

TIME:3 Hrs

MARKS:75

N.B:-Scientific calculator is allowed.

Q.No Choose the appropriate option

20 Marks

1. Which of the following comes under inferential statistics?
 - a) ANOVA
 - b) Median
 - c) Frequency distribution
 - d) Standard deviation
2. Which of the following plots is three dimensional?
 - a) Histogram
 - b) Contour plot
 - c) Pie chart
 - d) Surface response plot
3. In data set 21, 3, 49, 8, 12, 19, 23, 34, 11 the median is
 - a) 19
 - b) 21
 - c) 12
 - d) 20
4. Correlation co-efficient denoted as $R_{a, bc}$ indicates that
 - a) a is the dependent variable and b, c are the independent variables
 - b) a is the independent variable and b, c are the dependent variables
 - c) a, b are the dependent variables and c is the independent variable
 - d) a, b are the independent variables and c is the dependent variable
5. Which of the following values of r indicate a moderate correlation
 - a) 0.95
 - b) 0.1
 - c) 0.56
 - d) -0.88
6. In a linear regression analysis, the regression co-efficient and intercept were found to be 15.1 and 2.2 respectively. For an independent variable value of 0.8, what would be the value of the dependent variable?
 - a) 16.86
 - b) 34.24
 - c) 14.28
 - d) 2.44
7. In a certain population, 20% of individuals have a specific genetic trait. If a random sample of 100 individuals is selected from this population, what are the mean and variance of the number of individuals in the sample who have the genetic trait?
 - a) Mean = 20, Variance = 16
 - b) Mean = 20, Variance = 4
 - c) Mean = 5, Variance = 4
 - d) Mean = 5, Variance = 16

8. In a hospital, it is observed that the number of patients arriving at the emergency room follows a Poisson distribution with a mean of 5 patients per hour. What is the variance of the number of patients arriving in an hour?
- 5
 - 10
 - 25
 - 30
9. Suppose Z is a standard normal random variable. What is the probability that Z takes on a value between -1 and 1 ?
- 0.1587
 - 0.3413
 - 0.6826
 - 0.9544
10. While referring to a t distribution table, if the α is changed from 0.05 to 0.01 for the same degrees of freedom, the critical t value would
- Increase
 - Decrease
 - Remain same
 - Become ∞
11. In Mann-Whitney U test, if the two sample sizes are 10 and 11, then the sum of the two U values would be _____
- 21
 - 1.1
 - 110
 - 100
12. Which of the following tests can be used for comparison of medians
- Paired t test
 - One-way ANOVA
 - Correlation analysis
 - Mann Whitney U test
13. Type II error in hypothesis testing is the probability of
- Rejecting the null hypothesis when it should have been accepted
 - Accepting the null hypothesis when it should have been rejected
 - Incorrectly stating the null hypothesis
 - Incorrectly stating the alternate hypothesis
14. If a sample of size 8 is drawn for performing a single sample t test, the degrees of freedom would be
- 8
 - 9
 - 7
 - 6

15. A sample of 9 tablets have mean tablet weight of 102 mg with a standard deviation of 6 mg. What is the standard error of the mean?
- 17 mg
 - 2 mg
 - 0.66 mg
 - 1.5 mg
16. An orally disintegrating formulation of a drug was prepared with and without taste masking. The taste masked formulation was given to 7 volunteers and asked to rank the bitterness in a scale of 1 to 10. The formulation without taste masking was then given to 9 volunteers who were also asked to rank the bitterness in a scale of 1 to 10 i.e. the data is in ordinal scale. Which of the following tests can be used to compare whether the level of bitterness is same in the two types of formulation?
- Two independent samples t test
 - Mann Whitney U test
 - Kruskall Wallis test
 - ANOVA
17. Which of the following non-parametric tests uses a χ^2 table
- Mann Whitney U test
 - Spearman's rank correlation analysis
 - Kruskall Wallis test
 - Wilcoxon Sign Rank test
18. What is R?
- A database management system
 - A statistical programming language
 - A web browser
 - An operating system
19. In a factorial design, if the effect of five factors is to be investigated with each factor being taken at two levels, the minimum number of experiments to be performed would be
- 25
 - 10
 - 32
 - 7
20. Which term is used to represent the distance of the axial points from the center in CCD?
- Alpha
 - Beta
 - Gamma
 - Delta

Q II Answer the following (Any 2)

1A A biologist is studying the distribution of heights (in centimeters) of a particular species of plant in a field. She measures the heights of 50 randomly selected plants and records the following data: **(5 marks)**

157, 163, 152, 148, 155, 160, 158, 151, 154, 162,
150, 159, 156, 161, 153, 157, 162, 150, 155, 158,
164, 152, 157, 160, 156, 155, 162, 149, 154, 159,
161, 157, 153, 150, 158, 156, 155, 162, 160, 155,
153, 161, 159, 164, 158, 151, 152, 157, 155, 163

For the above data

- i. Construct a frequency distribution table
- ii. Calculate the mean

1B A researcher is investigating the effect of different irrigation methods on the yield of a particular crop. She randomly assigns 14 plots of land to four treatment groups representing different irrigation methods. The yields (in kg per plot) for each treatment group are as follows: **(5 marks)**

Treatment 1: 35, 38, 42
Treatment 2: 32, 36, 39, 41
Treatment 3: 30, 33, 36, 38
Treatment 4: 31, 34, 37

Perform an analysis of variance (ANOVA) to determine if there are any significant differences in the mean yields among the four irrigation methods. Use a significance level of $\alpha = 0.05$.

2A Consider a Phase II clinical trial designed to investigate the effectiveness of a new drug to reduce symptoms of asthma in children. A total of 11 participants are randomized to receive either the new drug or a placebo. Participants are asked to record the number of episodes of shortness of breath over a 1 week period following receipt of the assigned treatment. The data are shown below. **(5 marks)**

Placebo (x)	7	5	6	4	12	8
New Drug (y)	3	6	4	2	1	

Is there a difference in the number of episodes of shortness of breath over a 1 week period in participants receiving the new drug as compared to those receiving the placebo? Perform a Mann Whitney U test at 5% significance. Critical U value is 3.

2B Write a note on the various phases of clinical trials. **(5 marks)**

3A What is an experiential design? Give two examples. **(2.5 marks)**

3B The mean weight of a sample of 9 tablets was found to be 502mg with a standard deviation of 3mg. Is this sample taken from a batch whose mean weight is 500mg? Test at 5% level of significance. **(2.5 marks)**

- 3C** The data below are the release rates of drug from tablet obtained as the % polymer coating was increased. **(5 marks)**

% coating	Release rate mg/hour
5	3.7
10	3
15	2.74
20	2.34
30	1.41
40	0.56

Perform linear regression to calculate the slope and intercept of the least square line. What would be the release rate for 25% polymer coating?

QIII Answer the following (Any 7)

- 1A** The particle size analysis of powder shows normal distribution. Particle size analysis of data of 10,000 particles shows the mean size as 750 μ m and standard deviation 50. **(2.5 marks)**

Find:

- The proportion of particles with size less than 720 μ m.
- The proportion of particles with size between 675 μ m and 825 μ m.

- 1B** In a clinical trial for a new medication, it is known that 70% of patients with a certain medical condition respond positively to the medication. If 10 patients with this medical condition are randomly selected and treated with the medication, what is the probability that exactly 5 patients will respond positively? What is the probability that at least 1 patient will respond positively? **(2.5 marks)**

- 2** Write a note on multiple linear regression and hypothesis testing in multiple linear regression. **(5 marks)**

- 3** With the help of illustrations explain central composite design. Give one advantage of this design. **(5 marks)**

- 4** A researcher wants to compare the effectiveness of three different treatments (A, B, and C) for pain relief. A sample of patients was randomly assigned to one of the three treatment groups, and their pain scores were recorded after treatment. Perform a Kruskal-Wallis test to determine if there is a significant difference in pain relief among the three treatment groups. **(5 marks)**

Treatment A: 5, 7, 8, 9, 10

Treatment B: 6, 7, 7, 8, 9

Treatment C: 4, 5, 6, 6, 8

Critical value of the test statistic is 5.991

- 5** Write a note on factorial designs to cover the meaning of factorial designs, their advantages, and form of the equation that can be generated from factorial designs. Also suggest an experimental matrix for factorial design involving three factors each at two levels. **(5 marks)**

- 6** The following are the ages of 10 patients admitted in a hospital **(5 marks)**

35, 82, 21, 43, 39, 62, 36, 12, 74, 45, 87, 53

Calculate the standard deviation and standard error of the mean

- 7 Weights of 6 patients before and after treatment with Fenfluramine were as (5 marks) follows:

Before	92	106	107	130	99	127
After	91.5	105	110	120	102	120

Apply a suitable test and state if there is change in the weight of patients due to treatment with Fenfluramine.

- 8 Write a note on blocking and confounding in two level factorial designs. (5 marks)
 9 What are contour plots and surface response plots? Write a note on any one open source free statistical software/ programming language. (5 marks)

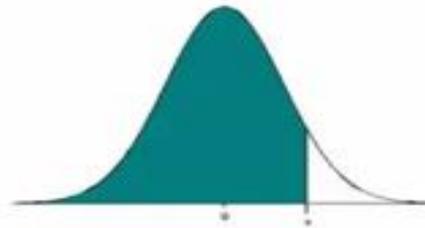
t Distribution: Critical Values of t

Degrees of freedom	Two-tailed test: One-tailed test:	Significance level					
		10% 5%	5% 2.5%	2% 1%	1% 0.5%	0.2% 0.1%	0.1% 0.05%
1		6.314	12.706	31.821	63.657	318.309	636.619
2		2.920	4.303	6.965	9.925	22.327	31.599
3		2.353	3.182	4.541	5.841	10.215	12.924
4		2.132	2.776	3.747	4.604	7.173	8.610
5		2.015	2.571	3.365	4.032	5.893	6.869
6		1.943	2.447	3.143	3.707	5.208	5.959
7		1.894	2.365	2.998	3.499	4.785	5.408
8		1.860	2.306	2.896	3.355	4.501	5.041
9		1.833	2.262	2.821	3.250	4.297	4.781
10		1.812	2.228	2.764	3.169	4.144	4.587
11		1.796	2.201	2.718	3.106	4.025	4.437
12		1.782	2.179	2.681	3.055	3.930	4.318
13		1.771	2.160	2.650	3.012	3.852	4.221
14		1.761	2.145	2.624	2.977	3.787	4.140
15		1.753	2.131	2.602	2.947	3.733	4.073
16		1.746	2.120	2.583	2.921	3.686	4.015
17		1.740	2.110	2.567	2.898	3.646	3.965
18		1.734	2.101	2.552	2.878	3.610	3.922
19		1.729	2.093	2.539	2.861	3.579	3.883
20		1.725	2.086	2.528	2.845	3.552	3.850
21		1.721	2.080	2.518	2.831	3.527	3.819
22		1.717	2.074	2.508	2.819	3.505	3.792

F Distribution: Critical Values of F (5% significance level)

v_1	1	2	3	4	5	6	7	8	9	10	12	14	16
1	161.45	199.50	215.71	224.58	230.16	233.99	236.77	238.88	240.54	241.88	243.91	245.36	246.46
2	18.51	19.00	19.16	19.25	19.30	19.33	19.35	19.37	19.38	19.40	19.41	19.42	19.43
3	10.13	9.55	9.28	9.12	9.01	8.94	8.89	8.85	8.81	8.79	8.74	8.71	8.69
4	7.71	6.94	6.59	6.39	6.26	6.16	6.09	6.04	6.00	5.96	5.91	5.87	5.84
5	6.61	5.79	5.41	5.19	5.05	4.95	4.88	4.82	4.77	4.74	4.68	4.64	4.60
6	5.99	5.14	4.76	4.53	4.39	4.28	4.21	4.15	4.10	4.06	4.00	3.96	3.92
7	5.59	4.74	4.35	4.12	3.97	3.87	3.79	3.73	3.68	3.64	3.57	3.53	3.49
8	5.32	4.46	4.07	3.84	3.69	3.58	3.50	3.44	3.39	3.35	3.28	3.24	3.20
9	5.12	4.26	3.86	3.63	3.48	3.37	3.29	3.23	3.18	3.14	3.07	3.03	2.99
10	4.96	4.10	3.71	3.48	3.33	3.22	3.14	3.07	3.02	2.98	2.91	2.86	2.83
11	4.84	3.98	3.59	3.36	3.20	3.09	3.01	2.95	2.90	2.85	2.79	2.74	2.70
12	4.75	3.89	3.49	3.26	3.11	3.00	2.91	2.85	2.80	2.75	2.69	2.64	2.60
13	4.67	3.81	3.41	3.18	3.03	2.92	2.83	2.77	2.71	2.67	2.60	2.55	2.51
14	4.60	3.74	3.34	3.11	2.96	2.85	2.76	2.70	2.65	2.60	2.53	2.48	2.44
15	4.54	3.68	3.29	3.06	2.90	2.79	2.71	2.64	2.59	2.54	2.48	2.42	2.38
16	4.49	3.63	3.24	3.01	2.85	2.74	2.66	2.59	2.54	2.49	2.42	2.37	2.33
17	4.45	3.59	3.20	2.96	2.81	2.70	2.61	2.55	2.49	2.45	2.38	2.33	2.29
18	4.41	3.55	3.16	2.93	2.77	2.66	2.58	2.51	2.46	2.41	2.34	2.29	2.25
19	4.38	3.52	3.13	2.90	2.74	2.63	2.54	2.48	2.42	2.38	2.31	2.26	2.21
20	4.35	3.49	3.10	2.87	2.71	2.60	2.51	2.45	2.39	2.35	2.28	2.22	2.18

Table of Standard Normal Probabilities for Positive Z-scores



z	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
0.0	0.5000	0.5040	0.5080	0.5120	0.5160	0.5199	0.5239	0.5279	0.5319	0.5359
0.1	0.5398	0.5438	0.5478	0.5517	0.5557	0.5596	0.5636	0.5675	0.5714	0.5753
0.2	0.5793	0.5832	0.5871	0.5910	0.5948	0.5987	0.6026	0.6064	0.6103	0.6141
0.3	0.6179	0.6217	0.6255	0.6293	0.6331	0.6368	0.6406	0.6443	0.6480	0.6517
0.4	0.6554	0.6591	0.6628	0.6664	0.6700	0.6736	0.6772	0.6808	0.6844	0.6879
0.5	0.6915	0.6950	0.6985	0.7019	0.7054	0.7088	0.7123	0.7157	0.7190	0.7224
0.6	0.7257	0.7291	0.7324	0.7357	0.7389	0.7422	0.7454	0.7486	0.7517	0.7549
0.7	0.7580	0.7611	0.7642	0.7673	0.7704	0.7734	0.7764	0.7794	0.7823	0.7852
0.8	0.7881	0.7910	0.7939	0.7967	0.7995	0.8023	0.8051	0.8078	0.8106	0.8133
0.9	0.8159	0.8186	0.8212	0.8238	0.8264	0.8289	0.8315	0.8340	0.8365	0.8389
1.0	0.8413	0.8438	0.8461	0.8485	0.8508	0.8531	0.8554	0.8577	0.8599	0.8621
1.1	0.8643	0.8665	0.8686	0.8708	0.8729	0.8749	0.8770	0.8790	0.8810	0.8830
1.2	0.8849	0.8869	0.8888	0.8907	0.8925	0.8944	0.8962	0.8980	0.8997	0.9015
1.3	0.9032	0.9049	0.9066	0.9082	0.9099	0.9115	0.9131	0.9147	0.9162	0.9177
1.4	0.9192	0.9207	0.9222	0.9236	0.9251	0.9265	0.9279	0.9292	0.9306	0.9319
1.5	0.9332	0.9345	0.9357	0.9370	0.9382	0.9394	0.9406	0.9418	0.9429	0.9441
1.6	0.9452	0.9463	0.9474	0.9484	0.9495	0.9505	0.9515	0.9525	0.9535	0.9545
1.7	0.9554	0.9564	0.9573	0.9582	0.9591	0.9599	0.9608	0.9616	0.9625	0.9633
1.8	0.9641	0.9649	0.9656	0.9664	0.9671	0.9678	0.9686	0.9693	0.9699	0.9706
1.9	0.9713	0.9719	0.9726	0.9732	0.9738	0.9744	0.9750	0.9756	0.9761	0.9767
2.0	0.9772	0.9778	0.9783	0.9788	0.9793	0.9798	0.9803	0.9808	0.9812	0.9817
2.1	0.9821	0.9826	0.9830	0.9834	0.9838	0.9842	0.9846	0.9850	0.9854	0.9857
2.2	0.9861	0.9864	0.9868	0.9871	0.9875	0.9878	0.9881	0.9884	0.9887	0.9890
2.3	0.9893	0.9896	0.9898	0.9901	0.9904	0.9906	0.9909	0.9911	0.9913	0.9916
2.4	0.9918	0.9920	0.9922	0.9925	0.9927	0.9929	0.9931	0.9932	0.9934	0.9936
2.5	0.9938	0.9940	0.9941	0.9943	0.9945	0.9946	0.9948	0.9949	0.9951	0.9952
2.6	0.9953	0.9955	0.9956	0.9957	0.9959	0.9960	0.9961	0.9962	0.9963	0.9964
2.7	0.9965	0.9966	0.9967	0.9968	0.9969	0.9970	0.9971	0.9972	0.9973	0.9974
2.8	0.9974	0.9975	0.9976	0.9977	0.9977	0.9978	0.9979	0.9979	0.9980	0.9981
2.9	0.9981	0.9982	0.9982	0.9983	0.9984	0.9984	0.9985	0.9985	0.9986	0.9986
3.0	0.9987	0.9987	0.9987	0.9988	0.9988	0.9989	0.9989	0.9989	0.9990	0.9990

Duration: 3 Hours

Total Marks: 75

Note:1. All Questions are compulsory.

2. Figures to right indicate full marks.

QNO. IA Choose the correct option and write it down

10

1 According to the _____, Hygiene refers to the conditions and practices that are used to maintain health and prevent the spread of the disease.

- A US-FDA
- B WHO
- C EMA
- D CDESCO

2 Vitamin C deficiency can lead to _____

- A Scurvy
- B Rickets
- C Haematuria
- D Night Blindness

3 Cancer of epithelial cells is referred to as:

- A Sarcomas
- B Adenocarcinomas
- C Carcinomas
- D Myeloma

4 What class of drugs is commonly used to manage blood sugar levels in diabetes?

- A Quinine Derivatives
- B Bronchodilators
- C ACE inhibitors
- D Biguanides

5 What is the significance of cold chain management in the Universal Immunization Program?

- A It ensures that vaccines are kept at optimal temperatures to maintain their potency
- B It refers to the distribution of vaccines through refrigerated trucks.
- C It involves the use of frozen vaccines for greater effectiveness.
- D It ensures that vaccines are stored in warm conditions to prevent degradation.

- 6 How does the Pulse Polio Program address challenges related to reaching remote or marginalized populations during vaccination campaigns?
- A By providing monetary incentives to individuals for vaccination
 - B By conducting door-to-door vaccination drives
 - C By promoting self-vaccination among the population
 - D By relying solely on healthcare facilities for vaccination
- 7 The Headquarter of WHO is located at_____.
- A United State
 - B Brazil
 - C Geneva
 - D Italy
- 8 Rashtriya Bal Swasthya Karyakram (RBSK) was launched in which year?
- A 2012
 - B 2013
 - C 2010
 - D 2014
- 9 Sanitization can be described as_____
- A Disposal of human excreta
 - B Supporting small scale entrepreneurs
 - C Educate people and community
 - D To develop a solid waste management system
- 10 Mobile based primary health care system was started in year.
- A 2008
 - B 2000
 - C 1999
 - D 2001

QNO. 1B Answer the following

10

- 1 Enlist ANY FOUR effects of poverty on health.
- 2 Enlist ANY FOUR factors affecting health.
- 3 Define Micronutrients.
- 4 Define drug addiction with examples.
- 5 How is chikungunya transmitted?

- 6 State any TWO MAIN objective of the Blindness Control Program in India?
- 7 State ANY FOUR objectives of Integrated disease surveillance program.
- 8 Health is a state of complete physical, _____ and social well-being and not merely the absence of disease or infirmity.
- 9 Skilled birth attendants are called as _____ workers.
- 10 Give the fulform of NUHM.

QNO. II Answer ANY TWO of the following

20

- 1 Define hypertension. Write in detail the general principle of prevention and control of hypertension.
- 2 Explain the Directly Observed Treatment, Short-course (DOTS) strategy implemented in the Tuberculosis Control Program in India. Write outcomes of Tuberculosis control program in India.
- 3 What is Tobacco Control Act 2003? Discuss in detail about the National Tobacco Control Programme.

QNO. III Answer ANY SEVEN of the following

35

- 1 Write a short note on sources and deficiency of Vitamin B.
- 2 Explain the Socio cultural factors related to health and disease.
- 3 Write a short note on corelation of personal hygiene and health care and avoidable habits.
- 4 Give a brief note on transmission of malaria, Discuss measures to be taken for prevention of Malaria.
- 5 Discuss in detail the mode of transmission, symptoms, and preventive measures for cholera.
- 6 Discuss roles of village health guides and medical officers in National leprosy eradication program.
- 7 Discuss two specific interventions or services provided under the Deafness Control Program to address hearing loss and improve access to communication for individuals with hearing impairment.
- 8 Discuss the objectives of the National Programme for the Health Care for the Elderly (NPHCE).
- 9 Describe the objectives of National Urban Health Mission. Add a note on the strategies and functions of the National Urban Health Mission.

Duration: 3 Hours

Total marks: 80 M

Note.: 1. All questions are compulsory
2. Figures to right indicate full marks

Q. 1 Choose appropriate option for following multiple choice based questions. 20

1 Centre for Pharmacovigilance Program of India is located at....

- a. IPC, Ghaziabad
- b. CDSCO, New Delhi
- c. AIIMS, New Delhi
- d. CDL, Kolkata

2 is an Activity associated with Pharmacovigilance.

- a. Vaccine Safety Surveillance.
- b. Pre-clinical Drug Development
- c. Translational Research
- d. Phase I Clinical Study

3 ICH Guideline entitled Pharmacovigilance Planning.....

- a. E 2 B
- b. E 19
- c. E 2 C
- d. E 2 E

4 Pharmacovigilance is done for monitoring of.....

- a. Drug Safety
- b. Drug Price Control
- c. Animal Experiments
- d. Toxicokinetic Studies

5 Which One of the following is ICH Efficacy Guideline.....

- a. Safety Pharmacology Studies
- b. Good Laboratory Practices
- c. Bioanalytical Method Validation
- d. Good Clinical Practices

- 6 The MedDRA (Medical Dictionary for Regulatory Activities) is used for:**
- Drug registration
 - ADR coding and classification
 - Clinical trial design
 - Drug manufacturing standards
- 7 The term "signal" in pharmacovigilance refers to**
- Any observable phenomenon after drug administration
 - A statistically significant association between a drug and an adverse event
 - An adverse drug reaction reported by a patient
 - A rare side effect observed in clinical trials
- 8 agency is responsible for pharmacovigilance in India.**
- USFDA (United States Food and Drug Administration)
 - MHRA (Medicines and Healthcare products Regulatory Agency)
 - CDSCO (Central Drugs Standard Control Organization)
 - EMA (European Medicines Agency)
- 9 The WHO Drug Dictionary is used primarily for**
- Tracking drug sales
 - Standardizing drug nomenclature
 - Assessing drug efficacy
 - Marketing authorization of new drugs
- 10 The causality assessment tool commonly used in pharmacovigilance is**
- Naranjo Algorithm
 - Beers Criteria
 - Braden Scale
 - Modified Early Warning Score (MEWS)
- 11 is an example of a serious adverse drug reaction**
- Mild headache
 - Nausea and vomiting
 - Dizziness upon standing up
 - Anaphylactic shock
- 12 ----- databases is commonly used for spontaneous reporting of adverse drug reactions?**
- EudraVigilance
 - PubMed
 - Google Scholar
 - Cochrane Library
- 13 regulatory activities falls under the scope of pharmacovigilance**
- Approving new drugs
 - Patenting drug formulations
 - Recalling unsafe drugs from the market
 - Setting drug prices

- 14 The process of causality assessment in pharmacovigilance aims to**
- Identify all potential adverse drug reactions
 - Establish a definitive link between a drug and an adverse event
 - Determine the severity of adverse drug reactions
 - Prioritize adverse drug reactions for further investigation
- 15 CIOMS VI deals with:.....**
- Benefit–Risk Balance for Marketed Drugs: Evaluating Safety Signals
 - Current Challenges in Pharmacovigilance
 - Management of Safety Information from Clinical Trials
 - Development Safety Update Report
- 16 Schedule Y is a Part of one of the following Act:**
- Indian Patent Law
 - Drugs & Cosmetic Act
 - Drug Price Control Order
 - The Pharmacy Act
- 17 The MedDRA (Medical Dictionary for Regulatory Activities) is used for.....**
- Drug registration
 - ADR coding and classification
 - Clinical trial design
 - Drug manufacturing standards
- 18 Pharmacovigilance Programme of India started in the year**
- 2010
 - 2009
 - 2005
 - 2012
- 19 WHO-ART has.....**
- 4 levels hierarchical structure
 - 10 levels hierarchical structure
 - 5 levels hierarchical structure
 - 6 levels hierarchical structure
- 20 CIOMS stands for**
- Centre for International Organizations of Medical Sciences
 - Council of International Organizations of Medical Sciences
 - Council of International Authority of Medical Sciences
 - Conference of International Organizations of Medical Sciences

Q. 2 Answer ANY ONE of the following 12M

- a. Give detailed account on various Active and Passive Surveillance Methods used in Pharmacovigilance.
- b. Explain in detail about history and development of pharmacovigilance program of India (PvPI)
- c. Enumerate the different types of information resources available in pharmacovigilance with drug dictionaries and coding used in pharmacovigilance.

Q. 3 Answer ANY FOUR of the following 48 M

- a. Define Adverse Drug Reactions. Classify ADR with suitable examples.
- b. What are causality assessment? What are various Do's and Don'ts for causality assessment?
- c. Explain spontaneous reporting of adverse drug reaction with suitable examples.
- d. Give a detailed account on: Vaccine Safety Surveillance
- e. Write a note on naranjo's causality assessment rule.
- f. Write short note on: a) CIOMS b) CDSCO and Pharmacovigilance
c) MedRA
- g. Write in brief Schedule Y of Drug and cosmetics act 1945.
- h. What are the objectives of ICH guidelines? Explain periodic safety update report.
- i. What is Pharmacovigilance Programme of India? Write a note on the history of Pharmacovigilance.

- 2 Answer any 2 questions (20 marks)
- 1 Explain drug approval process in Europe
 - 2 Explain steps in drug development process.
 - 3 What is ICH Guideline? What are the objectives? Write in detail CTD and its modules
- 3 Answer any 7 questions (35 marks)
- 1 Give an overview of orange book and purple book
 - 2 Write constitution of IRB and enlist its four functions.
 - 3 Write role of DMF and enlist its components
 - 4 Differentiate between innovator and generics drug product
 - 5 Enlist four GCP obligations of sponsor towards clinical trials and explain any two
 - 6 Explain the post approval changes for USFDA
 - 7 Write a note on drug regulatory authorities of Australia
 - 8 Differentiate between CTD and eCTD
 - 9 Write the drug regulatory body for India, Canada, Japan, EU and Australia
