



Agenda for the 8th Board of Studies (BoS) Meeting at School of Pharmacy.

ITM University Gwalior, Madhya Pradesh on17/07/2023 at 11.00 A.M

ITE No	ΞΜ ο.	ITEM
, 1		Welcome Address by the Dean School of Pharmacy
		INSTITUE ITEMS - Agenda for Ratification
lj ·		To consider and confirm the minutes of the 6th BoS Meeting held online on 18/02/2022 and its Action Taken Report (ATR)
111		Approval of Academic Calendar to B.Pharm (Odd Semester), and M.Pharm (I & III Semester) for AY 2023-24
İV		To discuss and review the feedback on curriculum of following programs for the AY 2022-23 semester examination (B.Pharm & M.Pharm.)
V	F	Approval of syllabi and course module for new PG program (M.Pharm – Pharmaceutical Analysis and M.Pharm – Pharmaceutical Regulatory Affairs) started from the current AY
VI		Approval of syllabi and course module for new Pharm.D Doctor of Pharmacy) program started from the current AY 2023-
ViI	Tw	o review and recommend the syllabus of new programs ith schemes, CO, PO, PEO, and PSO.
VIII	To	o review and recommend the syllabus of new programs for the dition of new value added courses in B Pharm and M Pharm AY 2023-24 with minimum credit to the Academic Council
IX	An	y other matter (with the permission of Chairman, BoS)
* Ann	line	and publicate

^{*} Applied and subject to consideration of approval by PCI

Minutes of the 8th of the Board of Studies of School of Pharmacy, ITM University Gwalior held on 17th July, 2023 at 11.00 AM

The 8th meeting of the Board of Studies (BoS) was held on 17.07.2023 at 11.00 AM at Dean's Office.

Members Present

	에 발표하는 그의 그는 집 하는 사람들이 있다면 그 이렇게 되었습니다. 이번 시간에 되었습니다.
1, Dr. M. Alagusundaram	Chairman
2. Mr. Nem Kumar Jain	Member (HOD i/c)
3. Dr. Subodh Kumar Dubey	Member (BOS Co-ordinator)
4. Dr. Tirthankar Choudhury	Member (M.Pharm Pharmaceutical
	Regulatory Affairs Co-ordinator
5. Dr. China Babu D	Member (M.Pharm Pharmaceutical
	Analysis Co-ordinator)
6. Dr. G Sai Sri Harsha	Member (Pharm.D Co-ordinator)
7. Dr. Goli Venkateswarlu	Member (Research Co-ordinator)
8. Mr. Shailendra Singh Nan	wariyaMember (Exam Co-ordinator)
9. Mrs. Vijeta Bhattacharya	Member (Class in-charge/Mentor)
10. Dr. Suman Jain	Expert nominated by the Vice-Chancellor ITM
11.Mr. Pawan Kumar	Member from the Industry
12. Dr. Dinesh Singh Tomar	Invited Member (COE ITM)
13. Dr. Ranjeet Singh Tomar	Invited Member (Dean Academics-I ITM)
14. Mr. Brajesh Singh	Alumni Member

Total No of Absent: Nil

At the outset, **Dr. M. Alagusundaram**, Professor and Dean, School of Pharmacy, ITM University & Chairman of the Board of Studies extended a warm welcome to Hon'ble expert **Dr. Suman Jain** (Director and Principal School of Pharmaceutical Sciences) **Dr. Ranjeet Singh Tomar** (Dean Academics I ITM University), **Dr. Dinesh Singh Tomar** (Controller of Examinations, ITM University) and members of the Board of Studies who, in spite of their busy schedules, made it possible to attend the meeting. The BoS members are also welcomed the Chairman. The list of members present in the meeting and leave of absence is annexed. Thereafter, the Chairperson highlighted important academic development that took place in the College in the recent past. After the brief introductory remarks, the agenda items of the meeting were taken up and discussed by the BoS members and resolved subsequently.

Mrs. Vijeta Bhattacharya (Member/ Class in-charge) to note down the minutes of the meeting and coordinated the overall conduct of the meeting. The detailed resolution for the proposed agenda on the 8th Board of Studies (BoS) meeting was appended below.

Item No. II To consider and confirm the minutes of the 6th BoS Meeting held online on 18/02/2022 and it's Action Taken Report (ATR)

The Minutes of the aforesaid Meeting of the Board of Studies conducted on 18.02.2022 were circulated to all the members. As per the basis of student feedback and complaints some faculties had been received show-cause notice Action Taken Report is placed and read out the same before the BoS for confirmation.

Resolution: The BoS members resolved to confirm its aforesaid minutes. The members also noted with satisfaction of the ATR on the Minutes of the Board of Studies mentioned under the captioned agenda.

Item No. III Approval of Academic Calendar to B. Pharm (Odd Semester), and M. Pharm (I & III Semester) for AY 2023-24

Proposed Academic Calendars for B. Pharm (Odd Semester), M.Pharm (I year & III year), for AY 2023-24, and necessary suggestions are invited.

Resolution: Members of the board perused and approved the Academic Calendar for B. Pharm (Odd Semester), and M. Pharm (I year & III year) for the AY 2022-23. The members suggested and recommended to be followed as per the university guidelines. The members of BoS felt that deliberate discussions or changes if any are required may be submitted for discussion in the next Academic Council meeting of the ITM University.

Item No. IV To discuss and review the feedback on the curriculum of the following programs for the AY 2022-23 semester examination (B. Pharm & M.Pharm)

The academic performance of the last AY 2022-23 was placed and details of feedback on the curriculum were also read out the same for the necessary suggestions are invited.

Resolution: The BoS Experts and members also suggested to collecting the feedback from Stakeholders, parents and alumni members for improvement in the curriculum towards the betterment and benefit of the students.

Item No. V Approval of syllabi and course module for new PG program (M. Pharm- Pharmaceutical Analysis and M.Pharm - Pharmaceutical Regulatory Affairs) started from the current AY 2023-24.

The Pharmacy Council of India approved to start of the new PG program (M.Pharm – Pharmaceutical Analysis and M. Pharm Pharmaceutical Regulatory Affairs) with the intake of 15 seats each from the current AY 2023-24 onwards. The eligibility criteria and duration of the course is also mentioned against each:

S. No.	Approved New Course*	Eligibility
1.	M.Pharm Pharmaceutical Analysis (Intake - 15 seats)	B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has
2.	M.Pharm- Pharmaceutical Regulatory Affairs	scored not less than 55 % of the maximum marks (aggregate of years of B.Pharm)
	(Intake – 15 seats)	

*Subject to the consideration of approval by PCI

Resolution: It was decided unanimously that the regulations, scheme and syllabi be adapted into as prescribed by PCI, New Delhi (Gazette Notification M.Pharmacy Course regulation-2014 (Notification in the gazette of India No.362, Dt: December 11, 2014). The BoS committees unanimously decided to follow the same pattern of value added/audit courses existing M.Pharm Pharmaceutics to be followed.

Item No. VI Approval of syllabi and course module for new Pharm.D (Doctor of Pharmacy) program started from the current AY 2023-24*.

Resolution: The committee unanimously decided to follow the PCI regulations
2008 (Regulations framed under section 10 of the Pharmacy Act,
1948 (8 of 1948). The following suggestions were made by the
committee members for updating syllabus and curriculum, decided
to add the following Value Added Courses up to 5th year Pharm.D
and the same is recommended to the Academic Council.

*Subject to the consideration of approval by PCI

- 1. 1st year PharmD-Communication Skill (Non-University Exam)
- 2. 2nd year PharmD-Environmental Science (Non-University Exam)
- 3. 3rd year Registration of students for Swayam and NPTEL examination
- 4. 4th year PharmD- (RPE-Research Publication Ethics-1) (Non-University Exam)
- 5. 5th Year PharmD- (RPE-Research Publication Ethics-2) (Non-University Exam)
- Item No. VII To review and recommend the syllabus of new programs with schemes, CO, PO, PEO, and PSO embedded.

Resolution: Reviewed and framed the syllabus with CO, PO, PEO, and PSO embedded.

Item No. Vill To review and recommend the syllabus of new programs for the addition of new value-added courses for AY 2023-24 with minimum credit to the Academic Council

Resolution: Reviewed and recommended the syllabus of new programs for the addition of new value-added/audit courses from the AY 2023-2024 by an expert committee and approved by the academic council.

Item No. IX To introduce new elective courses in B.Pharm 5th Semester for AY 2023-24 to enhance the learning capabilities of the students

• Resolution: With the recommendation of BoS committee, 4 new elective subjects were introduced;

A Credit

- BP510ET International Regulatory Requirement for GMP: Covers Good Manufacturing Practices (GMP) regulations, ensuring pharmaceutical quality and safety through compliance with international standards.
- 2. BP511ET Pharmaceutical Product Development: Focuses on the lifecycle of drug development, including research, formulation, clinical trials, and market launch.
- 3. BP512ET Purification of Pharmaceutical Compounds: Examines methods for purifying pharmaceutical compounds, emphasizing techniques like chromatography and the importance of drug purity.

4. BP513ET - Introduction to Intellectual Property Rights: Introduces intellectual property concepts relevant to pharmaceuticals, including patents and trademarks, and their impact on innovation and market competition.

Syllabus of new and approved courses are attached in annexure II.

and .

Item No. X To introduce new elective courses in B.Pharm 6th Semester for AY 2023-24 to enhance the learning capabilities of the students
Resolution: With the recommendation of BoS committee, 3 new elective subjects were introduced;

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- BP611ET Artificial Intelligence in Pharmaceuticals: Explores the applications of AI in drug discovery, development, and manufacturing, focusing on enhancing efficiency, precision, and decision-making in the pharmaceutical industry.
- BP612ET GMP in Pharma Industry: Delves deeper into Good Manufacturing Practices (GMP), emphasizing their critical role in ensuring product quality, compliance, and safety in pharmaceutical manufacturing.
- 3. BP613ET Healthcare Marketplace Capstone: A capstone project that integrates knowledge from previous courses, focusing on real-world challenges in the healthcare marketplace, encouraging practical application and problem-solving in a collaborative setting.
- Syllabus of new and approved courses are attached in annexure II.

Item No. XI To introduce new elective course in M.Pharm 1st Semester for AY 2023-24 to enhance the learning capabilities of the students

Resolution: To enhance learning capabilities, a new elective course was introduced in the M.Pharm 1st and 2nd Semester for AY 2023-24, based on the recommendation of the Board of Studies (BoS) committee.

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- 1. MPH108ET Good Manufacturing in Pharma: Focuses on Good Manufacturing Practices (GMP) in the pharmaceutical industry, covering quality assurance, regulatory compliance, and manufacturing processes to ensure product safety and efficacy.
- 2. MPH208ET Introduction to Intellectual Property Rights: Provides

foundational knowledge of intellectual property (IP) concepts relevant to pharmaceuticals, including patents, trademarks, and their implications for innovation and market strategy.

Syllabus of new and approved courses are attached in annexure III.

Item No. XIII Any other matter (with the permission of Chairman, BoS)

8th BOS successfully completed with the experts and committee members. All the agenda were approved and recommended by the Experts and committee members. Dr. Suman Jain advises are noted for the implementation.

The 8th Board of Studies meeting ended by proposing a vote of thanks by Dr. Tirthankar Choudhury, Professor and member.

Duration of Meeting: 11:00 AM to 01:00 PM



MEMBERS PRESENT:

S. No.	Name	Designation	Signature
1	Dr. M Alagusundaram	Professor and Dean	New Mon
2	Mr. Nem Kumar Jain	Associate Professor	Nes
3	Dr. Subodh Kumar Dubey	Professor	9
4	Dr. Tirthankar Choudhury	Professor	Ton X.
5	Dr. China Babu D	Associate Professor	
6	Dr. G. Sai Sri Harsha	Associate Professor	9.300
7	Dr. Goli Venkateswarlu	Associate Professor	See So
8	Mr. Shailendra Singh Narwariya	Associate Professor	And .
9	Mrs. Vijeta Bhattacharya	Associate Professor	Bhair.
10	Dr. Suman Jain	Professor and Director	Hair
11	Mr. Pawan Kumar	QA Manager	Attended Mayh On
12	Dr. Dinesh Singh Tomar	Professor	17/07/2023
13	Dr. Ranjeet Singh Tomar	Professor	dornie
14	Mr. Brajesh Singh	Representative	

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(SOP)(BPharm)

Title of the Course	Online certified courses related to Pharmacy I *	
Course Code	BP509ET	•

		Part A			
Year	Semester		Credits	1 . 0 0 °	C 1
Course Type	Theory only				
Course Category	Discipline Specific Elective				
Pre-Requisite/s	•		Co-Requisite/s		
Course Outcomes & Bloom's Level	CO1- To gain the skill and kn	owldege in pharmac	eutical domain(BL3-Ap	ply)	
Coures Elements	Skill Development ✓ Entrepreneurship × Employability × Professional Ethics × Gender × Human Values × Environment ×	SDG (Goals)			

Part B

Modules	Contents	Pedagogy	Hours
1	online course are available in coursera, edx, udemy and NEPTEL. Students are instructed to registered in mooc course and submit the certificate after completion	Blended	30

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REGISTRAR ITM University Gwalior (M.P.)

School of Pharmacy
School of Pharmacy
TTM University
Gwalior, Madhya Pradesh

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(SOP)(BPharm)

Title of the Course	International Regulator	y Requirement	s for Good Manufactu	uring Prac	tices		
Course Code	BP510ET						
	•	Part A	1				
Year	Semester		Credits	L .	0	P 0	C 1
Course Type	Theory only	11.74.41					
Course Category	Discipline Specific Ele	ctive					
Pre-Requisite/s			Co-Requisite/s				
Course Outcomes & Bloom's Level	CO1- Understand the CO2- To apply the knd	different qualit wldge of Qula	y level for global reguity management guid	latory ag elines in	ency (B	L2-Undenario(BL	erstand) -3-Apply
Coures Elements	Skill Development ✓ Entrepreneurship X Employability ✓ Professional Ethics X Gender X Human Values ✓ Environment X	SDG (Goals)	SDG3(Good health SDG4(Quality educ SDG12(Responsib SDG16(Peace Just	cation)		d productions	tion)

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Modules	Contents	Pedagogy	Hours .
JNIT 1	Overview on Product Life cycle Management, Good Manufacturing Practices and its Regulations, Functions of pharmaceutical and healthcare industries (Quality, Production, RA, R&	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
JNIT 2	Good Documentation Practices, Data Integrity Assurance, Qualification and Validation, Change Control, Deviation Management, Out of specifications, Data Integrity Assurance	Lecture based learning, improved ass, Peer tutorial, Class using ICT 1001/PP17/white board	10
JNIT 3	CAPA & QRM, Complaint Handling & Product Recall, GMP requirements in Medical Devices, GMP Requirements in Pharmaceutical Drug substances and products, GMP for Biologics products and guidelines for injectable products	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board REGISTRAR ITM University	10



/	Part D(Marks Distribution) Theory										
1	Minimum Passing Marks	External Evaluation	Min. External Evaluation	Internal Evaluation	Min. Internal , Evaluation						
KS	25	35	18	15	8						
	,		Practical								
Total Marks	Minimum Passing Marks	External Evaluation	Min. External Evaluation	Internal Evaluation	Min. Interna Evaluation						
			•								

	Part E
Books	https://iris.who.int/bitstream/handle/10665/64465/WHO_VSQ_97.01-eng.pdf? sequence=1&isAllowed=y
Articles	https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations, CDER-OPQ-Inquiries@fda.hhs.gov
References Books	https://iris.who.int/bitstream/handle/10665/64465/WHO_VSQ_97.01-eng.pdf?
MOOC Courses	https://www.itsligo.ie/courses/higher-certificate-in-science-in-good-manufacturing-practice-gmp/
Videos	https://www.youtube.com/watch?v=mFwA2KTiPwIhttps://www.youtube.com/watch?v=mFwA2KTiPwI

Course Articulation Matrix

COs	P01	PO2	PO3	P04	PO5	P06	P07	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSC
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(SOP)(BPharm)

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Title of the Course	Pharmaceutical Product D	evelopment					-					
Course Code	BP511ET											
		Part A '			1		_					
			Credits	L	T	P	C					
Year	Semester		Greatis	3	1	0	4					
Course Type	Theory only						<u>.</u>					
Course Category	Discipline Specific Elective	e					-					
Pre-Requisite/s			Co-Requisite/s			*	- 1					
Course Outcomes & Bloom's Level	Remember) CO2- To outline the role of Understand) CO3- To select the excipi CO4- To classify different and secondary packaging CO5- To choose optimizate (BL4-Analyze)	Understand) CO3- To select the excipients for a specific drug product (BL5-Evaluate) CO4- To classify different of packaging for the drug product and materials used for primary and secondary packaging. (BL3-Apply) CO5- To choose optimization technique in the development of pharmaceutical drug product										
Coures Elements	Skill Development ✓ Entrepreneurship ✓ Employability ✓ Professional Ethics × Gender × Human Values × Environment ×	SDG (Goals)	SDG3(Good health a SDG4(Quality educa	nd we	ell-beir	ng)						
	Mar Juin	or. Omveer Sing REGISTRAR ITM University Gwalior (M.P.)	School of Gwaliof	Drivere Orivere Prismi	acy!							

		Pa	art B			
(Conte		The state of the s	Pedagogy		Hours
1	Introduction to pharmac development, objectives to preformulation, formu- stability assessment, man quality control testing of dosage forms	s, regulations related lation development, anufacturing and	Lecture based lea tutorial, Class usin	irning, interac ng ICT tool/Pf	tive class, Peer PT/white board	10
JNIT 2	An advanced study of F Excipients in pharmace development with a spe following categories	utical product	Lecture based lea tutorial, Class usi	arning, interac ng ICT tool/Pl	ctive class, Peer PT/white board	10
JNIT 3	An advanced study of F Excipients in pharmace development with a spe following categories	utical product	Lecture based lea tutorial, Class usi	arning, interac ng ICT tool/P	ctive class, Peer PT/white board	10
JNIT4.	Optimization technique product development. A optimization techniques product development we examples. Optimization and their applications its application in pharm development.	A study of various of for pharmaceutical with specific of by factorial designs A study of QbD and	Lecture based lea	arning, intera ng ICT tool/P	ctive class, Peer PT/white board	08
JNIT 5	Selection and quality c packaging materials for product development-considerations.	r pharmaceutical .	Lecture based le tutorial, Class us	arning, intera ing ICT tool/F	ctive class, Peer PT/white board	07
	•		Part C			. ,
Modules	Т	itle	Indicative-AE Experiments/F Interns	ield work/	Bloom's Level	Hours
1	Evaluation of suspend agent	ling and emulsifying	Experiments		1	
		Part D(Ma	rks Distribution)			
			Theory		. ~	
Total Marks	Minimum Passing Marks	External Evaluation	Min. External Evaluation	Interna Evaluati	MOD Masel Migell Of Process of Section Migell 13	ternal ation
100	50	75	38	25 S ch	(M, M2013	,
		P	ractical	Cns	(1) 112 13	
Total Marks	Minimum Passing Marks	External Evaluation	Min. External ' Evaluation	Interna Evaluati	al Min. Ir	iternal ation
		RI ITI	omveer Singh EGISTRAR M University valior (M.P.)			

	Part E
oks .	1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.
Articles	https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-pharmaceutical-development_en.pdf
references Books	3. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman and Joseph B. Schwartz
MOOC Courses	https://www.coursera.org/courses?query=pharmaceutical https://www.youtube.com/watch?v=sesDthMPRC0&list=PLkxD16eG21tVre8GBj-
Videos	https://www.youtube.com/watch?v=sesDtrivir (Noodilet LbjfUUuq1qghVM

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. (SOP)(BPharm)

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Title of the C	Course	Purification of	of Pharmaceutical (Compounds							- .		
Course C		BP512ET											
				Part A	•			_	T,	P	C		
Year			Semester	•		Credits	-	1	0	0	1		
Course	Гуре	Theory only	•			•							
Course Ca	tegory	Skill Ennan	cement Courses										
Pre-Requi				Co-Requisite/s									
Course Out	tcomes	CO1- To un	nderstand the basic ain the knowledge on the basics of impuri	es of impurites in portection of techniques to puttes in pharmaceur	harm urify th ticals(aceuticals(BI ne compound BL3-Apply)	L2-Un Is and	ders I rem	ove II	1P			
Coures Ele	ements	Skill Develor Entreprene Employabil Profession Gender X Human Val Environme	urship X lity ✓ al Ethics X lues X	SDG (Goals)	SDG (Goals)								
				Part B	•		: .						
Modu	ıles :		Contents			Pedagogy	У			lours	S		
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/ ;	Part E
ooks	https://crescent.education/wp-content/uploads/2021/06/Pharmaceutical-Organic-Chemistry.pdf
Articles	https://www.mdpi.com/books/reprint/8083-extraction-and-purification-of-bioactive-compounds
eferences Books	https://crescent.education/wp-content/uploads/2021/06/Pharmaceutical-Organic-Chemistry.pdf
MOOC Courses	NA
Videos	

						Cou	irse A	rticula	tion N	latrix					
-	P01	PO2:	P03	P04	PO5	P06	P07	PO8	PO9	PO10	PO11.	PO12	PSO1	PSO2	PSC
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(SOP)(BPharm)

Title of the Course	Introduction to intellectual property rights									
Course Code	BP513ET									
	Part A L T P C									
Year	Semester Credits 3 1 0 4									
Course Type	Theory only									
Course Category	Skill Enhancement Courses Co-Requisite/s									
Pre-Requisite/s	(B) 2 (Inderstand)									
Course Outcomes & Bloom's Level	CO1- To create awareness of IPR among pharmacy students (BL2-Understand) CO2- To make the pharmacy students aware about the pharmaceutical R & D and the activities therein (BL2-Understand) CO3- Develop the understanding of the Intellectual Property Rights necessary for research activities in the pharmaceutical industry (BL3-Apply) CO4- To know the database of intellectual property and TKDL(BL2-Understand) CO5- To apply the Knowledge of IPR in drafting and filling of IPR(BL3-Apply)									
Coures Elements	Skill Development ✓ Entrepreheurship ✓ Employability ✓ Professional Ethics X Gender X Human Values ✓ SDG (Goals) SDG1(No poverty) SDG3(Good health and well-being) SDG4(Quality education) SDG6(Clean water and sanitation) SDG8(Decent work and economic growth) SDG17(Partnerships for the goals)									

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		Conte	nts	1	-1	Pedagogy			Hours
A	The pharmace pharmaceutic	euticai bus al R & D	iness and The		Lecture based lear tutorial, Class usin	rning, interac ig ICT tool/Pf	tive cla PT/whit	iss, Peer le board	10
NIT 2	Introduction a	bout pater dustrial De rade Secre	Property Rights: hts, copyright, esigns,Geographica ets, Module 4 – IPR to pharma	:	Lecture based lea tutorial, Class usin	ig IC1 1001/F1			10
JNIT 3	IPR: Indian p	atent scen	ario and Patent licensing		Lecture based lea tutorial, Class usin	te board	10		
JNIT 4	filing registra	ation gran	ent searches', pater ling World Intellectu WIPO) and its	nt ial	Lecture based lea tutorial, Class usin	* *	08		
JNIT 5	I in modicinal	plants INL	edge, TKDL databas DIAN WEB-PORTAL ECHNOLOGIES	se _S	Lecture based lea tutorial, Class usi	arning, intera ng ICT tool/P	ctive cl PT/wh	ass, Peer ite board	07
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Modules	•	, т	itle	•	Indicative-ABCA/PBL/ Experiments/Field work/ Internships			m's Level	Hours
-	patent draft	ing and fili	ng		Case Study	•	BL3,-/	Apply	5.
			Part D(M		o Distribution)				
Total Marks	Minimum		External Evaluation		Min. External Evaluation	Interna Evaluati		Min. In Evalu	
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100	,			Pra	ctical			1	
Total Marks	Minimum	Passing:	External Evaluation	•	Min. External Evaluation	Interna Evaluati		Min. li Evalu	
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	Books	for econo	IM. Intellectual promic research. The e	econ	omics of intellectu	ar property. 2	000 00	111.100.	
	articles	Apr 22;5:		1			7 /		-
Refere	nces Books	Prabu St	, Tnk S, editors. Inte	tellectual property rights. BoD—Flooks on Demand; 26					7 Jun 21.
, MOC	C Courses	NEPTEL	1		•	REGIS ITM Ur	iversi	ly	1
	Videos	NA .		!		Gwalio 	i (N.P	·) ,	The second second

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Marks

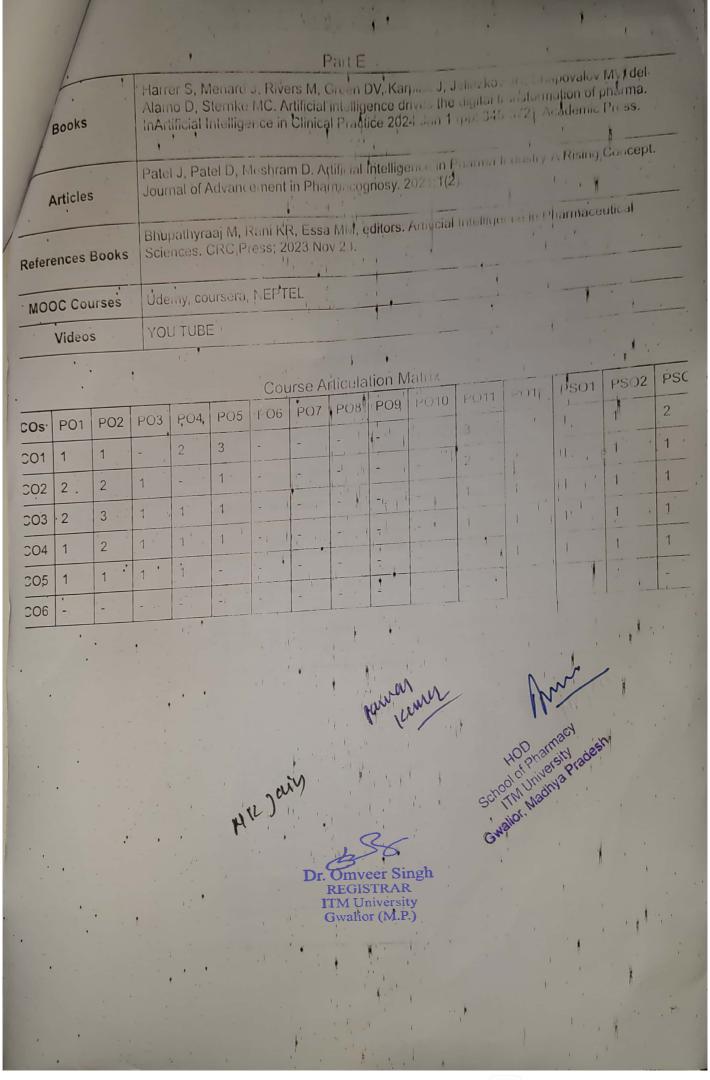
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Marks

Min. External REGESTRIARON M University Gwalior (M.P.)

Evaluation

Min. Internal Evaluation





(SOP)(BPharm)

itle of the Course	Good Manufacturing in Ph	narma					
Course Code	BP612ET		•				
Course		Part A		L	T	P	C
Year	Semester		Credits	1	0	0.	-1
Course Type	Theory only			•		•	
Course Category	Discipline Specific Elective	/e · ·	Co-Requisite/s			<u> </u>	<u> </u>
Pre-Requisite/s	CO1- To be able to under	the hasic	Cood Manufactur	ring Pra	ctice fo	r medic -Reme	mber)
Course Outcomes & Bloom's Level	products for field	ence to outline t	derstand)	tom and	quality	contro	ises,
Coures Elements	Skill Development ✓ Entrepreneurship X Employability ✓ Professional Ethics X	SDG (Goals)	SDG4(Quality educa SDG12(Responsible	ation) e consu r	otion ar	. · nd prod	uction)

1	Cont	ants :	Pai	T D	Pedagogy		Hour
1	Introduction What is G Practice? Why is GMP GMP Directivesthe ba Good Manufacturing P Pharmaceutical Qualit and overview of the PI System. Major update content and implement	ood Manufacturing important? Official asic requirements tractice., y System Principle narmaceutical Quass. Development,	of	Lecture based le tutorial, Class us	earning, interactive	class, Peer white board	8
NIT 2	Personnel Key person duties of the Qualified Head of production de the Head of quality co the batch. Consultants and hygiene, Premise Production area. Stor control areas. Ancillar	nel. Background a person. Duties of epartment. Duties of ntrol. Person relea s. Personnel trainings and Equipment	of asing ng	Lecture based le tutorial, Class us	earning, interactive sing ICT tool/PPT/v	class, Peer white board	8
JNIT 3	Documentation Prem control of documentation documents and speci Manufacturing formul instructions. Packagir Procedures and record General principles. Procedures and record amination in process arting materials. Procedures arting materials are Guidelines for finished.	ises. Generation artion. Types of fications. a and processing and instructions. rds., Production revention of cross-luction. Guidelines in processing operations and operations.	for	Lecture based le tutorial, Class us	earning, interactive sing ICT tool/PPT/v	class, Peer white board	8
JNIT 4	Quality Control Generatasks of the Quality Control Technical transfer of the Transfer protocol., Control GMP Guidelines related Classification of defect	ral principles. Main patrol department. esting methods. implaints and Reca	ills	Lecture based le tutorial, Class us	earning, interactive	VIII.0	8
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Total Marks	Minimum Passing Marks	External Evaluation		hin. External Evaluation	Internal Evaluation	Min. Inte	
100	50	75	38	1	25	13	
			Pract	tical		4-3.3	
Total Marks	Minimum Passing Marks	External Evaluation		lin. External Evaluation	Internal Evaluation	Min. Into	
						Dr. Omvee REGIST ITM Univ Gwalior (ersity

. 1	Part E . ·
Books	Karmacharya JB. Good manufacturing practices (GMP) for medicinal products. Promising Pharmaceuticals. 2014;101.
Articles	Patel KT, Chotai NP. Pharmaceutical GMP: past, present, and future—a review. Die Pharmazie-An International Journal of Pharmaceutical Sciences. 2008 Apr 1;63(4):251-5.
references Books	Durivage MA, editor. The Certified Pharmaceutical GMP Professional Planeses. Press; 2016 May 23.
MOOC Courses	UDEMY, COURSERA, PHARMASTATE ACADEMY
Videos	You tube

		- 1 - :				Cou	ırse A	rticula	tion N	//atrix_		-210	PS01	PSO2	PSC
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REGISTRAR
ITM University
Gwalior (M.P.)



(SOP)(BPharm)

	(30,1)	(B) Harry		
Title of the Course	Healthcare Marketplace Capstor	ie '	-	
Course Code	BP613ET			
	. Р	art A		LTPC
Year	Semester		Credits	1 0 0 1
Course Type	Theory only		-	
Course Category	Ability Enhancement Courses	· · · ·		
Pre-Requisite/s	This course is offered by the Uni Minnesota on the Coursera platf requested to enroll the programmer instructions given by institute	ne and follow the . '	Co-Requisite/s 2-Understand)	
Course Outcomes & Bloom's Level	CO1- Learn new concepts from income CO2- Gain a foundational under hands-on projects (BL3-Apply)	standing of a subject	ct or tool, Develop job-re	slevant skine w
Coures Elements	Skill Development X Entrepreneurship X Employability ✓ Professional Ethics X Gender X Human Values X Environment X	SDG (Goals)	SDG3(Good health ar SDG4(Quality educati SDG8(Decent work ar growth)	

Dr. Omveer Singh REGISTRAR ITM University Gwalior (M.P.)

School of Pharmacy

School of Pharmacy

ITM University

Gwalior, Madhya Pradesh



. 4	Jos		01	Part B		Hours
glo!	dules :		Cont	ents '	Pedagogy	
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		that yo	ou have a body of ng to advance you es into the healthca	illustrate your critical r career or switch		
		For the an analysis medic technology technology the provide agent.	e second mileston alysis of what the k al provider - will re blogy or innovation ill require you to a	sk medical nter about the and whether would er to always tell udent not a sales elivery course how care is the context and 2-3 page memo		
		Regular How W A great model you will three comarket market regulate reimbur identifyi	tory and IP Status ill the Innovation Grown innovation needs for survival-ability. It is a sked to use partones to general report. Identifying the space, voice of the ory path and final partones whether a mediadvance and be sure.	of the Innovation, enerate Revenue, a solid revenue in this milestone arts of the prior the innovation's customer, IP and ath roof components for cal innovation'		
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	Gwalior (N	1.P.)		Theory		4
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		1		Practical	O'	
Total larks	Minimum P		External Evaluation	Min. External Evaluation	Internal Evaluation	Min. Internal Evaluation

Part E Articles ferences Books https://www.coursera.org/learn/healthcare-marketplace-capstone MOOC Courses Videos Course Articulation Matrix PSC PS02 PS01 PO12 PO11 PO10 P09 P08 P07 .1 P06 PO₃ P04 PO5 P₀₂ P01 COs 1 3 1 2 1 1 1 3 201 1 2 2 1 1 1 2 002. 1 1 1 1 1 203 204 205 206 OMVEER SINGH

Annexure II

Syilabus-2023-2024

	(SOP)(MPharm-PharmaCeutics
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Title of the Course Good Manufacturing in Pharma Course Code

	7		Part	A! -	TIT	TTIP	, ,	C
Year	1st	Semester	dst	Credits	3	1 0)	4
Course Type	Theory	only						
Course Category	Disciplin	e Specific Elective	1				-	
Pre-Requisite/s				Co-Requisite/s manufacturing and pharma ocumentation and records(-	
& Bloom's Level				ocumentation and records QC), Quality Assurance (Q				
,	CO4- To	apply the GMP cer learn the documen	tification in industri tation and GMP So	y (BL3-Apply) OPs (BL3-Apply)			and divine minute	

Part'B Hours Pedagogy Contents Modules Introduction What is Good Manufacturing Practice? Why Lecture based learning, interactive class, Feer tutorial, Class using is GMP important? Official GMP Directives, the basic requirements of Good Manufacturing Practice., ICT tool/PPT/white board Pharmaceutical Quality System Principle and overview of UNIT 1 the Pharmaceutical Quarty System. Major updates. Development, content and implementation of PQS. Personnel Key personnel. Background and duties of the Qualified person. Duties of the Head of production Lecture based learning, interactive class, Figer tutorial, Class using department. Duties of the Head of quality control. Person releasing the batch. Consultants. Personnel training and ICT tool/PPT/white board UNIT 2 hygiene, Premises and Equipment Production area. Storage area. Quality control areas. Ancillary areas. Equipment. Documentation Premises. Generation and control of documentation. Types of documents and specifications. Manufacturing formula and processing instructions. Lecture based learning, interactive class, 1 cer tutorial, Class using Packaging instructions. Procedures and records.; UNIT 3 ICT tool/PPT/white board Production General principles. Prevention of crosscontamination in production. Guidelines for starting materials. Processing of erations. Packaging materials and operations. Guidelines for finished products. Quality Control General principles. Main tasks of the Quality control department. Technical transfer of testing Lecture based learning, interactive class. Feer tutorial, Class using UNIT4 methods. Transfer protocol., Complaints and Recalls ICT tool/PPT/white board GMP Guidelines related to complaints. Classification of

Modules		Title .	Indicative-ABCA/PBL/ Experiments/Field world Internships	Bloom's Level Hours
1	GMP		Seminar	Dr. Omveer Singh
				ITM University

Gwalior (M.P.)

defects. Product Recalls.



primer

(SOP)(MPharm-PharmaCeutics)

	(SOP)(MPharm-P,harma,Ceutics)
Title of the Course	Introduction to intellectual property rights
Course Code	MPH 208ET

			Part A	1	TL	T	P	C
Year	1st	Semester	2nd	Credits	3	1	0 -	4
Course Type	Theory o	nly						
Course Category	Skill Enh	ancement Courses		Co-Requisite/s				
Pre-Requisite/s				t deats (BL2-Unders	stand)	ativities the	rein.(BL	2-
Course Outcomes & Bloom's Level	CO3- De	velop the understand	ding of the Intellection	acy students (BL2-Unders out the pharmaceutical R & ual Property Rights necession and TKDL(BL2-Unders and filling of IPR(BL3-Appl	tand)	rch activitie		
	Entreprer	elopment ✓ neurship ✓ pility ✓ nal Ethics ×	SDG (Goals)	SDG1(No poverty) SDG3(Good health an SDG4(Quality education SDG6(Clean water an SDG8(Decent work an SDG17(Partnerships f	d sanitation)	growth)		•

		Part,B Pedagogy	Hours
Modules	Contents	Lecture based learning, interactive class, Peer tutorial, Class using	10
UNIT 1	The pharmaceutical business and The pharmaceutical R & D	ICT tool/PPT/white board	10
UNIT 2	Module 3 – Intellectual Property Rights: Introduction about patents, copyright, trademark, Industrial Designs, Geographical Indications, Trade Secrets, Module 4 – IPR: With specific reference to pharma	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	
UNIT 3	Module 4 – IPR. With specime IPR: Indian patent scenario and Patent commercialization and licensing		10
THE PARTY A	Patent drafting and Patent searches, patent filing, registration, granting World Intellectual Property Organization (WIPO), and its functions	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	
UNIT 5	IP in Traditional Knowledge, TKDL database in medicinal plants, INDIAN WEB-PORTALS FOR PATENTS AND TECHNOLOGIES	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	07

		Part C	-	
Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
		a Chidu	BL3-Apply	5
1	patent drafting and filing	Case Study	250,455,	