BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(END SEMESTER EXAMINATION)

CLASS: M.PHARMA **SEMESTER : I**
BRANCH: PHARMACY **SESSION : MO/19**

SUBJECT: MPH104T REGULATORY AFFAIR

TIME:3:00 HOURS **FULL MARKS: 75**

INSTRUCTIONS:
1. The question paper contains 7 questions each of 15 marks and total 105 marks.
2. Candidates may attempt any 5 questions maximum of 75 marks.
3. The missing data, if any, may be assumed suitably.
***4*. Before attempting the question paper, be sure that you have got the correct question paper.**
5. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.

Q.1(a)	Define IND. What are different contents of an IND application and explain the review process of an IND application?	[7]
Q.1(b)	Discuss Investigator Brochure and its contents.	[8]
Q.2(a)	Write a note on Hatch Waxman Act and its amendments.	[7]
Q.2(b)	Enlist and Discuss the contents of master formula record.	[8]
Q.3(a)	Describe the Drugs control organisation in different countries and also of Indian State and Central agency.	[7]
Q.3(b)	Describe Pharmcovigilance.	[8]
Q.4(a)	How BA and BE Study done?	[7]
Q.4(b)	How you would register a product?	[8]
Q.5(a)	Write importance and maintain of distribution record.	[7]
Q.5(b)	What is scale up in drug industry?	[8]
Q.6(a)	Define New Drug and Medical Devices.	[7]
Q.6(b)	Discuss Schedule Y of Drugs Rules.	[8]
Q.7(a)	Discuss CFR related to drug manufacturing.	[7]
Q.7(b)	Discuss ICH guidelines for drugs.	[8]

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