MAULANA ABUL KALAM AZAD UNIVERSITY OF TECHNOLOGY, WEST BENGAL

Syllabus of M. PHARM Industrial Pharmacy

Effective from academic session 21-22

Curriculum structure

Course Code	Course	Credit Hours	Credit Points	Hrs./w k	Marks
SEMESTER I					
MIP101	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP 102	Pharmaceutical Formulation Development	4	4	4	100
MIP 103	Novel drug delivery systems	4	4	4	100
MIP 104	Intellectual Property Rights	4	4	4	100
MIP191	Industrial Pharmacy Practical I	12	6	12	150
MIP 181	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
SEMESTER II					
MIP201	Advanced Biopharmaceutics and Pharmacokinetics	4	4	4	100
MIP202	Scale up and Technology Transfer	4	4	4	100
MIP203	Pharmaceutical Production Technology	4	4	4	100
MIP204	Entrepreneurship Management	4	4	4	100
MIP291	Industrial Pharmacy Practical II	12	6	12	150
MIP 281	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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(MIP 104)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

Objectives

On completion of this course it is expected that students will be able to understand,

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

THEORY		60 Hrs
1.	Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.	12 Hrs
2	Role of GATT, TRIPS, and WIPO	12 Hrs
3	Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector.	12 Hrs
4	Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA	12 Hrs
5	Regulatory requirements for contract research organization. Regulations for Biosimilars.	12 Hrs

REFERENCES :

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker

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