

**Time - 3 Hours****MM-50**

The question paper contains one printed page. Attempt any five questions. All question carries equal marks.

Q. 1. Describe the Pharmacovigilance system with its advantage & disadvantages. Along with application associated with hospitals and pharmaceutical industry. (10)

Q. 2. Describe following: (10)

- i. Prescription event monitoring
- ii. Drug Utilization study
- iii. De-challenge/ re-challenge
- iv. Signal Detection
- v. Efficiency of test

Q.3. A new diabetes testing kit with sensitivity, specificity of 80% tested with 400 persons, the people found positive were sent to hospital for another test with sensitivity, specificity of 90%. With assumption of prevalence of diabetes in the population as 10%, find the PPV & NPV of both tests. (10)

Q.4. a) Describe the ADR and its types. (5)

b) Define Pharmacoeconomics and its study designs (5)

Q.5. In a study adverse events were reported as provided in the table below

Find the relative risk, risk difference, risk fraction and odd's ratio of gastric Ulcer with celecoxib in comparison to Diclofenac. Also find the relative risk of gastric ulcer with use of diclofenac.

	Celecoxib (n=212)	Diclofenac (n=218)
Gastric Ulcer	38	74
Duodenal Ulcer	11	23

(10)

Q.6. Trial of tolbutamide: The effect of treating middle-aged and elderly diabetic subjects with a drug called tolbutamide vs. placebo as investigated in a famous randomized clinical trial (University Group Diabetes Program 1970). During a fixed follow-up period of 5 years with no losses, 30 out of the 204 patients randomized to tolbutamide died, and 21 out of the 215 patients in the placebo group died, too.

1. Calculate the following quantities:
 - a. Incidence proportions of death in both groups.
 - b. Estimate of the risk ratio between tolbutamide and placebo.
 - c. Estimate of the risk difference tolbutamide and placebo.
2. Is tolbutamide dangerous to diabetics?

(10)

IIHMR UNIVERSITY
School of Pharmaceutical Management
MBA Pharmaceutical Management
Batch-11 (2019-2021)
Essentials of Pharmaco-epidemiology
Term Examination
1 Year
October 2019



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Q. 1. Describe about the Pharmacoepidemiology and its study designs. (10)

Q. 2. Describe following: (10)

- i. ICER
- ii. NPV
- iii. Bias
- iv. Type II error
- v. Causality

Q.3. A study assesses the association between a investigational medicine and traffic accidents. It finds that people with investigational medicine have accidents at a rate of 11.1 per 10,000 miles traveled. People who do not have investigational medicine have accidents at the rate of 8.6 per 10,000 miles. Calculate the rate difference associated with investigational medicine use. Interpret your results. (10)

Q.4. a) Describe the Pharmacovigilance and its system of information flow. (5)

b) Define Pharmacoeconomics and its study designs (5)

Q.5. Use the following table to calculate and interpret the attributable risk associated with taking a supplement containing folate during pregnancy: (10)

	Annual Death Rate per lakh	
	Neural Tube Defect	Premature Birth
No Folate	631	727
Folate	24	563

Q.6. In a study of 550 participants with 210 had bed rest alone, 340 had bed rest + streptomycin, it was found that there were 14 deaths in the control group and 4 in the experimental group. The main side effect was eighth cranial nerve damage causing permanent deafness, which was observed in 55 of the experimental group and none of the control group. Would you have prescribed streptomycin for pulmonary TB? And Find: CER, EER, ARR, RRR, NNT, NNH, Odds ratio, Risk Ratio along with interpretation. (10)