15/2/2023

Total No. of printed pages = 2 motays motadiribile laborates managed (b)			
MP	H 1	vaasturastusen ja valuhukkoho akud e) HIPA kand aharkae tulness in elmical trials T 40	
Roll No. of candidate			
11011	INO. C	Totale have the salar on the read against the	
		(h) What is MFR? Describe the contents of MFR:	
		M.Pharm. 1st Semester End-Term Examination	
		REGULATORY AFFAIRS (THEORY)	
		as Evening the global submission of NDA and ANDA.	
	W av	(New Regulation) (b): Usive a decayled account of documentation in pharmaceutical industrial	
Full Marks - 75 Lun sloomer land leville gargelevel, mode für Time - Three hours sland leville gargelevel, mode für Time - Three hours			
		The figures in the margin indicate full marks for the questions.	
1.	Ans	swer <i>all</i> the questions: $(10 \times 2 =$	20)
	(a)	How patent and generic drug products are related?	
	(b)	Differentiate between emergency IND and treatment IND.	
	(c)	What is the significance of regulatory affairs?	
	(d)	Enlist the drug regulatory agencies in USA, India, Australia and Europe	•
	(e)	Write the contents of the drug master file.	
	(f)	What is an institutional review board?	
	(g)	What are the different aspects of ICH?	
	(h)	What is CFR?	
	(i)	What do you mean by regulated countries and ROW countries?	
	(j)	What is the orange book?	
2.	Answer any seven questions:		35)
	(a)	Explain the significance of the Hatch – Waxman Act.	
	(b)	Elaborate on the role and responsibilities of institutional review boar independent ethics committees in clinical trials.	ds /
	(c)	Write in detail about the investigator brochure.	

- (d) Describe the pharmaceutical distribution system in India particular to the latest the pharmaceutical distribution system in India particular to the pharmaceutical distribution system
- (e) HIPAA and its usefulness in clinical trials.

MPH 104 T

- (f) Describe various activities of CRO in detail with suitable examples.
- (g) Describe post-approval changes in approved ANDA.
- (h) What is MFR? Describe the contents of MFR.
- (i) Explain the In vitro drug product performance.
- 3. Answer any two questions:

 $(2 \times 10 = 20)$

- (a) Explain the global submission of NDA and ANDA.
- (b) Give a detailed account of documentation in pharmaceutical industries with suitable examples.
- procedures for conducting clinical trials.

my = c > mr

Answer all the question-

- (a) How outens and come accuracy products are political?
- the Differentiate between a notes are DVI and from ment DVI)
 - the What is the stemformer of results at allow-
- of Tabler the drug regulatorst agencies in USA India. Australia and Europe
 - of Write the contents of the drug master tile. *
 - the What is no mentional review board to
 - When are the different aspects of ICH
 - CHITO on mitW 1915
 - - Allert me attraction of the

v after in stip, so my Xino selves, i.e.

(iii) If all on the segnificance of the Parch - Wasneyur No.

(b) El dien der em abs. mehr trestjonerhilmere en met dentomet i entre i entre

and some reviews of the investment of the