal	Komal	Komal	Komal			
27	21013314031	Kritika Ravi	Kritika	Kritika	Kritika	Kritika			
28	21013314032	Lakshmi Sharma	Lakshmi	Lakshmi	Lakshmi	Lakshmi			
29	21013314033	Manisha Kumar	Manisha	Manisha	Manisha	Manisha			
30	21013314034	Meghna	Meghna	Meghna	Meghna	Meghna			
31	21013314035	Mohit Galaria	Mohit	Mohit	Mohit	Mohit			
32	21013314036	Mohit Sharma	Mohit	Mohit	Mohit	Mohit			
33	21013314037	Muskan	Muskan	Muskan	Muskan	Muskan			
34	21013314038	Namisha Sharma	Namisha	Namisha	Namisha	Namisha			
35	21013314039	Nishi Sharma	Nishi	Nishi	Nishi	Nishi			

36	21013314040	Nikhil Kumar	Nikhil Kumar	Nikhil Kumar	Nikhil Kumar	Nikhil Kumar
37	21013314041	Nikhil Kumar	Nikhil Kumar	Nikhil Kumar	Nikhil Kumar	Nikhil Kumar
38	21013314042	Nishant Sharma	Rana	Rana	Rana	Absent
39	21013314043	Palvi	Palvi	Palvi	Palvi	Palvi
40	21013314044	Payal	Payal	Payal	Payal	Payal
41	21013314045	Phulma Devi	Phulma	Phulma	Phulma	Phulma
42	21013314046	Piyush Kadiyap	Piyush	Piyush	Piyush	Piyush
43	21013314047	Poonam Patyal	Patyal	Patyal	Patyal	Patyal
44	21013314048	Pragya Rana	Pragya	Pragya	Pragya	Pragya
45	21013314049	Prashant Rana	Prashant Rana	Prashant Rana	Prashant Rana	Prashant Rana
46	21013314050	Prince Verma	Prince	Prince	Prince	Prince
47	21013314051	Priya Chandel	Priyachandel	Priyachandel	Priyachandel	Priyachandel
48	21013314052	Priyanka Devi	Priyanka	Priyanka	Priyanka	Priyanka
49	21013314053	Rahul Kumar	Rahul	Rahul	Rahul	Rahul
50	21013314054	Rashav	Rashav	Rashav	Rashav	Rashav
51	21013314055	Rishi Sharma	Rishi Sharma	Rishi Sharma	Rishi Sharma	Rishi Sharma
52	21013314056	Rishabh Kumar	Rishabh	Rishabh	Rishabh	Rishabh
53	21013314057	Sahil Sharma	Sahil	Sahil	Sahil	Sahil
54	21013314058	Sakshi Sharma	Sakshi	Sakshi	Sakshi	Sakshi
55	21013314059	Shagun Thakur	Shagun	Shagun	Shagun	Shagun
56	21013314060	Shakam	Shakam	Shakam	Shakam	Shakam
57	21013314061	Sheetal Kumari	Sheetal	Sheetal	Sheetal	Sheetal
58	21013314062	Shivani Thakur	Shivani	Shivani	Shivani	Shivani
59	21013314063	Sourav	Sourav	Sourav	Sourav	Sourav
60	21013314064	Sourav Patyal	Absent	Absent	Absent	Absent
61	21013314065	Sujal Saini	Sujal	Sujal	Sujal	Sujal
62	21013314066	Sumit Kumar	Absent	Absent	Absent	Absent
63	21013314067	Sumit Kumar	Sumit	Sumit	Sumit	Sumit
64	21013314068	Tarun Deep Kaulhal	Tarun	Absent	Tarun	Absent
65	21013314069	Vishal Kumar	Vishal	Vishal	Vishal	Vishal
66	22023314001	Abhay Thakur	Abhay	Abhay	Abhay	Abhay
67	22023314002	Akash	Akash	Akash	Akash	Akash
68	22023314003	Rajat Bhatia	Rajat	Rajat	Rajat	Rajat
69	22023314004	Ritik Kumar	Absent	Absent	Absent	Absent
70	22023314005	Ritik Saini	Ra	Ra	Ra	Ra
Present						
Absent						
Total strength						

Vc Samant

Vc Academic

Director cum Principal

RESULT

Gautam College Of Pharmacy , Hamirpur			
Awards List, 1st, Sessional Examination September 2024, Semester: 7th			
Subject Code: BP702 T Subject Name: Industrial Pharmacy-II			
Date			1st Sessional
			Max Marks (30)
Subject Code			
Sr No.	Roll No.	Student Name	
1	21013314001	Aarti Thakur	17
2	21013314002	Aaryan	6
3	21013314003	Abhishek Thakur	8
4	21013314004	Aditya	23
5	21013314005	Aditya Pathania	15
6	21013314006	Akanksha	22
7	21013314007	Akhil Sharma	10
8	21013314008	Aman Sharma	22
9	21013314009	Anchal Kumari	22
10	21013314011	Archna Kumari	25
11	21013314012	Arpan Thakur	7
12	21013314013	Arundhati Rana	29
13	21013314014	Aryan Singh Manhas	3
14	21013314015	Aryan Thakur	Absent
15	21013314017	Atul Sharma	21
16	21013314018	Bharti Doad	23
17	21013314019	Deeksha Kumari	21
18	21013314020	Dheeraj Kumar	17
19	21013314021	Diksha Koundal	22
20	21013314022	Disha	24
21	21013314023	Esha	20
22	21013314026	Isha Thakur	21
23	21013314027	Kanika Kaushal	18
24	21013314028	Karan	21
25	21013314029	Kartik Sharma	25
26	21013314030	Komal	27
27	21013314031	Kritika Rahi	14
28	21013314032	Lakshit Sharma	2
29	21013314033	Manisha Kumari	25
30	21013314034	Meghna	23
31	21013314035	Mohit Guleria	19
32	21013314036	Molli Sharma	11
33	21013314037	Muskan	26
34	21013314038	Namisha Sharma	20
35	21013314039	Nidhi Sharma	22
36	21013314040	Nikhil Kumar	20
37	21013314041	Nikhil Kumar	19
38	21013314042	Nishant Sharma	Absent
39	21013314043	Palvi	23
40	21013314044	Payal	23
41	21013314045	Phulma Devi	20

42	21013314046	Piyush Kashyap	15
43	21013314047	Poonam Patyal	28
44	21013314048	Pragya Rana	26
45	21013314049	Prashant Rana	27
46	21013314050	Prince Verma	21
47	21013314051	Priya Chandel	21
48	21013314052	Priyanka Devi	25
49	21013314053	Rahul Kumar	1
50	21013314054	Rashav	0
51	21013314055	Richa Sharma	26
52	21013314056	Ritish Kumar	4
53	21013314057	Sahil Sharma	11
54	21013314058	Sakshi Sharma	25
55	21013314059	Shagun Thakur	25
56	21013314060	Shaksam	16
57	21013314061	Sheetal Kumari	24
58	21013314062	Shivani Thakur	22
59	21013314063	Sourav	14
60	21013314064	Sourav Patiyal	Absent
61	21013314065	Sujal Saini	15
62	21013314066	Sumit Kumar	Absent
63	21013314067	Sumit Kumar	5
64	21013314068	Tarun Deep Kaushal	Absent
65	21013314069	Vishal Kumar	21
66	22023314001	Abhay Thakur	17
67	22023314002	Akash	25
68	22023314003	Rajat Bhatia	17
69	22023314004	Ritik Kumar	Absent
70	22023314005	Ritik Saini	18
Present			64
Absent			6
Total strength			70

Sumati Dandia
Signature of Subject
Incharge

[Signature]
I/c
Examination

[Signature]
I/c
Academics

[Signature]
Director
Cum
Principal.

13. SESSIONAL II: QUESTION PAPER, ATTENDANCE RECORD, RESULT

QUESTUION PAPER

Gautam College of Pharmacy, Hamirpur
B. Pharmacy Second sessional examination 2024

Subject: Industrial Pharmacy-II

Subject code: BP-702T

Time: 1 h

MM: 30

Attempt all question from section A. attempt any one question from section B and two question from section C.

Section A

Q.1(a) What is regulatory affairs & its goal. (b) GMP (c) TQM (d) QBD (e) Enlist the various Indian drug regulatory bodies. (f) NABL (g) Write objectives of DRAs (h) Clinical Trials (i) Define Electronic documentation. (j) Define Quality Assurance.

Section B

Q.1 Write a short note on GLP. Discuss the process of NABL accreditation for laboratory.

Q.2 Explain Investigation's brochure. What do you understand by IND also give information & instructions of IND applications.

Section C

Q.1 Define Quality risk management. Discuss the various risk management tools and methodologies.

Q.2 Define drug metabolism and toxicology. What do you mean by "non clinical drug development".

Q.3 Explain the responsibilities of regulatory affairs professionals. Q.4 Describe the steps of data presentation for FDA submissions.

ATTENDANCE RECORD

Gautama College Of Pharmacy, Hapur							
Attendance Sheet							
2nd Sessional Examination October 2024 7 th Sem							
Date		24-10-2024		25-10-2024		26-10-2024	
Session		Morning	Evening	Morning	Evening	Morning	Evening
Subject Code		HP 701T	HP 702T	HP 703T	HP 704T	HP 105T Labral Entry	HP 700 PS
Sl. No.	Roll No.	Student Name					
1	21013314001	Aarti Thakur	Aarti	Aarti	Aarti		Aarti
2	21013314002	Aaryani	Aaryani	Aaryani	Aaryani		
3	21013314003	Abhinav Thakur	Abhinav	Abhinav	Abhinav		Abhinav
4	21013314004	Aditya	Aditya	Aditya	Aditya		Aditya
5	21013314005	Aditya Pathania	Aditya	Aditya	Aditya		Aditya
6	21013314006	Akanksha	Akanksha	Akanksha	Akanksha		Akanksha
7	21013314007	Akhil Sharma	Akhil	Akhil	Akhil		Akhil
8	21013314008	Anam Sharma	Anam	Anam	Anam		Anam
9	21013314009	Anchal Kumari	Anchal	Anchal	Anchal		Anchal
10	21013314011	Archana Kumari	Archana	Archana	Archana		Archana
11	21013314012	Aryan Thakur	Aryan	Aryan	Aryan		Aryan
12	21013314013	Arundhati Rana	Arundhati	Arundhati	Arundhati		Arundhati
13	21013314014	Aryan Singh	Aryan	Aryan	Aryan		Aryan
14	21013314015	Aryan Thakur	Absent	Absent	Absent		
15	21013314017	Ash Sharma	Ash	Ash	Ash		Ash
16	21013314018	Bharti Dood	Bharti	Bharti	Bharti		Bharti
17	21013314019	Deeksha Kumari	Absent	Absent	Absent		
18	21013314020	Dheeraj Kumar	Dheeraj	Dheeraj	Dheeraj		Dheeraj
19	21013314021	Diksha Koundal	Diksha	Diksha	Diksha		Diksha
20	21013314022	Disha	Disha	Disha	Disha		Disha
21	21013314023	Esha	Esha	Esha	Esha		Esha
22	21013314026	Isha Thakur	Isha	Isha	Isha		Isha
23	21013314027	Kanika Khandel	Kanika	Kanika	Kanika		Kanika
24	21013314028	Karan	Karan	Karan	Karan		Karan
25	21013314029	Kartik Sharma	Kartik	Kartik	Kartik		Kartik Sharma
26	21013314030	Komal	Komal	Komal	Komal		Komal
27	21013314031	Kritika Rathi	Kritika	Kritika	Kritika		Kritika
28	21013314032	Lakshmi Sharma	Lakshmi	Lakshmi	Lakshmi		Lakshmi
29	21013314033	Manisha Kumari	Manisha	Manisha	Manisha		Manisha

30	21013314034	Meghna	Meghna	Meghna	Meghna	Meghna	Meghna
31	21013314035	Mohit Gulera	Mohit	Mohit	Mohit	Mohit	Mohit
32	21013314036	Mohit Sharma	Absent	Absent	Absent	Absent	
33	21013314037	Muskan	Muskan	Muskan	Muskan	Muskan	Muskan
34	21013314038	Namisha Sharma	Namisha	Namisha	Namisha	Namisha	Namisha
35	21013314039	Nidhi Sharma	Nidhi Sharma	Nidhi Sharma	Nidhi Sharma	Nidhi Sharma	Nidhi Sharma
36	21013314040	Nikhil Kumar	Nikhil Kumar	Nikhil Kumar	Nikhil Kumar	Nikhil Kumar	Nikhil Kumar
37	21013314041	Nikhil Kumar	Nikhil	Nikhil	Nikhil	Nikhil	Nikhil
38	21013314042	Nishant Sharma	Nishant	Nishant	Nishant	Nishant	Nishant
39	21013314043	Palvi	Palvi	Palvi	Palvi	Palvi	Palvi
40	21013314044	Payal	Payal	Payal	Payal	Payal	Payal
41	21013314045	Phulma Devi	Phulma	Phulma	Phulma	Phulma	Phulma
42	21013314046	Piyush Kashyap	Piyush	Piyush	Piyush	Piyush	Piyush
43	21013314047	Poonam Patyal	Poonam	Poonam	Poonam	Poonam	Poonam
44	21013314048	Pragya Rana	Pragya	Pragya	Pragya	Pragya	Pragya
45	21013314049	Prashant Rana	Prashant Rana	Prashant Rana	Prashant Rana	Prashant Rana	Prashant Rana
46	21013314050	Prince Verma	Prince	Prince	Prince	Prince	Prince
47	21013314051	Priya Chandel	Priyachandl	Priyachandl	Priyachandl	Priyachandl	Priyachandl
48	21013314052	Priyanka Devi	Priyanka	Priyanka	Priyanka	Priyanka	Priyanka
49	21013314053	Rahul Kumar	SARIN	SARIN	SARIN	SARIN	SARIN
50	21013314054	Rashav	Rashav	Rashav	Rashav	Rashav	Rashav
51	21013314055	Richa Sharma	Richa Sharma	Richa Sharma	Richa Sharma	Richa Sharma	Richa Sharma
52	21013314056	Ritish Kumar	Ritish Kumar	Ritish Kumar	Ritish Kumar	Ritish Kumar	Ritish Kumar
53	21013314057	Sahil Sharma	Sahil	Sahil	Sahil	Sahil	Sahil
54	21013314058	Sakshi Sharma	Sakshi Sharma	Sakshi Sharma	Sakshi Sharma	Sakshi Sharma	Sakshi Sharma
55	21013314059	Shagun Thakur	Shagun	Shagun	Shagun	Shagun	Shagun
56	21013314060	Shakram	Shakram	Shakram	Shakram	Shakram	Shakram
57	21013314061	Sheetal Kumari	Sheetal Kumari	Sheetal Kumari	Sheetal Kumari	Sheetal Kumari	Sheetal Kumari
58	21013314062	Shivani Thakur	Shivani	Shivani	Shivani	Shivani	Shivani
59	21013314063	Sourav	Sourav	Sourav	Sourav	Sourav	Sourav
60	21013314064	Sourav Patiyal	Absent	Absent	Absent	Absent	
61	21013314065	Sujal Saini	Sujal	Sujal	Sujal	Sujal	Sujal
62	21013314066	Sumit Kumar	Sumit	Sumit	Sumit	Sumit	Sumit

63	21013314067	Sumit Kumar	Sumit	Sumit	Sumit	Sumit	Sumit	Sumit
64	21013314068	Tarun Deep Kaulshal	Tarun	Tarun	Tarun	Tarun	Tarun	Tarun
65	21013314069	Vishal Kumar	Vishal	Vishal	Vishal	Vishal	Vishal	Vishal
66	22023314001	Abhay Thakur	Abhay	Abhay	Abhay	Abhay	Abhay	Abhay
67	22023314002	Akash	Akash	Akash	Akash	Akash	Akash	Akash
68	22023314003	Rajat Bhutia	Rajat	Rajat	Rajat	Rajat	Rajat	Rajat
69	22023314004	Ritik Kumar	Absent	Absent	Absent	Absent	Absent	Absent
70	22023314005	Ritik Saini	Ritik	Ritik	Ritik	Ritik	Ritik	Ritik
Present								
Absent								
Total strength								

checked by
Principal

26/10/24
VC Examination

H/c Academic

Director Cum
Principal

RESULT

Gautam College Of Pharmacy , Hamirpur			
Awards List, 2nd Sessional Examination October 2024, Semester: 7th			
Subject Code: BP702 T Subject Name: Industrial Pharmacy-II			
Date			2nd sessional
Subject Code			Max Marks (30)
Sr No.	Roll No.	Student Name	
1	21013314001	Aarti Thakur	19
2	21013314002	Aaryan	5
3	21013314003	Abhishek Thakur	0
4	21013314004	Aditya	24
5	21013314005	Aditya Pathania	20
6	21013314006	Akanksha	28
7	21013314007	Akhil Sharma	9
8	21013314008	Aman Sharma	21
9	21013314009	Anchal Kumari	28
10	21013314011	Archana Kumari	25
11	21013314012	Arpan Thakur	2
12	21013314013	Arundhati Rana	29
13	21013314014	Aryan Singh Manhas	5
14	21013314015	Aryan Thakur	Absent
15	21013314017	Atul Sharma	23
16	21013314018	Bharti Doad	23
17	21013314019	Deeksha Kumari	Absent
18	21013314020	Dheeraj Kumar	9
19	21013314021	Diksha Koundal	27
20	21013314022	Disha	25
21	21013314023	Esha	22
22	21013314026	Isha Thakur	25
23	21013314027	Kanika Kaushal	22
24	21013314028	Karan	0
25	21013314029	Kartik Sharma	27
26	21013314030	Komal	28
27	21013314031	Kritika Rahi	24
28	21013314032	Lakshit Sharma	8
29	21013314033	Manisha Kumari	27
30	21013314034	Meghna	27
31	21013314035	Mohit Guleria	10
32	21013314036	Mohit Sharma	Absent
33	21013314037	Muskan	28
34	21013314038	Namisha Sharma	27
35	21013314039	Nidhi Sharma	28
36	21013314040	Nikhil Kumar	25
37	21013314041	Nikhil Kumar	25
38	21013314042	Nishant Sharma	0
39	21013314043	Palvi	27
40	21013314044	Payal	28
41	21013314045	Phulma Devi	28

42	21013314046	Piyush Kashyap	16
43	21013314047	Poonam Patyal	29
44	21013314048	Pragya Rana	27
45	21013314049	Prashant Rana	29
46	21013314050	Prince Verma	19
47	21013314051	Priya Chandel	27
48	21013314052	Priyanka Devi	25
49	21013314053	Rahul Kumar	7
50	21013314054	Rashav	2
51	21013314055	Richa Sharma	25
52	21013314056	Ritish Kumar	26
53	21013314057	Sahil Sharma	23
54	21013314058	Sakshi Sharma	25
55	21013314059	Shagun Thakur	27
56	21013314060	Shiksam	22
57	21013314061	Sheetal Kumari	26
58	21013314062	Shivani Thakur	26
59	21013314063	Sourav	9
60	21013314064	Sourav Patiyal	Absent
61	21013314065	Sujal Saini	3
62	21013314066	Sumit Kumar	13
63	21013314067	Sumit Kumar	0
64	21013314068	Tarun Deep Kaushal	2
65	21013314069	Vishal Kumar	22
66	22023314001	Abhay Thakur	17
67	22023314002	Akash	20
68	22023314003	Rajat Bhatia	11
69	22023314004	Ritik Kumar	Absent
70	22023314005	Ritik Saini	15
Present			65
Absent			5
Total strength			70

Bumari Dada
Subject Incharge

25/12
I/c
Examination

Shiksha
I/c
Academics

Shiksha
Director
Cum
Principal

QUESTUION PAPER

Section A is compulsory.
Attempt any two questions from sections B & and one question from section C.

(5×2=10)

1. Define Common Technical Document.
2. What are the objectives of DRAs.
3. Define Electronic documentation.
4. Define NABL.
5. Name at least 4 agencies responsible for successful technology transfer in India.

(2×5=10)

1. Discuss in detail about the scale up technique for liquid orals.
2. Explain ISO 9000 series.
3. Write about Indian regulatory requirements at central and state levels.

(1×10=10)

1. Write in detail about certificate of pharmaceutical product.
2. Explain Investigation's brochure. What do you understand by IND also give information and instructions of IND applications.

ATTENDANCE RECORD

Dayton College of Pharmacy, Hamirpur										
Attendance Sheet										
Improvement Sectional Examination November 2024										
Date			18-11-2024				20-11-2024			
Session			Morning		Evening		Morning		Evening	
Subject Code			BP 701T		BP 702T		BP 703T		BP 704T	
Sl. No.	Roll No.	Student Name	BP 701T	BP 702T	BP 703T	BP 704T	BP 705T Lateral Entry	BP 706 PS		
1	21013314001	Aarti Thakur	Aash							
2	21013314002	Aaryan	Aaryan	Aaryan	Aaryan	Aaryan				
3	21013314003	Abhinav Thakur	Abhinav	Abhinav	Abhinav	Abhinav				
4	21013314004	Aditya								
5	21013314005	Aditya Patania	Aditya							
6	21013314006	Akash								
7	21013314007	Akash Sharma	Apnil	Akshil	Akshil	Apnil				
8	21013314008	Anam Sharma								
9	21013314009	Anchal Kumar								
10	21013314011	Anshu Kumar								
11	21013314012	Aryan Thakur	Aryan							
12	21013314013	Arunabh Rana								
13	21013314014	Aryan Singh Sharma	Aryan	Aryan	Aryan	Aryan				
14	21013314015	Aryan Thakur	Aryan							
15	21013314017	Ash Sharma								
16	21013314018	Bhaski Choud								
17	21013314019	Daksh Kumar	Daksh	Daksh	Daksh	Daksh				
18	21013314020	Dhruv Kumar	Dhruv	Dhruv	Dhruv	Dhruv				
19	21013314021	Disha Kumar								
20	21013314022	Disha								
21	21013314023	Esha	Esha							
22	21013314025	Isha Thakur								
23	21013314027	Kaash Kaushal								
24	21013314028	Karan	Karan							
25	21013314029	Kash Sharma								
26	21013314030	Karol								
27	21013314031	Kritika Rai	Kritika							
28	21013314032	Laksh Sharma	Laksh			Laksh				
29	21013314033	Mahesh Kumar								
30	21013314034	Megha								
31	21013314035	Mohit Sharma	Mohit		Mohit	Mohit				
32	21013314036	Mohit Sharma	Mohit	Mohit	Mohit	Mohit				
33	21013314037	Muskan								
34	21013314038	Muskan Sharma								
35	21013314039	Nishi Sharma								

36	21013314040	Nikhil Kumar			-		
37	21013314041	Nikhil Kumar			-		
38	21013314042	Nishant Sharma	Nishant	Nishant	Nishant	Nishant	
39	21013314043	Privi			-		
40	21013314044	Payal			-		
41	21013314045	Phulma Devi			-		
42	21013314046	Piyush Kashyap	Piyush		Piyush	Piyush	
43	21013314047	Poozhen Patyal			-		
44	21013314048	Pragya Rana			-		
45	21013314049	Prashant Rana			-		
46	21013314050	Prince Verma			-		
47	21013314051	Priya Chandel			-		
48	21013314052	Priyanka Devi			-		
49	21013314053	Rahul Kumar	Rahul	Rahul	Rahul	Rahul	
50	21013314054	Rashav	Rashav	Rashav	Rashav	Rashav	
51	21013314055	Richa Sharma			-		
52	21013314056	Rishabh Kumar		Rishabh	Rishabh	Rishabh	
53	21013314057	Sahil Sharma			-	Sahil	
54	21013314058	Sakshi Sharma			-		
55	21013314059	Shagun Thakur			-		
56	21013314060	Shakam	Sakam		-		
57	21013314061	Sheetal Kumari			-		
58	21013314062	Shivani Thakur			-		
59	21013314063	Sourav	Sourav	Sourav	Sourav	Sourav	
60	21013314064	Sourav Patyal			-		
61	21013314065	Sujal Saini		Sujal	Sujal	Sujal	
62	21013314066	Sumit Kumar	Sumit	Sumit	Sumit	Sumit	
63	21013314067	Sumit Kumar	Sumit	Sumit	Sumit	Sumit	
64	21013314068	Tarun Deep Kamhal	Tarun	Tarun	Tarun	Tarun	
65	21013314069	Vishal Kumar			-		
66	22023314001	Abhay Thakur			-	Aksh	
67	22023314002	Akash			-		
68	22023314003	Rajat Bhunia	Rajat		-		
69	22023314004	Ritik Kumar	Ritik	Ritik	Ritik	Ritik	
70	22023314005	Ritik Saini	Ritik Saini		Ritik	Ritik Saini	
Present					20		
Absent					49		
Total strength					69		

B/L
20/11/24

B/L
20/11/24

RESULT

Gautam College Of Pharmacy , Hamirpur			
Awards List, 3rd, Sessional Examination November 2024, Semester: 7th			
Subject Code: BP702 T Subject Name: Industrial Pharmacy-II			
Date			3rd sessional
			Max Marks (30)
Subject Code			
Sr No.	Roll No.	Student Name	
1	21013314001	Aarti Thakur	NA
2	21013314002	Aaryan	25
3	21013314003	Abhishek Thakur	23
4	21013314004	Aditya	
5	21013314005	Aditya Pathania	
6	21013314006	Akanksha	NA
7	21013314007	Akhil Sharma	25
8	21013314008	Aman Sharma	
9	21013314009	Anchal Kumari	
10	21013314011	Archna Kumari	NA
11	21013314012	Arpan Thakur	26
12	21013314013	Arundhati Rana	NA
13	21013314014	Aryan Singh Manhas	23
14	21013314015	Aryan Thakur	25
15	21013314017	Atul Sharma	
16	21013314018	Bharti Doad	NA
17	21013314019	Deeksha Kumari	22
18	21013314020	Dheeraj Kumar	26
19	21013314021	Diksha Koundal	
20	21013314022	Disha	
21	21013314023	Esha	
22	21013314026	Isha Thakur	
23	21013314027	Kanika Kaushal	NA
24	21013314028	Karan	24
25	21013314029	Kartik Sharma	
26	21013314030	Komal	
27	21013314031	Kritika Rahi	NA
28	21013314032	Lakshit Sharma	22
29	21013314033	Manisha Kumari	
30	21013314034	Meghna	
31	21013314035	Mohit Guleria	NA
32	21013314036	Mohit Sharma	24
33	21013314037	Muskan	
34	21013314038	Namisha Sharma	
35	21013314039	Nidhi Sharma	
36	21013314040	Nikhil Kumar	
37	21013314041	Nikhil Kumar	NA
38	21013314042	Nishant Sharma	28
39	21013314043	Palvi	
40	21013314044	Payal	
41	21013314045	Phulma Devi	NA

42	21013314046	Piyush Kashyap	
43	21013314047	Poonam Patyal	
44	21013314048	Pragya Rana	
45	21013314049	Prashant Rana	
46	21013314050	Prince Verma	
47	21013314051	Priya Chandel	
48	21013314052	Priyanka Devi	
49	21013314053	Rahul Kumar	23
50	21013314054	Rashav	24
51	21013314055	Richa Sharma	NP
52	21013314056	Ritish Kumar	22
53	21013314057	Sahil Sharma	
54	21013314058	Sakshi Sharma	
55	21013314059	Shagun Thakur	
56	21013314060	Shaksam	
57	21013314061	Sheetal Kumari	
58	21013314062	Shivani Thakur	
59	21013314063	Sourav	26
60	21013314064	Sourav Patiyal	NP
61	21013314065	Sujal Saini	24
62	21013314066	Sumit Kumar	23
63	21013314067	Sumit Kumar	23
64	21013314068	Tarun Deep Kaushal	24
65	21013314069	Vishal Kumar	
66	22023314001	Abhay Thakur	
67	22023314002	Akash	
68	22023314003	Rajat Bhatia	
69	22023314004	Ritik Kumar	26
70	22023314005	Ritik Saini	NP
Present			21
Absent			
Total strength			

[Signature]
Signature of Subject
Incharge

[Signature]
I/c
Examination

[Signature]
I/c
Academics

[Signature]
Director
Cum
Principal

15. ASSIGNMENT

16. SUBJECT NOTES

17. ADDITIONAL TOPIC COVERED:- None

18. MODEL ANSWERSHEET:-APENDIX VII

19. RESULT OF SUBJECT:- AWAITING

CO/PO AND CO/PO MAPPING: INDUSTRIAL PHARMACY-II (BP-702T)

CO-Course Outcome:

BP 702T.1	Know the process of pilot plant and scale up of pharmaceutical dosage forms
BP702T.2	Understand the process of technology transfer from lab scale to commercial batch
BP702T.3	Know different Laws and Acts that regulate pharmaceutical industry
BP702T.4	Understand the approval process and regulatory requirements for drug products

BL: Bloom Taxonomy

L1- Remember	L2- Understand	L3- Apply	L4 – Analyze	L5- Evaluate	L-6- Create
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PO-Programme Objectives:

1.	Pharmacy Knowledge	7.	Pharmaceutical Ethics
2.	Planning Abilities	8.	Communication
3.	Problem Analysis	9.	The Pharmacist & Society
4.	Modern Tool Usage	10.	Environment & Sustainability
5.	Leadership Skill	11.	Life Long Learning
6.	Professional Identity		

SESSIONAL EXAM -I

Code: BP702T Subject: Industrial Pharmacy-II Semester: 7th MM:30

Duration: 1:30 hrs

Staff: Mrs. Kumari Varsha

Q.No.		Marks	CO	BL	PO
Answer any 1					
1	What is Pilot plant scale up ? Describe in detail the general consideration for any pilot plant scale up.	10	CO1	L1, L2 & L4	PO1, PO6 & PO11
2	Discuss in detail about the scale up technique for solid dosage form.	10	CO1	L1 & L2	PO1, PO6 & PO11
Answer any 2					
3	Explain technology transfer sample protocol following WHO guidelines.	5	CO2	L1 & L2	PO1, PO6 & PO11
4	Discuss about the quality risk management in detail.	5	CO2	L1 & L2	PO1, PO6 & PO11

5	Write a note on technology transfer agencies in India.	5	CO2	L1, L2 & L3	PO1, PO4, PO6 & PO11
6	Write a note on SUPAC guidelines.	5	CO2	L1, L2 & L3	PO1, PO4, PO6 & PO11
Attempt all					
1	Multiple choice questions	1	CO1, CO2, CO3 & CO4	L1, L2 & L3	PO1, PO3, PO4, PO6 & PO11

CO/PO ATTAINMENTS

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO 11
BP702T.1	3	-	3	3	-	3	-	-	-	-	3
BP702T.2	3	-	3	3	-	3	-	-	-	-	3
BP702T.3	3	-	-	-	-	3	-	-	-	-	3
BP702T.4	3	-	-	-	-	3	-	-	-	-	3

Note: Correlation levels 1, 2 or 3 as defined below: 1: Slight (Low) 2: Moderate (Medium)

3: Substantial (High) ‘--’ Indicates there is no correlation.

CO/PO Attainments

Attainments of POs and COs for First Sessional

Table No. 1 Assessment of course outcome

Course Outcome	CO1		CO2		CO3		CO4	
	Q	Avg. %	Q	Avg. %	Q	Avg. %	Q	Avg. %
Measure	Q1	89	Q1		Q1		Q1	
	Q2	89	Q2		Q2	-	Q2	-
	Q3		Q3	89	Q3	-	Q3	-
	Q4		Q4	91	Q4		Q4	
	Q5		Q5	90	Q5		Q5	
	Q6		Q6	81	Q6		Q6	
	Q7	58	Q7	58	Q7	58	Q7	58
Total Average		79		82		58		58

Mechanism for the attainment of CO:

The student performance in continuous assessment exams is verified for each question.

$$CO \text{ Assessment (Direct)} = \frac{\text{Number of students reached in answering the question}}{\text{Number of students attempted the question}}$$

Attainment of PO's**Course outcome mapping with Program outcome (PO)**

PO1		Level of Mapping	PO's Assessment	PO's Attainment
CO1	79	3	69.25%	Yes
CO2	82	3		
CO3	58	3		
CO4	58	3		
PO3				
CO1	79	3	71.50%	Yes
CO2	82	3		
CO3	58	2		
CO4	58	2		
PO4				
CO1	79	3	71.50%	Yes
CO2	82	3		
CO3	58	2		
CO4	58	2		
PO6				
CO2	79	3	69.25%	Yes
CO2	82	3		
CO3	58	3		
CO4	58	3		
PO11				
CO1	79	2	67.00%	Yes
CO2	82	2		
CO3	58	3		
CO4	58	3		

* PO's Attainment= more than 70%= Yes, Less than 70%= No

Level of Mapping of PO with CO= $\frac{CO1 \times \text{Level of Mapping} + CO2 \times \text{Level of Mapping} + CO3 \times \text{Level of Mapping} + CO4 \times \text{Level of Mapping}}{\text{Level of Mapping}}$

$$PO1 \text{ Direct Assessment} = \frac{\sum(\text{level of mapping of PO with CO} + \text{Average of CO attainment})}{\sum(\text{level of Mapping of PO with CO})}$$

$$PO's \text{ Assessment} = 373.25/5 = 74.65\%$$

SESSIONAL EXAM -2					
Code: BP702T		Subject: Industrial Pharmacy-II		Semester: 7 th	MM:30
Duration: 1:30 hrs			Staff: Mrs. Kumari Varsha		
Q.No.		Marks	CO	BL	PO
Answer any 1					
1	Write a short note on GLP. Discuss the process of	10	CO3 CO4	L1, L2 & L4	PO1, PO6 & PO11

	NABL accreditation for laboratory.				
2	Explain the investigation Brochure. What do you understand by IND also give information and instruction of IND applications.	10	CO3 CO4	L1 & L2	PO1, PO6 & PO11
Answer any 2					
1	Define quality risk management. Discuss the various risk management tools and methodologies.	5	CO2 CO3	L1 & L2	PO1, PO6 & PO11
2	Define drug metabolism and toxicology. What do you mean by "Non Clinical drug development".	5	CO2 CO3 CO4	L1 & L2	PO1, PO6 & PO11
3	Explain the responsibilities of regulatory affairs professionals	5	CO4	L1 & L2	PO1, PO6 & PO11
4	Describe the steps of data presentation for FDA submission.	5	CO3	L1 & L2	PO1, PO6 & PO11
Attempt all					
1	Multiple choice questions	1	CO1, CO2, CO3 & CO4	L1, L2 & L3	PO1, PO3, PO4, PO6 & PO11

CO/PO ATTAINMENTS

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO 11
BP702T.1	3	-	3	3	-	3	-	-	-	-	3
BP702T.2	3	-	3	3	-	3	-	-	-	-	3
BP702T.3	3	-	3	3	-	3	-	-	-	-	3
BP702T.4	3	-	3	3	-	3	-	-	-	-	3

Note: Correlation levels 1, 2 or 3 as defined below: 1: Slight (Low) 2: Moderate (Medium)

3: Substantial (High) '--' Indicates there is no correlation.

Attainments of POs and COs for Second Sessional

Table No. 1 Assessment of course outcome

Course Outcome	CO1		CO2		CO3		CO4	
	Q	Avg. %	Q	Avg. %	Q	Avg. %	Q	Avg. %
Measure	Q1	82	Q1	82	Q1	82	Q1	82
	Q1		Q1	75	Q1	75	Q1	75
	Q2		Q2		Q2	100	Q2	100
	Q1		Q1	76	Q1	76	Q1	
	Q2		Q2	90	Q2	90	Q2	90
	Q3		Q3		Q3		Q3	73
	Q4		Q4		Q4	81	Q4	
Total Average		82		81		84		84

Mechanism for the attainment of CO:

The student performance in continuous assessment exams is verified for each question.

$$CO \text{ Assessment (Direct)} = \frac{\text{Number of students reached in answering the question}}{\text{Number of students attempted the question}}$$

Attainment of PO's

Course outcome mapping with Program outcome (PO)

PO1		Level of Mapping	PO's Assessment	PO's Attainment
CO1	82	3	82.75%	Yes
CO2	81	3		
CO3	84	3		
CO4	84	3		
PO3				
CO1	82	3	82.5%	Yes
CO2	81	3		
CO3	84	2		
CO4	84	2		
PO4				
CO1	82	3	82.5%	Yes
CO2	81	3		
CO3	84	2		
CO4	84	2		
PO6				
CO1	82	3	82.75%	Yes
CO2	81	3		
CO3	84	3		
CO4	84	3		
PO11				
CO1	82	2	83.00%	Yes
CO2	81	2		
CO3	84	3		

CO4	84	3		
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* PO's Attainment= more than 70%= Yes, Less than 70%= No

Level of Mapping of PO with CO= $\frac{CO1 \times \text{Level of Mapping} + CO2 \times \text{Level of Mapping} + CO3 \times \text{Level of Mapping} + CO4 \times \text{Level of Mapping}}{\text{Level of Mapping}}$

$$\text{PO1 Direct Assessment} = \frac{\sum(\text{level of mapping of PO with CO} \times \text{Average of CO attainment})}{\sum(\text{level of Mapping of PO with CO})}$$

$$\text{PO's Assessment} = 413.5 / 5 = 82.70\%$$

SESSIONAL EXAM -3					
Code: BP702T		Subject: Industrial Pharmacy-II		Semester: 7 th	MM:30
Duration: 1:30 hrs			Staff: Mrs. Kumari Varsha		
Q.No.		Marks	CO	BL	PO
Answer any 1					
1	Write in detail about certificate of Pharmaceutical Product.	10	CO4	L1, L2 & L4	PO1, PO6 & PO11
2	Explain the investigation Brochure. What do you understand by IND also give information and instruction of IND applications.	10	CO3	L1 & L2	PO1, PO6 & PO11
Answer any 2					
1	Discuss in detail about the scale up techniques for liquid orals.	5	CO1	L1 & L2	PO1, PO6 & PO11
2	Explain ISO 9000 series.	5	CO3	L1 & L2	PO1, PO6 & PO11
3	Write about the Indian regulatory requirements at central and state level.	5	CO4	L1 & L2	PO1, PO6 & PO11
Attempt all					
1	Multiple choice questions	1	CO1, CO2, CO3 & CO4	L1, L2 & L3	PO1, PO3, PO4, PO6 & PO11

CO/PO ATTAINMENTS

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO 11
BP702T.1	3	-	3	3	-	3	-	-	-	-	3
BP702T.2	3	-	3	3	-	3	-	-	-	-	3
BP702T.3	3	-	3	3	-	3	-	-	-	-	3

BP702T.4	3	-	3	3	-	3	-	-	-	-	3
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Note: Correlation levels 1, 2 or 3 as defined below: 1: Slight (Low) 2: Moderate (Medium)

3: Substantial (High) ‘--’ Indicates there is no correlation.

Attainments of POs and COs for Second Sessional

Table No. 1 Assessment of course outcome

Course Outcome	CO1		CO2		CO3		CO4	
	Q	Avg. %	Q	Avg. %	Q	Avg. %	Q	Avg. %
Measure	Q1	100	Q1	100	Q1	100	Q1	100
	Q1	100	Q2		Q2		Q2	
	Q2		Q3		Q3	100	Q3	
	Q3							100
	Q1							67
	Q2					100		
Total Average		100		100		100		87

Mechanism for the attainment of CO:

The student performance in continuous assessment exams is verified for each question.

$$CO \text{ Assessment (Direct)} = \frac{\text{Number of students reached in answering the question}}{\text{Number of students attempted the question}}$$

Attainment of PO's

Course outcome mapping with Program outcome (PO)

PO1		Level of Mapping	PO's Assessment	PO's Attainment
CO1	100	3	96.75%	Yes
CO2	100	3		
CO3	100	3		
CO4	87	3		
PO3				
CO1	100	3	97.40%	Yes
CO2	100	3		
CO3	100	2		
CO4	87	2		
PO4				
CO1	100	3	97.40%	Yes
CO2	100	3		
CO3	100	2		
CO4	87	2		
PO6				

CO1	100	3	96.75%	Yes
CO2	100	3		
CO3	100	3		
CO4	87	3		
PO11				
CO1	100	2	96.10%	Yes
CO2	100	2		
CO3	100	3		
CO4	87	3		

* PO's Attainment= more than 70%= Yes, Less than 70%= No

Level of Mapping of PO with CO= $\frac{CO1 \times \text{Level of Mapping} + CO2 \times \text{Level of Mapping} + CO3 \times \text{Level of Mapping} + CO4 \times \text{Level of Mapping}}{\text{Level of Mapping}}$

$$\text{PO1 Direct Assessment} = \frac{\sum(\text{level of mapping of PO with CO} + \text{Average of CO attainment})}{\sum(\text{level of Mapping of PO with CO})}$$

$$\text{PO's Assessment} = 484.40 / 5 = 96.88\%$$

21. Faculty Feedback: APPENDIX IX

NAME AND SIGN OF FACULTY

HOD

PRINCIPAL